Genetic Engineering Policy Alliance

Position Paper

Introduction

Since the advent of the commercial production of genetically engineered (GE) crops in 1996, more than 100 million acres of GE crops have been planted in the U.S. alone. Soy, corn, canola and cotton make up almost all the GE crop acreage, for use primarily in processed human foods and animal feed. In California, GE crops comprise very little of the state's agricultural acreage. However, federal regulators have approved herbicide resistant GE rice for market, though it has not yet been commercially planted due to widespread consumer and farmer rejection. Also, GE varieties of all of California's major crops are currently being field-tested and may be available for commercial production in the coming decade. Given that California is the country's largest producer of both conventional and organic crops, the state is at the center of the growing debate over GE. Many of California's farmers are concerned that they will lose markets if GE farming advances here, and consumers are demanding the right to know which foods contain GE ingredients.

Countries around the world restrict the use of GE crops and/or GE food ingredients because the human health and environmental impacts of these foods are largely untested and unknown. Some countries use mandatory science-based evaluations in determining which GE crops and foods to allow, and others have GE food and seed labeling laws. Among the countries with labeling and/or other restrictive laws are Japan, Taiwan, South Korea, all 25 European Union member countries, Australia, New Zealand, India, Hungary, Poland, Romania, Venezuela, Angola, Ghana, and Saudi Arabia.

Genetic Engineering Defined

Genetic engineering (GE) is a new technology that changes the DNA of cells by moving genes from one species to another in order to produce novel organisms that do not occur in nature and cannot be developed through traditional breeding. The two main categories of GE crops that comprise nearly all of the commercial acreage are insect resistant crops (engineered to withstand attack by certain classes of pests) and herbicide resistant crops (able to tolerate the application of an herbicide that would normally kill the crop).

In contrast, neither the State of California nor the U.S. federal government have implemented any policies or laws calling for mandatory human safety testing, labeling, or long-term environmental impact studies of GE crops and foods. Beginning in 2004, several California counties and cities moved to fill this regulatory void by enacting precautionary local ordinances restricting GE crop production, arguing that state and federal regulatory programs are not adequate to protect their economies, public health and environment. In response, powerful biotechnology industry and agricultural interests moved to pre-empt local authority over seed and crop restrictions. One such pre-emption bill, SB 1056 was introduced by Senator Florez in the California legislature in June 2005. The bill failed to pass at the end of the legislative session in August 2006 due to a groundswell of opposition from public interest organizations, citizens, and elected officials around the state.

The Genetic Engineering Policy Alliance believes that there is a need for state policy in California to protect farmers, consumers and the environment from certain risks inherent in GE agriculture. Because the technology involves living organisms that reproduce and spread through the environment, and can thus contaminate non-GE crops and foods, farmers and the public should know where they are grown and what seeds and plant material are genetically engineered. Because some consumers prefer to not eat GE foods, these foods should be labeled. Because there are likely to be damages suffered by farmers, consumers and the environment from this new technology, there should be liability laws to protect them. Finally, some classes of GE crops, such as crops engineered to produce experimental drugs, are simply too risky and should be prohibited from open-air cultivation.

Genetic Contamination Creates Legal and Financial Concerns for Farmers

Genetic contamination is a widely acknowledged risk of using GE in agriculture. Unlike the individual choice a farmer makes about which tractor to use or what herbicide to spray, choices involving the use of GE crops can have widespread, irreversible and unforeseen impacts. This section summarizes the ways in which contamination can occur and outlines the associated consequences for farmers.

Contamination by GE crops of cultivated crops and wild relatives is virtually impossible to control. An academic report examining incidents of transgenic movement between GE crops and non-GE crops or wild relatives concluded that, "the movement of transgenes beyond their intended destination is a virtual certainty."[1] Contamination can occur in hundreds of ways, from cross-pollination, transportation via birds, mammals or humans, mixing GE and non-GE material at the farm, mill, warehouse, packing house, or processing facility, or human error at various points in the food system. A 2004 study by the Union of Concerned Scientists sampled conventional non-GE seeds and found that non-GE varieties of corn, soybeans, and canola were pervasively contaminated with DNA from GE varieties.[2] Between 1999 and 2005 there were 115 documented cases of contamination worldwide; the U.S. has had more than twice the number of contamination events of any other country worldwide.[3]

Contamination can present both legal and financial burdens for farmers who knowingly choose to grow GE crops and also those who prefer to produce GE-free crops.

Economic harm due to market rejection

Experiences in the corn and soy industries show that the adoption of GE varieties has a negative effect on U.S. export markets. The American Farm Bureau estimates that U.S. corn farmers have been losing $300 million per year due to the closure of European markets since GE corn was commercially introduced.[4] It is estimated that U.S. taxpayers have paid out $12 billion in subsidies to make up for losses resulting from the production of GE soy and corn.[5]

Several of California's most important export markets have labeling laws, thresholds and restrictions on GE imports, and in some cases complete bans on GE foods and crops. The constant threat of contamination necessitates careful testing, segregation, and regulatory paperwork, creating additional financial burdens on farmers, handlers and processors who export to these markets.

Even in countries where governmental approval is obtained for importing GE products, consumers may reject those products and retailers may refuse to carry them. This is particularly true in many of California's key export markets such as Japan, South Korea, Taiwan, the Philippines, and the European Union. The British Retail Consortium, the lead trade association for the UK retail industry, informed the British government in 2003 that major British retailers would not stock GE products because "supermarkets are not going to give shelf space to something that doesn't sell."[6] Several important buyers of U.S. corn and soy from Japan and South Korea have started to purchase these crops from regions that can guarantee a GE-free supply in order to avoid the risk of contaminated shipments.[7]

Increasingly, the mere possibility of unwanted genetic contamination is leading to the closure of export markets. Farmers who do not grow GE crops are also impacted by consumer and retailer rejection of GE crops overseas. In 2003, a coalition of 400 Japanese consumer and food industry groups representing over a million consumers declared that "Japanese consumers would not buy wheat from the United States if it introduces genetically modified (GM) wheat."[8] A 2003 report by Dr. Robert Wisner at Iowa State University states: "Important market indicators point to a high risk that up to 30 to 50 percent of the foreign market for U.S. hard red spring wheat…could be lost if hard red spring GMO wheat is introduced into the U.S. in the next two to six years."[9] The 2006 rice contamination incident (see sidebar) provides a more recent illustration of market sensitivity to GE foods in yet another crop sector.

