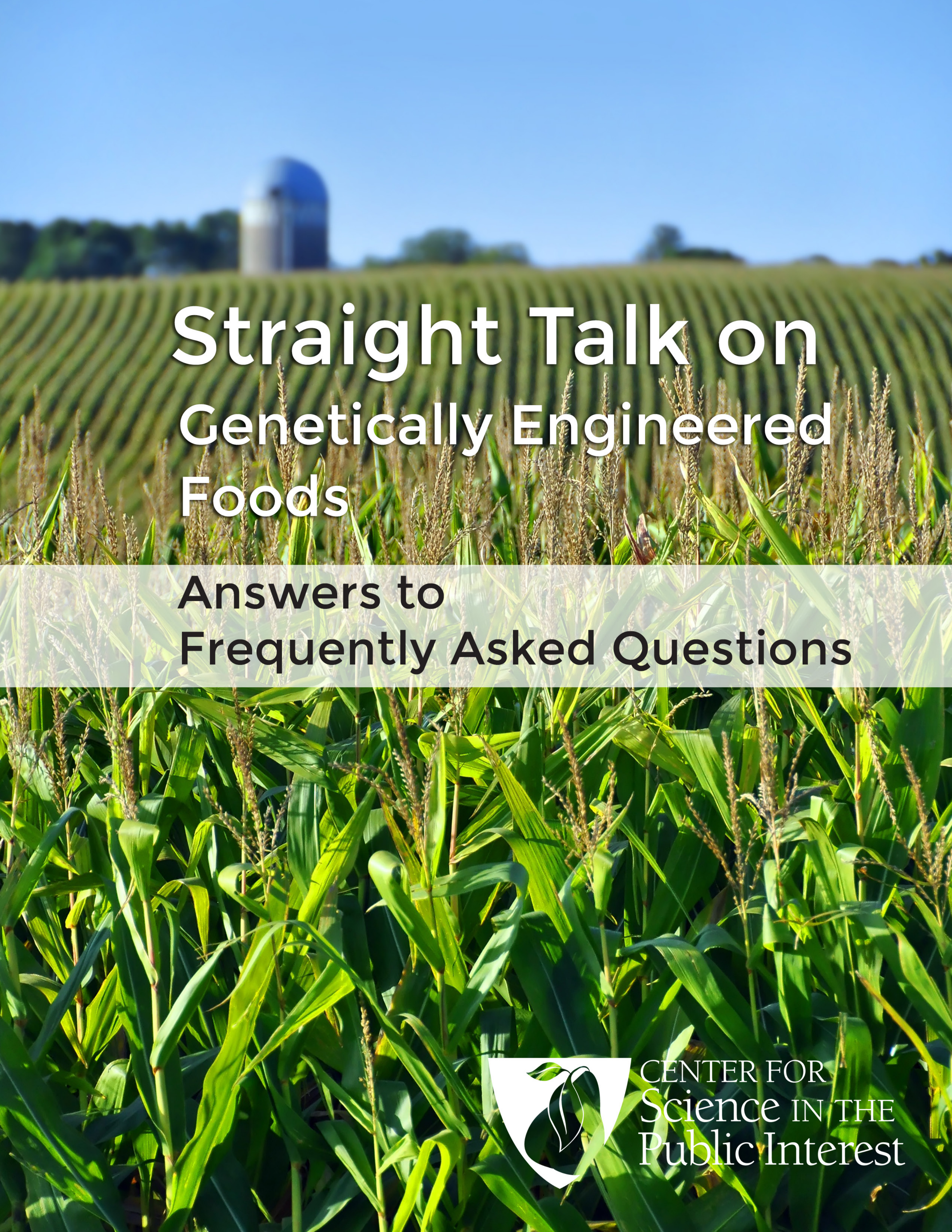

# Straight Talk on Genetically Engineered Foods

## Answers to Frequently Asked Questions

CENTER FOR Science IN THE Public Interest

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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 900,000 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 1996, farmers started growing genetically engineered (GE) crops, and they have become part of mainstream agriculture in high-income and low-income countries alike. American farmers planted almost 180 million acres of GE corn, soybeans, cotton, canola, sugarbeet, alfalfa, papaya, and squash in 2014. Food manufacturers estimate that most 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 U.S. and for low-income countries? These questions and many others are answered below based on evidence that has been accumulated over the past almost twenty years.

# Background on Genetically Engineered ("GE") Organisms in Agriculture

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

When scientists genetically engineer a plant or animal, they are generally removing a gene from one organism (or a specific variety of an organism) and transferring that gene to a different organism (or different variety) using recombinant DNA methods. The resulting organism is often referred to as "transgenic" because it has one or more genes from an unrelated species. 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 techniques that use genes or pieces of DNA from the organism itself. This technique may be used to silence an existing gene (i.e., to prevent its expression) or to get a plant to express an otherwise silent gene. Such organisms are called "cisgenic" because they involve the introduction of DNA from the same species or a closely related relative.

## 2. Is the use of genetic engineering different from classical breeding of plants and the way new plant breeds 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 red 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 decades to create varieties that would not otherwise be found in nature.

