

September 9, 2000

Commissioner Jane E. Henney *MD '00* SEP 25 P3:09
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Henney:

I am writing to you to share an article about genetically altered food, one of many I have read over the past several months and to express my concerns. I am personally opposed to such intervention in our food system unless it can be proven prior to commercial use that it is completely environmentally and biologically safe to all including the earth and the air with the exception of the specific pest insect it is intended to control. Further, it must not result in mutations of the pest insect or the point in altering the seeds is lost. Can we say that about any of the seeds that have been genetically altered to date? No, we cannot because no testing that would factually prove those results (or results to the contrary) have been done to date. Tests that have been done have generated controversy and much, much more testing needs to be done before such seeds should be released for any use.

I request that you reconsider, review and change the FDA's approach to this issue by making testing mandatory and creating other such standards that will protect our food supply, our environment and our health. Thank you for your attention to this critical emerging concern.

Sincerely,

Jane Keating-Jones

00P-1211

C6365

Test-Tube Food?



Does genetically engineered food present ripple effects that we can't anticipate—or reverse?

Is It a Problem?

It seemed like a reasonable question to ask from where we sat in her Los Angeles kitchen. But had we been in a London kitchen instead, it would have been a shamefully ignorant one. Since the first genetically engineered (GE) food—a new breed of tomato—hit the market in 1994, the issue has at times dominated headlines in Europe, caused protests, and led to vociferous public debates.

The controversy over the production and safety of GE food arrived on American shores quietly, but it's been gaining momentum. Increasingly, people are taking sides on the issue. At one extreme are those who believe in the promise and progress that GE food can bring to food production and world health; on the other are those who believe that creating and eating these new combinations—dubbed “Frankenfoods”—could have dangerous ramifications for the environment and our health.

Perhaps you're wondering how a bag of corn chips can trigger such controversial health questions. **In fact, about 60% of our processed foods now have some genetically engineered ingredients in them.** Perhaps, like me, you'd like some answers about how we ended up with all this genetically modified food, and what—if anything—we should do about it.

Be aware: Answers are in short supply. In fact, you may be surprised to learn that there are more geneti-

cally engineered foods in your kitchen than there are answers to your questions about them.

You're Already Eating Them

You would never *taste* genetically engineered ingredients in your cornflakes, frozen waffles, or soy burgers, but chances are good that they're there.

One-quarter of our farm fields are now filled with genetically engineered crops—including more than 35% of all corn, almost 55% of all soybeans, nearly half of all cotton, and a growing array of fruits and vegetables. Some of that ends up in our salads, oils, side dishes, and snacks. (See “From Field to Market” on p. 126.)

This “brave new world” of genetic engineering allows scientists to pick desired genes from one organism—say, a virus, bacteria, or even an animal—and insert them into a completely different life form, such as a corn or tomato plant. Up until now, scientists have been using the technology to create plants that can fight crippling viruses, to produce crops that are resistant to pests and herbicides, and to make food last longer. On the horizon is a plethora of intriguing possibilities—for example, inserting oral vaccines and vitamins into food, or even altering its fat content.

Many people consider it a revolution in the way we grow our food. The reason that many of us haven't heard much about it is that, after consultation with other experts in the field, the FDA

BE AWARE: Answers are in short supply. In fact, you may be surprised to learn that there are more genetically engineered foods in your kitchen than there are answers to your questions about them.

decided in 1992 that genetic engineering isn't a revolution at all. In fact, the FDA considers it not substantially different from the kind of conventional crop breeding that farmers have been doing for centuries. After all, we eat nectarines (bred from peaches), tangelos (tangerines crossed with grapefruits), and corn (crossbred from many different varieties) with no problems. These are foods crossbred from related genes—in other words, from other fruits and vegetables.

Surprisingly, the FDA considers inserting an animal gene into a plant—a fish gene into a tomato, for instance—to be so similar that it hasn't changed its policy since 1992. **This means that, as with nongenetically engineered foods, the FDA doesn't require safety testing before these products go to market.** Unfortunately for the consumer, it doesn't require labeling either, with these few exceptions: when a food's nutritional value has been significantly altered,

if it contains a known food allergen, or when the common name of the food no longer applies.

So who makes sure that these products are safe? The FDA relies on the manufacturer for that. But while the agency offers guidance and strongly encourages the manufacturers “for their own best interest” to conduct tests and to consult with the FDA on their new genetic combinations, the bottom line is that companies don't have to. So far, they have all complied, but there's no governing body to which they're

The FDA requires no special safety testing.



FROM FIELD TO MARKET

THE FARM

The USDA has approved 50 genetically engineered plants. Here are some of them:

beets	cotton	soybean
canola	melons	squash
chicory	papaya	tomato
corn	potato	

SOON TO COME:

apples	strawberries	walnuts
cucumbers	sugar cane	wheat
rice		

THE MARKET

When we started this article, we had hoped to give you a handy list of foods that contained genetically engineered ingredients so that you could make your own choices. Were we naive! Product lists can give examples, but the bottom line is that in the processed-foods aisle of your grocery store, most foods are likely to contain ingredients that come from genetically engineered organisms. That's because most processed foods contain something that comes from corn or soy.

