Transgenic Crops: An Introduction and Resource Guide

FAQs

What exactly is a transgenic plant?
A transgenic plant is one that contains a gene or genes which have been introduced artificially into the plant's genetic makeup using a set of several biotechnology techniques collectively known as recombinant DNA (rDNA) technology. DNA spliced to the coding portion of the genes that serves to regulate how they function is also transferred into the host plant. The inserted genes, called transgenes when they are inserted into the new host plant, may come from another plant of the same or a different species, or a completely unrelated kind of organism like bacteria or animals. Bt corn varieties, for example, contain a gene from a bacterium (*Bacillus thuringiensis*) found in the soil that causes the transgenic corn to produce an insecticidal protein. The gene being transferred may have its genetic code altered to modify its function, in addition to having different regulatory sequences spliced on to control how it is expressed (switched on or off) in the plant. The process of moving genes from one species to another is called transformation.

Once a transgenic plant is created, the transgenes can be inherited along with the rest of the plant's genes through normal mating by pollination. The offspring are also transgenic when they acquire the transgenes this way. Because of this, plant breeders can take a transgenic plant made in the laboratory and use conventional breeding methods to develop different transgenic varieties of the crop that are adapted for specific uses, all with the new trait provided by the introduced genes.

Transgenic plants are often referred to as genetically engineered (GE) plants, or genetically modified (GM) plants, although the latter term is not preferred by some who point out that all crop plants have been genetically modified from their original wild state by domestication, selection and controlled breeding over long periods of time. The U.S. Food and Drug Administration uses the term bioengineered to describe transgenic crops. The term genetic engineering is sometimes used more broadly to describe genetic modifications accomplished by more conventional methods, without using recombinant DNA techniques.

For more information, see our page on how transgenic plants are made.

Why do we want to make transgenic crops?
Very simply, the primary benefit derived from the ability to use genes from other organisms is to increase the amount of genetic variability available for breeders to use beyond that accessible by conventional breeding methods.

The goal is to allow plant breeders to produce more useful and productive crop varieties by exploiting genes from a wide range of living sources, not just those that can be found within the crop species itself. Progress in traditional plant breeding is limited by the genetic diversity within each crop species, the diversity sometimes available from closely related species, or occasionally useful diversity created within the crop itself by inducing mutations. Often, genes for traits that could be of benefit are not found in a particular crop species, so the ability to make plants with new, desirable traits borrowed from other species represents a major technological advance over conventional breeding methods. The transgenic crop varieties made by borrowing genes from other organisms could, potentially, be as seemingly ordinary as tomato plants that can produce good fruit when grown with saltier irrigation water (a trait that might someday be added with much effort using conventional methods) or as exotic as banana plants that produce vaccines to protect against human illness (novel traits that would be impossible to incorporate using traditional methods).

The methods used to make transgenic plants also allow scientists to change crop traits by altering the crop's own genetic code, changing the function of the products coded for by genes or changing the way genes are expressed (switched on or off). This strategy has been used, for example, to modify the way tomato fruits ripen to preserve quality.

In addition to the ability to produce crops with novel traits, genetic engineering also offers the promise of making plant breeding more efficient or for reducing the time required to make new varieties. The ability to insert just one or a few specific genes into varieties without also introducing many other genes that might negatively affect the quality of crop varieties is often cited as a major benefit of using technology to produce transgenic plants. Given the enormous investment of time and money spent identifying useful genes, applying cloning and transformation techniques, and testing and evaluating newly transformed plants, all before conventional crossing to incorporate the genetically engineered traits into adapted crop varieties, some would argue that we are far from realizing this potential benefit.

Research using transgenic plants is an extremely valuable and powerful tool to help scientists learn about how plants function. The knowledge gained from this kind of research can be applied in many areas of plant science, not just in the creation of new crop varieties with novel traits.

What genetically engineered crops are actually being grown now?
The most common genetically engineered (GE) crops now being grown are transgenic varieties of soybean, canola, cotton, and corn. Varieties of each of these crops have been engineered to have either herbicide tolerance or insect resistance (or in a few cases, both).

All of the genetically engineered insect-resistant crop varieties produced so far use specific genes taken from *Bacillus thuringiensis*, a common soil bacterium, to produce proteins that are toxic to certain groups of insects that feed on them. Currently, only Bt corn and Bt cotton varieties are being grown in the U.S., but Bt potatoes were on the market for several years until being discontinued in 2001.

Several different genetic modifications have been used to engineer tolerance to herbicides, the most widely adopted GE trait overall. Genetically engineered herbicide tolerant varieties of each of the four major crops listed above have been developed for use with glyphosate (Roundup®) or glufosinate (Liberty®) herbicides, and some cotton varieties grown in the U.S. have genetically engineered tolerance to bromoxynil or sulfonylurea herbicides. Monsanto's Roundup Ready® soybean varieties are the most widely grown type of genetically engineered plant.

About half of the papaya crop produced in Hawaii is now from genetically engineered virus-resistant varieties, but most of the world-wide papaya crop is not genetically engineered. There is currently some limited production of squash genetically engineered for virus resistance in the U.S.