Case Study: Food Supply Contaminated by Unapproved GE Rice

In August of 2006, the USDA announced that the U.S. food supply had been contaminated by an unapproved variety of GE rice ('Liberty Link 601') developed by Bayer Corporation. This rice was last grown in small field trials in 2001, yet five years later it was discovered across vast areas of the Southern U.S. in shipping bins, mills and fields. The long grain rice in question is not grown in California, but California's largest export market, Japan, immediately banned U.S. grown long grain rice and began testing all U.S. rice imports for contamination. The E.U. also restricted U.S. rice imports, many European retailers and mills rejected all U.S. rice, and the Philippines stopped buying any U.S. long grain rice.[10] The price of long grain rice fell dramatically, dropping $135 million at the farm gate in the first week after the contamination was announced .[11] Over 40 farmers have sued Bayer for economic damages, and the incident is reviving discussion about the need for liability laws holding GE manufacturers responsible for farmer and food company losses.

Liability

In the event of contamination, whether between farms or due to commingling further along the production line, questions of liability have yet to be addressed by the legislature and thus require lengthy and expensive litigation. For example, in 2000, corn contaminated with an unapproved GE corn variety called StarLink caused a massive disruption of the export market for U.S. corn and led to losses for thousands of farmers who were left with no market for their contaminated corn. Several farm belt states filed lawsuits on behalf of their farmers, yet after four years of litigation a settlement was reached that experts said only partially compensated U.S. farmers for the damages they suffered.[12]

Farm Insurance: Does it Cover Genetic Contamination?

Farm insurance companies in the U.S. do not currently offer coverage for damage due to genetic contamination, and thus far there have been no test cases of farmers filing insurance claims for crop damages due to genetic contamination. According to the U.S. Department of Agriculture (USDA), certain insurance companies have exclusions in their policies for claims arising from the presence of transgenic material, creating "uncertainty as to which agents in the food and feed chain will bear the liability for a transgenic-related claim."[13] In the United Kingdom, the five leading farm insurance underwriters have stated that they refuse to cover farmers who plant GE crops because they fear a public health disaster and huge compensation payouts, and they are unprepared to risk insuring farmers against accidental contamination with GE crops.[14]

Genetic Engineering Threatens the Organics Sector

Consumers expect that organic food will not contain GE ingredients. Contamination of organic crops can result in the loss of markets for organic growers, and the loss of consumer confidence in organic foods.[15] In California and nationally, the organic foods industry is the fastest growing sector of the food industry, with retail sales growing between 20% and 25% per year for the past six years.[16] GE contamination threatens the viability of this thriving industry and the associated reputation California enjoys for wholesome, healthy food production.

Environmental Impacts

There have been few published peer-reviewed studies on the environmental impact of GE crops, and none specific to California's ecosystems. However, there is mounting scientific evidence of adverse environmental effects from GE agriculture. Most demonstrably, GE technology is leading to an increase in pesticide use as well as a trend towards increasingly toxic chemicals. Additionally, GE crops can harm non-target animal and plant species, and the enhanced fitness arising from GE traits can out-compete endangered or sensitive native species. Finally, genetic contamination can threaten biodiversity and crop diversity in California and globally.

Increased pesticide use

GE crops can lead to increased usage of agricultural chemicals, including pesticides known to endanger human and ecological health. A study by the former head of the Board of Agriculture of the National Academy of Sciences found that after the first nine years of GE crop usage, pesticide use increased by 122 million pounds in the U.S. The study also found that farmers who plant Monsanto's GE Roundup Ready herbicide resistant soy use two to five times more herbicides than their conventional counterparts.[17] As the study notes, "Weed scientists have warned for about a decade that heavy reliance on HT [herbicide tolerant] crops would trigger changes in weed communities and resistance, in turn forcing farmers to apply additional herbicides and/or increase herbicide rates of application."

The trend towards increased pesticide use and increased pesticide toxicity can be explained in several ways as summarized here:

(i) Pesticide resistance in weeds and insects arising through natural selection

The evolution of weed and insect resistance to pesticides is a challenge that farmers deal with routinely. GE technology exacerbates this problem by creating a reliance on a single herbicide used in conjunction with herbicide resistant crops, or in the case of the Bt insecticidal GE crops by exposing target insects to the continuous presence of the Bt toxin in the GE plant itself.

To date there are nine weed species that have developed a resistance to Roundup, the herbicide used with Monsanto's 'Roundup Ready' herbicide resistant crops; six of these weeds are found in the U.S.[18] In California, University of California scientists have documented Roundup resistance in horseweed and warn that other weeds are showing increased tolerance. They state "Farmers dealing with the problem have been forced to repeatedly till their fields, rely on weeding, or on more toxic herbicides to control the tall, fast-growing pest."[19]

GE plants that are engineered to produce the insect toxin, Bacillus thuringiensis (Bt) can similarly lead to the development of resistance in target insects. A report by the National Research Council states that "the evolution of resistance to Bt crops is considered inevitable,"[20] and recent reports have begun proving this inevitability. In an Australian study, a cotton bollworm has been found to be resistant to Bt, and approximately 70% of the larvae were able to subsist entirely on a diet of Bt cotton.[21] In July 2006, a Cornell University study reported that GE cotton growers in China use just as much insecticide as conventional growers after seven years due to the development of pest resistance.[22] Bt has been called the world's safest biological pesticide, and it has been widely used for decades. Bt sprays are permitted in organic farming and are widely used on conventional farms. Insects resistant to Bt crops will also resist the natural Bt sprays, rendering this tool ineffective, forcing conventional growers to return to more toxic chemicals, and putting organic growers at risk of devastating losses.

(ii) Transfer of herbicide resistance to weed relatives via cross-pollination

Herbicide tolerance can be transferred when GE crops cross-pollinate with their wild relatives. For example, several studies demonstrate that cultivated rice, including herbicide resistant GE rice, can readily cross with red rice, an invasive weed found in parts of California and much of the southeastern U.S.[23,24,25] Conferring herbicide resistance to red rice will enhance the fitness of an already problematic weed for rice farmers.

