AGRICULTURAL BIOTECHNOLOGY IN CALIFORNIA SERIES PUBLICATION 8187

UNIVERSITY OF CALIFORNIA
Division of Agriculture and Natural Resources
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Some Food and Environmental Safety Issues with GE Products: A Scientific Perspective

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Genetically engineered (GE) soybeans, corn, canola, cotton, papaya, squash, and alfalfa are now being grown commercially in the United States. Many other GE crops are in the research pipeline. Genetic engineering enables the introduction of genes from the same species and, of more concern to some, genes from other species, using the modern tools of recombinant DNA, a process termed "genetic engineering." For some farmers and consumers, planting and consuming these crops is controversial based on questions concerning food and environmental safety. Consumers, farmers, producers, and scientists need to have accurate information about genetic engineering, its products, and their impact. Products of the technology must be evaluated on a case-by-case basis in order to make informed decisions about their utility and appropriateness. Although considerations beyond the scientific facts should be addressed, science needs to be a part of the discussion. A number of scientific issues related to GE crops and foods are discussed below, although all aspects of these issues are not addressed.

Did people die after consuming tryptophan made by GE bacteria?

In 1989 claims were made that a nutritional supplement, L-tryptophan, used to treat insomnia, premenstrual syndrome, and depression, caused an epidemic of eosinophilia-myalgia in the United States that affected 1,500 people and caused 37 deaths. All these people had consumed tryptophan manufactured by a single company in Japan (Roufs 1992). Although this company produced L-tryptophan prior to 1989 using GE bacteria without incident, in 1989 the company switched to a new strain of GE bacteria and changed to new manufacturing processes, eliminating certain filtration steps and reducing to half the amount of active carbon used to purify the tryptophan. Although the final product was 99.6 percent pure, it was later shown that it still contained 60 different impurities (Mayeno et al. 1994), which could have caused the illness. The cause of the problems was never conclusively linked to the organism or to the manufacturing process, but, in reconstruction experiments, it became likely that the presence of the causative impurity was not related to gene technology. In addition, in a legal brief, it was concluded that the causative contaminant was likely due to the fermentation process and later cooking of the industrial-sized lots of L-tryptophan (see Alexander 1998). Safety testing procedures should have been conducted after changes were made in the strains and production methods.

Have allergens have been introduced into foods through genetic engineering?

Using genetic engineering to introduce genes has the potential both to introduce allergens and also to remove them. In the first case, under the U.S. Food and Drug Administration's (FDA's) biotechnology food policy, GE foods must be labeled if the source of the gene is from one of the common allergy-causing foods, that is, cow's milk, eggs, fish and shellfish, tree nuts, wheat, and especially peanuts and soybeans (Clydessdale 1996), unless the foods are proven not to be allergenic through additional safety testing. Although not mandatory, to date all companies marketing new genetically engineered foods have consulted with the FDA. In this process, the FDA recommends analyzing whether introduced proteins have properties indicating that

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they might be allergenic: similarities to known allergens, small size, slow digestibility, and high heat stability (Taylor and Hefle 2002). Although in each category there are exceptions to the proteins' being allergenic, these characteristics indicate that the protein might be allergenic and merits further study.

One example of an introduced allergen was the introduction into soybean of a protein from Brazil nut, the methionine-rich 2S albumin, to improve soy's nutritional quality since it is deficient in the essential amino acid methionine. Attempts to manipulate this nutrient through traditional breeding failed because of lower yields or grain quality. Allergies to nuts in general are among the most common allergies, and allergies specific to Brazil nut have been documented (Arshad et al. 1991). Therefore, while still in precommercial development, testing of the new soybeans for allergenicity was conducted in university and industrial labs. Serum from people allergic to Brazil nut was found to react with the new soybean (Nordlee et al. 1996), and further development of the new soybean variety was halted and it was never marketed.

Were foods containing StarLink corn removed from the market because they caused allergic responses?

An example of a commercialized GE crop that was recalled due to fears of allergenicity is StarLink corn. Because of increased heat stability and slower digestibility of the Bt protein engineered into this corn variety, StarLink was approved initially only for animal consumption (since farm animals do not have food allergies), while additional testing of the protein was conducted to determine human safety. Due to the difficulty of segregating feed and food seed, StarLink corn got into the human food supply.

