Are bioengineered foods safe?

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Since 1994, a growing number of foods developed using the tools of the science of biotechnology have come onto both the domestic and international markets. With these products has come controversy, primarily in Europe where some question whether these foods are as safe as foods that have been developed using the more conventional approach of hybridization.

Ever since the latter part of the 19th century, when Gregor Mendel discovered that characteristics in pea plants could be inherited, scientists have been improving plants by changing their genetic makeup. Typically, this was done through hybridization in which two related plants were cross-fertilized and the resulting offspring had characteristics of both parent plants. Breeders then selected and reproduced the offspring that had the desired traits.

Today, to change a plant’s traits, scientists are able to use the tools of modern biotechnology to insert a single gene—or, often, two or three genes—into the crop to give it new, advantageous characteristics. Most genetic modifications make it easier to grow the crop. About half of the American soybean crop planted in 1999, for example, carries a gene that makes it resistant to an herbicide used to control weeds. About a quarter of U.S. corn planted in 1999 contains a gene that produces a protein toxic to certain caterpillars, eliminating the need for certain conventional pesticides.

In 1992, the Food and Drug Administration published a policy explaining how existing legal requirements for food safety apply to products developed using the tools of biotechnology. It is the agency’s responsibility to ensure the safety of all foods on the market that come from crops, including bioengineered plants, through a science-based decision-making process. This process often includes public comment from consumers, outside experts and industry. FDA established, in 1994, a consultation process that helps ensure that foods developed using biotechnology methods meet the applicable safety standards. Over the last five years, companies have used the consultation process more than 40 times as they moved to introduce genetically altered plants into the U.S. market.

Although the agency has no evidence that the policy and procedure do not adequately protect the public health, there have been concerns voiced regarding FDA’s policy on these foods. To understand the agency’s role in ensuring the safety of these products, FDA Consumer sat down with Commissioner Jane E. Henney, M.D., to discuss the issues raised by bioengineered foods:

**FDA Consumer:** Dr. Henney, what does it mean to say that a food crop is bioengineered?

**Dr. Henney:** When most people talk about bioengineered foods, they are referring to crops produced by utilizing the modern techniques of biotechnology. But really, if you think about it, all crops have been genetically modified through traditional plant breeding for more than a hundred years.

Since Mendel, plant breeders have modified the genetic material of crops by selecting plants that arise through natural or, sometimes, induced changes. Gardeners and farmers and, at times, industrial plant breeders have crossbred plants with the intention of creating a prettier flower, a hardier or more productive crop. These conventional techniques are often imprecise because they shuffle thousands of genes in the offspring, causing them to have some of the characteristics of each parent plant. Gardeners or breeders then look for the plants with the most desirable new trait.

With the tools developed from biotechnology, a gene can be inserted into a plant to give it a specific new characteristic instead of mixing all of the genes from two plants and seeing what comes out. Once in the plant, the new gene does what all genes do: It directs the production of a specific protein that makes the plant uniquely different.

This technology provides much more control over, and precision to, what characteristic breeders give to a new plant. It also allows the changes to be made much faster than ever before.

No matter how a new crop is created—using traditional methods or biotechnology tools—breeders must conduct field testing for several seasons to make sure only desirable changes have been made. They must check to make sure the plant looks right, grows right, and produces food that tastes right. They
also must perform analytical tests to see whether the levels of nutrients have changed and whether the food is still safe to eat.

As we have evaluated the results of the seeds or crops created using biotechnology techniques, we have seen no evidence that the bioengineered foods now on the market pose any human health concerns or that they are in any way less safe than crops produced through traditional breeding.

**FDA Consumer:** What kinds of genes do plant breeders try to put in crop plants?

**Dr. Henney:** Plant researchers look for genes that will benefit the farmer, the food processor, or the consumer. So far, most of the changes have helped the farmer. For example, scientists have inserted into corn a gene from the bacterium *Bacillus thuringiensis*, usually referred to as BT. The gene makes a protein lethal to certain caterpillars that destroy corn plants. This form of insect control has two advantages: It reduces the need for chemical pesticides, and the BT protein, which is present in the plant in very low concentrations, has no effect on humans.

Another common strategy is inserting a gene that makes the plant resistant to a particular herbicide. The herbicide normally poisons an enzyme essential for plant survival. Other forms of this normal plant enzyme have been identified that are unaffected by the herbicide. Putting the gene for this resistant form of the enzyme into the plant protects it from the herbicide. That allows farmers to treat a field with the herbicide to kill the weeds without harming the crop.

