What You See Depends On How You Grind the Lens

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> "The promise of agricultural biotechnology is immense. Advances in this technology will result in crops with a wide range of desirable traits that will directly benefit farmers, consumers, and the environment and increase global food production and quality."—*Seeds of Opportunity: an Assessment Of The Benefits, Safety, and Oversight of Plant Genomics and Agricultural Biotechnology*, United States House of Representatives, 1999
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> "Food biotech is dead."—Henry I. Miller, Hoover Institute, Stanford University (Eichenwald *et al*., 2001)

I believe agricultural biotechnology does indeed offer the promise of substantial benefits to farmers, consumers, and the environment. However, after almost twenty years of industry advocacy and government promotion, the American people have not embraced this new technology. Spurred by such events as the StarLink™ corn contamination and European rejection of genetically modified foods, there is an increasingly visible and contentious debate in this country about the potential risks and benefits of agricultural biotechnology and its appropriate role in our lives. Radical environmentalists trash biotech fields. Obdurate biotech advocates trash the intelligence and integrity of anyone who disagrees with them.

If we want to realize the potential benefits of agricultural biotechnology, we must achieve agreement and compromise. Beginning that process requires taking a realistic view of the public's willingness to accept agricultural biotechnology, appreciating some of the factors that contribute to continuing public concern, and considering changes in government regulation that might increase the public trust that is so vital to greater acceptance and full realization of agricultural biotechnology's promise.

[1]Ms. Foreman was scheduled to deliver this presentation at the meeting, but was unable to do so.

Public Acceptance of Agricultural Biotechnology and Genetically Modified Foods

Dozens of polls have examined the level of public acceptance of agricultural biotechnology and genetically modified foods in United States. Each poll is structured differently, asking slightly different questions, and getting somewhat different answers. If you support biotechnology, you can find a poll that agrees with your point of view. If you oppose the technology, you can find a poll that condemns it. Not surprisingly, poll questions are often structured in a manner to assure a response consistent with the views of the poll's sponsor.

But it is possible to get a snapshot of the general level of public acceptance. I reviewed five polls, taken between 1999 and 2001, and totaled the positive and negative responses (see below). There is good news and bad in the results of these surveys. The good news is that only one poll showed more people with negative than positive opinions. The bad news is that none of the polls showed strong public support for genetic engineering. Only one question came close to eliciting a positive response from two-thirds of those polled.

Survey/Questions	Total positive	Total negative
International Food Information Council Foundation (January 19–21, 2001)		
Would you purchase foods modified by biotechnology in ways that provided direct and obvious consumer benefits such as: fresher, tastier produce?	58%	38%
reduced saturated fat?	46%	17%
Do you expect benefits to your family from biotech within 5 years?	64%	22%
Pew Foundation Initiative on Food and Biotechnology (January 22–28, 2001)		
Are genetically modified foods: basically safe / unsafe	48%	21% (unsafe)
Harris Poll (June 8–12, 2000)		
Do benefits of developing / growing GE plants outweigh risks?	38%	48% (risks greater)
Gallup Poll (March 30–April 2, 2000)		
Do you support use of biotechnology in food / agriculture?	48%	41%
National Science Foundation / Texas A&M Public Policy Research Institute (April–May 2000) (Priest, 2000)		
Do you believe GE will improve our way of life in next 20 years?	53%	30%

Perhaps more troubling, Susan Horning Priest (2000), writing in *Nature Biotechnology,* reported that Americans are less enthusiastic about genetic engineering than about other recently introduced technologies.