In another study, a 2006 field trial of herbicide resistant creeping bentgrass in Oregon was found to have contaminated wild relatives more than 13 miles away, far exceeding the USDA recommended buffer zone of 900 feet.[26] Dr. Norman Ellstrand noted the GE bentgrass has the potential to contaminate more than a dozen other plant species that could also acquire resistance to Roundup. This could force land managers and government agencies like the U.S. Forest Service, which relies heavily on Roundup, to switch to "nastier" herbicides to control grasses and weeds.[27]

(iii) Herbicide resistant crops becoming weeds

Conventional farmers often apply herbicides between crop rotations to remove volunteers. Herbicides are often also used along field perimeters, roadways, railways and elsewhere to control agricultural crops that spread and volunteer. Herbicide resistant crops limit the choice of herbicides that can be applied, particularly if multiple herbicide resistance has developed by crosses between several GE crops. For example, canola plants with resistance to three commonly used herbicides have been discovered in Alberta, Canada,[28] reducing the effectiveness of these herbicides, and leading to the use of more toxic chemicals. Some farmers in Alberta are now adding 2,4-D to their herbicide mixtures to deal with the new weed.[29]

All of these situations have the effect of forcing farmers and other land managers to resort to increased pesticide applications and/or increased chemical toxicity to manage their weed and insect problems. In response to increased weed resistance, Monsanto has launched a website (www.weedresistancemanagement.com) devoted entirely to advising farmers on controlling herbicide resistant weeds in their GE fields. The web site recommends such chemicals as paraquat (a chemical banned in much of Europe), 2,4-D (banned in five countries), alachlor (not approved or banned in much of Europe), and other pesticides known to be carcinogens, reproductive toxins, or environmental pollutants.

Effects of insecticidal GE crops on non-target species

According to Dr. Norman Ellstrand, a leading University of California scientist and international expert on plant genetics and gene flow, "If a transgene moves unintended from one field of a crop to another field of the same crop, a number of adverse consequences are possible, including… effects on nontarget organisms in natural or agroecosystems."[30] Indeed, Cornell University researchers have demonstrated that Bt producing corn is toxic to Monarch butterflies.[31] Follow-up studies in the field indicated the need for more thorough research before widespread usage of Bt-producing GE crops, yet millions of acres of these crops are currently growing in the U.S. corn belt, which is on the migration route of these butterflies. In another study, lacewings, natural predators of corn borers, reared on corn borers fed Bt corn leaves showed increased mortality and delayed development.[32] It has been shown that some Bt plants release Bt toxins from their roots during their entire lifecycle and also from plant material left on the field after harvest, potentially impacting soil and aquatic microorganisms.[33]

Increasingly fit GE plants can crowd out other species

In the event that GE crops or their progeny develop increased aggressiveness or invasiveness as a result of their genetic modification, they pose a danger to other species in the environment.[34] This phenomenon has been inadequately studied, and presents a potential threat particularly to endangered or sensitive native plant species.

Genetic contamination of indigenous and heirloom crops and impact on indigenous ecosystems

DNA from GE corn has been found contaminating indigenous varieties of corn in Oaxaca, Mexico, despite the country's ban on planting GE corn. Oaxaca is a region where domestic corn originated, and to this day it is the center of the greatest genetic diversity of corn in the world. This contamination event threatens the genetic integrity of Oaxacan corn, posing a threat to all farmers and crop breeders worldwide who rely on this genetic diversity to develop new varieties. It also threatens the livelihoods of rural Oaxacan farmers who have bred these varieties to express characteristics that are specifically adaptive to their local ecological niche.[35]

Indigenous crops that have value to subsistence farmers but are considered weeds by commercial growers are threatened by the use of GE crops engineered to be resistant to herbicides. As illustrated by Indian scientist Vandana Shiva, "In Indian agriculture, women use up to 150 different species of plants…as medicine, food or fodder. For the poorest, this biodiversity is the most important resource for survival…Herbicides such as Roundup and the transgenic crops engineered to withstand them therefore destroy the economies of the poorest, especially women. What is a weed for Monsanto is a medicinal plant or food for rural people."[36]

Public Health Concerns

An estimated 81% of U.S. soy[37] and 40% of corn[38] are genetically engineered. Because corn and soy are ubiquitously used in processed foods, oils and sweeteners, and because GE corn is not separated from non-GE corn at processing mills, it is very likely that most processed foods contain some GE ingredients. Yet despite the widespread prevalence of GE soy and corn in most processed foods, very little independent, publicly available research has been conducted to ensure that GE food is safe for people to eat. GE foods are not required to be labeled in the U.S., so there is no way to trace health effects to consumption of these foods. A growing body of independent peer-reviewed scientific research shows that health risks of consuming GE foods can range from allergic reactions to toxicity to modified organ and cellular functioning, structure and growth. Some examples of these findings include:

- A 24-month Italian feeding trial found that GE soy changed the cell structure and cell functioning of the liver, pancreas and testes of mice fed Monsanto's Roundup Ready soy.[39]
- A decade-long Australian project to develop a GE pest-resistant pea was discontinued after tests showed it caused inflammations in the lungs of mice.[40]
- Two UK trials, one with humans and one with sheep, found that when GE foods are eaten, some of the inserted genes transferred into the gut bacteria.[41] Genetic engineering commonly uses antibiotic resistance "marker genes" in the process of gene splicing. This study has researchers concerned that this practice will diminish the effectiveness of antibiotics in treating illnesses.
- In a Scottish study on rats fed GE potatoes and non-GE potatoes it was found that diets containing GE potatoes had negative effects on different parts of the rat gastrointestinal tract and on their immune systems.[42]
- The French Biomolecular Engineering Committee, in evaluating a 2005 study by Monsanto of one of its own corn varieties ('Mon 863'), concluded that there was insufficient data to explain the anomalies in red and white blood cell counts, blood sugar levels and kidney functioning of rats fed the GE corn for 90 days.[43]

In the absence of labeling or testing for GE content, the only way consumers can currently choose to avoid GE foods is to purchase certified organic foods which must be produced without GE crops. However, the growing number of contamination incidences will increase the likelihood that even organic or GE-free foods may contain some genetically engineered material. In addition, organic foods are not always available and can cost on average 50% more than conventionally grown and processed foods,[44] making them cost-prohibitive for many families. As such, low-income communities bear a disproportionate burden of the health risks associated with GE food.