In October 2000 the FDA asked the Centers for Disease Control and Prevention (CDC) to investigate 51 reports of human illness apparently related to StarLink corn. Of the 51 reports, 28 described symptoms consistent with a possible allergic reaction to corn products; blood serum samples from 17 of these patients were tested using an ELISA assay, similar to a home pregnancy test, expected to detect antibodies in the blood of persons allergic to StarLink. The CDC study (see CDC 2001) concluded that StarLink-specific antibodies were not detected in any of the human sera; however, the study was not conclusive for two reasons. First, food allergies can occur in individuals even when they do not have detectable allergy-specific antibodies that bind to the allergen (Ogura et al. 1993). Second, the source of the protein used to make the antibodies was bacterial, not plant, and this might have changed the conformational shape of the protein, compromising the specificity of the antibodies raised for testing. Analyses of the corn-containing foods provided by 10 of the 17 CDC test subjects who reported allergic reactions (see EPA 2001), however, proved negative in 9 of the 10 samples; the tenth sample was inconclusive.

Taken together, these results suggest that the Bt protein in StarLink was not involved in the allergic reactions of the 17 individuals tested. But there are still questions that have not been answered, since blood and food samples were not received from all 28 individuals who experienced a true allergic reaction. Conclusions of a scientific advisory panel to the EPA were that, based on biochemical characteristics of the Bt protein, not on its level of presence in the food supply, the Bt protein in StarLink had a moderate chance of causing allergies (see EPA 2000). StarLink corn, however, was removed from the market in 2000, and, although small amounts might still persist in foods, remaining levels are not likely to cause allergy problems.

Can genetic engineering be used to remove allergens from foods?

The nature of the proteins causing allergic reactions in many foods has been well characterized. Therefore, using genetic engineering approaches it is possible to engineer cells to make lower levels of the proteins responsible for allergies or change their conformation, thus reducing allergic responses (Buchanan 2001), for example, allergens in grass pollen (Bhalla et al. 2001; Bhalla and Singh 2004) and in foods such as wheat, rice, and peanuts (Buchanan et al. 1997; Stanley et al. 1997; Tada et al. 1996).

Do only GE foods cause food allergies?

Allergies are not limited to just GE foods. An example of a conventionally bred food now known to cause allergic responses is the kiwi, introduced into the United States in the 1960s. Although not originally a problem, today the kiwi is known to cause allergic reactions (Steurich and Feyerabend 1996), some of them lethal due to cross-allergies with latex (Vozza et al. 2005). The question then is whether the kiwi should have undergone years of food safety testing and how this testing should have been done before introducing the kiwi into the U.S. food supply. Given the food safety testing conducted on GE foods that focuses on the introduced gene, its product, and the determination of substantial equivalence, it seems unlikely that food safety issues related to a commercialized GE food that has undergone FDA scrutiny will be greater than those for conventional foods. Does this mean GE foods are 100 percent safe? No; this is a statement that cannot be made about any food, be it conventional, GE, or organic. However, a 2002 U.S. General Accounting Office report concluded that to date the FDA had adequately safety-tested the new biotech foods before they entered the market, but also suggested room for improvement (see GAO 2002).

Were potatoes genetically engineered with a lectin protein found to be unsafe to eat?

In the late 1990s Arpad Pusztai conducted studies on rats that were fed potatoes engineered with a lectin gene from a snowdrop plant that was introduced into the potato to decrease insecticidal attack. The interpretation of the feeding studies was that rats developed stomach damage because of consuming GE potatoes (Ewen and Pusztai 1999). According to the authors, some effects on the stomach lining were due to the lectin, but other parts of the genetic construct used to introduce the lectin gene or the genetic transformation process itself (or both) also were believed to have contributed to the overall effects of the lectin potatoes.

The broader scientific community found this study to be conducted poorly with too few animals being used and inadequate controls. The study was published in the prestigious medical journal *Lancet* to provide researchers an opportunity to view the data for themselves, as it had been widely discussed in the popular press. The data presented in the paper left researchers with numerous scientific questions and unable to draw firm conclusions (Lachmann 1999) or to confirm or deny the results. The Royal Society criticized the report for its lack of proper controls. In the same issue of *Lancet*, scientists from the Netherlands said that the toxic effects could have come from nutritional differences between the potatoes, not from the GE process (Kuiper et al. 1999). Certainly, to reach firm conclusions on the effects of the lectin gene, the experiments should be repeated on larger numbers of animals and with proper controls. It is important to note that this was not a product that was ever on the market, nor was it intended to go to the market in its tested form. Also, these results do not extend to the safety analysis of other GE crops, which must be tested on a case-by-case basis. For example, similar feeding studies with Roundup Ready soybeans showed that this GE crop is just as safe to eat as its nonengineered counterpart (Harrison et al. 1996; Hammond et al. 1996).

