



December 20, 2001

Rena A. Bloom, N.D.
1181 South Parker Road, Suite 101
Denver, Colorado 80231

Dear Dr. Bloom,

Thank you for your letter of November 21, addressed to the Food and Drug Administration, conveying your concerns and comments on the labeling of foods produced by biotechnology, sometimes called genetic engineering or bioengineering. FDA established a public docket to solicit comments on these issues. Although the comment period closed on January 13, we have forwarded your letter to our Docket Management Branch to be included in the record.

I have enclosed FDA's latest Consumer Magazine article, "Are Bioengineered Food Safe?" This article explains the agency's role in ensuring the safety of these products. I also recommend you look to our website at <http://www.fda.gov/oc/biotech>.

As requested, our email address is execsec@oc.fda.gov.

I hope you find this information helpful.

Sincerely,

Kelly Malone
Correspondence Analyst
Office of the Executive Secretariat

cc:
HFA-305, Dockets Management

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Table of Contents
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U.S. Food and Drug Administration

Are Bioengineered Foods Safe?

by Larry Thompson

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. (See "Methods for Genetically Engineering a Plant.") 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

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 there are no safety issues.

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 the foods that do 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

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.

Larry Thompson is a member of FDA's public affairs staff.

[Table of Contents](#) | [How to Subscribe](#) | [Back Issues](#) | [FDA Home Page](#)

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