All together, about 50 different kinds of genetically engineered plants (each developed from a unique "transformation event") have been approved for commercial production in the U.S. These include 12 different crops modified to have six general kinds of traits:

Transgenic trait	**Crops**
Insect resistance	Corn, Cotton, Potato, Tomato
Herbicide tolerance	Corn, Soybean, Cotton, Canola, Sugarbeet, Rice, Flax
Virus resistance	Papaya, Squash, Potato
Altered oil composition	Canola, Soybean
Delayed fruit ripening	Tomato
Male sterility and restorer system (used to facilitate plant breeding)	Chicory, Corn

Not all of the genetically engineered varieties that have received regulatory approval are currently being grown. Some have not yet been marketed (herbicide tolerant sugarbeets and most kinds of GE tomatoes, for example), and some have been commercially grown but were later withdrawn from the market (see Discontinued Transgenic Products). More details on the transgenic crops listed in the table above and short descriptions of how each of the transgenic traits works are available at http://www.comm.cornell.edu/gmo/traits/traits.html. The AgBios GMO Database at http://www.agbios.com/dbase.php?action=ShowForm is a useful source of information about genetically engineered crops that have received or are undergoing regulatory approval in the United States and other countries. You can find detailed information on how each variety was produced, background information on why it was done, and what concerns were addressed during the risk assessments for environmental and food safety. Summary statistics and more information about world-wide production of genetically engineered crops can be found on our Current Transgenic Products page.

Are there really economic benefits for farmers growing transgenic crops? I've read they haven't improved yields and cost more to plant.

Many conflicting news stories and reports have appeared concerning the economic benefits realized by farmers adopting the major transgenic crops. It is true that farmers pay a premium for genetically engineered (GE) corn, soybean, and cotton varieties, and these varieties do not have increased yield potential *per se* over the best available conventional varieties. The potential economic benefits of the major GE crops currently available could result from enhanced protection from yield loss due to pests, increased efficiency in the production system, or both. Actual benefits appear to vary with a number of factors including the particular crop grown, the transgenic trait in the crop (herbicide tolerance or Bt-derived insect resistance), the region where the crops are grown, the type of farm operation adopting the technology, production factors (particularly actual pest pressures) that can vary from year to year and from farm to farm, and the current premium paid for the transgenic seed.

Different methods used to analyze or summarize the limited data available for these diverse situations can lead to very different interpretations. The Economic Research Service of the USDA has issued reports attempting to take these factors into consideration, but their analyses do not yet include data for the most recent production years. While particular cases may vary, some of the general conclusions of the studies are:

- GE herbicide-tolerant cotton and GE herbicide-tolerant corn both have had positive economic impacts on farms overall.
- GE herbicide-tolerant soybeans have not had a positive economic impact overall, but adoption was "quite" profitable for some farms.
- Bt cotton had a positive economic impact on farms overall.
- Bt corn had a negative economic impact on farms overall.

While these generalizations may provide a reasonably unbiased "simple answer" to the question, please refer to the original reports listed below for a discussion of the factors influencing the calculated impacts, and for an analysis of how these findings relate to the adoption of GE crops by U.S. farmers. For example, even though the analysis showed GE soybeans increased net returns only for some farmers, but not GE soybean growers overall, GE soybean plantings have increased each year from their introduction to an estimated 75% of the U.S. crop in 2002. It has been suggested that other benefits recognized by farmers that are more difficult to measure, such as simplified management options, may be important in the adoption of GE-herbicide tolerant soybeans. The AES report Adoption of Bioengineered Crops is available at http://www.ers.usda.gov/publications/aer810/, and Genetically Engineered Crops: U.S. Adoption and Impacts is available at http://www.ers.usda.gov/publications/agoutlook/sep/2002/ao294h.pdf.

Has there actually been a reduction in pesticide use resulting from planting transgenic crops? I understand this is supposed to be one of the major benefits of these GE crops.

The potential for reduction in pesticide use or the substitution of less environmentally hazardous pesticides for those currently used on conventional crops has been proposed as a benefit of certain genetically engineered (GE) crops. This was certainly the case for genetically engineered corn and cotton varieties incorporating Bt genes for resistance to certain classes of insects, where the insecticidal compounds produced by the plants were expected to negate the need for additional insecticide applications to control the targeted pests. GE herbicide-tolerant crops are designed to be used with specific herbicides, so reductions in pesticide use might be realized if switching to a new herbicide application program compatible with a particular GE crop requires less pesticide than the pesticide applications it replaces. Unfortunately, it is difficult to directly compare the impact of these substitutions because application rates, as well as toxicity and environmental hazards, vary for different herbicides. Pesticide use patterns also change for reasons unrelated to the switch to GE crops, and this can complicate comparisons made over time.

Several studies have used data collected by the USDA or industry sources to compare the amount of insecticides or herbicides applied to GE crops compared to conventional crops. Different ways of expressing pesticide use (see Fun with Pesticide Numbers at http://www.comm.cornell.edu/gmo/issues/pestnum.html for a simple example) and grouping data have resulted in different conclusions. An aspect that is obscure in most analyses is the correlation of effects on production with actual changes in the amount or type of pesticides applied. For example, changing pesticide applications can affect yields based on the effectiveness of pest control, but yield changes could also be due to some other production factor.

Although not indisputable, several studies have offered these general conclusions:

- A USDA-ERS econometric model that attempts to control for other variables suggests that, overall, a reduction in pesticide use in the U.S. was associated with the adoption of GE insecticide resistant and herbicide tolerant crops.

- Most comparisons of insecticide use have shown small or not statistically significant reductions attributable to use of Bt corn compared to conventional corn varieties overall. Reasons for this may be because many U.S. Corn Belt corn acres are not actually sprayed specifically for European corn borer (the primary pest targeted by current Bt corn varieties), since outbreaks of this pest are difficult to control and are extremely variable. Also, insecticides used against the European corn borer are also used to control other insect pests and generally would still be applied independently of European corn borer pressure. Some studies have attributed regional increases in yield to better control of European corn borer in Bt corn. In cases where this is true, although the total amount of pesticides released into the environment may not decrease, yield per unit of pesticide applied may increase. (Note that these estimates do not count the Bt toxin produced by the plants as a pesticide application.)