Do some GE crops cause adverse effects on unintended insects?

The only gene used in commercially available GE crops to prevent insect attack codes for Bt, a protein from a naturally occurring soil bacterium, *Bacillus thuringiensis*. The specific Bt proteins (also called Cry proteins) present in many current cultivars of Bt corn are toxic to the larvae of lepidopteran insects (butterflies and moths), but not to other classes of insects or to higher animals, including humans (see Deacon n.d.). The main intended target is the European corn borer, a destructive pest of corn in the United States. Lepidopteran larvae, such as the corn borer, are exposed to the toxin when they eat corn tissues since Bt is made in nearly all tissues.

In most cases, only corn pests encounter the toxin; however, nontarget insects can be exposed by, for example, eating corn pollen of varieties that contain Bt in their pollen, since pollen is carried through the air, landing on plants other than corn. In 1999, Cornell researchers reported that monarch butterfly larvae suffered adverse effects from eating milkweed leaves dusted in the laboratory with pollen from a particular variety of Bt corn (Losey et al. 1999). Larvae offered undefined amounts of Bt pollen in laboratory dishes ate less, gained less weight, and died in greater numbers than control larvae fed milkweed leaves dusted with pollen from non-Bt corn.

This laboratory finding led to further research to better define the risks Bt corn pollen might present in the field to monarch larvae that eat only milkweed, a preferred diet for monarch larvae frequently found in and around corn. To analyze risks associated with Bt corn pollen to monarch butterflies, researchers in subsequent studies asked many questions: how much Bt toxin is present in pollen of different commercial varieties of Bt corn, at what concentrations is Bt pollen harmful to monarch larvae, how much Bt pollen is found on milkweed leaves in or near cornfields, is it likely that monarch larvae will be in or near Bt cornfields when pollen is shed, and how does the risk of exposure to Bt corn pollen compare with the risks of chemical insecticide exposure. Answers to these questions were used to estimate risks monarch butterfly populations face from Bt corn pollen; results were published in a scientifically reviewed journal (see Oberhauser et al. 2001; Sears et al. 2001; Stanley-Horn et al. 2001), and summarized by others (Gatehouse et al. 2002).

As in the laboratory studies, the research on monarch larvae in actual cornfield settings found no acute adverse effects associated with two corn varieties tested, but results did show lower survival rates and less weight gain associated with pollen from one variety. However, when compared to fields of non-Bt corn sprayed with a chemical insecticide, Warrior 1E (lambda-cyhalothrin), rates of survival and weight gain observed in fields of Bt corn were much greater (Stanley-Horn et al. 2001), emphasizing the fact that the impacts observed depend on the comparisons made. Researchers also found that land in and near cornfields is an important habitat for monarch larvae, a fact of importance in Europe, where hedgerows are used to protect nontarget birds and insects. Additionally, researchers noted that young monarch larvae in the northern United States are more likely to encounter corn pollen than larvae further south, where pollen is shed earlier (Oberhauser et al. 2001).

A risk assessment that took all these data, as well as other information, into account concluded that, at current levels of use, Bt corn poses a negligible hazard to the monarch butterfly population (Sears et al. 2001). Other factors, such as habitat destruction and weather conditions, appear to have significantly greater impacts.

What happens when pollen flows from GE to non-GE crops in areas of genetic diversity?

In November 2001, researchers at the University of California, Berkeley, reported in the scientific journal *Nature* that transgenes introduced into genetically engineered insect-resistant corn had been found in kernels harvested from native Mexican corn grown in Oaxaca, Mexico (Quist and Chapela 2001). They further stated that promoters, and possibly genes, were moving around in the genome of the native corn varieties. This event occurred despite a 1998 moratorium on cultivation of GE corn in Mexico and likely happened because of illegal planting of corn imported for food or feed use.

The *Nature* report aroused great interest because Central America, where corn originated, has the most genetically diverse populations of corn in the world, and these native populations are important sources of genetic variation for classical breeding approaches to maize improvement. Native farmers use these varieties to create landraces, varieties bred to perform optimally under local conditions. The report raised concerns that landraces would receive genes from genetically modified corn, which would threaten biodiversity of native corn populations.