Happily, if you're talking about the fresh produce aisle, you're not nearly as likely to encounter genetically engineered food. Even whole foods for which there have been some approvals of genetically engineered versions (such as tomatoes) are, for the most part, still a much better bet in their fresh form.

There are two grocery store chains that have taken a pledge to eliminate genetically engineered ingredients from their store brands: Whole Foods Market, Inc. (including Fresh Fields, Bread & Circus, Bread of Life, and Wellspring Grocery) and Wild Oats Markets, Inc. (including Alfalfa's Market, Oasis Fine Foods, Sunshine Grocery, Ideal Market, and Wild Oats Community Market).

You can also look for products from companies that don't use genetically modified ingredients. These include the following:*

Barbara's Bakery	Freshlike	Nature's Path Foods
Ben & Jerry's	Gerber (baby foods)	Newman's Own
Bird's Eye	H.J. Heinz Company (baby foods)	Stonyfield Farm
Eden Foods		

*Source: *Organic Gardening* magazine, Jan/Feb 2000

held accountable. And there's no way to know for certain what the long-term effect of GE foods will be.

Breeding Controversy

The lack of an official overseer and required safety testing troubles many scientists, who see a big difference between traditional breeding of close relatives on the farm and the new technique of combining genes from totally different species in the laboratory. "It's completely artificial; it snips out genes and moves them via test tubes into other organisms," says Margaret Mellon, PhD, a molecular biologist with the Union of Concerned Scientists in Washington, DC.

Philip Regal, PhD, professor of ecology, evolution, and behavior at the University of Minnesota in St. Paul, worries that **scientists won't be alerted to any risks posed by genetic engineering "because they begin with the presumption that there aren't going to be any problems."**

The Risks

Just as no one has concrete proof that genetically engineered foods on the market today are unsafe to eat, there is no proof that they are absolutely safe either. On one side we have the presumption that they ought to be okay; on the other we have reasoning that some might not be okay, as well as a collection of relatively small, often preliminary experiments that suggest that they may not be. Here are the most

Melons are one of 50 genetically altered plants.



troubling questions that those studies raise about GE foods: **Will these foods contain hidden allergy-producing substances?**

Although most of us know what foods trigger our particular allergies and how to avoid them, there's concern that if genes from another organism can be inserted into a plant, we will no longer be able to recognize those allergy-causing foods.

In the mid-'90s, the biotech seed company Pioneer Hi-Bred International tried putting Brazil nut genes in soybeans to boost their nutritional value. In a small study, researchers discovered that human volunteers who

were allergic to Brazil nuts experienced strong allergic reactions to extracts of the soybeans. The company halted its plans.

Although the FDA requires companies to label *known* allergens and to investigate suspected ones, some scientists, such as Dr. Mellon, worry about the potential allergens that we don't recognize—such as proteins that come from soil bacteria, not from food. (Most allergens are proteins.) "How do you know whether that bacteria, if it were eaten in the same quantities that you eat a food such as shrimp, would cause allergies or not?" There is no adequate way to test that, she says.

Others argue that such concerns are overblown. "Whenever these new things go into the market, there are standard allergenicity tests that are done. We look for new proteins," says Charles Arntzen, PhD, professor

of molecular biology and president and CEO of the Boyce Thompson Institute for Plant Research at Cornell University in Ithaca, NY.

Will these foods increase resistance to antibiotics?

Some scientists have suggested that the process of genetic engineering could accelerate antibiotic resistance in humans. When genetic engineers transfer a gene from one life form to another, they also include a "marker" gene that confers antibiotic resistance. This helps them identify and select the cells that have successfully taken up the gene of interest. Some worry that ingesting these genes could not only reduce the effectiveness of a dose of antibiotics, but also eventually render antibiotics virtually powerless to fight some of our most serious infections.

Abigail Saylers, PhD, professor of microbiology at the University of Illinois in Urbana, recently testified before

Coming Soon to a Supermarket near You?

- ▶ Fruit that delivers vitamins
- ▶ Rice with vitamin A to reduce blindness (for use in the developing world)
- ▶ Nuts, milk, and cereals that don't cause allergies
- ▶ Plant "toothbrushes" containing antibodies to reduce dental decay
- ▶ Artichoke genes in sugar beets to produce fructans that promise low-calorie sweetness without sugar
- ▶ Milk with less lactose
- ▶ Crops that can withstand frost and drought
- ▶ Healthier oils containing increased unsaturated fats
- ▶ Improved protein in food

TRANSFERRING a gene from one species into another may result in unpredictable changes.

Congress that the chances of this happening are extremely slim. "These resistance genes are already very widespread in naturally occurring bacteria. What little would be added by cloning is like adding a cup of water to the ocean," she says. She also points out that there are bigger worries, such as the overuse of antibiotics by doctors and livestock farmers.

