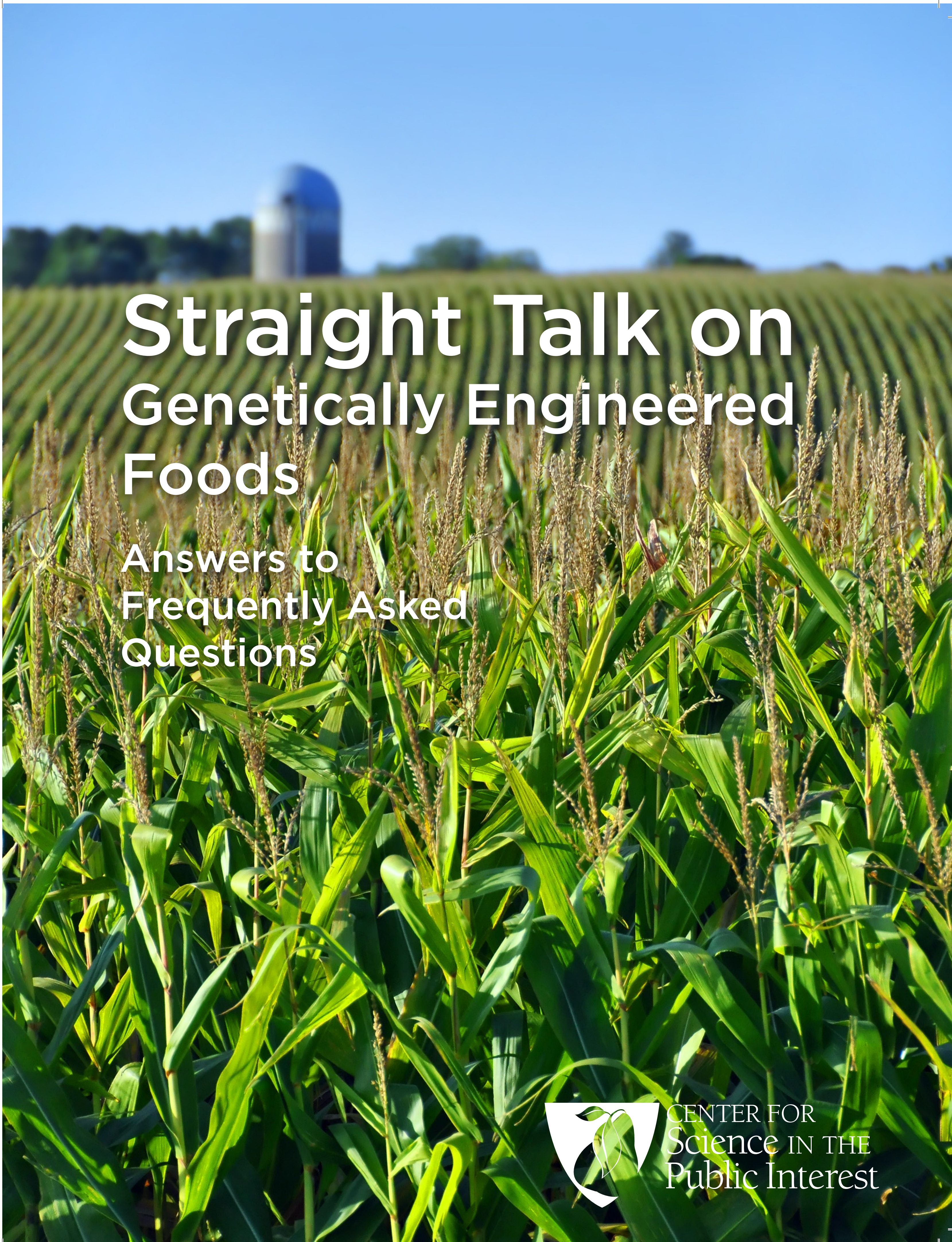
Straight Talk on Genetically Engineered Foods

Answers to Frequently Asked Questions



CENTER FOR Science IN THE Public Interest

First Printing April 2012
Printing: 5 4 3 2 1

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We would also like to thank Debra Brink and Jorge Bach for designing and producing
the pamphlet and Cassie Boles for reviewing the pamphlet.

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About the Center for Science in the Public Interest and its Biotechnology Project

The Center for Science in the Public Interest (CSPI) is a nonprofit education and advocacy organization that focuses on improving the safety and nutritional quality of our food supply. CSPI seeks to promote health through educating the public about nutrition; it represents citizens' interests before legislative, regulatory, and judicial bodies; and it works to ensure advances in science are used for the public good. CSPI is supported by the 850,000 member-subscribers to its Nutrition Action Healthletter and by foundation grants. CSPI receives no funding from industry or the federal government.

The CSPI Biotechnology Project addresses scientific concerns, government policies, and corporate practices concerning genetically engineered (GE) plants, animals, and other organisms that are released into the environment or that may end up in our foods. Accurate identification of the risks and benefits of agricultural biotechnology, ensuring that the U.S. regulatory system is up to the task of preventing significant risk, and keeping the public informed are some of the goals of CSPI's Biotechnology Project.

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Introduction

In the past 15 years, genetically engineered (GE) crops have become part of mainstream agriculture in developed and developing countries alike. American farmers planted 170 million acres of GE corn, soybeans, cotton, canola, sugar beets, alfalfa, papaya, and squash in 2011. Food manufacturers estimate that 70 percent of processed foods contain at least one ingredient made from those GE crops. Their advent, however, has not been without controversy and concern for human health and the environment, and critics, as well as devotees, are plentiful.

Are GE foods harmful to eat? Do GE crops benefit the environment? What is the federal oversight of GE crops and animals and is it adequate? What can we expect from this technology in the coming years both in the United States and for developing countries? These questions and many others are addressed in this booklet.