- When considering insecticides directed at pests targeted by Bt cotton (cotton bollworm, tobacco budworm, and pink bollworm), both the number of insecticide applications and the pounds of insecticide used on cotton were significantly lower in 1998 and 1999 in six cotton growing states compared to applications in 1995, prior to the introduction of Bt cotton. These reductions are substantial, representing about 10-14% of the total amount of pesticides used in those states. It is unclear precisely how much of this reduction is directly attributable to the use of Bt cotton. Reductions of insecticide applications (acre-treatments, adjusted for changes in acreage planted) for Bt-targeted pests and significant decreases in yield loss due to Bt-targeted pests were reported in twelve of sixteen cotton producing states in the U.S. in 1998 and 1999 compared to 1995.

- Herbicide applications to soybeans, quantified as total pounds of herbicide active ingredient applied, have increased slightly overall with the adoption of herbicide-tolerant GE varieties, largely because the increased number of pounds of glyphosate applied to Roundup-Ready® soybeans (the most widely adopted type of GE crop in the U.S.) exceeded the reduction in the number of pounds of other herbicides replaced by glyphosate. It has been proposed that the substitution of glyphosate for other herbicides is environmentally beneficial since glyphosate has lower toxicity to mammals, fish, and birds, is less likely to leach, and is less persistent in the environment than the herbicides it replaces.

References and additional resources:
Agricultural Biotechnology: Updated Benefit Estimates, sponsored by the National Center for Food and Agricultural Policy; available at http://www.ncfap.org/reports/biotech/updatedbenefits.pdf
Genetically Engineered Crops: U.S. Adoption and Impacts; available at http://www.ers.usda.gov/publications/agoutlook/sep2002/ao294h.pdf
Genetically Engineered Crops: Has Adoption Reduced Pesticide Use?; available at http://www.ers.usda.gov/publications/agoutlook/aug2000/ao273f.pdf
Genetically Engineered Crops for Pest Management in U.S. Agriculture; available at http://www.ers.usda.gov/publications/aer786/
Additional discussion of this issue, including more references, is available in our discussion of the potential for reducing herbicide applications.

What are the chances I'm eating food made from genetically engineered crops?
Depending on what you eat, the chances could be fairly high that you are eating some genetically engineered (GE) food. About twelve different kinds of GE food crops have been developed for commercialization, but only six of these are currently being grown (corn, soybeans, canola, cotton, squash, and papaya) and have some chance of being part of the food you eat. Even though there are only a few different kinds of GE crops now being grown, it has been estimated that as much as 60 to 70% of the food now in the U.S. marketplace may contain at least a small amount of some ingredient derived from a genetically engineered crop, most commonly corn or soybeans. Since there are no genetically engineered varieties of most kinds of food crops in production, you can be sure those whole foods are not genetically engineered. But knowing exactly which processed foods may have some GE ingredient, or knowing what percentage of those foods might have come from a GE crop is usually difficult.

How do the few kinds of GE crops end up in such a high percentage of our food?
Almost all of the genetically engineered content in food currently comes from just four major crops: soybeans, corn, canola, and cotton (as cottonseed oil). But products made from these major crops are used as ingredients in a wide array of processed food. Just a few examples include such common corn-based ingredients as corn starch, corn flour, masa, corn syrup, corn oil, sweeteners, and certain vitamins. Common soy-based ingredients include soybean oil, flour, lecithin, protein extracts, and Vitamin E. Similarly, canola and cottonseed oils are used in many products including salad dressings, margarines, processed cheese, "non-dairy" products, potato and corn chips, cookies, and pastries.

Since GE and conventional varieties of these crops are not usually kept separate as they move from the farm to the processor, foods made with ingredients derived from these four major crops may have some GE content. Many of the ingredients derived from these crops are so highly processed or refined that it could be difficult to determine whether they came from GE, non-GE, or mixtures of both kinds of crops.

Certified organic food is handled differently. To be sold as "organic", detailed record-keeping during all phases of production and processing is required to assure crops or ingredients made from them are not mixed with non-organically grown or GE food. The Cooperative Extension Service at Cornell University (Genetically Engineered Organisms -- Public Issues Education Project) has developed an informative discussion of how likely you are to encounter GE food in today's market based on which genetically engineered crops have been approved for production in the U.S. For more information, visit GE Foods in the Market at http://www.comm.cornell.edu/gmo/crops/eating.html.

Can I avoid GE food if I buy only organically grown food?
Yes, if you buy food labeled "100% organic", "organic" (95% or more organic content) or "made with organic [food or food group]" (70-95% organic content) you have some assurance the food has not been genetically engineered. By law, foods with these label designations (which appear on the product label's principal display panel) cannot be genetically engineered single foods or contain genetically engineered ingredients, including the non-organic ingredients. Foods with a total content of less than 70% organic ingredients may have the organic components identified specifically in the list of

ingredients, but the non-organic components are not required to be free of genetically engineered products. Food in this last category cannot have the word "organic" on the principal display panel of the label.

Labeling requirements for food sold as organic in the U.S. are defined in the final rules for the National Organic Program, which operates under the direction of the Agricultural Marketing Service of the USDA. The program was authorized by the Organic Foods Production Act of 1990. The list of "excluded methods" pertaining to genetically modified organisms includes "cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology)." The excluded methods do not include "the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture."

