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BIOTECHNOLOGY: FOOD SECURITY AND SAFETY

Encouraging Creation of Living Inventions

Reshaping Global Agricultural Markets

From Green Revolution to Gene Revolution

October 1999

ECONOMIC PERSPECTIVES

Biotechnology: Food Security and Safety

U.S. DEPARTMENT OF STATE   ELECTRONIC JOURNAL   VOLUME 4, NUMBER 4, OCTOBER 1999

Who could have imagined that research on a little known bacterial plant pathogen, which causes a disease called "crown gall," would revolutionize the future of agriculture? Yet that is what happened. In the early 1980s, research on the plant pathogen Agrobacterium led to the first successful and dependable genetic engineering system for crops.

Since then the science underpinning genetic engineering has come a long way. Genes from any species now can be specifically tailored to function not only in plants, but also in certain plant tissues and at defined times. The genetic tools and databases emerging from the rapidly developing field of genomics are making this even easier. Plant breeders now have a vastly expanded reservoir of possible genes for disease and pest resistance, drought tolerance, improved nutritional properties, and other beneficial traits that can be used to improve the profitability of farms, improve consumer health, and protect the environment.

In short, the promise and potential of biotechnology is extraordinary. Yet as promising as agricultural biotechnology is, it has raised concerns on several fronts. For example, some critics contend the current state of knowledge is insufficient to be certain genetically engineered crops will not harm the environment or human health. Others believe wide-scale adoption of genetically engineered crops will shift control of genetic resources away from farmers to large multinational corporations, thereby threatening food security for poorer countries.

This issue of ***Economic Perspectives*** *explores many of the multifaceted policy questions associated with the worldwide debate on agricultural biotechnology. I hope this presentation will inform the reader and shed some light on a highly charged debate that often lacks a scientific foundation or an appreciation of what will be required of agriculture in the 21st century. You can be confident that the United States will continue to pursue agricultural biotechnology policies based on scientific analysis and a commitment to human health and safety.*

— Neal Lane, Assistant to the President for Science and Technology Policy

ECONOMIC PERSPECTIVES
An Electronic Journal of the U.S. Department of State

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ECONOMIC PERSPECTIVES

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❑ BIOTECHNOLOGY: FINDING A PRACTICAL APPROACH TO A PROMISING TECHNOLOGY

By Alan Larson, Acting Under Secretary of State for Economics, Business, and Agricultural Affairs, U.S. Department of State

A poorly informed and often emotional public debate over the nature of biotechnology risks disrupting global agricultural trade in biotechnology products. Thoughtful discussions are essential in defining the issues and in resolving the controversies, says Acting Under Secretary of State Alan Larson.

In this article, Larson discusses the issues and proposes several points to consider in seeking the best way forward in pursuit of a consensus.

Biotechnology is emerging as one of the most controversial issues in the global economy. A poorly informed and at times emotional public debate risks disrupting global agricultural trade, inflaming transatlantic relations, and stifling the development of a promising technology. It is important to have thoughtful discussions about this issue and for responsible voices to be heard.

Let's begin by defining terms. Biotechnology in agriculture is a collection of scientific techniques, including genetic engineering, that are used to improve or modify plants and microorganisms. The scientific foundations of biotech agriculture include not only basic plant biology but the knowledge gained in recent decades on the information contained in DNA and the particular functions of genetic material in nature.

Traditional crossbreeding has been practiced around the world for hundreds of years as a way to improve agriculture. When I was a youngster growing up in Iowa, any drive through the country inevitably would pass by fields of hybrid corn. There was never anything mysterious about it. Readers from rural areas anywhere in the world likely have had similar experiences. Modern biotechnology has dramatically improved on traditional crossbreeding by permitting a much more targeted approach to genetic modification. It offers solutions to longstanding problems, such as pest damage, that rely on more precise approaches. Biotech allows minute genetic changes that can make a plant unappealing to a specific pest, for example, and may render unnecessary broad spectrum pesticides that negatively affect both water and soil, and even damage the health of people who work on farms. Corn and soybean varieties produced with the help of modern biotechnology already are permitting reduced use of herbicides and pesticides, with important benefits to the environment.

Biotechnology has the potential to make agriculture much more productive. This is an immensely important consideration in a world where millions die of starvation, where population growth continues to place great stress on food production capacity, where there is a pressing need to avoid cultivation of environmentally fragile land, and where many families still rely on farming for their livelihood. Biotechnology agriculture is also therefore a useful tool in our efforts to fight hunger and poverty.

TRADE IN BIOTECHNOLOGY PRODUCTS

Scientists believe that biotech has the potential to increase crop yields by 20 percent or more with no greater use of natural resources, even on small farms. Developing country farmers and consumers should have access to the same agricultural choices and benefits that the rest of the world does.