Background on Genetically Engineered Organisms in Agriculture

1. What does it mean to "genetically engineer" an organism?

When scientists genetically engineer a plant or animal, they remove a gene from one organism (or a specific variety of an organism) and transfer that gene to a different organism (or different variety) using recombinant DNA methods. The new gene becomes integrated into every cell of the organism and is inherited by the organism's offspring. In most cases, the new gene produces a new protein, which then provides the organism with some useful trait. In some cases, scientists use this technique to silence an existing gene (i.e. to prevent its expression) or to get a plant to express an otherwise silent gene.

2. Is the use of genetic engineering different from classical breeding of plants and the way new plant varieties have long been developed?

Yes and no. With classical breeding, reproduction can only occur between closely related species. That means that a corn plant can only mate with another corn plant or a closely related species. Similarly, a cow can only mate with another cow. Thus, classical or conventional breeding is usually limited to the DNA variety found within a species. With genetic engineering, however, any gene from any organism can be transferred to a different organism. Thus, that allows a snippet of DNA that codes for an insecticidal protein from a bacterium, such as *Bacillus thuringiensis* (Bt), to be transferred into a corn or cotton plant.

Plant breeders, however, have long used a variety of techniques to introduce variation into the DNA of a species and obtain varieties with desirable traits. For example, scientists have used chemicals to cause DNA mutations and then selected the organisms with the desired trait. Similarly, scientists have blasted plant cells with x-rays and gamma radiation to induce mutations. Americans have eaten varieties of wheat, rice and pink grapefruits that were generated from radiation mutagenesis. So while moving single genes from one species to another in the laboratory is a relatively new agricultural breeding method, scientists have been manipulating plants in "unnatural" ways for over fifty years to create varieties that would not otherwise be found in nature.

MAKING A GE PLANT

Using genetic engineering, scientists can create plants that produce their own relatively benign pesticide. That can replace millions of pounds of far more dangerous chemical pesticides. Here's how.

1. Scientists find a bacterium in soil that naturally contains a protein that kills insect pests that feed on corn plants. They extract from the bacteria's DNA the segment, or gene, that makes the toxic protein.

2. They use a gene gun to shoot copies of the segment into the nucleus of corn cells. They grow the cells into plants, harvest the seeds from the plants, and grow the seeds into new corn plants.

3. Every cell in the new corn plants—and in their offspring—is now programmed to make the toxic protein, which kills the insect pests when they try to eat the plants.

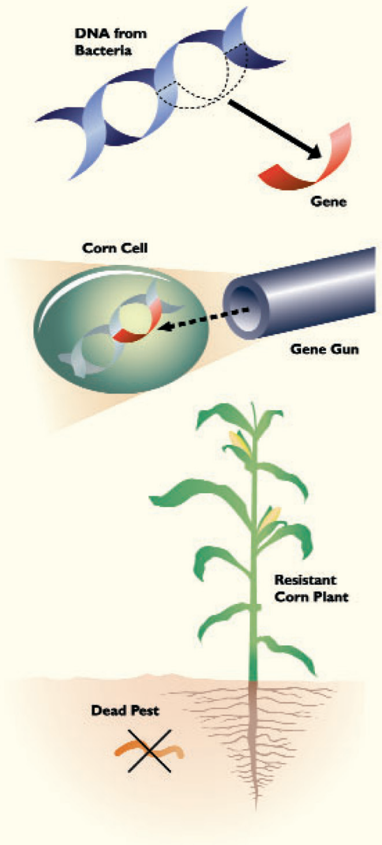

Illustration: Ball Siripanich for *Nutrition Action Healthletter*

Genetically engineering a plant is not a panacea for addressing the agricultural constraints faced by farmers. Conventional breeding can often be used to obtain the same advantageous traits as obtained through genetic engineering, though adding a new gene through genetic engineering can often be quicker and more precise. Rather, genetic engineering should be seen as one of the many tools available for use by plant breeders to improve crop varieties so that we increase food production, control pests, and improve farm profits.

3. What kinds of traits have been engineered into agricultural crops?

Most of the commercial genetically engineered ("GE") crops grown in the United States contain genes that provide either resistance to pests or tolerance to herbicides. GE corn and cotton contain genes from the soil bacterium *Bacillus thuringiensis* (Bt). The proteins produced from those genes kill certain insect pests when they are ingested, eliminating the need to use chemical pesticides. Different Bt genes produce proteins that target different pests.

GE soybeans, corn, canola, sugar beets, cotton, and alfalfa contain one of several bacterial genes that protect the crop from particular herbicides. Those genes allow certain herbicides to be applied to the crop without harming it, giving farmers more flexible use of herbicides to control weeds, such as treating a field after the crop has emerged, not just before.

Finally, some varieties of squash and papaya have been engineered with plant virus genes that render those crops resistant to those plant viruses. More recently, scientists engineered plum trees to resist plum-pox virus, but those varieties have not been commercialized yet. Countless other traits – such as drought tolerance and more-healthful fatty acids in soybeans and other oilseeds – have been engineered into plants in the laboratory, but also have not yet commercialized in the United States.

4. How prevalent are genetically engineered crops in the United States?

In 2011, approximately 88% of all field corn (mostly used for cattle feed and ethanol production), 94% of all soybeans, 95% of all sugar beets, and 90% of all cotton grown in the United States was genetically engineered with one to as many as seven different genes. U.S. farmers also grew GE canola as well as small amounts of genetically engineered papayas, summer squash, and insect-resistant sweet corn. All these engineered crops totaled approximately 170 million acres in 2011.