One concern that some people opposed to genetically engineered foods have expressed about the rules for the National Organic Program is that they do not specifically address issues that could arise from inadvertent cross-pollination of organically grown crops by genetically engineered crops.

For more information on labeling organic food, see the National Organic Program's labeling fact sheet. Complete information about the National Organic Program is available at http://www.ams.usda.gov/nop/.

Why do organic farming advocates object to transgenic crops using Bt genes while accepting the use of Bt sprays as an acceptable insect control measure?
Bt (*Bacillus thuringiensis*) is a naturally occurring soil bacterium that produces proteins (called Cry proteins) toxic to certain insects. Various kinds of the insecticidal Cry proteins, with effectiveness against different groups of insects, are produced by different strains of Bt. Spray formulations of Bt have been used as insecticides for over forty years, and recently the genes that encode certain Bt Cry proteins have been cloned and used to genetically engineer several crop species to produce insect resistant varieties.

A major concern of many people, not just organic growers, is that widespread use of Bt genes in genetically engineered crops will increase the likelihood that pest populations will develop resistance to the Bt toxins. If this occurs, not only will the utility of Bt crops be diminished, but farmers who currently rely on Bt foliar pesticide applications could suffer important losses as well. At least one case where an insect (the diamondback moth) has developed resistance to Bt in response to heavy use of spray applications in an agricultural environment has been documented, and the development of resistance to Bt by several species of insects has been demonstrated in the laboratory. Most scientists agree that the development of resistant insect populations is a potential hazard associated with the use of genetically engineered Bt crops. There is a concern that genetically engineered Bt crops may pose a higher risk for insects developing resistance than that posed by conventional spray applications because they place a very high selection pressure on the pests, and they currently lack additional insecticidal components or synergistic compounds found in Bt spores that might act to prevent or delay development of resistance.

In response to these concerns, the EPA has imposed several requirements for developing and implementing resistance management strategies, and for monitoring insect populations for resistance. Provisions for remedial actions, such as prohibiting Bt crops in certain areas based on the results of pest monitoring, are part of these regulations. A major component of the resistance management strategy is a requirement for planting refuge areas of specified size to non-Bt varieties along with Bt crop varieties. The purpose of the refuge is to maintain an adequate breeding population of susceptible insects to intermate with insects that might carry a mutation for resistance, hopefully keeping the frequency of the resistance alleles low in the insect populations. Companies marketing Bt crop seed are required to inform growers about the proper methods of integrating non-Bt refuge areas with Bt crops, and growers must sign contracts agreeing to comply with resistance management practices. The companies also are required to monitor the development of insect resistance, provide annual reports on the efficacy of resistance management plans, and implement remedial action plans in the event that resistance is detected among pest populations. There is an ongoing debate over the requirements for effective refuge designs, and there is some concern about how well the refuge strategy will work. Additional strategies to avoid resistance, such as including more than one Cry gene in crop varieties, are being developed.

More details about refuge requirements and resistance management strategies can be found at the following links:
http://www.ext.colostate.edu/pubs/crops/00708.html
http://www.extension.umn.edu/distribution/cropsystems/DC7055.html
http://www.epa.gov/pesticides/biopesticides/regofbtcrops.htm
http://www.asmusa.org/acasrc/pdfs/Btreport.pdf (large file).

How do we know genetically engineered crops are safe to eat?
The primary concern many people have about genetically engineered (GE) crops is the safety of food made from them. Although there continues to be quite a bit of controversy over this issue, no evidence has been found that foods made with the genetically engineered crops now on the market are any less safe to eat than foods made with the same kinds of conventional crops. Genetically engineered crop varieties are being subjected to far greater scientific scrutiny than that ordinarily given to conventional varieties, even though many scientists have argued that there is no strict distinction between the food safety risks posed by genetically engineered plants and those developed using conventional breeding practices.

Safety assessments of foods developed using genetic engineering include the following considerations:

- evaluation of the methods used to develop the crop, including the molecular biological data which characterizes the genetic change
- the evaluation for the expected phenotype
- the general chemical composition of the novel food compared to conventional counterparts
- the nutritional content compared to conventional counterparts
- the potential for introducing new toxins
- the potential for causing allergic reactions.

The goal is not to establish an absolute level of safety, but rather the relative safety of the new product so that there is a reasonable certainty that no harm will result from intended uses under the anticipated conditions of production, processing and consumption. Since conventional crops have known histories of safe use given certain identifiable risk factors, genetically engineered crops are considered to have the same relative safety as their conventional counterparts if they do not differ significantly from conventional crops for these risk factors. See http://www.agbios.com/cstudies.php?book=FSA&ev=MON810&chapter=Preface and http://www.agbios.com/cstudies.php?book=FSA&ev=GTS&chapter=Preface for examples of the food safety assessment for two genetically engineered crops.

Some critics of GE crops point out that a lack of evidence for harmful effects does not mean they do not exist, but just as likely could mean that we have not done the proper studies to document them. Some reject the idea that we face the same kinds of risks from GE crops as from conventionally developed crops, believing the genetic engineering process itself introduces unique risks. A major concern often expressed about GE food safety is the risk for unintentional, potentially harmful changes that may escape detection in the evaluation process. It is true that the number of factors that are examined for change is small compared to the total number of components produced by plants. Also, more extensive comparisons of plant chemical compositions would be difficult because complete data describing the composition of conventional crop plants, including knowledge of variability among different cultivars or that due to environmental influences, is lacking. The random nature of transgene insertion when making GE plants, it is argued, may cause disruption of important genes, causing significant effects but little obvious change to the plant's phenotype. Additional opinions and considerations about the safety of genetically engineered foods can be found in our discussion of risks to human health and at

http://www.comm.cornell.edu/gmo/issues/issues.html
http://www.royalsoc.ac.uk/files/statfiles/document-165.pdf
http://www.nap.edu/books/0309069300/html/

Why is there so much debate about mandatory labeling of genetically engineered foods?