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.

## 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 feeds 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.

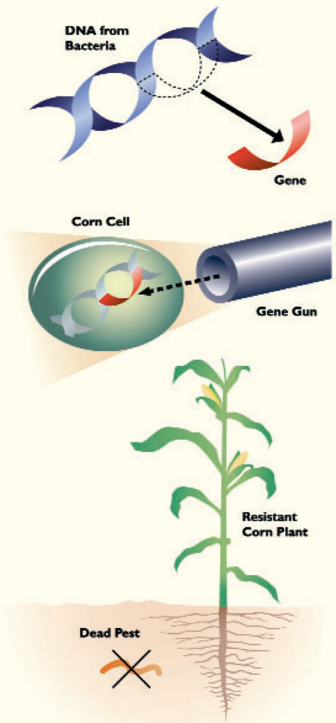


Illustration: Ball Siripanich for *Nutrition Action Healthletter*

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 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. In fact, they originate from Bt microbial sprays that organic farmers use as an environmentally friendly insecticide to prevent pests from damaging their crops.

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 flexibility in using herbicides to control weeds, such as treating a field after the crop has emerged, not just before. The most common herbicide-tolerant seeds protect those crops from the herbicide glyphosate (commercially named "Roundup"). Farmers also have planted herbicide-tolerant seeds that are tolerant to glufosinate, and in 2015 first had access to seeds tolerant to the herbicide 2,4-D.

Some varieties of squash and papaya have been engineered with plant virus genes that render those crops resistant to those plant viruses. Scientists engineered plum trees to resist plum-pox virus, but those varieties have not been commercialized yet.

Finally, farmers have begun planting in limited quantities corn engineered to be drought-tolerant and soybeans engineered to produce oils with a more healthful fatty acid profile. It is unclear whether such traits will become niche market crops or gain wide acceptance among either farmers or consumers.

## 4. Do some GE crops have more than one gene introduced into them?

Biotech companies sell GE seed varieties to farmers that have more than one new gene, which are called "stacked" varieties. A stacked variety allows farmers to get seeds that have multiple beneficial traits, such as both a built-in pesticide and herbicide tolerance. Some GE seeds have as many as seven different genes, including genes coding for tolerance to several different herbicides and Bt genes that kill corn borer and corn rootworm pests.

Some of the stacked varieties are also called "pyramided" varieties, because they have two or more genes that target the same insects with different pesticidal proteins that kill the pest in different ways. 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, thus preserving the effectiveness of crops with built-in pesticides for future farmers. Pyramided Bt corn varieties are favored by the EPA, which has reduced some of the obligations it imposes on these varieties. Pyramided Bt corn seeds require farmers to plant smaller refuge plots (which is a portion of a farmer's corn field that has non-Bt varieties) and sometimes even employ a "refuge in a bag" (non-Bt seeds mixed within the Bt seed bag), which should increase farmer compliance and protect Bt proteins for future generations of farmers (see Question 19 for more information on insect resistance and refuge compliance).

### 5. How prevalent are GE crops in the United States?

According to the U.S. Department of Agriculture, in 2014, approximately 93% of all field corn (mostly used for cattle feed and ethanol production), 94% of all soybeans, 95% of all sugar beets, and 96% 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 GE papayas, summer squash, and sweet corn. All these engineered crops totaled almost 180 million acres in 2014.

### 6. How prevalent are GE crops outside the United States?

According to the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), 18 million farmers in 28 countries planted over 447 million acres of biotech crops in 2014. The largest adopters outside the United States include Brazil, Argentina, India, Canada, and China. Even in Europe, where opposition to GE runs high, five countries—Portugal, Spain, the Czech Republic, Slovakia, and Romania—had a limited number of farmers who grew GE corn.

### 7. Can GE crops be grown by organic farmers or be part of a sustainable agricultural system?

If a farm has been certified as "organic" under USDA's organic standard, then that farmer cannot plant GE seeds. That is why one way to avoid GE foods is to buy certified organic products. However, the only commercial crops in the United States that have GE varieties are corn, cotton, soybeans, canola, alfalfa, papaya, squash, and sugar beets.

There is currently no national standard for what is considered "sustainable" agriculture, so people may differ in their views as to whether GE crops could or should be a part of a sustainable agricultural production process. A book titled *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 GE seeds with organic production methods to create a more sustainable agricultural system, although the resulting products could not be certified as "organic."



## Genetically Engineered Foods and Labeling

### 8. Am I currently eating GE foods?

Although most soybeans and field corn are genetically engineered, the harvest from those crops goes primarily to feeding cows, pigs, and chickens. Some GE 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 cottonseed 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 are produced from GE crops, the process of producing the oil, sugar, and HFCS from the crop eliminates all of the DNA and protein, including the transgene and its protein product. So although Americans consume thousands of foods with ingredients derived from GE crops daily, our diets actually expose us to very little of the engineered genes or their protein products. The only whole fruits and vegetables that have GE varieties currently would be papayas from Hawaii, some sweet corn varieties, and certain varieties of green and yellow squash. That may change soon with commercial products in the pipeline such as the GE salmon (see Question 31) and now that GE potatoes and apples completed all the steps in the federal oversight of GE crops in early 2015 (See Question 38 on future GE products).