Favorable Attitudes Toward New Technologies

The NSF/Texas A&M survey asked respondents their views of whether particular technologies would improve their lives:

Technology	Positive response
Computers/information technology	88%
Solar energy	88%
Telecommunications	82%
The Internet	72%
Space exploration	62%
Genetic engineering	53%

Unfavorable Attitudes: Genetic Engineering Versus Nuclear Energy

The NSF/Texas A&M survey found that Americans are equally as negative about genetic engineering as they are about nuclear energy, a technology that has had limited application in the United States because of a lack of public acceptance:

Technology	Positive response
Genetic engineering	30%
Nuclear energy	32%

Now many biotech advocates take comfort in the fact that polls show many Americans are still not aware of genetic engineering. They assume that, as people become more familiar with the technology, they will feel more comfortable with it. Unfortunately, research indicates that familiarity with agricultural biotechnology does not breed affection. Priest (2000) compared responses to genetic engineering over seventeen years. The number of people who had negative attitudes toward agricultural biotechnology almost doubled, rising from 16 to 30%:

Genetic Engineering Will Make the Quality of Life Worse	Positive response
1982	16%
1986	22%
1999	30%

Last year we accepted the election of the President of the United States by something less than a convincing majority. We are much more demanding when it comes to new products. They do not survive unless they gain popularity and do it quickly. A new technology that affects the safety and quality of our food supply will almost surely have to secure an overwhelming level of public acceptance if it is to survive.

Why Americans Are Unenthusiastic About Genetically Modified Foods

I can identify three reasons why Americans have embraced computers and cell phones and medical biotechnology, but are less accepting of genetically modified foods.

First, food is special. The manufacturers of genetically modified products think they are purveying commodities. Consumers believe they are tinkering with something more basic to the human psyche: a "cultural metaphor for life."

We eat to live, but we also live to eat. Food provides energy and essential nutrients, but food is more than fuel for the body. It is sustenance for the soul. From the Apple in the Garden of Eden to the golden arches on the highway, food is a key component of human civilization. Food is a cultural and religious icon. Throughout history, people have been defined by what they are obligated or forbidden to eat. Even in twenty-first century America what you eat reveals who you are and where you are from. If you want to experience true cultural isolation, walk into a New York deli and order corned beef on white with mayo.

Food is intensely personal. In 1996, the Agriculture Council of America commissioned an intensive study of our emotional attachments to food. They found that food is integrally tied to nurturance, bonding and love. Participants in the study viewed unsafe food as a hostile invader of their homes and an assault on themselves and their families.

Second, agricultural biotechnology presents an unbalanced distribution of risks and benefits. When it comes to food, most of us are risk-averse. This is especially true if the risk is imposed on us by someone else, is invisible, and lacks a countervailing direct and specific personal benefit.

It is easy to see why genetically modified foods light up all the risk-aversion receptors. The products on the market today have no direct consumer benefit. They were developed to enhance the economic fortunes of farmers and

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chemical companies. Lowering farmers' input costs is important to farmers, but not to American consumers. Lowering the cost of producing corn, does not translate to cheaper meat at the supermarket.

There are promises of nutritionally superior products, but we cannot eat promises. And, the adamant refusal to label genetically modified products cannot help but increase consumer suspicion that these foods carry some risk. Most consumers believe that if you have to hide it, there must be something wrong with it. In short, there is no reason for consumers to willingly accept any risk from genetically engineered food.

Third, acceptance of agricultural biotechnology is affected by the social and political context into which it has been introduced, including instantaneous communication and globalization. No product or technology comes to market in a vacuum. Unfortunately, the advent of genetically modified crops has coincided with a rash of food-safety disasters. Because we live in an era of instantaneous communication, the details of those disasters are flashed into our homes. Because we eat from a global plate, we can never be sure that a food safety disaster half-way around the world will not end up on our dining-room table.

Finally, the very fact of globalization creates discomfort for many people. Agricultural biotechnology is associated with increasing global corporate power. This, coupled with a diminishing level of trust in both private and public institutions compounds the problem for those seeking to gain acceptance of agricultural biotechnology.

The Role of Government in Assuring Safety and Acceptance

Given all these impediments to public acceptance of genetically modified food products, it would seem reasonable that supporters of agricultural biotechnology would benefit from, even insist upon, a food safety regulatory system in the United States so rigorous and credible and above reproach that it cannot fail to dispel doubt and instill public trust.