Whether or not to require mandatory labeling of genetically engineered (GE) foods is a major issue in the debate over the risks and benefits of food crops produced using biotechnology. The issue is complex because (1) many arguments put forth in the debate are based on disagreements about the adequacy of our scientific understanding of the consequences of genetic engineering; and (2) significant changes to our current food marketing and manufacturing system, with potentially large economic impacts, would be required to implement mandatory labeling.

Central to the arguments for mandatory labeling is that consumers have a right to know what is in their food. This is especially true for some products made with biotechnology where health and environmental concerns have not been satisfactorily resolved. Some people do not wish to use genetically engineered products for religious or ethical reasons. Labeling is the only way consumers can make informed choices, whatever their reasons may be.

Major arguments against mandatory labeling have addressed the practical concerns about the expense and complex logistics that would be required to ensure GE and conventional foods are kept separate or to test all foods for GE content. It is argued that such measures are unnecessary since no significant differences have been found between today's GE foods and conventional foods.

Enacting mandatory labeling will also require resolving certain other questions. Major issues include defining exactly what kinds of technologies would be covered, deciding on tolerance levels for genetically engineered content or ingredients before labeling would be required, and choosing a method for verifying that products are properly labeled. Please see the fact sheet Labeling of Genetically Engineered Foods for a full discussion of the arguments for and against mandatory labeling and the issues that will have to be resolved if such legislation is enacted.

Aren't there some food labeling requirements for genetically engineered foods now?

Under current policy, the U.S. Food and Drug Administration does not automatically require all genetically engineered food to be labeled. Conventional and genetically engineered (GE) foods are all subject to the same labeling requirements, and both may require special labeling if particular food products have some property that is significantly different than what consumers might reasonably expect to find in that kind of food. Therefore, particular genetically engineered foods are subject to special labeling requirements if the FDA concludes they have significantly different properties including:

- a different nutritional property from the same kind of conventional food
- a new allergen consumers would not expect to be in that kind of food (a hypothetical example would be an allergenic peanut protein in GE corn or some other crop)
- a toxicant in excess of acceptable limits.

Examples of genetically engineered foods that require special labeling are those that contain vegetable oil made from varieties of GE soybeans and canola where the fatty acid composition of the oils extracted from the seeds of these crops was altered. Since the oils from these varieties have different nutritional properties than conventional soy and canola oils, foods made with them must be labeled to clearly indicate how they are different. You might see "high laurate canola" or "high oleic soybean" on food labels if these products were used. The FDA does not require them to be labeled as "genetically engineered", but that information could also be included on the label.

So far, no approved, commercially grown genetically engineered food crops have known properties that would require foods made from them to be labeled because they contain a new allergen or excess levels of toxic substances.

The FDA has recently proposed voluntary guidelines for labeling food that does or does not contain genetically engineered ingredients to help industry provide information to consumers in a manner the FDA considers to be accurate and not misleading in accordance with established food labeling policy. Federal legislation has been proposed that would require mandatory labeling of genetically engineered foods, and similar initiatives at the state or local level have been considered or are currently pending. For more information, see the fact sheet Labeling of Genetically Engineered Foods.

Haven't people had allergic reactions from eating transgenic corn and soybeans?
Some people are allergic to proteins that occur naturally in soybeans, and they could have a reaction if they are exposed to either conventional or transgenic soybeans or soy products. Soybeans are one of the eight most common sources of food allergies. Although less common, some people have food allergies associated with corn and they could be affected by either conventional or transgenic corn. No allergic reactions attributable to the proteins present as a result of genetic engineering have been reported in the transgenic soybeans being grown commercially at this time. Reports of an allergenic protein made as a result of genetic engineering in one particular type of transgenic corn could not be confirmed by subsequent testing.

While there isn't any evidence that allergens have been introduced into food crops by genetic engineering, two incidents have received quite a bit of publicity and caused public concern about food allergies resulting from transgenic crops.

The first incident involved soybean plants being developed by Pioneer Hi-Bred in the early 1990's. Pioneer used a gene from Brazil nuts to make soybeans that contained higher levels of the amino acid methionine. They wanted to make a more nutritious chicken feed that would eliminate the need for expensive feed supplements. While these transgenic soybeans were being tested, research funded by Pioneer discovered that the protein made by the Brazil nut gene could cause allergic reactions in humans. Pioneer stopped development of these soybeans in 1993, and they were never sold or grown for market. You can find Pioneer's account of this story at http://www.pioneer.com/biotech/brazil_nut/default.htm.