5. How prevalent are genetically engineered crops outside the United States?

According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), 16.7 million farmers in 29 countries planted over 395 million acres of biotech crops in 2011. The largest adopters outside the United States include Brazil, Argentina, India, Canada, and China. Even in Europe, where opposition to GE runs high, eight countries – Portugal, Spain, Germany, Sweden, Czech Republic, Poland, Slovakia, and Romania – had a limited number of farmers who grew either GE corn or potatoes.

6. Am I currently eating genetically engineered foods?

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Although most soybeans and field corn are genetically engineered, the harvest from those crops goes primarily to feeding cows, pigs, and chickens. Some genetically engineered corn and soybeans, however, do get used for human food products. Field corn is used to make corn meal for products like muffins, corn chips, and tortillas. Far more field corn is used to produce high-fructose corn syrup (HFCS) which is used to sweeten soda pop and other foods, and corn oil that might be used for cooking or baking.

GE soybeans are processed to make soybean oil and soy lecithin, an emulsifier used in many foods. GE canola and cotton are also processed to produce canola oil or cotton-seed oil, both of which are used for cooking. GE sugar beets are used to produce sugar, which can be found in many foods. Therefore, countless processed foods contain ingredients that were derived from GE corn, soybeans, canola, sugar beets, or cotton.

Although products such as soy oil, beet sugar, and fructose sweeteners were produced from GE crops, the process of producing the oil, sugar, and HFCS from the crop eliminates virtually all of the transgene and its protein product. So although Americans consume thousands of foods with ingredients derived from genetically engineered crops daily, our diets actually expose us to very little of the engineered gene or their protein products.

7. Are genetically engineered foods safe to eat?

There is no evidence at all that the current GE foods pose any risk to humans. The food-safety tests conducted by GE seed producers and others (but few independent scientists) have not found any evidence of harm, including allergic reactions. Those tests have included short-term, high-dose animal feeding studies of the GE protein (such as the Bt toxins and proteins that confer resistance to herbicides) and determine whether and how quickly the GE protein is broken down in the stomach (which prevents exposure to the rest of the body). Tests also check the levels of a number of naturally occurring plant components (including nutrients) to make sure they have not been changed in the GE crop. While some of the tests have not used the best available methods, the combined results indicate that current GE crops are safe.

In addition to safety testing, other information about current GE proteins suggests that they are unlikely to cause harm to people. For example, the bacterial protein added to herbicide-tolerant soybeans is very similar to a protein already found in soybean and other plants and functions in a similar manner. The Bt protein in insect-resistant plants comes from a bacterium used by organic food growers for many years (although, because it is produced continuously throughout the transgenic plant, we would consume more of it than when applied occasionally by organic growers). GE virus-protected crops contain plant viral components that we commonly eat in naturally virus-infected plants without harm.

Finally, GE crops have been grown and consumed by Americans since 1996 with no apparent ill effects. However, since no monitoring of GE food consumption is conducted, some adverse effects, such as food allergies, could go undetected or could be mistaken to have other causes.

http://www.ams.usda.gov/AMSv1.0/nop

8. Can Americans avoid eating food produced from genetically engineered crops?

Although the currently grown GE crops and the foods made from them are as safe as their conventional counterparts, some people want to avoid eating foods made with such crops. That is not easy to do in the United States because food manufacturers are not required to label whether their products have any ingredients that came from GE crops. So, it is impossible to know whether most products contain a genetically engineered ingredient. Some manufacturers have voluntarily labeled their products as not containing any genetically engineered ingredients, but no government or third-party verification system exists to ensure the accuracy of those label claims. In addition, some of those label claims are misleading, because they falsely imply that the food made without GE ingredients is somehow safer than or superior to the same product made with GE ingredients. And as noted above, the great majority of foods that contain highly purified oils, corn sugars, and cornstarch ingredients made from GE crops contain essentially no genetically modified DNA or protein.

If one wants to avoid GE crops, the best way to do that is to buy "organic." If a product is certified as "organic" under federal standards, then the ingredients in that product cannot come from GE crops. Products produced from organic crops will contain either no or only inadvertent trace amounts of genetically engineered ingredients. (Organically grown crops provide more important benefits, such as avoiding the use of synthetic pesticides and fertilizers, promoting biodiversity of crops, insects, and other organisms, and building the soil.)

9. Can genetically engineered crops be grown by organic farmers or be a part of a sustainable agricultural system?

If a farm has been certified as "organic" under USDA's organic standard, then that farmer cannot knowingly use genetically engineered seeds for his organic crops. That is why the best way to avoid genetically engineered foods is to buy certified organic products. However, except for corn, cotton, soybeans, canola, alfalfa, and sugar beets, most crops don't have genetically engineered varieties.

There is currently no national standard for what is considered "sustainable" agriculture so people may differ in their views as to whether genetically engineered crops could or should be a part of a sustainable agricultural production process. A recent book entitled *Tomorrow's Table* by Pamela Ronald, a plant biologist, and Raoul Adamchak, an organic farmer, argues that instead of narrowly defining production systems, farmers should use whatever particular inputs and production practices minimize agriculture's footprint on our ecosystem. That could involve using engineered seeds with organic production methods to create a more sustainable agricultural system, although the resulting products could not now claim to be "organic."

Federal Regulation of GE Crops

10. How does the government regulate GE crops?

The Federal government decided in 1986 that the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA) would regulate GE crops using existing statutes. It is the responsibility of those government agencies to make sure GE crops are safe for humans, animals, and the environment. In particular, the FDA is responsible for the food safety of GE crops, while the USDA is responsible for ensuring that GE crops don't harm agriculture or the environment. The EPA is responsible for the safety of pesticides, including plants such as Bt corn or Bt cotton, which have been engineered to produce a pesticide.