This promising beginning has been marred already by Europe's refusal to permit imports of biotech corn varieties approved by competent European authorities. As a result, American corn producers are now losing some $200 million in legitimate exports annually.

An even larger concern is the risk of serious and broader disruption of about a half a trillion dollars in annual agricultural trade worldwide. These trade flows help ensure adequate food supplies at reasonable prices for people everywhere.

The current situation has already caused a worrisome strain in transatlantic trade relations and has the potential to affect trade relations worldwide. Additional measures by Europe would open the possibility of opening a far more serious transatlantic rift, at precisely the time when Europe and the United States need to be working together and with others to launch a new trade round. And the new round is essential to spurring global growth, which translates into new jobs at higher wages and resources to improve living standards for people everywhere.

ASSURING FOOD SAFETY

American farmers understand that some consumers in Europe and elsewhere have sincerely felt questions and concerns about biotech food. As governments and citizens address these issues, it is important to be guided by what science actually tells us about the safety of these products. I have had to look carefully myself at what the scientists have found. The overwhelming majority of scientific experts worldwide — both private and public — based on years of research, believe that biotech foods are safe for people to eat. In fact, all the evidence that we have — and it is considerable — indicates that biotech foods are as safe as conventional foods, even those foods that have been around for hundreds of years. If some consumers find them unappealing that is another matter, but not one that justifies government-mandated trade barriers or food safety-related restrictions.

Readers should be clear on one point. Food safety is a paramount, overriding concern for Americans. Americans eat food produced through the aid of biotechnology. In fact, they eat lots of it. If there were scientific evidence that biotech food posed a threat to human health, such food would not be on the market in the United States.

Consumer acceptance of biotech food in the United States is largely grounded in our experience with it and in the credibility of the U.S. food safety program. Biotech companies do extensive testing of all new crops before marketing them. They consult with the Food and Drug Administration (FDA) on any safety or regulatory questions. The FDA has been consulted on every biotech food that is now on the market.

Some of my European friends, while not debating the science, defend blocking imports of biotech food on cultural grounds, perhaps because they believe they have higher standards for purity and safety. Americans, they argue, somehow take less interest in the safety of the food they eat than do Europeans. As a diplomat who recently spent three wonderful years in France, I find this argument hard to swallow. To be sure, some Europeans still buy food daily, prepare it lovingly, and make meals a leisurely, social occasion in a manner. But these practices, however admirable, do not speak to the question of concern over food safety.

Americans, in fact, despite our penchant for so-called "fast foods," are rather fussy about the safety of the things we ingest. We have insisted on very strict rules on the use of food additives. We have created scientifically grounded, apolitical, and respected entities like the FDA to oversee food safety. American shoppers inspect labels of food products to avoid foods that contain cholesterol, sugar, and saturated fat, substances that have been scientifically shown to pose health risks for some people. And, of course, tobacco products contain strong warning labels in light of their demonstrated link to lung cancer and heart disease.

In Europe, I did not see greater, or even the same, level of concern about substances people ingest into their bodies. It is telling that Europeans still smoke much more than do Americans, despite what we know from science about the damaging effects to human health. There is also still no effective, Europe-wide food safety regulatory body.[1] Some national European food safety agencies, however, have an unfortunate record of being susceptible to political influence. Politicians in Europe sometimes have slowed the removal of contaminated food from supermarkets. And as many have pointed out, governmental credibility on food safety was eroded when some European political leaders dismissed the seriousness of "mad cow" disease. All things considered, I see no evidence that ordinary citizens from Europe or anywhere else are more concerned than the ordinary American about what they put into their bodies. The bottom line is that all of us have an interest in assuring a safe food supply in a manner that allows this new technology to achieve its potential.

A MORE PRODUCTIVE AGRICULTURAL SECTOR

It is important to understand that biotechnology has enormous potential benefits. Not least among these benefits is the potential to reduce the environmental impact of agriculture.

Some biotech crops can decrease the need for pesticides and herbicides to control pests, weeds, and plant diseases and allow more selective application of agricultural chemicals. For example, biotech potato, corn, and cotton plants have been engineered to produce a bacterial toxin (*Bacillus thuringiensis*, or Bt delta endotoxin) found in natural soils to ward off destructive insects on their own. And biotech herbicide-tolerant cotton, corn, and soybeans have given farmers a choice to make fewer applications of herbicides or to use more environmentally friendly herbicides.

Biotech has as well the potential to provide enhanced resistance to variations in temperature, soil salinity, and the availability of water. For example, plants can potentially be enhanced to withstand a drop in temperature and frost by modifying their production of linoleic acid.

Even the land's ability to support continued farming can potentially be supported through the use of herbicide-tolerant biotech crops that require less tillage to reduce plant pests. Cutting back on tillage lessens both soil and water runoff and soil nutrient depletion.