## 9. Are GE foods safe to eat?

There is no evidence whatsoever that current GE foods like papayas or sweetcorn, or ingredients made from GE crops such as sugar or corn meal, pose any risk to humans. The U.S. Food and Drug Administration, the National Academy of Sciences, the European Food Safety Agency, and numerous other international regulatory agencies and scientific bodies have all reached that same conclusion.

The food-safety tests conducted by GE seed producers and others (but few independent scientists) on current crops 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). Other tests 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 be harmful. 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 for many years by growers of organic crops (although, because it is produced continuously throughout the transgenic plant, we may consume more of it than when applied occasionally by organic growers). GE virus-protected crops contain plant viral components that we commonly ingest from naturally virus-infected plants without harm.

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

Finally, while herbicide-tolerant crops are safe to eat, they are used in conjunction with herbicides, such as glyphosate, that could end up on food that is made from those crops. In early 2015, the respected International Agency for Research on Cancer (IARC) determined that glyphosate is a “probable” cancer-causing compound.

However, IARC's determination is a hazard evaluation that does not evaluate the likelihood of exposure to that compound in food. For the currently engineered crops that are tolerant to glyphosate (corn, soybeans, cotton, canola, alfalfa, and sugar beets), the primary foods made from those are highly processed ingredients where the processing eliminates any glyphosate. It may pose a risk to farmers, farm workers, and others who may ingest or inhale glyphosate.

## 10. Can Americans avoid eating food produced from GE 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 or ingredients made from such crops. In the United States, food manufacturers are not required to label whether their products have any ingredients that came from GE crops. However, consumers can easily purchase products that were not made from GE crops simply by buying products labeled "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 GE ingredients. Organically grown crops provide actual benefits compared to conventional or GE crops, such as avoiding the use of synthetic pesticides and fertilizers, promoting biodiversity of crops, insects, and other organisms, and building the soil.

In addition to "organic" products, consumers who wish to avoid foods with GE ingredients will find that some manufacturers and supermarket chains produce products without ingredients from GE crops. For example, Trader Joe's states that all of its private label products are non-GE. Similarly, Safeway's Open Nature line of products is partially non-GE now and will be completely non-GE in 2015. Target's private label Simply Balanced line of products also are all non-GE. Some manufacturers have also voluntarily labeled their products as not containing any GE ingredients. In many cases, those claims are backed by a third-party verification system such as the Non-GMO Project, but not a government labeling system that ensures the accuracy of those label claims. As of the end of 2014, more than 24,000 products have qualified for certification under the "non-GMO Project." CSPI believes that the federal government should oversee non-GE label claims to ensure their truthfulness, accuracy, and uniformity.

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

For all the different non-GE label claims consumers can find in the grocery store, it is important to remember that some of those label claims may be misleading. They may falsely imply that the food made without GE ingredients is somehow safer than or superior to the same product made with ingredients from GE crops or that a GE version of that crop even exists. And as noted above, the great majority of foods that contain highly purified oils, corn sugars, and cornstarch ingredients made from GE crops contain no genetically modified DNA or protein.

## 11. Should consumers be able to learn if their food contains GE ingredients?

Yes. CSPI understands that some consumers want to know whether the food they eat contains GE ingredients or not and companies should respond to those consumers' desire for that information. That could be achieved with or without mandatory on-package labeling of GE foods and ingredients. Manufacturers could provide information through voluntary labeling, information on their websites, bar codes, QR codes, apps for smart phones, pamphlets, or other means. The information provided should be accurate and not misleading. The federal government should set forth national standards for any voluntary labeling so that consumers would trust the veracity of the information that is provided to them about products both containing and not containing GE ingredients.

## 12. Should the government require food labels to disclose if products contain ingredients made from GE crops?

CSPI doesn't support mandatory government-imposed labeling of foods that contain ingredients made from GE crops. Information mandated by the government to be included on a label should primarily address food safety, nutrition or quality, such as the listing of ingredients, identifying allergens, or specifying the calorie or sodium content. Mandatory GE labeling is not justified out of concern for food safety, because the current GE crops have been found safe to eat and nutritionally equivalent to their conventional counterparts (see Question 9). The FDA should determine a GE food's safety before the food is marketed, instead of requiring labeling that may imply that the food is unsafe. Only safe foods, genetically engineered or not, should be allowed to be grown and marketed (see Question 17). That said, companies could include voluntary, non-deceptive labeling on their labels, if they wish.

## 13. If some consumers want to be told when a food contains GE ingredients, why not require labeling?

It is critical that information on a food label be truthful and not misleading to the consumer. Unfortunately, the labeling of many "GMO" foods and ingredients that would be required by various federal and state proposals could mislead consumers in several ways. First, when a scientist creates a GE seed, a small amount of new DNA and one or more new proteins are introduced into a seed that already has comparatively huge amounts of preexisting DNA and protein. When a crop grown from those seeds is processed into certain ingredients, all the DNA and proteins are eliminated, including the newly introduced "engineered" ones. Thus, many food ingredients made from GE crops, such as sugar, high-fructose corn syrup, corn oil, soybean oil, canola oil, and cornstarch, are biologically and chemically identical to ingredients made from non-GE crops, so labeling the thousands of foods with those ingredients as "GE" would be misleading or not truthful.