11. Who ensures that GE crops can be safely eaten by humans or animals?

The FDA is responsible for ensuring that all the foods we eat are safe. However, the FDA does not have clear legal authority to formally approve GE crops before they are commercialized. The FDA regulates GE food and feed crops through a *voluntary notification* process rather than by a *mandatory* pre-market *approval* process. In that voluntary process, the developer of a GE crop submits to the FDA a summary of data that shows that the GE crop is substantially equivalent to its traditionally bred counterpart and does not pose any novel health risk. The FDA reviews the submitted data and alerts the developer to any concerns it has about the developer's food safety assessment.

A CSPI report on the FDA's oversight of GE food safety found that the process is not as rigorous or as independent as it should be, and that the FDA often does not get all of the data it needs to perform a fully informed safety review. For more information on this issue, see CSPI's report: "Plugging Holes in the Biotech Safety Net" which can be found on-line at http://www.cspinet.org/new/pdf/fda_report__final.pdf.

12. What should the government be doing to ensure the food safety of GE crops?

Before any GE crop is turned into food, the FDA should have to formally approve that the crop is safe for human and animal consumption. Congress needs to amend the Federal Food, Drug, and Cosmetic Act to require a mandatory pre-market approval process that is open to public participation and review. In 2004, Senator Richard Durbin (D- IL) introduced legislation that would give the FDA such authority (S. 2654), but Congress did not act on that proposed legislation. CSPI continues to advocate for specific provisions in the Federal Food, Drug, and Cosmetic Act that would address the food safety of engineered crops and hopes that other consumer groups and food industry representatives will support those needed changes. Formal approval of GE crops might lengthen the approval process, but also would result in greater assurance of safety and greater public confidence, around the world, in the safety of these widely consumed crops.

13. Which agencies regulate the environmental safety of GE crops?

If a crop has been engineered to make its own pesticide (such as Bt corn or Bt cotton), the EPA reviews and approves the safety of that crop or at least the effects of the added pesticide. In its regulatory process, the EPA performs a risk assessment to determine the benefits and risks to the environment from the pesticide and imposes any conditions needed to minimize or eliminate any potential harm to the environment. The EPA's approval process also assesses the safety to humans and animals if they eat the pesticidal compound. The EPA establishes a safe tolerance level below which the pesticide is considered safe to eat in food consumed by humans.

For all genetically engineered crops (such as herbicide-tolerant canola or soybeans, as well as Bt corn or Bt cotton), the USDA is responsible for ensuring that growing those crops will not adversely effect agriculture or the environment. The USDA has established a notification and permitting process for field trials with engineered crops that developers must comply with before planting most GE crops on open fields. The USDA also has established a regulatory process that allows developers to petition the agency to deregulate its GE plant, allowing crops to be grown commercially without any regulatory restrictions or requirements. To date, over 15,000 field trials have gone through the USDA's regulatory procedures and over 80 crops have been deregulated (although many of those deregulated crops have not been commercialized). The inadequacies in the USDA's regulatory process are discussed below in the answer to question #15.

14. Is the EPA adequately ensuring that GE crops producing pesticides are safe for the environment?

The EPA does a reasonably good job regulating pesticide-producing plants, although there are areas that need improvement. For each engineered plant producing a pesticide, the EPA usually conducts a thorough environmental assessment of that crop before it is allowed to be used commercially. That process is transparent and the EPA provides the public with an opportunity to provide comments before each major decision. The EPA's decisions to register pesticide-producing plants are also time-limited, so the EPA can revise or revoke registrations if new information becomes available. The EPA's regulatory process could be improved by establishing specific data and testing guidelines unique to GE crops. Currently, the EPA uses *ad hoc* standards for GE crops, because its existing testing guidelines, developed for chemical and microbial pesticides, are usually not applicable.

The EPA could also improve its oversight of those engineered crops after they are commercialized. In particular, the EPA needs to ensure that farmers comply with refuge requirements. When the EPA registered corn and cotton varieties with engineered Bt pesticides, the agency imposed obligations on farmers who planted those crops to reduce the chance that resistant pests would develop and limit the technology's effectiveness for future generations of farmers. Each farmer is required to plant a portion of their farm with non-Bt varieties, which acts as a refuge for pests that are not resistant to the Bt pesticide.

A 2003 report by CSPI found that about 20% of Midwest farmers did not comply with government planting restrictions for Bt crops (The CSPI report, "Planting Trouble: Are Farmers Squandering Bt Corn Technology?", can be found on-line at http://www.cspinet.org/new/pdf/bt_corn_report.pdf). Then in 2009, CSPI issued another report entitled "Complacency on the Farm" (http://cspinet.org/new/pdf/complacencyonthefarm.pdf) that found, using industry survey data, that farmer noncompliance with the EPA planting restrictions had increased to approximately 30%. The most recent industry survey data submitted to EPA for the 2011 growing season showed similarly high levels of noncompliance. This noncompliance with government refuge requirements could lead to insects developing resistance to the Bt crops. If that happens, both the Bt crops and Bt microbial insecticides used widely by organic and other farmers would lose some of their effectiveness.

15. Is the USDA's regulation of GE crops adequate?

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The USDA's regulation of engineered plants to safeguard farming and the environment is not as good as the EPA's regulation. The USDA's environmental assessments of engineered crops are not necessarily thorough and the USDA conducts them only on crops they deregulate and a handful of field trials. In fact, in 2009 and 2007, federal courts ruled that the USDA's environmental assessment of both engineered sugar beets and alfalfa did not comply with the National Environmental Policy Act (NEPA). The courts required the USDA to conduct a more thorough environmental impact study. The USDA also needs to improve enforcement of its field trial permits. The USDA claims to conduct inspections, but does not provide the public with any information to judge whether inspectors are doing a sufficient job. The few instances when violations have been made public and the USDA has taken enforcement action, the company self-reported the violation and the offending companies generally received a mild slap on the wrist

The USDA also does not regulate all engineered crops, only those it considers to be a possible "plant pest." A "plant pest" is any organism that can harm a plant or plant product. While most engineered crops to date have some plant pest component used in the engineering process, developers can also engineer crops without the use of a plant pest. In 2011, the USDA announced that it did not have legal jurisdiction to regulate a GE grass where a "gene gun" was used to insert the new DNA. (A gene gun is a mechanical tool that shoots the gene of interest into the cell, which then incorporates the new DNA on its own into its chromosomes.)