The United States government and agricultural biotechnology industry chose another course. Our government, especially the Food and Drug Administration (FDA):

- opted for a system that favored a rush to market over assurance of safety and acceptance. The White House, in an election year, became actively involved in writing FDA's 1992 Policy Statement on Foods Derived from New Plant Varieties. Vice President Quayle described the Statement as "regulatory reform," designed to help American agricultural biotechnology companies gain advantage in a new field. This effort to speed genetically modified foods to market has served instead to deny genetically modified products the most valuable assets they could acquire: a rigorous and transparent pre-market safety approval by FDA, and resulting public comfort level.

- contorted existing statutes to regulate a technology that was never contemplated when the relevant laws were written in 1906 and 1958. Contrast this to the course chosen in the European Union, which enacted new law specifically designed to deal with "novel foods."
- established what amounts to a system of "nonregulation" (based on McGarity and Hansen, 2001). Foods altered by agricultural biotechnology are not subject to rigorous premarket safety testing and FDA approval. Today FDA does not require notice that a firm intends to market a genetically modified food organism so long as the firm concludes that its product is "generally recognized as safe" (GRAS). Changes under consideration by the agency will not require FDA to approve products before they are marketed.

How FDA Avoids Regulation of, and Responsibility for, Genetically Modified Foods

The FDA has determined that adding a new gene to a conventional food falls under the 1958 Food Additive provisions of the Food Drug and Cosmetic Act, unless the resulting genetically modified food is "substantially equivalent" to a conventional food that is GRAS.

Substantial equivalence—limiting the factors that would cause a product to be considered different. The new genetically modified food is considered "substantially equivalent" to its conventional counterpart unless the transfer involved genes coding for fats, proteins, or carbohydrates that might cause allergic reactions, are known to be toxic, or change the nutritional value of the food. Some FDA scientists urged that at least basic toxicological testing be done on all genetically modified foods. The FDA has established no protocols to detect unanticipated effects, no chemical analyses of the molecular characteristics of the altered food, no tests for stability of the transferred gene or of the key nutrients and toxicants.

Accepting the manufacturer's assertion that a product is GRAS. For all practical purposes a company that produces a genetically modified food is the judge of whether the product falls within the "GRAS" category. The GRAS determination relies almost exclusively on a manufacturer's finding that the food meets this requirement.

When the FDA approves a petition for a new food additive, it publishes a regulation stating that FDA finds that the additive is safe, making public the data that support its decision, establishing requirements for the use and labeling of the additive.

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responsibility for the safety of the product. There is no *Federal Register* notice and no explanation of reasoning. Virtually all of the FDA-regulated genetically modified products now on the market got there because the producing company claimed the product is GRAS. The company receives a letter from FDA, the operative language of which is that the company has determined that the product is the same as a safe product.

For example, on January 27, 1995, FDA wrote to Monsanto regarding the Roundup Ready® soybean, stating, "…it is our understanding that, based on the safety and nutritional assessment you have conducted, you have concluded that the new soybean variety is not materially different in composition, safety, or any other relevant parameter from soybean varieties now on the market… as you are aware, it is Monsanto's continued responsibility to ensure that foods the firm markets are safe, wholesome and in compliance with all applicable legal and regulatory requirements."

FDA and the biotechnology industry express surprise that anyone objects to the current system of bringing modified foods to market. The argue that all the new products are tested are rigorously reviewed. However, the products are tested by the company that makes them, and, although FDA reviews summaries of the tests, the agency does not provide a formal pre-market safety approval of genetically modified foods. The FDA never states that it finds a new genetically modified product is safe. It is hard to account for the inability of the FDA and industry to see that allowing a company that produces a GM food to determine that it is safe—based on data collected by the company and opinions of experts that the company may have hired—creates the potential for serious problems.

The GRAS process assumes that a company with a large investment in a new product will never be unduly influenced by its self-interest in the product's development and success. It assumes that a company and its experts will never make a mistake in their assessments. A regulatory system that does not require the regulatory agency to take public responsibility for allowing a new and

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untried product on the market, and explaining its reasons why, assumes that a company that must meet its profit goal will never put its own interest above that of the public and excludes the possibility of human error, is a regulatory system that is likely to fail both the regulated industry and the public.