Scientists are also looking at ways to use biotech to deliver more nutrients and better taste in our foods. Damaging deficiencies in Vitamin A and other nutrients among the poor worldwide may well be addressed cost-effectively through biotech agriculture. In a non-agricultural application, scientists are also looking at how biotech might render mosquitoes unable to transmit malaria. Millions of lives could be saved and the use of highly toxic chemicals against mosquitoes reduced or done away with. Another potential benefit of biotech is increased income for farmers, both small and large. For example, biotechnology has improved the quality of seed grains and the ability to produce bigger harvests from currently cultivated land. Equally important, increased yields and reduced chemical and labor costs can represent increased income for the farmer. Finally, farmers can save in the cost of bringing their product to market with biotech crops that require less handling, are easier to store, need no refrigeration, and have a longer shelf-life.

PROMOTING A GLOBAL DIALOGUE

Views on biotech around the world are still being formed and influenced. There are important questions to address and differing viewpoints to examine. What is the best way forward in pursuit of a consensus? I would suggest the following points:

1. Cool the Rhetoric. It can be difficult to have a rational public debate on a question that is both scientific and emotionally charged. It is troubling to see slogans such as "Frankenstein food" substituting for intelligent discussion. It makes no sense to consider new scientific developments as "Frankenstein" and existing science as "natural." In a free society, those who engage in irresponsible sloganeering will find their speech securely protected but rarely respected.

2. Don't Take Precipitous Actions. People and governments everywhere are struggling to ensure that rapid technological changes in an increasingly integrated world bring widely shared benefits. With biotech, as with other important breakthroughs, this needs to be done on the basis of sound information and science. It requires an objective effort to safeguard against real risks while making benefits and choices available to everyday people. On complex issues, a rush to judgment seldom allows for such a process. As Romano Prodi, the new president of the European Commission, said recently, "we want to avoid knee-jerk reactions" on food safety issues and "not rush in foolishly."

3. Restore Predictability. The world's farmers are the backbone of our food supply. They and all those people and companies involved with agriculture and food deserve to know the rules under which they must operate, and to have the criteria and application of those rules be predictable and transparent. Agricultural planning decisions and investments are made long in advance of when products hit the market. Governments have the primary responsibility to bring predictability to food safety regulations and to create consumer confidence through apolitical, technical implementation processes that are themselves predictable.

4. Use Established Multilateral Discussion Fora. We already have the institutions and mechanisms for international discussions of biotechnology. Chief among them is the Codex Alimentarius, an organization jointly sponsored by the U.N. Food and Agriculture Organization (FAO) and the World Health Organization (WHO). The Codex, comprised of independent scientists from around the world, is not a very flashy or politically powerful organization. Nonetheless, it has for many years kept the international community well informed of the scientific basis for food safety considerations and the implications in the international arena.

Codex's strength lies in its broad membership, its extensive, international technical capacity, and the fact that it deals at arms-length from the policy process of regions and countries. It would be impossible to duplicate what we have already created in the Codex, in protection for our consumers and support for an open, international economy based on fair rules of the game.

5. Stress Science-based Approaches. We must be acutely aware of protecting the scientific basis for decisions that can block trade, stifle innovation, feed isolationism and fear, and deny our citizens the right to choose new products out of nostalgia or our own discomfort. Sound science, continually applied, remains the best foundation for food-safety decisions and practices.

6. Address Public Questions. The public's curiosity and fears are being aroused by misleading and partial stories about biotech foods and about the science behind them. It is important to respond to those concerns and to facilitate an open exchange of information, particularly well-grounded information. In a cynical age, it is hard to combat lightening-quick "one-liners" and Internet tales, but there is still a difference between information and spin. Science is by no means perfect, but the information on the safety of biotech foods we have gotten from careful, scientific analysis, properly reviewed and established over time, should be shared with everyday consumers. Even if it is unpopular, we should be straight with consumers that extensive analysis has turned up no special health risks from biotech foods. As one scientist put it, there are substantial known risks to a high-fat diet and a lack of exercise, but you do not see that making the headlines on a regular basis like biotech does.

7. Preserve WTO Rules. The reason all 134 members of the World Trade Organization (WTO) have agreed to abide by its rules is extremely simple. We all know that we are better off with clear rules rather than chaos, and that the rules help prevent every one of us from seeking unfair advantage in the global trading system. The rules-based trading system may not be perfect and may even occasionally transgress our sense of independence or uniqueness, but they also bind us as a community and enable the incredible choices and benefits of trade we have come to enjoy. There is nothing about biotech food that would make it necessary or worthwhile to abrogate WTO rules. I cannot stress enough how important it is to protect this institution and to strengthen it without damaging its fundamental purpose, which is to facilitate fair trade among all countries.