Obviously, there is a loophole in the USDA regulatory system that has allowed some GE varieties to be released into the environment without any regulation. That procedure could be used by developers in the future to avoid the time and cost of the USDA regulation, but at the expense of the federal government's not being able to ensure that those crops don't pose any risks to the environment or agricultural interests.

The Benefits and Risks of GE Crops

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16. Do current GE crops provide any benefits?

The benefits from GE crops are sometimes difficult to determine. They tend to be crop specific and depend on both the particular environment where the crop is grown and the agricultural system in place at that location. However, several benefits seem well substantiated. The use of Bt cotton in several regions of the United States has substantially reduced the use of broad-spectrum and highly poisonous insecticides. Thus, Bt-cotton clearly provides significant environmental benefits because it is gentler on the environment than the pesticides it replaces.

Similar benefits have been documented when Bt cotton has been used in China, India, and other countries. Some farmers reduced their pesticide use while other farmers who did not use pesticides, obtained higher yields. Farmers using Bt cotton also have significantly fewer hospitalizations because they avoid poisonings from the application of chemical pesticides. In short, farmers, who typically have tiny plots, enjoy greater yields, lower costs, fewer illnesses, and higher income, with reduced harm to insects, birds, and other species.

Herbicide-tolerant crops – soybeans, corn, cotton, canola, and sugar beets – have simplified farming by reducing the effort (and time) needed to battle weeds. Farmers who plant herbicide-tolerant soybeans save time on their farms and that allows them to increase overall household income through a second job (though because they pay a premium for GE seeds, their farm income may not increase). Though the evidence is mixed, the use of herbicide-resistant soybeans also may have contributed to the adoption of conservation tillage, which conserves soil that is more easily eroded when fields are conventionally cultivated. In addition to conservation tillage, GE soybeans require on average about one less application of herbicide per year compared to other conventional soybean varieties. Roundup Ready (RR) soybeans save resources (like tractor fuel) used in herbicide applications. The total amount of herbicide use, however, has not decreased because so many acres of farmland now are sprayed with the herbicide Roundup.

Genetically engineered crops also benefit non-GE farmers. Scientific studies have shown that farmers growing Bt corn reduce the total insect population not only on their farm, but also on the farms of neighbors who don't grow engineered corn. Thus, those farmers have less damage to their farms and obtain a higher yield even though they didn't purchase or plant the Bt corn.

17. What are the primary health concerns related to GE crops?

Potential harm from GE crops could include the production of new allergens or toxins, or unexpectedly increased levels of naturally occurring toxicants or allergens found in crops. Such unexpected changes may be caused by disruption of native genes, unexpected interactions between the GE genes and plant components, or the GE process itself. A more remote possibility is that new harmful substances could be produced by the plant.

It is important to understand that all of those categories of unexpected changes also could occur through traditional forms of plant breeding (and, especially the use of gamma radiation and chemical mutagenesis to produce new varieties) that have been carried out for many decades. In fact, the only known cases of increased or new harmful compounds have been due to traditional breeding methods, not genetic engineering (but see next question). Nonetheless, it is clear that many genes that have never been in the food supply, and that could not be introduced by traditional means, can be introduced by genetic engineering. Uncertainties about the properties of new genes and uncertain interactions with the native genes of the plant warrant a cautious approach to the approval of GE plants and the employment of a rigorous regulatory process.

18. Can GE foods cause new allergies?

Allergies are typically caused by proteins, and because most engineered crops produce new proteins, it is possible that new allergens could be present in a GE plant. In fact, in the 1990s, Pioneer Hi-Brid inadvertently transferred an allergen from the Brazil nut into a genetically engineered variety of soybeans. That allergen was detected by safety tests and the GE soybeans were never commercialized.

No tests currently exist that could predict conclusively whether or not a GE protein new to the food supply, as is the case with many engineered crops, will cause allergic reactions. Instead, several tests are used that together provide some confidence that the new protein will not be an allergen. Those tests have been conducted for the already commercialized products, but often not with the best test procedures. (For more on the inadequacies of the current safety testing at the FDA see "Plugging Holes in the Biotech Safety Net" which can be found on-line at http://www.cspinet.org/new/pdf/fda_report__final.pdf).

It is also important to keep in mind that while we consume tens of thousands of different proteins, most serious food allergies are caused by only a handful of them, such as a few proteins from peanuts, milk, or tree nuts. The likelihood that any particular protein will be an allergen is small. On the other hand, government regulators should ensure to the greatest extent possible that new allergens are not introduced into the food supply, because foods allergies can cause significant discomfort and, in extreme cases, death.

To date, there is no evidence that anyone eating food made from a GE crop grown in the United Sates has had an allergic reaction. When Starlink corn, an engineered corn with a specific Bt gene, was grown in the U.S., several dozen people contacted government agencies complaining of reactions to Starlink that resembled an allergy. Subsequent testing by FDA and the Centers for Disease Control determined that those reactions were not to the Starlink protein, although some experts were not entirely satisfied that the tests were completely reliable.

http://ucce.ucdavis.edu/files/repository/calag/img5802p92.jpg

19. What are the major environmental risks from the growing of GE crops?

GE crops might harm the environment in several ways. One way is if the crop produces substances that kill beneficial insects, birds, or other organisms above or below ground. Those toxic effects would be limited primarily to the crop fields, but since crops are a major land use, the harm could be substantial. Initial evidence suggested that Monarch butterflies might be harmed by certain Bt corn varieties, but additional and more extensive experiments showed that harm to be unlikely.