For people wanting to take a precautionary approach in selecting the food they consume, labeling of GE foods provides that choice. The best way to provide all consumers with access to information about the presence of GE ingredients in their food is to implement mandatory product labeling.

Because GE crops lead to the development over time of insecticide and herbicide resistance and a concurrent increase in pesticide use as well as a reversion to more toxic chemicals (see the Environmental Impacts section above for more details), GE crops could be associated with increased health problems for farm workers and rural communities. The health and safety of farm workers and the low-income communities often living adjacent to chemically intensive farms are disproportionately and seriously affected by the use of toxic pesticides in agriculture,[45] and the increased use of the chemicals associated with GE crops is likely to exacerbate these trends.

Pharmaceutical and Industrial Chemical Crops – A Special Case

Two special classes of GE food crops that are engineered to produce pharmaceutical drugs (also known as 'pharm crops') and industrial chemicals pose unique risks to public health, the environment and the economy. These crops are of great concern because they contain compounds not intended and often not safe for general human consumption. This combined with the many opportunities for contamination of the food supply make these crops potentially the most dangerous of all GE crops.

There are several dozen field trials in the U.S. involving open-air production of pharm and industrial chemical crops, often in close proximity to food producing regions. The kinds

Case Study: Ventria's Pharmaceutical Rice

Opposition to so-called 'pharming' has already driven one company out of California. In 2004, a California-based company, Ventria Biosciences, applied for a permit to plant two varieties of rice genetically engineered with human genes to produce experimental drugs. Farmer groups in California as well as food safety and environmental organizations strongly opposed Ventria's plan on the basis that this would severely threaten the California rice industry, as well as put consumers and the environment at risk. Ventria abandoned its plans in California, and their second attempt to grow the rice in Missouri was also aggressively opposed and rejected by Missouri rice farmers in 2005.

of pharmaceutical and industrial chemicals that are being engineered into plants include:

- Pharmaceuticals or Drugs - Proteins for healing wounds and treating conditions such as anemia, liver cirrhosis, and cystic fibrosis; anticoagulants; blood substitutes and hormones.
- Antibodies - Substances that target disease-causing molecules with great specificity. Examples are antibodies to fight cancer and tooth decay.
- Vaccines - Substances to be injected or given orally to humans and animals to confer immunity to diseases.
- Industrial Chemicals - Compounds used in the manufacture of products such as paper, plastics, personal care items, and laundry detergents. Examples are trypsin and laccase.
- Research Chemicals - Used in laboratories. Examples are avidin and beta-glucuronidase.

A National Academy of Sciences expert committee warned in 2002 that the environmental risks of pharm crops "cannot be predicted" and that pharm crops could cross with food crops "with the unanticipated result of novel chemicals in the human food supply."[46] Already pharm crops have contaminated the food supply, with near disastrous consequences. In a famous case study, the USDA announced in late 2002 that untested pharm crops produced by ProdiGene, the country's leading pharm crop producer, had contaminated fields of natural corn and soy in two states. "Volunteers" of an experimental pharm corn contaminated a soybean field, and the soybeans were then shipped to a grain elevator, where they contaminated over 500,000 bushels of soy destined for the food supply. In addition to the obvious danger this incident posed for consumers, it placed a high financial burden on farmers and processors, who lost nearly $3 million when the contaminated soybeans were destroyed.

Proponents of GE maintain that using food crops to produce pharmaceuticals or industrial chemicals will produce cheaper drugs. However, a comprehensive 2002 study by Friends of the Earth revealed that this assertion does not stand up. In fact, one of the only commercialized pharmaceutical crop products, the research chemical avidin grown in corn, costs the same as the conventional version extracted from eggs.[47] In addition, the high costs of research and development and threats of contamination, litigation and liability, technical difficulties in extraction, purification and other production processes, and other unforeseen obstacles are never accounted for in claims that production will be cheaper.

Inadequacy of Federal and State Oversight

Genetically engineered ingredients are present in an estimated 70% of all processed food in the U.S., GE crops are planted on over 100 million U.S. acres, and in October 2006 there were 1,294 issued field trial permits for 48 crops in California alone.[48] In spite of their pervasiveness in food and agriculture, the federal government has no mandatory environmental or human safety testing requirements for GE crops or labeling regulations for GE food. The state of California has no laws or regulations governing GE plants or animals nor any mechanisms for public notification of the presence of GE in the environment or food.

There are three federal agencies involved in the oversight of GE crops and foods:

U.S. Department of Agriculture

The USDA reviews GE crops to determine if they are "plant pests," and issues field trial permits for experimental GE crops that produce pharmaceuticals and industrial chemicals. The Union of Concerned Scientists has pointed out that "Ninety-nine percent of all field trials can be undertaken without [USDA] review. Developers need send only a brief notice to USDA along with a promise to conduct the tests safely."[49] The agency does not look at human health or economic impacts of GE crops, and its environmental assessments have been criticized by the National Academy of Sciences for lack of rigor.[50] Once the USDA has deregulated GE crops, the agency has no further authority over them and cannot require monitoring for long term environmental harm or restrict their production.

The USDA's own Inspector General late last year reported that the agency "lacks basic information about the field test sites it approves and is responsible for monitoring, including where and how the crops are being grown, and what becomes of them at the end of the field test."[51] A 2002 National Academy of Sciences report also criticized USDA oversight, noting the lack of scientific peer review of field experiments, the absence of a public input process, and as the failure of applicants to clearly present their data, methods, analyses and interpretations.[52]

USDA found to be 'negligent' in oversight of GE crops

U.S. District Judge Seabright found in his Aug. 10, 2006 decision that the USDA's Animal and Plant Health Inspection Service (APHIS) acted negligently in granting permits for GE field trials in Hawaii by not first investigating whether the plants posed a threat to any of that state's hundreds of endangered species. He said: "APHIS's utter disregard for this simple investigation requirement, especially given the extraordinary number of endangered and threatened plants and animals in Hawaii, constitutes an unequivocal violation of a clear congressional mandate."[53]

Environmental Protection Agency

The EPA is responsible for evaluating pesticide-producing crops (to date represented by Bt crops which constitute 30% of the GE crops currently on the market) for environmental safety and to establish exposure limits to protect human health. The EPA has so far exempted all of these GE crops from pesticide tolerance levels, and in over a decade of evaluations, the agency has never yet conducted a complete Environmental Impact Review of any Bt crops. Moreover, the EPA has developed no formal safety testing guidelines for GE crops, relying instead on ad hoc review and guidelines developed for chemical pesticides and microorganisms.