I hope this is a useful addition to the discussion on biotech agriculture. We have also established a Web site at *www.usia.gov/topical/global/biotech* where you can learn more about biotech agriculture and find links to many other sites. I urge all of you to explore them and to make up your own minds about this promising technology. There are also contact numbers for people within the U.S. government who can help answer your questions. I can assure you that the United States Government will continue to safeguard the safety of its consumers, even as we work with others to shed real light on this issue. ❑

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1. There are some indications of interest by the European Commission leaders in establishing one, and the FDA is cited as a potential model. We certainly applaud efforts to establish apolitical, science-based food safety agencies to protect consumers.

❑ BIOTECHNOLOGY: RESHAPING GLOBAL AGRICULTURAL MARKETS

An Interview With Timothy J. Galvin, Administrator of the Foreign Agricultural Service, U.S. Department of Agriculture

Advances in the use of agricultural biotechnology in food production have become sweeping economic and trade policy issues in the last half of this decade, forcing governments to rethink how to manage trade and at the same time ensure food safety. The United States is not alone in developing new genetically modified organism (GMO) products or in offering them for commercial production. There have been GMO varieties planted in a number of countries — the United States, Argentina, Canada, Australia, Spain, France, and others. Some European Union companies have also developed a substantial presence.

In this interview, FAS Administrator Timothy Galvin discusses some of the central issues confronting the United States and many of its trading partners worldwide. This interview was conducted by Economic Perspectives *editors Jonathan Schaffer and Merle D. Kellerhals, Jr.*

QUESTION: Food production enhanced through the application of agricultural biotechnology has been touted as producing greater yields. Beyond that, how do consumers directly benefit from biotech products?

GALVIN: With this first generation of biotech products on the market, the public benefits from the potential for reduced pesticide use. And, of course, if there is reduced pesticide use then there is probably less pesticide in the final commodity and there is also less potential for the pesticide chemicals leeching into groundwater. So I think consumers benefit from the fact that there is a cleaner environment. However, a number of people are looking forward to the so-called second generation of biotech products because those products are likely to have end-use characteristics that directly benefit consumers, such as agricultural commodities that have a higher vitamin content, or iron content, or perhaps reduced fat levels.

Some of the most exciting agricultural research currently is happening in the area of rice. There has been a lot of discussion this summer about progress with biotech rice varieties. Those varieties have higher iron and vitamin content. And it is thought that they could be grown easily and at a relatively low cost by even the smallest subsistence farmers.

Q: There has been some criticism that the U.S. regulatory process established specifically for biotechnology products is not adequate to provide for the protection of human health and the environment. How do you respond to the safety issue?

GALVIN: Three different regulatory agencies in the United States typically are involved in approving these products — the U.S. Department of Agriculture (USDA), the Food and Drug Administration (FDA), if it's a food or animal feed product, and the Environmental Protection Agency (EPA). And each one of these agencies examines these products to ensure that they are safe for release in the general environment, as well as safe for consumption by humans or by animals. The process that these regulatory agencies follow is essentially the same as that followed in the case of human or animal drugs that are approved or pesticides that are approved for use on crops.

Q: Consumer advocates, however, have raised concerns that some of these biotech products have not been adequately tested to evaluate such issues as allergenicity, environmental risks, and the accidental crossover to non-genetically modified plants, and do not address cultural considerations. What is being done to assure that regulatory authorities address these issues?

GALVIN: All new varieties — before they are approved — first have to undergo testing. And that testing involves actual planting in test plots. Then the test plots that are harvested are analyzed, and are tested to make sure they are safe for consumption. The products are certainly tested with respect to safety for humans or animals. They are tested for allergenicity as well. There is a question as to what their long-term impact might be, especially on the environment. That issue was addressed in part by U.S. Agriculture Secretary Dan Glickman this past summer when he announced that USDA would continue ongoing tests on long-term environmental impacts. With respect to the final point about cultural considerations, I concede that such considerations do not enter into the regulatory approval process here in the United States. In our view, it's basically up to consumers whether or not they want to purchase individual products.

Q: You just mentioned that we are going ahead with long-term analysis. Critics argue that we should not be moving ahead as quickly as we are until we have some of these long-term results. What is your response?

GALVIN: Basically, the regulatory agencies involved believe that there is a sufficient body of scientific evidence in hand that demonstrates that these products are safe; otherwise, the products would not have been approved in the first place. As with any new technology, you never really know the long-term impact until you have had long-term experience with the product, the sort of experience that, unfortunately, you can only gain with additional time.

Q: Some environmental groups and elements in the media have used Cornell University preliminary research on the monarch butterfly and Bt corn to condemn the use of genetically engineered plants in agriculture. What are the implications of this research?

GALVIN: A number of scientists have commented on that study. They have pointed out that the Cornell research was a laboratory test; it is not at all certain that the findings from that test could be replicated in the actual environment under which this particular variety is used. Indeed, even the Cornell scientists who were involved in that study have said essentially the same thing, that it is not clear really how relevant the results are in terms of real-life experience.