Another way GE crops could harm the environment is if they grow where they are not wanted. While most cultivated crops do not survive beyond well-tended fields, seeds from one year's crop that are not harvested may grow the following year, when a different crop may be planted. Those "volunteer" plants may be undesirable in the new crop. If the "volunteer" is an herbicide-resistant variety, there may be fewer or less desirable herbicides to control it. That has occurred with some herbicide-resistant canola in Canada. Those volunteer plants have now become weeds that farmers need to address with other control options.

Another problem might result from mating between GE crops and their wild relatives (some of which may be serious weeds). Many crops have sexually compatible wild relatives, often in the regions where the crop originated. In the United States, corn and soybeans do not have wild relatives, but squash, canola, and wheat do. A gene for herbicide-resistance, for instance, could be transferred to the wild relative by pollination from the GE crop. If the new gene does not harm the wild relative, it might persist and spread. Unlike the crop, it is almost impossible to eradicate a widely dispersed wild relative containing a new gene. Crop genes in wild relatives are not necessarily harmful, but could cause harm if they made those wild relatives hardier and those plants spread at the expense of other species. Indeed, in several cases, natural crop genes have enhanced the weediness of important weeds. In a GE example, experiments show that a Bt gene put into sunflowers might enhance the survival of wild sunflowers in places where they are not wanted. Conversely, agricultural genes might weaken wild relatives and cause the demise of limited populations of those plants – such as corn's ancestral relatives in Mexico and potato's relatives in Peru. That is especially a concern in centers of origin for the crop, where wild relatives are important sources of biodiversity, serving as sources of such traits as disease resistance or stress tolerance to crop breeders.

20. Will overuse of engineered crops result in resistant pests and weeds?

If an herbicide or pesticide is used too widely, pests or weeds could develop resistance, requiring farmers to use a different, and possibly more harmful or expensive chemical to eliminate the resistant organism. For this reason, there is a public interest in the judicious use of fairly benign herbicides and pesticides. The herbicide Roundup, which is used with most crops engineered to be herbicide-tolerant, is one such herbicide. The Bt pesticides engineered into corn and cotton are environmentally favorable insecticides.

For several years now, farmers in the United States and elsewhere have been growing large acreages of herbicide-tolerant varieties of soybeans, corn, cotton, and sugar beets. This has led to tremendous use of the glyphosate herbicide, Roundup, and the development in the United States of resistant weeds. In 2010, the National Academy of Sciences issued a report identifying the increase in glyphosate resistant weeds as a major concern with biotech crops that needs to be addressed. To date, the federal government has not analyzed the cumulative impact of all the herbicide-tolerant crops nor set forth policies or requirements to minimize the development of resistant weeds. Those actions are needed if future generations of farmers and the environment are to benefit from herbicide-tolerant crops.

For insect pests that are killed by eating Bt corn or cotton plants, no major resistant strains of insects have developed so far. However, those crops are now being grown on many more acres than a few years ago, which may increase the likelihood of developing resistant insects. The EPA has put in place planting restrictions designed to prevent or postpone the development of resistant pests, but data from the biotech-seed industry shows high levels of non-compliance. (See "Complacency on the Farm" report from 2009 found on-line at http://cspinet.org/new/pdf/complacencyonthefarm.pdf). If high levels of both adoption and non-compliance continue, the likelihood of resistant pest development will increase, jeopardizing the technology's benefits to future farmers. The EPA needs to require seed companies to better implement the current planting restrictions or revoke their registrations.

The biotech-seed industry is also developing Bt corn seeds with two or more genes that attack the same pest and reduce the likelihood of developing resistant insects. If farmers adopt these new products and abide by the EPA's reduced refuge obligations, the likelihood of resistant insects may be put off for many more years, allowing farmers to continue to realize the benefits of this relatively benign method of controlling pest damage. In the interim, if farmers implemented simple farm management practices such as crop rotations and integrated weed management, they could reduce the likelihood of developing both resistant weeds and pests.

21. Are the benefits and risks from genetically engineered crops different from the benefits and risks for other technologies used in agriculture?

In general, genetic engineering can be viewed like any other technology: it could provide benefits and it could cause harm. The challenge is to maximize the benefits while minimizing any harm. The documented benefits from current engineered crops (see question #16 above) could also arise from other technologies used in agriculture. Chemical mutagenesis, irradiation, genomics, and other "conventional" breeding methods could result in varieties that increase yield, resist diseases, or tolerate stressful planting conditions. Similarly, the fact that plant varieties engineered with herbicide tolerance or built-in pesticides could lead to resistant weeds or insects is not unique to engineered crops. There have been numerous documented examples of weeds and insects becoming resistant to chemical pesticides and herbicides. Conventional pesticides also kill many non-target insects and other organisms found in farmers' fields. While it is important to maximize the benefits and minimize the risks of GE crops, similar benefits and risks also exist for numerous other technologies used to produce our food.

Genetically Engineered Animals

22. How do scientists create a genetically engineered animal?

Similar to genetically engineered crops, genetically engineered animals are created in a laboratory by scientists. A specific gene from one organism that codes for a desired trait is introduced into an egg cell of an animal. The new foreign DNA integrates into the animal's DNA and becomes part of the animal and its progeny, which then are generated through traditional animal breeding methods.

http://www.glofish.com

23. Are genetically engineered animals (and their products) currently available to scientists, producers, and consumers?

Private companies and academic scientists have been experimenting with creating genetically engineered (GE) animals for over 20 years. So far, those experiments only have resulted in a few commercially available genetically engineered animals. Pet owners can purchase "Glofish," which are zebra fish with an inserted gene that makes them glow different fluorescent colors. Academic and industry scientists can purchase engineered mice and rats to use for scientific and medical research.

