

16 The Importance of a Rigorous Regulatory Regime in Developing Public Trust

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In the past few months, Americans have become increasingly aware of and concerned about genetically engineered (GE) foods. There are bills in Congress to require additional safety testing and labeling. Gerber has promised not to put GE soybeans in its baby food; Frito-Lay says no GE products will pollute its corn chips. Food retailers have pledged not to sell genetically engineered foods. Giant mock-ups of ears of GE corn march in picket lines, and charges of “Frankenfood” are heard across the land.

Most scientists are surprised by this concern. Scientists know this is the century of biology. They are confident that genetically engineered foods are safe. They are sure that this technology can help reduce pesticide use, improve nutritional quality of basic foodstuffs, and contribute to feeding a growing world population. The public is less sure, less confident, less certain—both about the benefits of agricultural biotechnology and the prescience of scientists.

Americans have generally been enthusiastic about science and technology. We loved the space race and we have embraced the new information technologies. We have welcomed the benefits of genetically engineered drugs. On the other hand, an increasingly well-educated population with access to virtually instantaneous information on every subject

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is less likely to defer automatically to everything postulated by a Ph.D. Also, there have been those occasions when scientists were shockingly wrong. Noted scientists assured us that DDT and nuclear power were safe and wonderful. In fact, advocates for those technologies used much the same language as today's advocates for agricultural biotechnology.

The sheer volume of new scientific discovery can sometimes be troubling to the public, especially when a new discovery contradicts another one announced just days before. Scientists do disagree. One expert with many degrees and honors appears on the *PBS NewsHour with Jim Leher* to praise a new drug. An equally qualified scientist who says the drug will prove disastrous follows her. Both scientists, it turns out, have been funded by pharmaceutical firms and, not surprisingly, each has taken a position that is consistent with the financial interests of the sponsoring company.

While the scientific and agricultural communities have been talking about genetically engineered food for 15 years, most of the products have entered the marketplace only recently. Consumers were surprised to learn that this year as much as half of the nation's corn, soybean, and cotton crops will be planted with genetically altered seeds. There are reasons that Americans are not entirely comfortable with this great leap into genetic modification of basic crops. We all understand that there are potential risks in this technology. One type of GE corn may actually kill monarch butterflies. It is possible that we will reap a crop of super weeds. There may be unanticipated allergic reactions to GE foods. It is certain that some farmers and some suppliers will not survive the transition to agricultural biotechnology. There are also religious and ethical issues raised by genetic manipulation.

That does not mean we should abandon agricultural biotechnology, but it does require information, dialogue, and ultimately, an appropriate regulatory regime sufficient to assure the public that the products are safe and will be used appropriately.

Why are American consumers so enthusiastic about technology in general but so reluctant to include GE food in their diet? First, Americans do not need agricultural biotechnology to ensure access to an adequate supply of nutritious food at reasonable prices. In the United States, food expenditures as a percentage of disposable income dropped from 14 percent in 1970 to under 11 percent in 1997. Hunger in this country arises from inadequate income, not short supply. Malnutrition is more and more likely to result from overconsumption. Thanks to increasing inter-

national trade, we eat from a global plate, with year-round access to a variety of fresh foods previously available only during our domestic season.

Second, food is special to us. We eat to sustain life and health. New studies on the relationship between diet and health seem to appear on a weekly basis. We are an aging population, obsessed with defying the physical and mental limitations of aging and hopeful that good nutrition will help.

Third, some data suggest that our squeamishness about GE foods is rooted in very basic instincts. Food is more than fuel for the body. It is sustenance for the soul. Food is inextricably linked to our social rituals, our family ties, and perhaps, our sense of self. Some have gone so far as to argue that food is a “cultural metaphor for life.” In 1996, the Agriculture Council of America commissioned an intensive study to explore our emotional attachments to food. The study found that food is integrally tied to nurturance, bonding, and love.

The study also revealed that food safety is an enormously important, but slightly concealed, concern. If a researcher asks people what’s bothering them, they’ll say crime and drugs. They probably will not name food safety among their three or four great concerns. But if asked specifically about food safety issues, the respondents react strongly and angrily. Participants in the study viewed unsafe food as a hostile invader of their homes and an assault on themselves and their families. Like many Americans, this group felt the strains of modern society in their families. According to the Agricultural Council study, their anxiety about food safety may reflect anxiety about the safety and security of the family more generally.

Given the important role of food in our lives, it is not surprising that the population tends to be extremely risk-averse and not always rational about food. We may eat too much or choose to gamble on a steak tartar, but most of us are unwilling to tolerate any food-safety risk that is imposed on us by someone else, that is invisible, and that lacks a countervailing direct and specific consumer benefit. Genetically engineered foods fail in all three categories. They were developed to meet the needs of farmers and chemical companies, not consumers. They are invisible in the retail product, and not labeled, so consumers do not have the option of choosing to avoid them. The GE products now on the market have no direct consumer benefit.

Proponents of agricultural biotechnology like to speak of the benefits it brings, but the existing benefits accrue to farmers and corpora-

tions while food-safety risks fall on those who eat the food. It may seem both obvious and harsh, but we purchase foods because they meet our needs, not those of biotech companies or farmers.