Q: Some countries have begun arguing for the mandatory labeling of genetically engineered food imports. What is the current U.S. position on labeling?

GALVIN: Our position is that voluntary labeling is appropriate. With respect to mandatory labeling, some of the countries that currently support it are also struggling with the operational details of just how to implement it. The best example, of course, is the European Union (EU), where they announced their mandatory labeling policy one year ago but, even to this day, are struggling with such implementing details as where to set a tolerance level. That tolerance level would allow a certain amount of GMO (genetically modified organism) product to be included in a variety that was otherwise considered non-GMO. Apparently they are thinking of setting that tolerance level at about 1 percent. A related question is what testing procedures are going to be sanctioned in determining the presence of genetically modified varieties, and the EU has still not decided that issue. A third major question is who is actually going to do the testing? Will it be government authorities, or will the private sector be allowed to do the testing and self-certify? Those are all questions that the EU continues to struggle with, and, as I have said, they have been wrestling with the issue for more than a year now.

Q: What would be the implications for U.S. exports of a GMO tolerance level at 1 percent?

GALVIN: The implications would be significant. And not just for U.S. exports, but for exports of GM products by a whole host of countries that currently produce them, including Argentina, Canada, Australia, and even countries in the EU, where this past year, for example, more than 20,000 hectares (49,400 acres) were planted to certain GM corn varieties. So, I think it is going to be a major issue for a number of countries. Frankly, I think the EU is going to find that the 1 percent tolerance level is a very, very difficult level to meet and presents the potential for substantial trade disruptions as a result.

Q: How do you balance the need for intellectual property protection, such as patents, in the development of biotechnological products, such as wheat germplasm, with the rights of farmers in the developing world to take advantage of this new technology?

GALVIN: I think you balance it by making sure that there continues to be a substantial government role in research and also in germplasm preservation. Related to that, there is an ongoing need for the role that certain international agencies play in obtaining this germplasm and providing it to countries that could not develop it on their own. To me, whether one is talking about the latest varieties of conventionally produced seed or the latest varieties of the products of genetic modification, we are faced with the question of who is going to have access to the latest seeds. And I think it really requires a continuing government role or a continuing role on the part of international organizations like the United Nations to make sure that at least a portion of this research is done in the public sector and that at least some of the germplasm remains in the hands of government authorities so that it can be provided to these countries.

Q: If you have a biotech product that has been patented by a private company, how can these rights be transferred to an international institution?

GALVIN: In the case of a specific variety that has been patented by the private sector, you would not be able to transfer it unless that company was to provide some sort of license under its patent. That's why it important that governments continue to stay involved in the basic research and development of other varieties that also offer potential benefits to farmers.

Q: How much farmland is currently planted to genetically engineered varieties worldwide?

GALVIN: The best information we have for worldwide plantings is for 1998, and for that year the figure is about 29 million hectares (71.63 million acres) in total. Most of that would be in the United States. We are also assuming that biotech acreage increased in 1999. We know for a fact that occurred in the United States. Indeed for this year, we are currently projecting that one-third of our corn (maize) acreage, half of our soybean acreage, and about 60 percent of our cotton acreage is planted to biotech varieties.

Q: Is the United States the only industrial country that has developed genetically engineered products? If not, then who are the other key players in the global marketplace and which GMO products have they developed?

GALVIN: The United States is not alone in developing new GMO products or in offering them for commercial production. In fact, it's quite the opposite. As I mentioned earlier, we've seen GM varieties planted in a number of countries — the United States, Argentina, Canada, Australia, Spain, and France, just to name a few. In addition, even in the United States it's not just U.S. companies that are involved in the field. In fact, there is a substantial presence of EU companies. For example, AgrEvo, a German company, and Novartis, a Swiss company, both have very active biotechnology programs here under which they've offered commercial varieties such as different genetically modified corn and soybean varieties. And even though the EU regulatory approval system for biotech crops right now has ground to a virtual halt, fully one half of the applications for biotech crops currently pending in the EU approval pipeline are applications sponsored by European companies.

Q: Are these European companies being stymied in what they can do, or is there any competitive advantage being given to them relative to U.S. companies in Europe?

GALVIN: I don't think there is any competitive advantage being given to them. In fact, I think part of the reason we've seen some research efforts moving to the United States is because the regulatory climate in Europe frankly is so hostile toward the technology. I think that is causing some concern among these European companies as well as among European farmers, who worry that they may lose a technological edge. And I think it's also of some concern to policy-makers generally in Europe because, as you know, Europe is struggling with unemployment rates that are typically far higher than in the United States, sometimes two to three times higher.

Q: Is it feasible to segregate genetically engineered products for export from "GMO-free" products, as some trading partners have suggested?