Food and Drug Administration

The FDA oversees the introduction of GE foods under a 1992 policy which considers GE foods not significantly different from conventional foods and "generally regarded as safe" (GRAS), meaning that they are not subject to mandatory review, safety testing or food labeling laws. At that time, FDA political appointees and other officials essentially ignored the recommendations of FDA scientists, who proposed a mandatory system involving required tests for toxicity and other unintended health effects.[54] Instead, the FDA calls for only voluntary consultation, simply asking the developer to submit new GE foods to a cursory safety evaluation. This is well-illustrated by the letter FDA sends companies after a consultation is complete, a typical example of which reads as follows:

> …it is our understanding that Monsanto has concluded that corn products derived from this new variety are not materially different … from corn currently on the market, and that the genetically modified corn does not raise issues that would require pre-market review or approval by FDA … as you are aware, it is Monsanto's responsibility to ensure that foods marketed by the firm are safe, wholesome, and in compliance with all applicable legal and regulatory requirements.[55]

In international forums, FDA and other U.S. representatives have endorsed at least three agreements on safety assessments and pre-market review to protect consumers around the world from the risks of GE foods. But FDA's own guidelines for American consumers do not follow these international safety standards.

Conclusion

Based on our understanding of the risks associated with GE crops and foods, and the lack of federal and state government oversight addressing these risks, the Genetic Engineering Policy Alliance educates policymakers and California citizens about the need for California policies that prohibit the most dangerous classes of GE crops; provide information to farmers and consumers about the whereabouts of GE crops, seeds and foods so that they may make informed choices for themselves, their businesses, and their families; and provide legal recourse in the event of harm caused by genetic contamination.

Specifically, the Genetic Engineering Policy Alliance informs California policymakers and the public of the need for policies that address:

1. Public notice – of all open-air plantings of genetically engineered crops through appropriate agencies.
2. Labeling – of all genetically engineered foods, seeds and plants.
3. Assignment of Liability – providing remedies for farmers and communities in the event of genetic contamination of crops, damage to the environment, or harm to the public.
4. Prohibition – of open-air food crops genetically engineered to produce pharmaceuticals or industrial chemicals.

The following four sections expand upon these policy areas and outline factors to be considered in developing effective state policies on genetic engineering in agriculture. ■

Public Notice

Public notice of all open-air plantings of GE crops, including field trials, would give farmers and other neighbors the opportunity to know whether they are at risk from unwanted contamination. There is currently very little acreage of commercial GE crops in California, so programs requiring notification of all open-air planting of GE crops would primarily affect field trials. As of October 2006, APHIS reported that there were 1,294 active permits in California for open-air field trials of GE crops,[56] however, the locations are not known by the California Department of Agriculture, county Agriculture Commissioners, or neighboring farmers.

The following provisions should be considered in developing an effective public notification system for GE in agriculture:

- Responsibility on the part of the grower using GE technology to inform public agencies of the type, extent and planting, seeding, and harvesting timelines.
- Availability of information about where GE seeds are planted either through a publicly accessible central registry or other means of communication.
- Notification to immediate neighbors about the presence and type of GE in their environs.

Precedents

California's Pesticide Use Reporting Program
In 1990, California became the first state to require full reporting of agricultural pesticide use, and its system is now considered among the most comprehensive in the world. The program arose in response to demands for more accurately estimating dietary risk and exposure to farm workers. It requires county-by-county reporting of pesticide applications, public access to these records, and it provides the basis for annual summaries by county.

Healthy School & Day Cares Acts (CA)
The Healthy Schools Act of 2000 (AB 2865) requires California's public schools to notify parents of all pesticide products expected to be applied during the upcoming year; give registered parents at least 72 hours notice before each pesticide application; post warnings prior to applications; and keep records of pesticide applications by pest control businesses. The Act also established databases to track pesticides used in school environments. The Healthy Day Cares bill of 2006 extends the Healthy Schools Act to licensed day cares.

Pesticide Sensitivity Registers
Eleven states (CO, CT, FL, LO, ME, MD, MI, PA, WA, WV, WI) have Pesticide Sensitivity Registers that require notification to registrants of impending pesticide applications in their vicinity.[57] Although the state of California does not have such a registry, in 2002, San Luis Obispo County established a Pesticide Sensitivity Register that requires the County Agriculture Commissioner to notify registrants in advance of any pesticide spraying.

Labeling

By labeling foods, seeds, and plants that contain GE material, citizens and farmers could decide for themselves what kind of food they grow, sell and feed their families.

Labeling GE Food — There are currently no mandatory GE food labeling laws in the U.S. in contrast to the over 30 countries worldwide with such laws. In a 2004 Pew Initiative study on Americans and GE food, 89% of interviewees said that GE food should be labeled, indicating that Americans want access to the information afforded to citizens all over the world.[58] Currently, the only sure way for consumers to avoid GE foods is to purchase certified organic products, which are more costly than conventional foods and less accessible.

California is already a national leader in food safety, having passed some of the country's strongest regulations, including:

- Proposition 65: The Safe Drinking Water and Toxic Enforcement Act: Prop 65 warnings alert consumers to the presence of chemicals known to cause cancer or birth defects in food, drinking water and many other products.
- Food Additive Limits: California law places strict limits on the amount of certain additives and colorings in our food.
- Shellfish Testing: Rigorous testing of shellfish keeps shellfish with dangerous toxins off store shelves.[59]

Labeling GE Seed and Plants — There are no GE seed or plant labeling laws federally or in California. It is important for farmers who intend to produce GE-free products, and whose markets demand it, to be confident their seeds are GE-free.

Precedents

Food labeling — Oregon, Washington and California have all attempted to pass GE labeling laws but these efforts drew heavy opposition from seed companies who insisted that any label at all constitutes a 'warning' and would prejudice consumers against products.