The new form of the enzyme poses no food safety issues because it is virtually identical to nontoxic enzymes naturally present in the plant. In addition, the resistant enzyme is present at very low levels and it is as easily digested as the normal plant enzyme.

Modifications have also been made to canola and soybean plants to produce oils with a different fatty acid composition so they can be used in new food processing systems. Researchers are working diligently to develop crops with enhanced nutritional properties.

**FDA Consumer:** Do the new genes, or the proteins they make, have any effect on the people eating them?

**Dr. Henney:** No, it doesn’t appear so. All of the proteins that have been placed into foods through the tools of biotechnology that are on the market are nontoxic, rapidly digestible, and do not have the characteristics of proteins known to cause allergies.

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As for the genes, the chemical that encodes genetic information is called DNA. DNA is present in all foods and its ingestion is not associated with human illness. Some have noted that sticking a new piece of DNA into the plant’s chromosome can disrupt the function of other genes, crippling the plant’s growth or altering the level of nutrients or toxins. These kinds of effects can happen with any type of plant breeding—traditional or biotech. That’s why breeders do extensive field-testing. If the plant looks normal and grows normally, if the food tastes right and has the expected levels of nutrients and toxins, and if the new protein put into food has been shown to be safe, then they can be presumed to be as safe as conventional foods.

**FDA Consumer:** You mentioned allergies. Certain proteins can cause allergies, and the genes being put in these plants may carry the code for new proteins not normally consumed in the diet. Can these foods cause allergic reactions because of the genetic modifications?

**Dr. Henney:** I understand why people are concerned about food allergies. If one is allergic to a food, it needs to be rigorously avoided. Further, we don’t want to create new allergy problems with food developed from either traditional or biotech means. It is important to know that bioengineering does not make a food inherently different from conventionally produced food. And the technology doesn’t make the food more likely to cause allergies.

Fortunately, we know a lot about which foods trigger allergic reactions. About 90 percent of all food allergies in the United States are caused by cow’s milk, eggs, fish and shellfish, tree nuts, wheat, and legumes, especially peanuts and soybeans.

To be cautious, FDA has specifically focused on allergy issues. Under the law and FDA’s biotech food policy, companies must tell consumers on the food label when a product includes a gene from one of the common allergy-causing foods unless it can show that the protein produced by the added gene does not
make the food cause allergies.

We recommend that companies analyze the proteins they introduce to see if these proteins possess properties indicating that the proteins might be allergens. So far, none of the new proteins in foods evaluated through the FDA consultation process have caused allergies. Because proteins resulting from biotechnology and now on the market are sensitive to heat, acid and enzymatic digestion, are present in very low levels in the food, and do not have structural similarities to known allergens, we have no scientific evidence to indicate that any of the new proteins introduced into food by biotechnology will cause allergies.

FDA Consumer: Let me ask you one more scientific question. I understand that it is common for scientists to use antibiotic resistance marker genes in the process of bioengineering. Are you concerned that their use in food crops will lead to an increase in antibiotic resistance in germs that infect people?

Dr. Henney: Antibiotic resistance is a serious public health issue, but that problem is currently and primarily caused by the overuse or misuse of antibiotics. We have carefully considered whether the use of antibiotic resistance marker genes in crops could pose a public health concern and have found no evidence that it does.

I'm confident of this for several reasons. First, there is little if any transfer of genes from plants to bacteria. Bacteria pick up resistance genes from other bacteria, and they do it easily and often. The potential risk of transfer from plants to bacteria is substantially less than the risk of normal transfer between bacteria. Nevertheless, to be on the safe side, FDA has advised food developers to avoid using marker genes that encode resistance to clinically important antibiotics.

FDA Consumer: You've mentioned FDA's consultative process a couple of times. Could you explain how genetically engineered foods are regulated in the United States?

Dr. Henney: Bioengineered foods actually are regulated by three federal agencies: FDA, the Environmental Protection Agency, and the U.S. Department of Agriculture. FDA is responsible for the safety and labeling of all foods and animal feeds derived from crops, including biotech plants. EPA regulates pesticides, so the BT used to keep caterpillars from eating the corn would fall under its jurisdiction. USDA's Animal and Plant Health Inspection Service oversees the agricultural environmental safety of planting and field testing genetically engineered plants.

If a bioengineered food is significantly different from its conventional counterpart—if the nutritional value changes or it causes allergies—it must be labeled to indicate that difference.