GALVIN: It's very, very difficult if one insists on 100 percent certainty with segregation. Yes, an attempt can be made to segregate crops just as we currently try to segregate organically grown crops from conventional crops. But as we've seen in the case of organically produced crops, those crops typically command a premium in the marketplace. And, in fact, farmers generally command a premium for growing those crops because of the additional cost of producing them, as well as the additional cost of sorting, segregating, and handling those commodities through the marketplace. Certainly, if you look at how our major crops — corn, soybeans, and the like — are produced and the way they are harvested and marketed, there is always potential for at least the inadvertent mingling of conventional and biotech varieties. And that is why those who are insisting on very low tolerance levels to guard against co-mingling are going to find from a practical standpoint that that is nearly impossible.

Q: How does the U.S. government determine that biotech agricultural products banned by other countries are not reaching export channels?

GALVIN: The government does not play a formal role in that area. What we have done is to work with the companies involved to encourage them to put in place a system for channeling the varieties that have not been approved for export into domestic consumption, especially into domestic livestock consumption, so that we can be somewhat more assured that the products are not finding their way into processed commodities here in the United States.

Indeed, those companies that currently offer for sale certain varieties not yet approved in Europe have put in place a rather extensive channeling system that begins when farmers purchase the seed before planting. A farmer is asked to sign a statement acknowledging that the variety in question has not yet received all the necessary international approvals; in the course of the growing season, the farmer is sent letters reminding him that necessary approvals have not yet been granted and providing him with additional information on where he can market those unapproved varieties. For example, the companies might provide a list of local livestock feeding operations or local grain elevators that might be able to sell the product to livestock facilities in the United States.

Q: How will biotechnology issues be addressed in the upcoming World Trade Organization (WTO) ministerial in Seattle?

GALVIN: It is not at all clear yet just how they are going to be addressed, or even if they are going to be addressed. There are a number of proposals on the biotech issue. From the standpoint of the United States, we submitted a proposal in Geneva a few weeks ago that focuses very simply and directly on the issue of the regulatory approval processes that may be put in place in each country. We certainly don't question the right of any country to have its own review and approval process in place. But what we have said is that whatever process a country has, it should be transparent, predictable, timely, and science based. Those are four principles that are reflected in the current U.S. regulatory system, and we believe that other countries would do well to accept them as a part of their regulatory systems as well.

Q: What is the U.S. view about creating a WTO study group on biotechnology?

GALVIN: We have not yet said that we support a study group approach. That is an approach that Canada has suggested. We have said that we would prefer to go directly into negotiations on the issue, but only along the lines of the targeted concept that I just outlined — one that is rather narrowly focused on the issue of regulatory approvals and how those approvals should be conducted. It's conceivable that other countries may suggest that biotech be addressed in a much more wide-ranging way, a way that perhaps also addresses labeling and other related issues. The United States has not endorsed that broader approach.

Q: There has been a lot of misperception about the terminator gene that prevents the germination of seeds and whether the United States has contributed to the development of the seed. Can you comment?

Galvin: As you know, about 10 days ago Monsanto announced that they have no plans to ever commercialize the technology, and I don't know of any other entity that currently plans to use it. ❑

❑ REGULATING THE PRODUCTS OF BIOTECHNOLOGY

By Sally L. McCammon, Science Advisor to the Animal and Plant Health Inspection Service, U.S. Department of Agriculture

"Advances in biotechnology — being able to determine what has actually happened at the molecular and biochemical levels — have increased the ability of regulators to scrutinize product safety and the effect of product modification upon safety," says Sally McCammon. In this article, she discusses the science-based approach to evaluating products derived from biotechnology, especially agricultural biotechnology, and the role U.S. government agencies play in the detailed and often complex process.

If genetically engineered organisms are to gain greater acceptance, decisions that address concerns associated with the application of biotechnology to agriculture must be science based. Science also must be the base by which regulatory officials can assure and build upon credibility, remain current, and assure a rational basis for decision-making. In this way, science and the legal processes are inextricably linked for regulations that evaluate biological products. This article outlines how U.S. regulatory authorities examine biotechnology products and coordinate their evaluation procedures to assure the highest degree of safety.

A SCIENCE-BASED REGULATORY APPROACH

To say that an assessment is science-based means that the review of any particular product is done using scientific criteria relevant to that product. Advances in biotechnology — being able to determine what has actually happened at the molecular and biochemical levels — have increased the ability of regulators to scrutinize product safety and the effect of product modification upon safety. The scrutiny of certain products and the rigor by which evaluations are performed have also increased due to biotechnology. The approach to review is constantly evolving due to new types of products and the availability of new scientific information.

The current regulatory approach in the United States is based on a determination in 1987 by the U.S. National Academy of Sciences (NAS) that "the risks associated with the introduction of rDNA-engineered organisms are the same in kind as those associated with the introduction into the environment of unmodified organisms and organisms modified by other genetic techniques." In 1989, NAS articulated the Concept of Familiarity, saying "familiar does not necessarily mean safe. Rather, to be familiar with the elements of an introduction [into the environment] means to have enough information to be able to judge the introduction's safety or risk." The familiarity criterion is central to a framework for evaluation of genetically modified plants and microorganisms. For plants, familiarity comes from comparison with the parent line or crop species with similar traits, as well as from actual field tests. With genetically modified plants, the standard of comparison is the unmodified plant.