The second incident involved reports of allergic reactions in people who may have eaten food containing the insecticidal protein called Cry9C, one of several forms of the Bt insecticide. The gene for this protein had been genetically engineered into Starlink corn by Aventis CropScience. Starlink corn had only been approved for use as animal feed or for industrial purposes, but not for human consumption, because tests made when Starlink was being developed showed the Cry9C protein had certain characteristics in common with other proteins known to be allergenic. When food from grocery shelves tested positive for Cry9C, demonstrating that Starlink had accidentally made its way into the food supply, a massive screening and recall effort was put into effect. During this time, the reports surfaced of allergic reactions in people who had eaten corn products that may have been contaminated by Cry9C. The Food and Drug Administration and Centers for Disease Control investigations that followed found 28 cases where people had apparently suffered allergic reactions to something, but the special test developed by the FDA (an enzyme-linked immunosorbent assay, or ELISA test, to detect people's antibodies to the Cry9C protein) did not find any evidence that the reactions in the affected people were associated with hypersensitivity to the Cry9C protein. The test isn't 100% conclusive, though, partly because food allergies may sometimes occur without detectable levels of antibodies to allergens. The EPA ruled on July 27, 2001, to keep a zero tolerance policy for Cry9C in food, based on the original suspicions of potential allergenicity. You can review the CDC report at http://www.cdc.gov/nceh/ehhe/Cry9cReport/default.htm. More information about the Starlink corn incident can be found in our discussion on StarLink corn. A more detailed discussion of concerns about food allergies resulting from transgenic crops is available in our discussion of allergies.

How does the government regulate genetically engineered crops?
The federal government first adopted a "Coordinated Framework for Regulation of Biotechnology" in 1986. Under this system, three federal agencies have regulatory authority over genetically engineered (GE) crops. Each agency has a different role to

ensure safety under specific legislation. These agencies and their regulatory responsibilities are:

- The U.S. Department of Agriculture (USDA), through the Animal and Plant Health Inspection Service (APHIS), is responsible for assuring that any organism, including genetically engineered organisms, will not become pests that can cause harm if they are released into the environment. APHIS has used their authority to grant permission and set the rules for field testing of genetically engineered crops. These crops cannot be commercialized until they are granted "non-regulated" status by APHIS upon satisfactory review of the field testing data. Detailed information about the procedures APHIS uses to regulate genetically engineered plants is available at http://www.aphis.usda.gov/ppq/biotech/.

- The Food and Drug Administration (FDA) is responsible for ensuring the safety of most food (except for meat, poultry and some egg products, which are regulated by the U.S. Department of Agriculture), including food from genetically engineered crops. If the allergen, nutrient and toxin content of new GE foods fall within the normal range found in the same kind of conventional food, the FDA does not regulate the GE food any differently. So far, all genetically modified foods in the U.S. marketplace have gone through a voluntary review process where the FDA determines whether they are "not substantially different" from the same conventional foods by consulting with developers of new GE foods to identify potential sources of differences, then reviewing a formal summary of data provided by the developer. Recently, the FDA has announced a new rule that would make pre-market consultation mandatory. The FDA has the authority to order foods to be pulled from the market at any time if are found to be unsafe, or to require labeling of any food that has different amounts of allergens, nutrients, or toxins than a consumer would expect to find in that kind of food. Information from the FDA about their role in regulating GE foods is available at http://vm.cfsan.fda.gov/~lrd/biotechm.html.

- The Environmental Protection Agency (EPA) evaluates the safety of any pesticides that are produced by genetically engineered plants. The EPA calls novel DNA and proteins genetically engineered into plants to protect them against pests "plant incorporated protectants" (PIPs) and regulates them the same way they regulate other pesticides. EPA documents concerning plant incorporated protectants can be found at http://www.epa.gov/pesticides/biopesticides/.

Under the Coordinated Framework, some kinds of genetically engineered crops might not be subject to the oversight of all three agencies. For example, an ornamental flower like petunias engineered to have longer lasting blooms may only have to meet the requirements of APHIS, but a food crop like soybeans engineered to produce an insecticidal compound would be subject to the rules of all three agencies. Additional regulations are imposed by some states, but Colorado does not currently have additional requirements. Also, the National Institutes of Health has developed safety procedures for research with recombinant DNA. Most institutions developing genetically engineered crops follow the NIH guidelines, and they are required for federally funded research.

A useful overview of the U.S. regulatory process, including links to information about the laws granting authority to the agencies and their primary rules and regulations, is available at http://www.aphis.usda.gov/ppq/biotech/usregs.html. The regulatory process is complex and changes are being proposed by the regulatory agencies themselves, independent scientific review panels, and the public. Detailed discussions of how the regulatory system works and some issues raised by critics of the current system can be found in the following links:
our page on evaluation and regulation of crops at /TransgenicCrops/evaluation.html, Cornell University's page at http://www.comm.cornell.edu/gmo/regulation/reg.html, and the AgBios web site at http://64.26.172.90/agbios/regulate.php?action=USA

How is "substantial equivalence" used to determine the safety of genetically engineered food?

The principle of substantial equivalence is a functional part of the current risk assessment process used to evaluate the safety of new foods produced using biotechnology. Basically, the concept of substantial equivalence is that novel crops or foods, such as those made using genetic engineering, can be compared with the same kinds of conventional crops or foods that have established histories of safe use given certain known risk factors.

A number of properties of the novel and conventional products, including the levels of nutrients, toxic substances, and potential allergens, may be compared taking into account established patterns of processing and consumption. If the comparison reveals that there are no significant differences between the two kinds of food, the novel food is presumed to be no less safe than the conventional food.

Substantial equivalence is not an evaluation of the absolute safety of a novel biotech product, but rather a practical method to establish food safety relative to an analogous conventional product with familiar levels of safety and risks. In practice, if the Food and Drug Administration finds that bioengineered foods are "not substantially different" from conventional foods, they are not regulated any differently and are considered interchangeable with the conventional foods for use in the U.S. Where a product is found not to be substantially equivalent to an existing one, further investigations focusing on the identified differences would be required to establish risk factors.