In 2005, Alaska became the first state to pass a law mandating the labeling of a GE food product. SB 25 requires Alaska retailers to label foods containing fish and shellfish that have been genetically modified. The bill's sponsors made the following argument for Alaska's state interest: "The message that Alaska seafood is more natural than seafood that has been engineered or bred is a highly important marketing tool. This bill, by requiring a differentiation between GM and wild seafood helps highlight Alaska seafood as distinct from GM seafood, thereby doing away with any vagueness that may exist to the consumer when purchasing seafood without labeling, and reinforcing the natural message."[59]

Seed labeling — In April 2004, the Vermont legislature passed a bill that mandated the labeling of all GE seeds sold in the state and required reporting on GE seed sales by biotechnology corporations. This law made Vermont the first (and so far the only) U.S. state to require that GE seeds be labeled and registered.

Assignment of Liability

There is no legal precedent to protect farmers or food handlers and processors whose products are contaminated by GE crops. In addition, the cost of litigation is high and out of reach of many farmers. By contrast, farmers who unknowingly use GE seed or plants can be and often are successfully sued by GE seed manufacturers for patent infringement. This practice has forced many farmers into years-long court battles that can cost hundreds of thousands of dollars. A specific state liability law would level the playing field, allowing non-GE farmers a more adequate and less burdensome legal pathway to recover damages in the event that GE seeds or traits contaminate their non-GE crops.

The following elements should be considered in addressing liability:

- A farmer who unknowingly comes into possession or uses patented seeds or plants as a result of inadvertent mixing of GE seeds or plant material would be shielded from liability.
- The manufacturer would be liable to any party injured by the release of its GE crop into California. The prevailing plaintiff in an action may recover compensable damages, reasonable attorney's fees and other litigation expenses as a part of the costs.
- A manufacturer would have a defense against liability for third party damages if any third party acted in gross negligence causing contamination; or if a farmer growing GE crops under a contract with the manufacturer acted in gross negligence.

Precedents

Liability Bill (CA)
In 2005, California Assemblymember John Laird introduced a bill (AB 984) that shifted to the GE crop manufacturer the liability for economic injuries caused by the contamination of non-GE crops. Additionally, the bill provided relief to California farmers facing lawsuits arising out of the unintended presence of GE seeds and crops on their land. The bill was not pursued, but remains a good model for future consideration.

Farmer Protection Act (VT)
A similar bill, the Farmer Protection Act (S. 18), was passed by a large margin of both houses of the Vermont legislature in 2006, but was ultimately vetoed by the Governor.

Prohibition of Pharmaceutical & Industrial Chemical Food Crops

GE food crops that produce drugs or industrial chemicals pose unacceptable risks to public health, the environment and the economy. As with other GE crops, contamination of the food supply is inevitable if these crops are planted in the open air, and because these crops produce chemicals and drugs that are not fit or intended for general human consumption, they expose the public and the environment to potentially harmful substances. Many of California's export markets have a zero-tolerance policy for pharm and industrial GE crops.

Many sectors of the domestic food industry have already expressed their concern about the use of food crops to produce pharmaceuticals. In March 2003, the National Food Processors Association (NFPA), representing the world's largest food producers, submitted a statement to USDA that said: "Given a voice during the early development of this promising technology, NFPA would not have supported the use of food crops for the production of [pharm crops]. The risks and impact of contamination of the food supply is simply too great…"[60]

In Texas in 2003, Frito Lay Corporation lobbied for a ban on pharmaceutical food crops. Dr. Robert Drotman, a senior scientist representing the company, stated in testimony: "We believe that the use of food or feed crops for the production of drugs should not be permitted ... the only acceptable outcome for this issue is a guaranteed zero percent contamination of the food supply and currently the only way to achieve this is through using non-food and non-feed crops."[61]

Even Nature Biotechnology, the leading biotechnology science journal, published an editorial calling for the industry to avoid the use of food crops for pharmaceutical production saying: "Simply don't use food crops for producing drugs."[62]

Producing pharmaceuticals or industrial chemicals in food crops in the open air puts the California food supply, markets and public health at unnecessary and potentially costly risk. It is important that any plants genetically engineered to produce pharmaceutical or industrial chemicals be non-food crops grown only in confinement.

Precedents

Federal Endangered Species Act
Under the Act, restrictions are placed on planting certain crops if they impact endangered species. For example, Florida has banned the growing of Bt cotton because of concerns about gene flow to wild relatives of cotton.

Oregon's SB 570
In 2005, a bill was introduced in Oregon to ban the outdoor cultivation of pharm and industrial chemical food crops. The bill did not pass, but a Biopharmaceutical Committee was established to make policy recommendations on the subject, and this report will likely lead to future state legislation.

References

[1] Marvier M., vanAcker R.C. Can crop transgenes be kept on a leash? Frontiers Ecol. Environ. 2005; 3:99-106.

[2] Mellon M., Rissler J. Gone to Seed, Transgenic Contamination in the Traditional Seed Supply. Cambridge, MA: Union of Concerned Scientists; 2004.

[3] GeneWatch UK and Greenpeace International, GM Contamination Report 2005, A review of cases of contamination, illegal planting and negative side effects of genetically modified organisms. Genewatch UK Website. 2005. Available at: http://www.genewatch.org/pub.shtml?als%5Bcid%5D=492774. Accessed October 13, 2006.

[4] Pew Initiative on Food and Biotechnology. U.S. vs. EU: An Examination of the Trade Issues Surrounding Genetically Modified Food, Pew Initiative on Food And Biotechnology. 2003.

[5] Soil Association. Seeds of Doubt: Experiences of North American Farmers of Genetically Modified Crops. Soil Association Website. 2003. Available at: www.soilassociation.org/seedsofdoubt. Accessed on October 13, 2006.

[6] Townsend M. Supermarkets tell Blair: we won't stock GM. The Observer. June 8, 2003.

[7] Greenpeace. The Lost Markets of Genetic Engineering. Digest prepared by Greenpeace, April 2001. Accessed on-line October 3, 2006 at: http://archive.greenpeace.org/geneng/reports/food/lostmarkets2.htm

[8] Dakota Resource Council. One Million Japanese Say NO to GM Wheat: Japanese coalition presents petition to Agriculture Commissioner Roger Johnson. April 8, 2004. Western Organization of Resource Councils website. Available at: http://www.worc.org/issues/art_issues/gm-Japan.html#. Accessed on October 13, 2006.