Approaches to review were developed in the United States by the NAS and, among industrialized countries, by the Organization for Economic Cooperation and Development (OECD). In 1993, the OECD published principles for reviewing large-scale plantings of transgenic crop plants. That organization identified and discussed the general safety issues associated with new plant lines and crop cultivars, as well as risk management. These safety issues, including gene transfer, weediness, and effects on non-target organisms, are now generally accepted globally as the basis for evaluating transgenic plants. The OECD elaborated on the Concept of Familiarity, identifying familiarity with the crop plant, the trait, the environment, and the interaction of these three factors as being critical in the evaluation of transgenic plants.

THE U.S. DECISION-MAKING PROCESS

Since the White House Office of Science and Technology Policy published the "Coordinated Framework for the Regulation of Products of Biotechnology" in 1986, the United States has gained 13 years' experience in evaluating the products of biotechnology for safety. The Coordinated Framework established a strong federal commitment to the safe development of the products of biotechnology from the laboratory, through field-testing and development, and into the marketplace. The underlying assumption of the Coordinated Framework is that any risks from the products of biotechnology are the same in kind as those of similar products — risks to agriculture, the environment, and human health. Thus, the existing statutes for addressing these risks have been deemed adequate to address any risks posed by product development using biotechnology, and no new "gene law" has been considered necessary.

Regulations, developed to implement statutes, establish procedures and criteria by which specific types of products are evaluated, including those produced using biotechnology such as vaccines, plant varieties, pesticides, animal products, and pharmaceuticals. In the United States, the agencies that examine plants and plant products are the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA) of the Department of Health and Human Services, and the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture.

Under the U.S. regulatory system, a new genetically engineered plant could be reviewed by one or all three regulatory agencies, depending on the plant and the trait engineered into it. For instance, a Bt gene in a food crop would be reviewed by APHIS, EPA, and FDA; a plant with modified oil content for food would be reviewed by FDA and APHIS; modified flower color in a horticultural crop would be reviewed by APHIS alone. It usually takes at least five years of field testing, under APHIS oversight, for the developer of a new plant variety to evaluate the new line and to collect the data needed to pass through the regulatory system. Another two years may be needed for APHIS, EPA, and/or FDA (depending on the plant variety) to complete their reviews. The U.S. regulatory structure is based upon risk rather than process to assure safety, and its success is due to the fact that regulatory agencies with established credibility and expertise have been designated to evaluate the products of biotechnology.

THE REGULATORS' ROLES

APHIS regulates the development and field testing of genetically engineered plants, microorganisms, and certain other organisms under the authority of the Federal Plant Pest Act and the Plant Quarantine Act. APHIS regulations provide procedures for obtaining a permit or for providing notification of the intent to field test, prior to importation, interstate movement, or release into the United States. Authority is based on the use of plant pests to engineer plants so as to supply the genes inserted, to allow those genes to be expressed in plants, or to transfer the genes into plants. The APHIS review process evaluates agricultural and environmental safety issues.

APHIS has been reviewing applications for permits and notifications by industry, academia, and nonprofit organizations of field tests of transgenic crop plants since 1986, when it proposed the first regulation for these products. After several years of field tests, an applicant can petition the agency to be released from requirements under the APHIS regulatory process. If the applicant can provide evidence that there is no plant pest potential (including the lack of change in disease and pest resistance, as well as the absence of the potential of new genetic material to create a new pathogen or pest), along with answers to a variety of other environmental questions, APHIS will grant the petition. At that time, the applicant is free to commercialize the plant line or use it in other breeding programs without coming to APHIS for permission, subject to obtaining any necessary approvals from EPA or FDA. To date, 51 petitions have been granted and more than 5,000 permits and notifications have been issued for field testing at more than 22,000 sites. Although no petitions have been denied, 13 have been withdrawn due to insufficient information or other inadequacies in the application.

APHIS maintains comprehensive field testing and petition databases. These databases are used not only by domestic customers and stakeholders, but increasingly by foreign governments to verify that the U.S. government has reviewed the risk for products being considered for field testing or importation. These databases, as well as access to federal home pages on biotechnology regulation, are available at www.aphis.usda.gov.

EPA's responsibility is to ensure the safety of pesticides, both chemical and biological, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) through regulation of the distribution, sale, use, and testing of plants and microbes producing pesticidal substances. Under the Federal Food, Drug and Cosmetic Act (FFDCA), EPA sets tolerance limits for substances used as pesticides on and in food and feed, or establishes an exemption from the requirement of a tolerance if such a tolerance is not necessary to protect the public health (determined after evaluation by the agency).