Second, many labeling proposals would label the whole processed food "genetically engineered" even if only one trivial ingredient came from a GE crop. For example, a frozen pizza might have to be labeled "GE" even if the only ingredient that came from a GE crop was a tiny amount of maltodextrin (made from cornstarch), not the tomato, cheese, wheat, or other major ingredient. Famously, Post had to remove vitamins from its Grape Nuts cereal (vitamins A, D, B-12 and B 2) when the company began labeling the cereal with the non-GMO project label; the process of producing the vitamin might have involved a GE microorganism or the microorganism producing the vitamin might have been fed sugar from GE sugar beets.

Third, mandatory GE labeling could mislead consumers because it singles out just one method used to modify crops and animals, yet many other methods, including chemical mutagenesis, X-ray mutagenesis (the source of Rio Red and Star Ruby grapefruits), cloning, hybridization, and so forth, are used to modify seeds. In fact, one survey from Oklahoma State University found that over 80 percent of consumers wanted foods labeled if they contained DNA—which, of course, all natural foods contain. GE labeling could mislead consumers into thinking that foods without the GE label have not been changed in the laboratory or field. In reality, though, almost all crops have been genetically modified in one way or another over the years and centuries.

## 14. Would mandatory labeling increase consumer choice?

If the government mandated labels for products containing GE foods or ingredients derived from GE crops, you might think that labeled and unlabeled cereal boxes would be side by side in the supermarket. Yet in the dozens of countries around the world that require labeling, the reality is quite different.

The European Union's mandatory GE labeling law has spurred manufacturers to use more expensive ingredients from non-GE plants to avoid having to put "genetically modified organisms" on their labels. Companies fear losing even a small percentage of sales to consumers who are scared off by the GMO phrase or by activists' campaigns urging consumers not to buy that labeled product. It is likely that many American food manufacturers would follow the same path if states or the federal government mandated "GMO" labeling. And sourcing non-GE ingredients would slightly raise the cost of their products.

In some countries with mandatory GE labeling, farmers are not permitted to grow engineered crops, so domestically produced foods are GE-free. Enforcement of labeling laws on imported packaged foods is typically non-existent, so imported packaged foods arrive without "GMO" labels, whether or not such labeling would be required under those countries' laws.

While 62 or more countries have laws mandating the labeling of GE foods, the reality is that most of those countries have virtually no products labeled "GE." Mandatory labels have not given consumers a choice between cereal boxes with and without GE ingredients—just non-GE cereals that cost more to produce and are no safer.

The United States' current voluntary labeling system likely provides more choice for consumers. All certified organic products do not contain GE ingredients, and thousands of other products are certified "GE-free" by private labeling systems such as the Non-GMO Project. Consumers can assume that most unlabeled products contain ingredients from engineered crops if any ingredient is made from corn or soybeans. While that system is not perfect and may lead to consumer confusion and some misleading or inaccurate label claims, Americans probably have more choice at the grocery store than consumers in any country with mandatory labeling.

## Federal Regulation of Genetically Engineered Crops

### 15. 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 biological pesticide.


### 16. 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 and consultation* 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: "Holes in the Biotech Safety Net" which can be found online at http://www.cspinet.org/new/pdf/fda_report__final.pdf.

### 17. 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.

## 18. Which agencies regulate the environmental safety of GE crops?

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If a crop has been engineered to make its own biological 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 biological 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 GE 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 impact U.S. 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 their GE plants, allowing crops to be grown commercially without any regulatory restrictions or requirements. To date, over 25,000 field trials have gone through the USDA's regulatory procedures and over 95 crops have been deregulated (although many of those deregulated crops have not been commercialized). The inadequacies in the USDA's regulatory process are discussed in the answer to Question 20.

## 19. 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 with the pesticide 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 Bt 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 reduce the technology's effectiveness. Farmers are required to plant a portion of their farms 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 online 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 35%. More recent industry survey data from 2010 through 2013 showed similarly high levels of noncompliance. That noncompliance with government refuge requirements may have contributed to the development of Bt-resistant corn rootworm populations throughout the Midwest (see Question 27).

EPA has a responsibility to preserve the Bt technology, which is a relatively benign and highly effective biological pesticide. It is also valuable to organic and conventional farmers who use Bt microorganism sprays as a biological form of pest control. With the development of resistant pest populations, EPA needs to impose additional conditions on the marketers of Bt corn and the farmers who use it so that those resistant pests do not spread and reduce the overall effectiveness of those beneficial GE crops.

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

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.