Lack of substantial equivalence does not necessarily mean the novel product isn't safe. For example, soybeans genetically engineered to produce oil with a different fatty acid composition (an identified nutritional difference) from conventional soybeans might have an advantage over conventional soybean oil when used for cooking because the GE soybean oil eliminates the need for industrial hydrogenation, which produces undesirable trans-fatty acids. Totally new foods, where no similar materials have ever been consumed, could not be evaluated using substantial equivalence and would have to be evaluated solely on the basis of their own unique properties.

Critics of our current evaluation process argue that comparing genetically modified and conventional foods for differences in a few known risk factors is not adequate evidence that they are safe for human consumption. Concerns center on possible unexpected effects that may escape study and that substantial equivalence has never been properly defined or cannot really be fully tested.

A more detailed discussion of how substantial equivalence is used to evaluate novel food safety and what some of the major limitations are is available at http://www.agbios.com/cstudies.php?book=FSA&ev=MON810&chapter=Concepts. A recent scientific review published by The Royal Society of the United Kingdom also contains a detailed critique of substantial equivalence. This report can be found at http://www.royalsoc.ac.uk/files/statfiles/document-165.pdf.

Why do GE plants have antibiotic resistance genes? Doesn't this pose a risk for developing resistant strains of bacteria?

Antibiotic resistance genes are frequently used at several stages in the creation of genetically engineered plants as convenient "selectable markers". Bacteria or plant cells without a gene for resistance to the antibiotics used can be killed when the antibiotic is applied to them. So when scientists link the gene for the desired trait being introduced into a plant with an antibiotic resistance gene, they can separate cells carrying the desired gene from those that don't by exposing them to the antibiotic. The antibiotic resistance genes end up in the genetically engineered plants as excess baggage whose function is no longer required after the process of making them is complete.

Concern has been raised about the possibility that antibiotic resistance genes used to make transgenic plants could be transferred to microorganisms that inhabit the digestive tracts of humans or other animals that eat them, and therefore might contribute to the already serious problem of antibiotic resistant pathogens. Transfer of DNA from one microbe to another (horizontal gene transfer) is known to occur in nature and has been observed in some laboratory experiments under specific conditions, but the likelihood of DNA being transferred from plant material in the digestive system to microbes has not yet been experimentally determined. It is thought that for such a transfer to be possible, it would have to come from consumption of fresh food since most processing would degrade the plant's DNA. Also, there is evidence that most DNA is rapidly degraded by the digestive system. However, results of one recent experiment have suggested that horizontal transfer of DNA from genetically engineered plants can occur in the human digestive tract under some circumstances. But overall, the risk of antibiotic resistance genes from transgenic plants ending up in microorganisms appears to be low.

A second concern about the use of some antibiotic resistance genes is that they could reduce the effectiveness of antibiotics taken at the same time transgenic food carrying the resistance gene for that antibiotic was consumed. In cases where this has been identified as a risk based on the mechanism of resistance, studies have suggested the chance of this happening was probably very low due to rapid digestion of the inactivating enzymes produced by the transgenic resistance gene. Most transgenic plants do not carry resistance genes for antibiotics commonly used to treat infections in humans.

While the risk of creating additional problems of antibiotic resistance in microorganisms from the use of the resistance genes in transgenic plants appears to be low, steps are being taken to reduce the risk and to phase out their use. The FDA recommends that developers of transgenic crops use only antibiotics that are not commonly used for treatment of diseases in humans. Scientists are developing and using different selectable markers, and are also experimenting with methods for removing the antibiotic resistance genes before the plants are released for commercial use. Further discussion of concerns about the use of antibiotic resistance genes in genetically engineered plants can be found in our discussion of antibiotic resistance genes and in a report by the Royal Society at http://www.royalsoc.ac.uk/files/statfiles/document-56.pdf

Are there health risks from eating the foreign DNA in transgenic plants?
It is unlikely that eating DNA poses any significant risk to human or animal health, and there is no evidence to suggest that there is any additional risk from the transgenes present in genetically engineered plants.

Normal diets for humans and other animals contain large amounts of DNA. This DNA comes not only from the cells of the various kinds of plants or animals constituting the food, but also from any contaminating microorganisms or viruses that may be present in or on the food. We have been exposed to this variety of DNA throughout our entire history.

Most of the DNA we eat is degraded in the digestive system, but some experiments have shown that small amounts of it can be found in some cells in the body. It is thought to be unlikely that this DNA would be incorporated into the DNA of those cells, but even if it was, the chance of any undesirable effect on the whole organism is thought to be very low.

There is evidence to suggest that certain kinds of intact genetic elements have been incorporated into human DNA sometime during our history, but there is a lack of recognized negative consequences to our health that can be attributed to this. It seems that we are well adapted to handling exposure to DNA, and there is no obvious reason that the DNA from other organisms introduced into crops by genetic engineering would have any additional effect. References for research in this area and further discussion can be at found in our discussion of eating DNA or in a longer review of risks posed genetically engineered crops published by The Royal Society of the United Kingdom. The report is available at http://www.royalsoc.ac.uk/files/statfiles/document-56.pdf.

I hear the terms "genetic drift" and "genetic trespass" in the debate about transgenic crops. What do they mean?
"Genetic drift" or "pollen drift" used in this context refers to the unintentional transfer of pollen from transgenic crops to nearby conventional crops by wind or insects. Seeds produced on the conventional crop resulting from pollination by the transgenic crop will also contain the genes of the transgenic crop. The term is meant to describe problems with contamination of non-genetically engineered crops by transgenes in the same way "pesticide drift" is used to describe contamination of non-target crops by errant pesticide applications. You might also see the phrase "crop-to-crop gene flow" used to describe the transfer of genes from one crop variety to another by cross-pollination. "Genetic drift" has a different meaning in the field of population genetics.