[9] Wisner, R. GMO Spring Wheat: Its potential short-term impacts on U.S. wheat exports markets and prices. Western Organization of Resource Councils website. 2003. Available at: http://www.worc.org/issues/marketrisk-reports.html. Accessed on October 13, 2006.

[10] Ricenews. Philippines To Buy Only Medium Grain Rice From US. Oryza website. September 4, 2006. Available at: http://www.oryza.com/topic27.html. Accessed on October 13, 2006.

[11] US Rice Producers Association. Rice Producer Update Alert No. 2. August 29, 2006: 2.

[12] Des Moines AP, December 29, 2004. Merry payday For Iowa Farmers. http://www.calgefree.org/news/2004/iowapayout.shtml

[13] United States Department of Agriculture. "Opportunities and Challenges in Agricultural Biotechnology: The Decade Ahead. A report prepared by the USDA Advisory Committee on Biotechnology and 21st Century Agriculture." July 13, 2006

[14] FARM, "The Independent Voice of Farmers," July 10, 2003. Available at: www.connectotel.com/gmfood/fa071003.txt.

[15] Altieri M. The Myth of Coexistence: Why Transgenic Crops Are Not Compatible With Agroecologically Based Systems of Production. Bulletin of Science, Technology and Society. 2005; 25(4): 361-371.

[16] Union of Concerned Scientists. Risks of Genetic Engineering, Union of Concerned Scientists Website. 2005. Available at: http://www.ucsusa.org/food_and_environment/genetic_engineering/risks-of-geneticengineering. Accessed on October 13, 2006.

[17] Benbrook C.M. Genetically Engineered Crops and Pesticide Use in the United State: The First Nine Years. Biotech Infonet Technical Paper No. 7. 2004. Available at: http://www.biotech-info.net/highlights.html#technical_papers.

[18] Heap I. TheInternational Survey of Herbicide Resistant W eeds. W eed Science website. 2006. Available at: www.weedscience.com. Accessed on October 13, 2006.

[19] Warnert, J. UC scientists find herbicide-resistant horseweed in California. University of California, Agriculture and Natural Resources website. Available at: http://news.ucanr.org/newsstorymain.cfm?story=690. Accessed online November 15, 2006.

[20] Committee on Genetically Modified Pest-Protected Plants, National Research Council. Genetically modified pest-protected plants: science and regulation. Washington, DC.: National Academies Press; 2000: 261.

[21] Gunning, R.V., Dang H.T., Kemp F.C., Nicholson I.C., and Moores G.D. New Resistance Mechanism in Helicoverpa armigera Threatens Transgenic Crops Expressing Bacillus thuringiensis Cry1Ac Toxin. Applied and Environmental Microbiology. 2005; 71(5): 2558-2563.

[22] Lang S. Seven-year glitch: Cornell warns that Chinese GM cotton farmers are losing money due to 'secondary' pests. Cornell University, Chronicle Online. Available at: http://www.news.cornell.edu/stories/July06/Bt.cotton.China.ssl.html. July 25, 2006.

[23] Chen L.J. et al. Gene flow from cultivated rice (Oryza sativa) to its weedy and wild relatives. Ann. Bot.: London, 2004; 93(1):67-73. Song Z.P. et al. Fitness estimation through performance comparison of F1 hybrids with their parental species Oryza rufipogon and O. sativa. Ann. Bot: London. 2004: 93(3):311-316

[24] Langevin, S. A., K. Clay, and J. B. Grace. The incidence and effects of hybridization between cultivated rice and its related weed red rice (O. sativa L). Evolution. 1990; 44:1000-1008.

[25] Oard, J., M. A. Cohn, S. Linscombe, D. R. Gealy, and K. Gravois. Field evaluation of seed production, shattering, and dormancy in hybrid populations of transgenic rice (Oryza sativa) and the weed, red rice (Oryza sativa). Plant Science. 2000; 157:13-22.

[26] Gurian-Sherman D. Contaminating the Wild. Washington D.C.: Center for Food Safety; 2006: 6.

[27] McCall W. Engineered Grass Found Growing in Wild. Associated Press. August 17, 2006.

[28] Hall L.K., Topinka J, Huffman et. al. Pollen flow between herbicide-resistant Brassica napus is the cause of multiple-resistant B. napus volunteers. Weed Science. 2000; 48:688-94.

[29] MacArthur M. Triple-resistant canola weeds found in Alberta. Western Producer. February 10, 2000.

[30] Ellstrand N. When transgenes wander, should we worry? California Agriculture, 2006; 60(3):116-125.

[31] Losey J.E. et al. Transgenic pollen harms monarch larvae. Nature. 1999; 399: 214. OR Hansen L C, Obrycki J J. Field deposition of Bt transgenic corn pollen: lethal effects on the monarch butterfly, Oecologia, 2000; 125(2): 241-248.

[32] Hilbeck A., Moar W., Pusztai-Carey M., Filippini M., Bigler F. Toxicity of the Bacillus thuringiensis Cryl Ab toxin to the predator Chrysoperla carnea (Neuroptera: Chrysopidae). Environmental Entomology. 1998; 27(1):255 -63.

[33] Carrierre Y. et al. 2001. Large-scale management of insect resistance to transgenic cotton in Arizona: Can transgenic insecticidal crops be sustained? European Journal of Entomology. 2001; 94: 315-325.

[34] Ellstrand N. Scientists evaluate potential environmental risks of transgenic crops. California Agriculture, 2006; 60(3):119-120.

[35] Quist D, Chapela I.H. Transgenic DNA introgressed into traditional maize landraces in Oaxaca, Mexico. Nature. 2001; 414: 541-543.

[36] Shiva V. Stolen Harvest: The Highjacking of the Global Food Supply. Cambridge, MA: South End Press; 2000.