**U.S. Coordinated Framework**

| New Trait/Crop | Agency | Review |
|---|---|---|
| Insect resistance in food crop (e.g., Bt corn) | USDA<br>EPA<br>FDA | Agricultural and environmental safety<br>Environmental, food/feed safety of built-in pesticide<br>Food/feed safety (voluntary) |
| Herbicide tolerance in food crop (e.g., glyphosate-tolerant sugar beets) | USDA<br>FDA | Agricultural and environmental safety<br>Food/feed safety (voluntary) |
| Herbicide tolerance in ornamental crop | USDA | Agricultural and environmental safety |
| Modified oil in food crop (e.g., high oleic acid soybean) | USDA<br>FDA | Agricultural and environmental safety<br>Food/feed safety (voluntary) |
| Herbicide-tolerant bentgrass using agrobacterium | USDA | Agricultural and environmental safety |
| Herbicide-tolerant soybeans using gene gun | FDA | Food/feed safety (voluntary) |
| Herbicide-tolerant Bluegrass using gene gun | | No regulation |

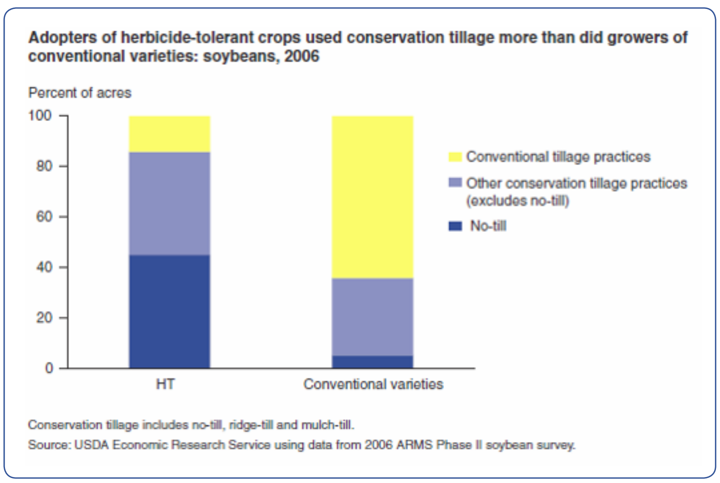
The USDA also does not regulate all engineered crops, only those it considers to be potential "plant pests." A "plant pest" is any organism that can harm a plant or plant product, such as an insect or virus. While most engineered crops to date have some plant pest component used in the engineering process (such as using the microorganism agrobacterium as the method of introducing the new DNA into a plant cell), 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 device that shoots the gene of interest into the cell, which may then incorporate the new DNA into its chromosomes). More recently, USDA has also stated that it will not regulate certain new DNA editing techniques, such as the use of zinc finger nucleases. Obviously, there is a loophole in the USDA regulatory system that will allow some GE varieties to be released into the environment without any regulation at all (such as an herbicide-tolerant turf grass being developed by Scotts). That decision is made depending on the techniques and DNA components used by the developer, not based on whether or not the engineered organism presents any potential agricultural or environmental risks. That loophole 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 are safe for the environment and agricultural interests.

The USDA also needs to expand its regulations for GE crops so it can address some of the agricultural and environmental impacts it identifies in the environmental assessments it has conducted under the National Environmental Policy Act. For example, USDA has acknowledged that herbicide-tolerant GE seeds can result in herbicide-resistant weeds. Similarly, USDA has found that introduced genes can move by biological means (e.g. pollen) to non-GE crops and related species, resulting in agricultural and economic impacts. While USDA would need a new law from Congress to thoroughly address that weakness, in the interim it could incorporate the authority Congress granted to it to address risks posed by "noxious weeds" to address some of those identified impacts. In 2008, USDA proposed adding that "noxious weed" authority, but never finalized that proposal and withdrew it in early 2015. USDA needs to propose new regulations so it could address potential noxious-weed impacts that might be caused by future GE crops.

## The Benefits and Risks of Genetically Engineered Crops

### 21. Do current GE crops provide any benefits?

The benefits from GE crops 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 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, many small-scale low-income country 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). The use of herbicide-tolerant crops has also 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 (a trend that will continue with the addition of 2,4-D, Dicamba, and other herbicide-tolerant crops).

Farmers growing Bt corn in the United States has resulted in a significant reduction in the amount of chemical insecticides used by those corn farmers. However, the recent development of resistant corn-rootworm populations is reversing that trend as farmers use chemical insecticides to kill those resistant insect populations.

GE 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, reduce their use of insecticides, and obtain a higher yield even though they didn't purchase or plant the Bt corn.

Finally, engineered papaya grown in Hawaii has allowed papaya farmers to continue growing that crop. Without the virus-resistance trait, most, if not all, of the Hawaiian papaya trees would have become infected and no longer would have produced commercially viable fruit.

## 22. 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 (such as 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.

## 23. 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-Bred inadvertently transferred an allergen from the Brazil nut into a GE 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 "Holes in the Biotech Safety Net" which can be found online 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 States has had an allergic reaction. When Starlink corn, an engineered corn with a specific Bt gene, was grown in the U.S back in the year 2000, 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.