The FDA's decision, in its 1992 Policy Statement, to examine genetically modified foods on the basis of GRAS has been determined by at least one court to fall within FDA's regulatory discretion. The GRAS process has been around for a long time. It was devised in part to shorten the period of time needed to move new, but uncontroversial, food additives to market. The question is why FDA decided to apply this doctrine to move the products of a new and controversial technology to market.

Again, the record indicates that the Bush administration was eager to give American companies an advantage in getting a new technology on the market quickly. In addition, the FDA apparently was driven to pursue this policy of "nonregulation" in order to avoid asking Congress either to write new law needed to address the new technology appropriately or to provide the additional staff and resources required to perform more intensive safety reviews.

The decision was shortsighted and unwise. The policy has failed the test of public trust. Under the pressure of increasing public criticism, FDA asked for comments on the existing system. It received 35,000 responses, most unfavorable. The agency is now trying to buy a little more credibility by making small changes to its review process, but it adamantly refuses to make the changes necessary to assure the kind of scrutiny that builds public trust. Instead it has given those who oppose the technology a powerful weapon to use against the new products.

If the products of agricultural biotechnology are as benign as both industry and government insist, why not subject them to the most searching scrutiny?

Is it Possible to Regrind the Lens and Secure Consumer Acceptance of Biotechnology?

Scientists and public officials have advocated a regulatory system that inspires public trust. Perry Adkisson, chair of the National Academy of Sciences Committee on Genetically Modified Pest-Protected Plants, has stated, "Public acceptance of these foods ultimately depends on the credibility of the testing and regulatory process" (Bettleheim, 1999).

And in 1999, Secretary of Agriculture Dan Glickman urged, "With all that biotechnology has to offer, it is nothing if it's not accepted. That boils down to a matter of trust—trust in the science behind the process . . . trust in the regulatory process that ensures a thorough review. . . ."

Proponents of agricultural biotechnology have tended to dismiss critics as either ignorant, intellectually dishonest, or extremist. It is a serious mistake. In the end, the biotechnology industry and its supporters will succeed neither in insulting people into buying these products nor concealing their presence.

We would all benefit if we could find some way to improve the regulatory regime, increasing public confidence in the safety of genetically modified foods without imposing such expense and delay that the industry fails. There is at least one example where representatives of the stakeholder groups demonstrated that it is possible to reach some agreement on key issues related to agricultural biotechnology, as follows.

Cognizant of the increasing disagreement between the trans-Atlantic partners on this subject, President Prodi of the European Union and President Clinton appointed a Consultative Forum comprising twenty private individuals, ten from each side of the Atlantic, to meet and try to reach some consensus. It was an extremely diverse and impressive group—including a former Prime Minister of the Netherlands, Nobel Laureate Norman Borlaug, officials of DuPont and Unilever; a farmer from Portugal and one from Missouri, a consumer advocate from the United Kingdom and one from the United States, and three scientists actively engaged in agricultural biotechnology. It also included a scientist from Environmental Defense, a representative from European Friends of the Earth, and a bioethicist from Georgetown University. I was privileged to be part of the American delegation.

We reached agreement and produced a report. None of us loved every line. Each of us disliked some part of it. But we were able to agree on the following about agricultural biotechnology:

- It has promise that must not be squandered.
- It can be a major contributor to fighting hunger in the developing world.
- It presents the threat of unforeseen, unintended, negative consequences that must be addressed.

- Its successful use requires public trust and that trust will be generated by a rigorous, comprehensive and open regulatory process, including mandatory pre-market safety review of each product and a determination by the appropriate government agency that the product is safe.
- Final products containing novel genetic material should be labeled.

In December 2000 we presented our recommendations (US-EU, 2000), which—at the urging of industry and government agencies—have been ignored by Presidents Clinton and Bush. The EU has begun to respond to the recommendations, positively in most cases.

I disagree with Henry Miller that agricultural biotechnology is doomed. The recommendations of the US-EU Consultative Forum offer a way to have the technology and some assurance of safety. The report is evidence that a wide range of people would like to see agricultural bioechnology move forward and can agree on changes that would facilitate progress.

Without actions similar to those recommended by the US-EU Biotechnology Consultative Forum, it is unlikely that agricultural biotechnology will gain the public trust essential to the fulfillment of its promise.

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