More recently, a company received FDA approval for goats that were engineered with a human gene to produce a "biologic." The goat acts like a pharmaceutical factory, producing the biologically active molecule in its milk. The active molecule is then separated out from the milk and sold as the drug "Atryn," which is used to treat patients with a rare clotting disorder. About 200 goats being raised near Boston are producing Atryn. The FDA requires those goats to be highly confined so that they do not escape and their milk and meat does not enter the food supply.

24. Will genetically engineered animals and their products become part of our food supply?

Several applications for genetically engineered food animals are pending at the FDA. The one that will most likely be decided first is AquaBounty's AquAdvantage salmon, which was the subject of hearings at the FDA in September 2010. It is an Atlantic salmon that grows almost twice as fast as other farm-raised salmon because scientists added a growth hormone gene from a Chinook salmon and a promoter sequence from an ocean pout fish that turns on the growth hormone gene. The introduced DNA produces the growth hormone in the fish year round, leading to the quicker growth. If raised on a large scale, the company claims that the salmon would reduce producers' costs, lower the cost of farm-raised salmon, and benefit the environment by decreasing the amount of feed used and waste produced by fish-farming operations. They also claim that growing them at local inland farms would lower the cost of transporting the fish to market.

The next GE animal on the horizon after the salmon is probably the "enviropig," a pig that has been engineered to use phosphorus more efficiently than conventional pigs. This trait reduces the need to supplement the pig's feed with phytase, which breaks down phytic acid and makes phosphorus more available to the pigs. Additionally, the manure the pig produces is more environmentally friendly because it contains less phosphorus, which can impact nearby streams, lakes, and ponds. Companies and academics are also working with engineered cattle, goats, and other fish and shellfish for eventual introduction into the food supply, but it is unknown how far along those products are toward commercialization. The FDA is prevented by law from discussing pending applications (see question #27 for criticisms of the regulatory system).

25. Do genetically engineered animals pose health or environmental risks?

When GE animals are commercialized, they will present similar risk issues as GE plants. There will be a need to ensure that eating the meat or drinking the milk from the engineered animal will be safe. In addition, there could be environmental risks from an engineered animal if it escapes confinement and breeds with wild species. Engineering animals may also raise ethical or animal welfare concerns, such as whether the adding of a gene somehow causes the animal to suffer pain or reduce its quality of life.

26. How does the federal government regulate genetically engineered animals?

Oddly enough, the federal government regulates GE animals using the FDA's legal authority to regulate "new animal drugs." According to the Federal Food Drug and Cosmetic Act, a new animal drug is "an article (other than food) intended to affect the structure or any function of the body of … animals." The FDA has stated that introduced foreign DNA meets the definition of a "new animal drug," and it must regulate that introduced DNA, not the animal itself, as the drug.

To approve a new animal drug, the FDA must determine whether the drug is safe for the health of the animal, which involves determining whether the animal's health is adversely affected by the introduced gene and the protein it produces. Second, the FDA must determine that food from the GE animal is safe for humans or other animals to eat. In other words, the FDA must apply its "reasonable certainty of no harm" standard to any food products that would come from the GE animal. Also, it must determine that the drug does what it is intended to do.

Finally, the FDA must meet its obligations under the National Environmental Policy Act (NEPA) to assess the environmental impacts of any major federal action, which includes the approval of a new animal drug. NEPA is a procedural statute that requires the FDA to assess the environmental impacts of the GE animal and then work with the sponsor to mitigate any potential impacts. NEPA, however, does not provide the FDA with legal authority to deny its approval of a GE animal based on any actual or potential impacts that may be identified by the NEPA analysis.

27. Is the federal regulation of genetically engineered animals adequate?

The FDA's regulation of GE animals has some significant advantages over the process for plants. The "new animal drug" approval process provides the FDA with *mandatory* pre-market authority so that the sponsor cannot market the drug until the FDA has formally approved it. It requires the FDA to determine that the drug is safe for the animal and that there is a reasonable certainty of no harm to humans or animals if they eat anything from the animal that has "received" the drug. In contrast, the FDA does not formally approve plants – it just says it does not have any objections.

While the FDA is reviewing and approving a GE animal, however, the public may not know what is going on or have the opportunity to provide its input into the FDA's decision. Congress imposed on the FDA strong confidentiality provisions surrounding animal (and human) drugs, which shroud the approval process in secrecy and greatly limit access to information or any opportunity for public participation until the drug is approved. The FDA's release of its AquAdvantage salmon analysis at an advisory committee meeting was a creative way to increase transparency and public involvement. The FDA, however, did not release all of the company's safety data nor did it provide a formal public comment period. After the advisory committee in 2010, members of Congress sent a letter to the FDA complaining about the regulatory process for the GE salmon, specifically criticizing its lack of transparency and public participation.

While the FDA has the expertise to address food-safety questions, it has less expertise in analyzing environmental concerns presented by GE animals. The Environmental Protection Agency, the Fish and Wildlife Service, and other federal agencies with expertise and experience with environmental assessments have been surprisingly silent about any role they might play in regulating GE animals. A strong regulatory system that safeguards the environment should draw on the expertise of agencies other than the FDA to ensure that the potential environmental risks of GE animals have been analyzed by those with the most expertise in that area. While the FDA is required to assess the environmental impact of a GE animal, it has no authority to deny approval if that animal could have a significant impact on the environment. Some other agencies, however, may have the legal authority to prevent the release of a GE animal that might harm the environment.