## 24. 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 years ago suggested that Monarch butterflies might be harmed by exposure to the pollen from 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, the herbicides that could control it might be more toxic or expensive than the glyphosate that is usually used. 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 and canola 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 for crop breeders of such traits as disease resistance or stress tolerance. Fortunately, none of the current GE crops or anticipated future GE crops (see Question 38) have their center of origin in the United States.

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

The herbicides sprayed on herbicide-tolerant crops can also impact the environment by harming other organisms or polluting soil, rivers, or groundwater. When Dicamba or 2,4-D are sprayed on GE crops tolerant to them, those herbicides could drift to nearby farms and harm crops. For crops that allow spraying of glyphosate, the glyphosate could impact the health of farm workers, since the International Agency for Research on Cancer has determined that glyphosate is a "probable" carcinogen. Of course, many farm workers use protective gear or equipment when they spray herbicides but the herbicide still could be inhaled or ingested by workers, their families, and others near the sprayed crops.

## 25. Has the overuse of engineered crops resulted in resistant weeds?

If an herbicide is used too widely, weeds could develop resistance, requiring farmers to use a different and possibly more harmful or expensive chemical, to eliminate the resistant weeds. For this reason, there is a public interest in the judicious use of fairly benign herbicides. The herbicide Roundup (active ingredient glyphosate), which is used with most crops engineered to be herbicide-tolerant, is one such herbicide. It is a broad-spectrum herbicide that is easy to use, inexpensive, and breaks down relatively quickly in the environment.

For many years now, farmers in the United States have been growing large acreages of herbicide-tolerant varieties of soybeans, corn, cotton, and sugar beets. This has led to tremendous use of glyphosate 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.[1] Two National Academy of Sciences Weed Summits, in 2012 and 2014, documented the problem of herbicide-resistant weeds and discussed possible solutions, with special emphasis on weeds resistant to glyphosate.[2,3]

As of the end of 2014, there were 14 documented species of glyphosate-resistant weed species in the U.S. that were the direct result of overuse of glyphosate in conjunction with glyphosate-tolerant seeds. Those weeds now cover millions of acres of farmland (estimated by one industry survey to be over 60 million acres) in 22 states and force farmers to take additional weed-management measures, including the spraying of other chemical herbicides, to control those weed species.

## 26. What should be done to prevent resistant weeds from developing?

The development of resistant weeds is an issue that all farmers face, regardless of whether they grow GE crops or not. The singular reliance on GE glyphosate-resistant seeds with glyphosate, however, is the primary reason for the surge in glyphosate-tolerant weeds.

The use of herbicide-tolerant seeds and their corresponding herbicides need not have resulted in the development of numerous resistant weed species, as has happened with glyphosate-tolerant crops and glyphosate. Development of resistance can be delayed through simple weed-management practices. First and foremost, farmers need to rotate the herbicides they use on their fields so they don't use herbicides with the same mode of action year after year. The mode of action is the particular biological method that kills the weed. Second, farmers need to rotate the crops they grow in the same field, since that impacts the weed profile of the field. Finally, farmers need to use additional practices that reduce the likelihood of developing resistant weed populations, such as scouting for weeds, tilling, spraying herbicides at the proper rate, and so forth. The actions needed to prevent the development of herbicide-resistant weeds are well known; the issue is getting farmers to take those actions. In 2013, CSPI urged EPA to require farmers to rotate their herbicides in a field and carry out integrated weed management to stop the spread of glyphosate-resistant weeds (see http://cspinet.org/new/pdf/letter-to-epa-feb-4.pdf). Without government intervention, there may be little incentive for individual farmers to carry out such actions until the resistant weed problem appears on their farms.

Due to the recent development of many glyphosate-resistant weeds and the reality that few new herbicides will be available to farmers in the immediate future, EPA recently decided to proactively require developers and farmers to adopt measures that would help prevent resistant weeds from developing when using herbicide-tolerant seeds and their corresponding herbicide. In EPA's registration to use 2,4-D on emerged corn and soybean plants that are 2,4-D tolerant, EPA adopted a number of provisions to prevent the spread of herbicide-resistant weeds if they develop. For example, EPA required Dow AgroSciences (the developer of 2,4-D-tolerant seeds and the producer of the herbicide 2,4-D) to develop and implement a detailed "Herbicide Resistance Management Plan." The agency also included language on the approved 2,4-D herbicide label requiring farmers to implement resistance-management activities, such as rotating crops, rotating herbicides, and scouting for weeds. Farmers are also required to report to Dow any weeds that unexpectedly survive the herbicide application. This will enable the company to determine whether they are resistant and then ensure that their offspring do not survive to the next planting season. Finally, EPA reserved the right to amend the registration if resistant weeds develop and could cancel the registration when it comes up for renewal after five years of use. While EPA actions didn't go as far as CSPI wanted, CSPI applauded the agency for taking a good "first step," as well as acknowledging that EPA has a statutory role to play in minimizing resistance.