Proponents of GE foods speak of consumer benefits to be derived from GE foods, but there is no product on the market now that offers a direct benefit to consumers. The products that might be of value are in the early stages of development, so far back in the pipeline that they are still underground. In fact, none of the present crop of GE foods was designed to benefit consumers. Round-up Ready soybeans and cotton, Bt (*Bacillus thuringiensis*) corn, and bovine growth hormone were all developed to lower input costs. Lowering costs for producers has a value, but not to American consumers. No reduction in the cost of raising corn is likely to be reflected in lower meat costs. The farmer's share of each dollar spent for food at retail is a mere 22 cents.

I believe agricultural biotechnology has the potential to provide enormous benefits to society. The benefits will not be realized, however, unless the products of the technology can be demonstrated to be safe and the technology itself is managed so that the public reaps the benefits and avoids the risks to the greatest extent possible. Proponents of agricultural biotechnology argue that GE foods are safe, insisting they have been subjected to rigorous testing, are supported by sound science, and present no risk to the environment or to human health. They urge consumers to relax: "Don't worry." "Be happy." "Everything is going to be just fine."

The arguments have not persuaded the public, and for good cause. First, in science there are no final answers. Data are never complete; they are always evolving. The soul of the scientific process is challenge and revision based on new information. Three years ago sound science indicated the Food and Drug Administration (FDA) should approve the diet drug Phen-Fen. Last year new information, new sound science if you will, caused FDA to declare the drug extremely dangerous and to order the manufacturer to get it off the market immediately.

Second, the phrase "sound science" has taken on a mantra-like quality that robs it of all meaning in public debate. Would anyone act on "unsound" science?

Third, public policy on genetically engineered food products should be based on the most complete data and the most rigorous science. But in the end public policy is more than science. Policy represents a choice among competing interests and values. Policymakers must balance a

corporation's desire to bring new products to market and thereby enhance shareholder value and a farmer's interest in increasing yield against the public's concern that this new technology has not been sufficiently examined for long-term safety effects and holds no benefit for consumers.

The current U.S. policy governing the safety of genetically engineered foods will not support the level of public confidence necessary for the technology to succeed. It needs more than a little cleaning up here and there. It must be completely rethought and revised. The products of agricultural biotechnology have been robbed of the rigorous review that would make it possible for both government and industry to rebut attacks on their safety. A recent report from the National Academy of Sciences on genetically engineered pest-protected plants acknowledges the need for major changes in the system.¹ The chair of the committee, Dr. Perry Adkisson, stated, "Public acceptance of these foods ultimately depends on the credibility of the testing and the regulatory process, but given the level of public concern and following our review of the data, it is the committee's belief that agencies must bolster the mechanisms they use to protect human health and the environment."

I regret the committee did not encourage the government to examine the basic thesis of the system. That is, testing should be based on the properties of the plant as well as the process by which it was derived. Such an examination might reaffirm that decision, but it should be subjected to the kind of rigorous and transparent process that did not occur originally.

My organization has just begun a project that seeks to develop an optimum regulatory regime. I think it will have to include the following: First, the U.S. government, beginning with the President, must make a clear statement that human safety will be the primary component of decision making in approving GE foods. The statement should also say that the FDA, the Department of Agriculture, and the Environmental Protection Agency will have adequate structure and sufficient resources to carry out the mission to ensure the safety of GE foods. There must be no question that safety is ever compromised to meet trade or regulatory-reform goals.

Second, FDA should review and approve every GE product prior to marketing. The rigor of the review should be consistent with the risks involved in a particular process or product. For GE products made from gene transfers between closely related species, or if the donor organism

is a traditional food and does not cause allergies, a company would have to notify FDA and provide specified summary data. There could be a specified period (e.g., 60 to 90 days) during which FDA would review and could demand additional information. For GE products containing genes from an organism that causes allergic reactions, FDA would require thorough testing for allergenicity. GE products containing a gene for a common allergen would be prohibited. For GE products in which gene products were different from traditional foods or were present in significant quantity, food-additive petitions and more extensive safety testing, possibly including animal feeding studies, would be required. In some cases, post-approval monitoring will be appropriate.

Third, consumers must have and will have a role in this debate. The only question is whether consumer influence will be built into the process from the beginning or whether it will be manifested through lawsuits, street demonstrations, and ballot boxes. In my view, the best way to ensure a high level of consumer confidence would be the creation of a national advisory committee to review all elements of the process for approving genetically modified products and to examine the role of this technology in our society. A committee composed of all stakeholders would bring transparency to a process that has not been open.

Fourth, in addition to policy development, this field needs an independent scientific research establishment that can raise key regulatory questions and sponsor research into them. The Health Effects Institute, funded by government and industry but independent of both, has helped develop the data necessary for good regulatory decision making on clean air issues. This type of institution is sensitive to the needs of the regulatory agency but not captive to it or industry.

It would be a mistake to underestimate the barriers to full public acceptance of agricultural biotechnology. The public is protective of its food supply and skeptical, even cynical, with regard to the benefits of genetically engineered foods. They hold neither government, nor industry, nor the scientific community in particularly high regard. They surely do not value the work of consumer and environmental advocates as much as we would wish.

There is no quick fix. No advertising blitz will prevail in the long run. Nothing will protect the industry if there is a major unanticipated and negative outcome. Those who want to see the benefits of the technology realized for the long term will have to go back now and build, through a transparent and participatory process, the structure of regu-

latory rigor and public confidence that was not constructed originally. Many of us in the consumer and environmental movements are prepared to work with industry, government, and the scientific community in that effort.

Endnote

1. *Genetically Modified Pest-Protected Plants: Science and Regulation*. Committee on Genetically Modified Pest-Protected Plants, National Research Council, Washington, DC. 2000.