28. How should the federal regulatory system for GE animals be improved?

Congress should provide the FDA with adequate authority to ensure the safety of all engineered animals through a transparent and participatory regulatory process. The FDA needs authority to both analyze and also address the full range of environmental concerns that GE animals might pose, including the powers to deny an application if it could result in significant environmental impacts and to "recall" those animals if problems arise after commercialization. The FDA should be directed to consult with other agencies with expertise in assessing environmental risks of animals. Also, Congress should eliminate the confidentiality requirements so safety data and the FDA's analysis could be reviewed by outside experts before granting any approvals. Additionally, Congress should require that the FDA provide a formal public comment opportunity before any decisions are completed. Senator Richard Durbin's Genetically Engineered Foods Act, which was introduced in 2004, would do all that, and Congress should take it up again.

29. Should I be concerned about the application for AquAdvantage fast-growing salmon that is pending at the FDA?

Based on the publicly available data about the AquaBounty fast-growing salmon, there is no need to be concerned about eating that fish. However, that could change if the FDA approves the salmon and releases the complete data package and its analysis of that information.

To prevent any potential impacts of the fish on the environment, AquaBounty has proposed multiple layers of biological, physical, and geographical containment. Those redundant containment strategies include producing only sterile female fish that would be grown in secure facilities away from the ocean or other salmon populations. The company also has picked facilities where an escaped egg or fish would encounter harsh conditions (such as water temperatures above or below which salmon can survive), greatly reducing the likelihood of survival and reproduction. Its pending application also is quite limited. It applies only to one egg production facility in Canada and one fish production facility in Panama with four inland tanks, not unrestricted sale of the GE salmon eggs to any salmon farmer. If however, AquaBounty decides to produce the salmon in additional inland tanks or in ocean pens, the FDA and other relevant federal agencies should conduct a much more extensive environmental risk assessment to ensure that the engineered salmon do not adversely impact the environment.

http://www.aquabounty.com

Future Agricultural Applications of Biotechnology

30. What new GE crops are being developed in the United States?

Biotech companies continue to develop versions of herbicide-tolerant and Bt insect resistant corn, soybeans and cotton, which have been enormously popular with farmers. They are releasing those traits to farmers in seed varieties with both a single gene and with multiple genes (called "stacked" genes). A "stacked' variety allows farmers to get seeds that have multiple beneficial traits, such as both a built-in pesticide and herbicide tolerance.

Biotech companies are also planning on releasing "pyramided" varieties, with two or more genes that target the same pests. Those crops provide farmers with two modes of action to kill the target pest and greatly reduce the likelihood of insects developing resistance to the pesticides. They can reduce the size of the refuges of non-Bt corn that farmers are required to plant, which should increase farmer compliance and protect Bt proteins for future generations of farmers.

In the next ten years, biotech companies plan to release both stress-tolerant crops and nutritionally enhanced crops. Companies are working on drought-tolerant, salt-tolerant, and nitrogen-utilizing crops (which use nitrogen in a more efficient manner), all of which are supposed to help farmers deal with non-ideal farming conditions. Some companies also hope to release engineered crops that produce food ingredients with a healthier profile. For example, Monsanto and other companies are developing soybeans with higher oleic oil content. Monsanto is also developing a soybean that contains the beneficial omega-3 fatty acids. Scientists are developing products such as a potato that would yield less acrylamide, a carcinogen, when it is cooked, but it is unclear if those products will be commercial successes. Scientists and biotech companies continue to research beneficial traits for potatoes, wheat, rice, and other food crops but, again it is unclear whether any will become commercial products that are accepted by American or other consumers. Many observers believe that public resistance would wilt if genetically engineered foods that provide unique benefits to consumers – such as tastier tomatoes – were marketed. (So far, the benefits are to farmers and, of course, the seed developers.)

http://www.goldenrice.org

31. What new GE crops are being developed for developing countries?

The last few years have seen a large increase in funding to develop GE crops for farmers in developing countries. Chinese researchers have developed several varieties of engineered rice, which could be released commercially to farmers in the next couple of years (some observers say that Bt-rice is already being widely grown illegally). Similarly, Indian researchers have developed a Bt eggplant, a staple in that country, which could be grown commercially in the near future. If adopted, farmers who plant those crops might obtain similar benefits – increased yields, reduced pesticide use, less farmer poisonings – as do the small-scale farmers who already grow other approved and commercialized GE crops in those countries.

Governments and nonprofits are providing substantial funding to engineer crops that are important to small-scale subsistence farmers in Africa. In some instances, researchers are taking known genes that have been useful to commercial farmers (such as Bt pesticidal genes) in developed countries and transferring them to developing country crops (such as cowpea, sorghum, or potato). In other instances, they are engineering virus resistance into bananas and cassava, both staples in many African countries. If such crops are found safe and effective, they could help large numbers of farmers who rely on their harvest for most of their family's calories and income.

Finally, philanthropic foundations have invested heavily to bring "golden rice" to market in several Asian countries. "Golden rice" is engineered with several genes so that it produces beta carotene (a precursor to Vitamin A) and other nutrients. It is hoped that when eaten, golden rice will prevent blindness and other health conditions caused by lack of vitamin A in the diet. While the developers of "golden rice" are hopeful that they will have a commercial product in one or more countries by 2014 or 2015, the development process has been ongoing for over a decade. During that long time period, the scientists working on the project have had to address intellectual property issues and regulatory hurdles in order to plant field trials in countries without operational biosafety regulatory systems. They also needed to work in the laboratory to develop a second-generation "golden rice" with higher levels of beta carotene and then conduct studies to ensure that the beta carotene in the rice will be absorbed by persons who eat the rice. "Golden rice" is an example of how the development process for nutritionally enhanced crops can be extremely long and uncertain.

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