EPA also stated that the conditions it established for 2,4-D would become the standard for any future herbicides that are used in conjunction with herbicide-resistant weeds (such as with the registration of Dicamba with Dicamba-tolerant seeds). CSPI supports that decision. However, CSPI continues to press EPA to amend

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[1] Ervin, D. E., Carriere, Y., Cox, W. J., Fernandez-Cornejo, J., Jussaume Jr, R. A., Marra, M. C., ... & Zilberman, D. (2010). The impact of genetically engineered crops on farm sustainability in the United States. *National Research Council, Washington, DC.*

[2] National Summit on Strategies to Manage Herbicide-Resistant Weeds; Proceedings of a Symposium. (2012). Board on Agriculture and Natural Resources; Division on Earth and Life Studies; National Research Council.

[3] Herbicide Resistance Summit II. (2014). National Research Council. http://wssa.net/weed/resistance-summit-ii/.

its registration of the use of glyphosate with glyphosate-tolerant seeds (for corn, soybeans, cotton, canola, alfalfa, and sugar beets) to impose similar herbicide-resistance-management conditions.

## 27. Has the overuse of engineered corn resulted in resistant pests?

The many Bt pesticides engineered into corn and cotton (and in the future soybeans) are environmentally favorable. In fact, they originate from Bt microbial sprays that organic farmers use as an environmentally friendly insecticide to prevent pests from damaging their crops. When EPA approved the engineered versions in corn plants, they determined those pesticides to be "public goods" and imposed planting restrictions on farmers designed to delay the development of resistant pests. Those regulations included the planting of non-Bt refuges. Unfortunately, data from the biotech-seed industry show high levels of non-compliance with those planting restrictions (see "Complacency on the Farm" report from 2009 found online at http://cspinet.org/new/pdf/complacencyonthefarm.pdf, testimony to the EPA FIFRA Science Advisory Panel meeting in late 2013 found online at http://www.cspinet.org/biotech/epa-fifra-sap-2013.pdf, and Question 19).

As of the end of 2014, pests have developed resistance to at least three Bt protein somewhere around the world. In the United States. western corn rootworm in several Midwestern states have developed resistance to the Cry 3Bb1 protein, although it is not clear how widespread resistance is within those states. Additionally, cross-resistance exists between Cry3Bb1 and mCry3A in some resistant populations. That resistance may be attributed to a number of factors including farmers not planting the required refuge, farmers planting corn in the same field for many consecutive years without rotating to another crop, farmers using the same Bt corn protein in the same field each year, and the fact that this Bt protein only provides the pest with a moderate dose of toxin (which does not always kill the pests with resistant alleles). If farmers want to protect their crop from corn rootworm pests, their best strategy would be to use Bt corn in conjunction with integrated pest management practices that include rotating between corn and soybeans and switching among other rootworm management tactics including Bt proteins and non-Bt-rootworm corn with soil-applied insecticide. Instead, many farmers are layering multiple management tactics including Bt corn and soil-applied insecticides to protect their harvest. That practice may have the unintended effect of masking the degree of Bt resistant corn rootworm populations and intensifying selection for resistance to multiple management tactics.

For Bt corn plants that kill European corn borer pests, no resistance has developed, in large part because those products are high-dose toxins. In order to preserve the efficacy of these Bt traits farmers still need to do a better job of complying with EPA's refuge planting requirements. Planting Bt corn seeds with two or more genes that attack the same pest, called "pyramided" products, reduces the likelihood that insects will develop resistance. If farmers adopt these new products and abide by the EPA's reduced refuge obligations, the likelihood of resistant insects would probably be postponed for many more years, allowing farmers to continue to realize the benefits of this relatively benign method of reducing pest damage.

## 28. Are the benefits and risks from GE 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 21) 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.

It is also important to understand that impacts caused by industrial agriculture may or may not be directly caused by engineered crops. For example, the North American population of monarch butterflies has decreased tremendously.  One of the many causes for that problem is the reduced milkweed populations in Midwestern fields (milkweed is the major food source for monarchs).  The reduction in milkweed in fields is a result of farmers doing a better job of killing off weeds (milkweed is a weed to a farmer).  Farmers today have better weed control options, which include herbicide-tolerant crops and their corresponding herbicide.  However, farmers work hard to have weed-free fields and would seek to kill all the milkweed plants even if they did not use herbicide-tolerant seeds.  Thus, GE crops help farmers kill weeds, including milkweed, but even without them, farmers would strive to eliminate the milkweed on which monarchs feed on.

## Genetically Engineered Animals

### 29. How do scientists create a GE animal?

Similar to GE crops, GE 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.

### 30. Are GE animals (and their products) currently available to scientists, producers, and consumers?

Private companies and academic scientists have been experimenting with creating GE animals for over 20 years.  So far, those experiments only have resulted in a few commercially available GE 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.

http://www.glofish.com

In addition, 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.

### 31. Will GE animals and their products become part of our food supply?

Several applications for GE 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 unknown.  Companies and academics are 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 34 for criticisms of the regulatory system).

## 32. Do GE animals pose health or environmental risks?

When GE animals are commercialized, they will present similar risks to GE plant risks. 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.

## 33. How does the federal government regulate GE 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.

## 34. Is the federal regulation of GE 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 EPA, 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.