Some scientists questioned both the methods and conclusions drawn by the researchers (Christou 2002; Kaplinsky et al. 2002; Metz and Futterer 2002). An editorial note was published in the same issue of *Nature* casting doubt on the paper, stating that evidence provided by Quist and Chapela was incomplete and did not justify its original publication (Nature 2002). The *Nature* editor suggested that readers "judge the science for themselves." Another analysis of the situation was also published that summarized the arguments and looked at the ramifications of the purported illicit transgene flow into corn (Stewart 2002).

Despite serious doubts over the validity of the conclusion by Quist and Chapela that transgenes move around the genome during generation advance, most plant biologists concede, and the Mexican government has molecular evidence, that transgenes did move to Mexican landraces and that this likely traces to transgenic corn that was being illegally grown in Mexico. The issue then becomes not *whether* transgene movement occurs, but what the consequences of this movement are. Does this pose a threat to the genetic variation of landraces, a key to the future improvement of corn? According to a report by the Commission for Environmental Cooperation (CEC) in 2004, "There is no reason to expect that a transgene would have any greater or lesser effect on the genetic diversity of landraces or teosinte than other genes from similarly used modern cultivars" (CEC 2004). Certainly the Bt transgene is not the first gene that moved from modern corn hybrids to landraces. Farmers have had to manage introgression of genes from commercial hybrids for many years (Bellon and Risopoulos 2001). In fact, some farmers have even tried to bring genes from hybrids into landraces to improve certain characteristics (Perales et al. 1998).

It is possible that the farmers could find certain introduced transgenes, like those for herbicide resistance, to be positive traits that they would want to maintain in their landraces, but this might also bring up issues of patent rights. Alternatively, such transgenic traits could be viewed as negative traits that would be specifically selected against. The Mexican government has undertaken several studies to determine the impact of transgenes on maize biodiversity in Mexico (see CEC 2006). Although various moratoria have been in effect, in February 2005 the Mexican government passed legislation that authorizes the planting and selling of GE crops. The new legislation does not grant approval for any GE crop per se, but rather sets out a process and framework for such approval to be granted in the future. Attempts to address genetic resource conservation calls for a yet-to-be-established special protection regime for varieties of maize native to Mexico and requires all GE products to be labeled according to guidelines that will be issued by the Ministry of Health.

The real lesson of the Quist and Chapela work is that genes flow freely from corn plant to corn plant. Scientists and farmers should be aware of the nature of the genes introduced and their possible environmental and health safety consequences and develop methods to deal with the situation.

What happens when pollen flows from GE crops to organic crops?

Another possible impact of gene movement involves passage of genes to organically grown crops. U.S. federal policy, developed by organic farmers themselves, states that GE crops cannot be designated as "organic" (see NOP 2006b). Therefore, although genes have moved from conventional to organic crops for years, movement of engineered genes from conventionally grown to organic crops can cause problems for organic farmers. Will this happen? Pollen will move from plant to plant, but the frequency and its impact depends on a number of variables, including the particular crop (self-pollinating, wind-pollinated, or insect-pollinated), the weather (rain, wind, or temperature), and the distance between crops.

But will organic farmers lose certification if pollen from GE crops drifts onto organic plants and cross-pollinates? The National Organic Program regulations speak to the issue of "GMO contamination" of organic crops by genetic drift. "This regulation prohibits the use of excluded methods [which include GMOs] in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded methods and takes reasonable steps to avoid contact with the products of excluded methods, as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation." According to the Organic Supervisor for the California Department of Food and Agriculture, Dr. Ed Green, the only time an organic farmer will lose certification is when he or she intentionally grows GE crops and they contaminate his or her organic crops. If a certifying agent recommends certification loss, the decision can be appealed.

However, if a certifying agent suspects that an organic product came into contact with prohibited substances or was produced using excluded methods, the agent can call for testing, which under certain conditions could result in the product not being considered "organic" (NOP 2006a), and the farmer losing the ability to sell the crop as organic. So, if a GE corn variety were grown near organically grown corn varieties, could this cause a problem? It is possible for pollen (male cells) from one plant to fertilize the eggs (female cells) of another plant, primarily due to wind. But, according to the Organic Supervisor for CDFA, if this occurs by accident, the grower should not lose his or her organic certification and can sell the product as organic. But the ability to sell the product as organic is up to the discretion of the organic certifying agent, so decisions regarding this aspect can vary from individual to individual.

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Publication 8187

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This publication has been anonymously peer reviewed for technical accuracy by University of California scientists and other qualified professionals. This review process was managed by the ANR Associate Editor for Animal, Avian, Aquaculture, and Veterinary Sciences.

Content is current as of July 2005.

pr-2/06-SB/CR ISBN 978-1-60107-401-0