Let me talk about FDA's role. Under the federal Food, Drug, and Cosmetic Act, companies have a legal obligation to ensure that any food they sell meets the safety standards of the law. This applies equally to conventional food and bioengineered food. If a food does not meet the safety standard, FDA has the authority to take it off the market.

In the specific case of foods developed utilizing the tools of biotechnology, FDA set up a consultation process to help companies meet the requirements. While consultation is voluntary, the legal requirements that the foods have to meet are not. To the best of our knowledge, all bioengineered foods on the market have gone through FDA's process before they have been marketed.

Here's how it works. Companies send us documents summarizing the information and data they have generated to demonstrate that a bioengineered food is as safe as the conventional food. The documents describe the genes they use; whether they are from a commonly allergenic plant, the characteristics of the proteins made by the genes, their biological function, and how much of them will be found in the food. They tell us whether the new food contains the expected levels of nutrients or toxins and any other information about the safety and use of the product.

FDA scientists review the information and generally raise questions. It takes several months to complete the consultation, which is why companies usually start a dialog with the agency scientists nearly a year or more before they submit the data. At the conclusion of the consultation, if we are satisfied with what we have learned about the food, we provide the company with a letter stating that they have completed the consultation process and we have no further questions at that time.

FDA Consumer: Since genes are being added to the plant, why doesn't FDA review biotech products under the same food additive regulations that it reviews (Continued on page 23)
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food colors and preservatives?

Dr. Henney: The food additive provision of the law ensures that a substance with an unknown safety profile is not added to food without the manufacturer proving to the government that the additive is safe. This intense review, however, is not required under the law when a substance is generally recognized as safe (GRAS) by qualified experts. A substance’s safety can be established by long history of use in food or when the nature of the substance and the information generally available to scientists about it is such that it doesn’t raise significant safety issues.

In the case of bioengineered foods, we are talking about adding some DNA to the plant that directs the production of a specific protein. DNA already is present in all foods and is presumed to be GRAS. As I described before, adding an extra bit of DNA does not raise any food safety issues.

As for the resulting proteins, they too are generally digested and metabolized and don’t raise the kinds of food safety questions as are raised by novel chemicals in the diet. The proteins introduced into plants so far either have been pesticides or enzymes. The pesticide proteins, such as BT, would actually be regulated by EPA and go through its approval process before going on the market. The enzymes have been considered to be GRAS, so they have not gone through the food additive petition process. FDA’s consultation process aids companies in determining whether the protein they want to add to a food is generally recognized as safe. If FDA has concerns about the safety of the food, the product would have to go through the full food additive premarket approval process.

FDA Consumer: Why doesn’t FDA require companies to tell consumers on the label that a food is bioengineered?

Dr. Henney: Traditional and bioengineered foods are all subject to the same labeling requirements. All labeling for a food product must be truthful and not misleading. If a bioengineered food is significantly different from its conventional counterpart—if the nutritional value changes or it causes allergies—it must be labeled to indicate that difference. For example, genetic modifications in varieties of soybeans and canola changed the fatty acid composition in the oils of those plants. Foods using those oils must be labeled, including using a new standard name that indicates the bioengineered oil’s difference from conventional soy and canola oils. If a food had a new allergy-causing protein introduced into it, the label would have to state that it contained the allergen.

We are not aware of any information that foods developed through genetic engineering differ as a class in quality, safety, or any other attribute from foods developed through conventional means. That’s why there has been no requirement to add a special label saying that they are bioengineered. Companies are free to include in the labeling of a bioengineered product any statement as long as the labeling is truthful and not misleading. Obviously, a label that implies that a food is better than another because it was, or was not, bioengineered, would be misleading.

FDA Consumer: Overall, are you satisfied that FDA’s current system for regulating bioengineered foods is protecting the public health?

Dr. Henney: Yes, I am convinced that the health of the American public is well protected by the current laws and procedures. I also recognize that this is a rapidly changing field, so FDA must stay on top of the science as biotechnology evolves and is used to make new kinds of modifications to foods. In addition, the agency is seeking public input about our policies and will continue to reach out to the public to help consumers understand the scientific issues and the agency’s policies.

Not only must the food that Americans eat be safe, but consumers must have confidence in its safety, and confidence in the government’s role in ensuring that safety. Policies that are grounded in science, that are developed through open and transparent processes, and that are implemented rigorously and communicated effectively are what have assured the consumers’ confidence in an agency that has served this nation for nearly 100 years.

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