Will genetic engineering change the nutritional value of food?

Marc Lappé, a health policy expert and director of the Center for Ethics and Toxics in Gualala, CA, tested some soybeans that were genetically engineered to resist the herbicide Roundup (known as "Roundup Ready" soybeans), and discovered that genetic engineering just might change the nutritional value. Lappé's group found that the Roundup Ready soybeans showed as much as a 20% drop in valuable phytoestrogens, which evidence has shown may be beneficial in fighting osteoporosis and heart disease.

Although Lappé acknowledges that more testing needs to be done, he says that the implications of his work might be significant, given that 50% of the soybean crop in the US is Roundup Ready. Beyond soybeans, he suggests that without more extensive testing, we may not

be able to anticipate such nutritional changes in other foods.

Will genetic engineering make food toxic? When a group of rats that were fed GE potatoes showed signs of intestinal changes, heated debate ensued about whether the process could make foods toxic. In the study, published in the British medical journal *The Lancet* last October, the researchers suggested that inserting the genetic engineering



Some experts worry that familiar foods could harbor foreign allergens.

material "package" to help make the potatoes resistant to pests is what caused a thickening of the rats' guts and dramatic changes in their organ weights. But Stanley Ewen, PhD, one of the study's authors, says, "I hesitate before using words such as 'poisonous' or 'toxic.'"

Some people argued that the experiments were seriously flawed. While agreeing that the results of the study are "preliminary," the editor of *The Lancet* defended the journal's decision to publish the early findings as an attempt to draw attention to the need for further investigation in this new field. Regardless of the study's merit, others conclude that the results also suggest that **transferring a gene from one species into another may result in unpredictable changes.**

"They have this model in which they're putting in, with laser precision, one or two new genes, and this is going to change just one or two traits. Otherwise this organism will be just like any other crop out there," says John Fagan, PhD, a molecular biologist and former genetic engineer. Dr. Fagan

founded a company called Genetic-ID, based in Fairfield, IA, to identify genetically engineered ingredients in foods and crops. "But they forget that living things are very complex and that all of the components interact. So when you change one gene, you change a whole slew of other things as well—and you can neither predict those changes, nor can you control them."

Can the unexpected happen?

It already has. Despite claims that genetic engineering is more "precise" than traditional breeding, some experiments have gone awry and very unexpected results have turned up. They range from a GE soil microbe that unexpectedly killed wheat plants to a field of petunias genetically engineered to turn white that bloomed in a riot of colors.

Although scientists caught these potential problems before the products

were on the market, that may not always be the case, as suggested by a recent controversial study at Cornell University. This study showed that monarch butterfly larvae died after eating milkweed dusted with GE corn pollen containing a pesticide. The study itself has since been criticized and its eco-

Where to Write

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logical implications widely debated, but **it reinforces the concern that genetically engineered food may present ripple effects that we can't completely anticipate—or reverse.**

To Eat or Not to Eat

Perhaps it's partly the newness of it all that troubles me—that and the idea that we're currently growing and eating genetically engineered food without realizing it and without solid evidence of what the ultimate health and environmental effects, if any, might be. Yes, eating those corn chips or any other genetically engineered food may turn out to be harmless. But for the moment, we don't really know for sure. So what can we do if we're concerned?

Eat organic. Most supermarkets now provide a wide variety of organic foods—as good a guarantee as you can get that a product is chemical-free and not genetically altered.

Demand labeling. As we were going to press, the US Congress was holding hearings and considering a bill—HR 3377, the Genetically Engineered Food Right to Know Act—that would require both the FDA and the USDA to label *all* foods that are genetically engineered or made from genetically engineered ingredients. Write or call your state representative to express your opinion. Or e-mail your congressional representative at the House of Representative's Home Page at www.house.gov/writerep/.

Speak your mind. A number of federal regulatory agencies are currently reconsidering their stance on genetically engineered foods. Toward the end of 1999, the FDA held a series of three public meetings to "take the pulse of the American public on the issue of genetically engineered foods." Based on comments from these meetings, the agency was reviewing its policy at press time. The Environmental Protection Agency (EPA) is considering requiring more test data from seed companies to ensure that crops genetically engineered to resist pests and herbicides are safe for wildlife, the soil, and water sources.

The USDA has announced several recent measures regarding genetically engineered agriculture, including a joint effort with the National Academy of Sciences. They will undertake an independent, ongoing scientific review of the agency's regulatory process for biotech-derived plants and requested reporting of adverse or unexpected environmental or agricultural effects of genetically engineered plants. Write to them (see "Where to Write" on p. 130) and tell them how you feel about genetically engineered food. •

Los Angeles-based freelance writer Andrea Malin was a writer/producer for NBC-TV news anchor Tom Brokaw. She worked closely on this article with Pamela Boyer, an associate research editor at Prevention. Assistance was also provided by the editors of Organic Gardening magazine.

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