Seed producers have long been concerned with preventing cross-pollination among crop varieties in order to maintain the purity (the genetic identity) of each of the varieties they grow. The chance of pollen drift from transgenic crops has raised additional issues about the purity or "identity" of crops entering the marketplace. For example, crops grown for the organic market cannot be genetically engineered. What happens if they are partially cross-pollinated by a genetically engineered crop? Can they be sold as organic? What tolerance levels, if any, should be established to account for small amounts of cross-pollination? Who is responsible for preventing cross-pollination? Is a grower guilty of "genetic trespass" if pollen from his crop affects the marketability of a neighbor's crop? Producers of conventionally grown crops for export are also facing these issues because some markets have banned genetically engineered food.

Pollen drift is more likely with naturally cross-pollinating crops like corn than with highly self-pollinating crops like soybeans. Problems can be prevented by carefully maintaining crop-specific isolation distances between different varieties. Sometimes additional strategies are employed, such as using border strips around fields to trap pollen. More information about the concerns arising from the potential for "genetic trespass" is available in our discussion of crop-to-crop gene flow.

I'm concerned by the reports of transgenic DNA found in Mexican corn landraces. Isn't this evidence that transgenic crops will cause environmental damage by reducing genetic diversity?

Genes engineered into crops can be transmitted to other plants of the same species or to sexually compatible wild relatives by pollination. Hybridization of transgenic crops with other plants raises environmental concerns on several fronts, including the possible introduction of traits that could increase the weediness of some species, the potential for affecting the genetic diversity or ecological status of natural, non-weedy plant populations, and the potential for affecting the genetic diversity found in crop landraces (traditional, locally adapted varieties). Of course, gene flow from conventional, non-genetically engineered crops also occurs, and has been implicated in causing undesirable changes in certain natural plant populations and in the evolution of more aggressive weeds for several crops. Many factors influence the potential consequences of gene flow from crops, and whether transgenic crops are more or less likely to cause undesirable effects is unknown.

The recent reports of transgenic DNA in corn growing in southern Mexico, despite a government moratorium since 1998 on planting transgenic corn, generated a great deal of concern, since this region is a center of genetic diversity for maize (corn) and the potential effects of transgenes introduced from genetically engineered varieties on the landraces or wild maize relatives growing there are unknown. While the study reporting the presence of transgenic DNA in Mexico has generated controversy over the methodology used and certain conclusions, the plausibility of transgenic corn growing in Mexico is generally not questioned. Continued monitoring and additional research, however, will be needed to understand the actual effect on genetic diversity, if any, of introducing a few, specific genes into the maize populations of Mexico. Concerns about the difficulty of controlling the spread of transgenes via crop-to-crop or crop-to-wild gene flow are valid. Examples from existing population genetics research suggest there will not be a universal answer to describe the risks of gene flow from any particular transgenic crop. Each kind of transgenic crop developed should be specifically evaluated for the various environmental risks related to potential gene flow.

For an in-depth review of the reported discovery of transgenic DNA found in Mexican maize, the controversy surrounding the studies, and the possible consequences, please see our discussion of GM Maize in Mexico. Additional information about concerns of gene flow from transgenic crops:
http://www.comm.cornell.edu/gmo/issues/hgt.html
/TransgenicCrops/croptoweed.html Ellstrand, Norman C. 2001. When Transgenes Wander, Should We Worry? Plant Physiology, Vol. 125, pp. 1543-1545, available at http://www.biotech-info.net/wandering_transgenics.html.

Does herbicide-tolerant Clearfield® wheat, such as the cultivar 'Above' developed at CSU, incorporate a transgenic trait?

Both transgenic and conventional crop varieties are sold under the Clearfield® brand. Buyers should check the information provided for the particular variety of interest.

'Above' wheat is not a transgenic cultivar. Researchers at American Cyanamid, now part of BASF Corporation, identified the trait for tolerance to imidazolinone (IMI) herbicides in a wheat plant after exposure to a chemical mutagen. The herbicide tolerance trait was transferred to adapted wheat cultivars by conventional crossing, and 'Above' was subsequently selected from breeding populations segregating for herbicide tolerance and other traits. The process of induced mutagenesis used to develop the herbicide tolerance trait is considered to be a conventional breeding technique, and 'Above' is not considered to be genetically engineered or a genetically modified organism.

BASF Corporation still owns the gene for IMI herbicide tolerance that is used in 'Above'. More information about the 'Above' wheat variety and the Clearfield® production system is available at http://wheat.colostate.edu/03116.html (html file) or http://wheat.colostate.edu/03116.pdf (pdf file).

BASF Corporation also owns imidazolinone-tolerance genes used in varieties of corn, canola, rice, and sunflower in addition to imidazolinone tolerant wheat, like 'Above'. All are marketed as Clearfield® varieties. The herbicide tolerance genes used in these crops also were individually derived through mutagenesis (the sunflower IMI tolerance gene was identified as a mutation in a natural population of sunflowers), and varieties incorporating these genes alone are not transgenic. Some confusion exists, however, because some corn varieties incorporate both the IMI herbicide-tolerance gene and a transgenic trait, Bt-derived insect resistance. These Clearfield® corn varieties are genetically engineered, transgenic plants, but the herbicide tolerance is not the transgenic trait. More information can be found on the BASF website at http://www.clearfieldsystem.com/html/gmo.html.

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