### 35. 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.

### 36. Should I be concerned that the FDA might approve the application for AquAdvantage fast-growing salmon?

Based on the publicly available data about the AquaBounty fast-growing salmon, there is no need to be concerned about eating that fish. However, FDA has not yet approved the salmon nor released the complete food-safety data package and its final analysis of that information.

http://www.aquabounty.com

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 those in 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.

## Future Agricultural Applications of Biotechnology

### 37. What new GE crops are being developed in the United States by the large biotech companies?

Biotech companies continue to develop versions of herbicide-tolerant and Bt insect-resistant corn, soybeans, and cotton, which have been enormously popular with farmers throughout the world. One new product will be a soybean variety with a Bt gene introduced into it. More controversial are new lines of herbicide-tolerant crops that have partially or fully completed the regulatory processes at USDA and EPA. Dow AgroSciences has received government approval for engineered corn and soybeans tolerant to the herbicide 2,4-D and has an application pending for cotton. Monsanto has engineered tolerance to Dicamba into those same crops. 2,4-D and Dicamba are two herbicides that pose more environmental risks than glyphosate. Once those products are commercially available, farmers will be able to spray them at times that previously would not have been possible, greatly increasing the use of those two herbicides. In addition to potential environmental impacts from the increased use, farmers are concerned about harm to their crops if those herbicides drift over from neighboring farms. Finally, if those herbicides are overused as glyphosate has been, resistant weeds might well develop before too long.

In the next 10 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 designed 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, DuPont has developed and already released on a limited basis a soybean that produces a high oleic oil (which is healthier than and could replace some partially hydrogenated oil, but is not as healthful as polyunsaturated oil). Monsanto is developing a soybean that contains beneficial omega-3 fatty acids.

## 38. What GE crops are on the horizon from the fruit and vegetable industries?

An Innate™ Russet Burbank potato (left) next to a conventional Russet Burbank potato 30 minutes after peeling. (J.R. Simplot Company)

Arctic® Granny (right) doesn't brown like a conventional Granny (left). (Okanagan Specialty Fruits, http://www.arcticapples.com/)

Several fruit and vegetable industries have begun exploring GE as a tool that could either enhance the value of their products in consumers' eyes or help farmers grow their crops more efficiently. Okanagan Specialty Fruits, Inc., has created "Arctic Apples," which are GE varieties of Golden Delicious and Granny Smith apples that are "non-browning," (that don't turn brown when cut up). To do this, the developers did not add any new DNA from another species into the apples, but used DNA from the apple itself to silence an existing gene in the apple. Similarly, Simplot has developed five different varieties of its "Innate" potato, which are engineered to be non-browning, low in acrylamide (a carcinogen that forms when carbohydrate-rich foods are cooked at high temperatures), and have reduced black spot bruises. As with the GE apple, Simplot used only potato DNA, so this product is also cisgenic, not transgenic. Both of those products completed the federal regulatory review process in the first half of 2015 and it is anticipated that those varieties will be available to consumers in the near future.

Further in the future, all the orange juice from Florida trees might come from engineered citrus trees. Southern Gardens Citrus, Texas A&M AgriLife Research, The University of Florida, Cornell University, Integrated Plant Genetics, the USDA, and the Florida Department of Agriculture are working with the Florida citrus industry to develop an engineered citrus tree that is resistant to citrus greening disease. The Florida citrus industry is currently being devastated by that disease, and no naturally resistant trees have been found. Without either the engineered trees or some other solution, that industry might not exist in a few years. Many observers believe that public resistance to GE crops would wilt if such crops provided real benefits to consumers, and not just to seed developers and farmers. A citrus tree resistant to the greening disease might be the first such "home run" product.

## 39. What new GE crops are being developed for low-income countries?

The last few years (2010–2015) have seen a large increase in funding to develop GE crops for farmers in low- and middle-income 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). The Chinese have also developed disease-resistant wheat and engineered corn varieties that are easier for chickens and pigs to digest. Similarly, Indian and Bangladeshi researchers have developed a Bt eggplant, a staple in both countries, which is currently being grown in Bangladesh and could be grown in India in the future. If adopted, farmers who plant those crops might obtain similar benefits—increased yields, reduced pesticide use, fewer 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 pesticide genes) in high-income countries and transferring them to low-income country crops (such as cowpea, sorghum, or potato). They also are engineering virus resistance into bananas and cassava, both staples in many African countries. Other biotech crops under development in Africa include crops that address agricultural constraints (such as nitrogen use efficiency, salt tolerance, and water efficient rice or water efficient maize) and crops with nutritional enhancements (such as cassava with increased provitamin A and iron or sorghum with bioavailable iron, zinc, protein, and vitamin A). 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. Golden rice is intended to prevent blindness and other health conditions caused by lack of vitamin A in the diet. While the developers of golden rice are hopeful that the rice will be marketed commercially in one or more countries by 2016, the development process has been ongoing for over a decade. During that 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 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 would be absorbed when the rice was consumed. There has also been much opposition to this product around the world. Golden rice is an example of how long and uncertain the development process for nutritionally enhanced crops can be.

http://www.goldenrice.org

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