[37] Cornell Cooperative Extension. Am I eating GE soybeans? Geopie - Genetically Engineered Organisms Public Issues Education Project website. 2005. Available at: http://www.geo-pie.cornell.edu/crops/soybeans.html. Accessed on Oct 13, 2006.
[38] Cornell Cooperative Extension. Am I eating GE corn? Geopie - Genetically Engineered Organisms Public Issues Education Project website. 2005. Available at: http://www.geo-pie.cornell.edu/crops/corn.html. Accessed on Oct 13, 2006.
[39] Malatesta M., Biggiogera M., Manuali E., Rocchi M.B.L., Baldelli B., Gazzanelli G. Fine structural analyses of pancreatic acinar cell nuclei from mice fed on GM soybean. European Journal of Histochemistry, 2003; 47:385-388; Malatesta M, Caporaloni C, Gavaudan S., Rocchi M B L, Tiberi C, Gazzanelli G. Ultrastructural morphometrical and immunocytochemical analyses of hepatocyte nuclei from mice fed on genetically modified soybean. Cell Structure and Function. 2002; 27: 173-180; Malatesta M, Caporaloni C, Rossi L, Battistelli S, Rocchi M B L, Tonucci F, Gazzanelli G. Ultrastructural analysis of pancreatic acinar cells from mice fed on genetically modified soybean. Journal of Anatomy, 2002; 201:409-416; Malatesta M, Tiberi C, Baldelli B, Battistelli S, Manuali E, Biggiogera B. Reversibility of hepatocyte nuclear modifications in mice fed on genetically modified soybean. European Journal of Histochemistry. 2005; 49:237-242; Vecchio L, Cisterna B, Malattesta M, Martin T E, Biggiogera B. Ultrastructural analysis of testes from mice fed on genetically modified soybean. European Journal of Histochemistry, 2004; 48: 449-453.
[40] Prescott et al. Transgenic Expression of Bean-Amylase Inhibitor in Peas Results in Altered Structure and Immunogenicity. Journal of Agricultural and Food Chemistry. 2005; 53(23): 9023-9030.
[41] Netherwood et al. Assessing the survival of transgenic plant DNA in the human gastrointestinal tract. Nature Biotechnology. 2004; 22: 204-209; Duggan et al. Fate of genetically modified maize DNA in the oral cavity and rumen of sheep. British Journal of Nutrition. 2003; 89(2): 159-166.
[42] Ewen S. and Pusztai A. Effect of diets containing genetically modified potatoes expressing Galanthus nivalis lectin on rat small intestine. The Lancet. 1999; 354:1353-1354.
[43] Foucart S. Controversy Surrounds a GMO. Le Monde. December 14, 2004.
[44] Consumer Reports. When it pays to buy organic. Consumer Reports website. 2006. Available at: http://www.consumerreports.org/cro/food/organic-products-206/overview/index.htm?resultPageIndex=1&resultIndex=1&searchTerm=cost%20of%20organic%20food. Accessed online on Oct. 13, 2006.
[45] PANNA, United Farm Workers, California Rural Legal Assistance Foundation, and Californians for Pesticide Reform. Fields of Poison 2002: California Farmworkers and Pesticides. PANNA. 2002. Available at: http://www.panna.org/resources/labor.html.
[46] Board on Agriculture and Natural Resources. Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation, Washington, DC.: National Academy of Sciences Press. 2002: 79
[47] Freese B. Manufacturing Drugs and Chemicals in Plants: Biopharming Poses New Threats to Consumers, Farmers, Food Companies and the Environment. Friends of the Earth website. 2002. Available at: http://www.foe.org/biopharm/bioqanda.pdf. Accessed on Oct 2, 2006.
[48] For a full database of field test releases of GE crops in the U.S., searchable by state, see http://www.isb.vt.edu/cfdocs/fieldtests1.cfm
[49] Union of Concerned Scientists. USDA Retreats from Transgenic Crop Oversight. The Gene Exchange. Fall, 1997.
[50] Board on Agriculture and Natural Resources. Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation, Washington, DC.: National Academy of Sciences Press. 2002: 79.
[51] Audit Report: Animal and Plant Health Inspection Service Controls Over Issuance of Genetically Engineered Organism Release Permits, U.S. Department of Agriculture Office of the Inspector General, Southwest Region, Audit #50601-8-Te, December 2005:i.
[52] Board on Agriculture and Natural Resources. Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation, Washington, DC.: National Academy of Sciences Press. 2002: 79.
[53] Center for Food Safety v. Johanns, Civ. No. 03-00621 (D. Haw., Aug. 10, 2006)
[54] Alliance for Bio-Integrity. Index: Key FDA Documents Revealing (1) Hazards of Genetically Engineered Foods – and (2) Flaws with How the Agency Made Its Policy. Alliance for Biointegrity website. Available at: http://biointegrity.org/list.html. Accessed on Oct 13, 2006.
[55] US Food and Drug Administration. Biotechnology Consultation Agency Response Letter BNF NO. 000034. CFSAN/Office of Premarket Approval website. September 25, 1996. Available online at: http://www.cfsan.fda.gov/~rdb/bnfl034.html. Accessed online on November 15, 2006.
[56] Information Systems for Biotechnology. Field Test Releases in the U.S. Information Systems for Biotechnology website. 2006. Available at: http://www.isb.vt.edu/cfdocs/fieldtests1.cfm. Accessed on Oct. 13, 2006.
[57] Folse, S. Pesticide Sensitivity Registries: Descriptive Summary of a Survey of State Pesticide Sensitivity Registries and Evaluation of Louisiana's Registry for Pesticide Hypersensitive Individuals. Louisiana Department of Health and Hospitals, Office of Public Health, Section of Environmental Epidemiology and Toxicology. Louisiana. 2003.
[58] Hallman W.K., Hebden W.C., Cuite C.L., Aquino H.L., and Lang J.T. Americans and GM Food: Knowledge, Opinion and Interest in 2004. (Publication number RR-1104-007). New Brunswick, New Jersey; Food Policy Institute, Cook College, Rutgers - The State University of New Jersey. 2004.
[59] Senator Kim Elton, Senator Gary Stevens. SB25 Sponsor Statement. Alaska State Legislature. 2005. Available at: http://www.akrepublicans.org/senres/24/pdfs/senres_sb025.pdf#search=%22alaska%20salmon%20sb25%22. Accessed on Oct. 13, 2006.
[60] National Food Processors Association. Statement submitted to USDA Re: Docket No. 03-031-1. Field Testing of Plants Engineered to Produce Pharmaceuticals and Industrial Compounds. 68 Federal Register 11337, March 10, 2003.
[61] Testimony by Robert Drotman, Ph.D, Frito-Lay Company, April 10, 2003, to the Texas House Agriculture and Livestock Committee On House Bill 3387.
[62] Editorial. Nature Biotechnology. February 2004; 22(4)