EPA issues experimental use permits for field testing of "pesticidal" plants and registrations for commercialization of these plants. The *Bacillus thuringiensis* (Bt) toxin, which occurs naturally in soil bacterium, is considered a biological pesticide. For plants containing Bt toxin, the manufacturer must prepare a resistance management plan as a condition for registration with EPA. The plan describes how the manufacturer registering the plant product will assure that resistance does not build up in affected insect populations and reduce the effectiveness of Bt applied topically or used through the plant's genetics. EPA also evaluates the new use of herbicides on herbicide-tolerant transgenic plants.

FDA assesses food (including animal feed) safety and nutritional aspects from new plant varieties as part of a consultation procedure published in the 1992 Statement of Policy: Foods Derived From New Plant Varieties. Consistent with its 1992 policy, FDA expects developers of new plant varieties to consult with the agency on safety and regulatory questions under the authority of the FFDCA. FDA policy is based on existing food law and requires that genetically engineered foods meet the same rigorous safety standards as is required of all other foods. The FDA biotechnology policy treats substances intentionally added to food through genetic engineering as food additives if they are significantly different in structure, function, or amount from substances currently found in food. Many of the food crops currently being developed using biotechnology do not contain substances that are significantly different from those already in the diet and thus do not require pre-market approval.

Science informs the decision-making process of the regulators at a variety of levels. The available published scientific literature, particularly from peer-reviewed journals, is used by regulators in evaluating specific products. Applicants cite this literature in their applications for regulatory approval. As in the case of the NAS, the scientific enterprise can be asked to identify the scientific issues and recommend approaches to particular types of products. Meetings of scientists can be called to address specific issues, as have past meetings on Bt, viral recombination, and relevant biological factors for evaluating crop plants. Information can even be requested on specific products. The EPA meets with its scientific advisory panels. The FDA refers questions to its Food Advisory Committee. Recently, U.S. Agriculture Secretary Dan Glickman requested that the NAS review the scientific underpinnings of the regulatory decisions made by USDA. The USDA also has a Risk Assessment Grants Program that specifically funds research on emerging issues with genetically engineered organisms. All of this information is used by regulators to assure that the most current information and thinking is available to inform regulatory decisions.

BEYOND THE UNITED STATES

Internationally, the appropriate scientifically based standards, guidelines, and recommendations for transgenic products and other products as they move into the international marketplace, are being developed by the representatives of national governments at working groups and task forces devoted to these issues under the standard-setting bodies — Codex Alimentarius, the International Plant Protection Convention, and Office des International Epizooties. The use of the existing standard-setting bodies to address concerns about products of biotechnology focuses attention on harmonization of risk-assessment methodologies and evaluation of specific products or classes of products. ❑

❑ FROM GREEN REVOLUTION TO GENE REVOLUTION

By Ismail Serageldin, Chairman of the Consultative Group on International Agricultural Research and Vice President of Special Programs, The World Bank

Some 40,000 people die every day worldwide from hunger-related causes, says Ismail Serageldin. The demands for food to meet the expanding global population are growing faster than the ability of food producers to meet those demands. Increases in food production will have to come from increasing biological yields, and not from area expansion and more irrigation. Agricultural transformation, says Serageldin, "will be essential to meet the global challenges of reducing poverty, feeding the world's burgeoning population, and protecting the environment."

The world's population is expected to exceed 8 billion by 2025 — an increase of 2.5 billion over the current level. Much, but not all, of the increase will occur in developing countries, and there will be many more mouths to feed in complex circumstances.

Nobel laureate Norman Borlaug, father of the Green Revolution, calculates that "to meet projected food demands, by 2025 the average yield of all cereals must be 80 percent higher than the average yield in 1990." These increases must come primarily from increasing biological yields, not from area expansion and more irrigation; over-consumption and waste in rich countries and population pressure in poor countries have already placed dangerous burdens on the ecosystems on which we all depend.

Meanwhile, poverty and hunger persist in our world of plenty despite the enormous burst of output and productivity, the dazzling changes shaped by science and technology, and the amazing achievements recorded on the social indicators for so many of the people on the planet. Food production capacity is widespread and substantial, yet millions are too poor to provide for their essential needs. Some 40,000 people die from hunger-related causes every day.

MEETING THE GLOBAL AGRICULTURAL CHALLENGE

Agriculture is central to our management of these problems in the new millennium. Agricultural growth is essential to economic growth in most developing countries. Very few low-income countries have achieved rapid nonagricultural growth without corresponding rapid agricultural growth. Conversely, most of the developing countries that grew rapidly during the 1980s experienced rapid agricultural growth in the preceding years. Agriculture, moreover, is the primary interface between people and the environment.

So agricultural transformation will be essential to meet the global challenges of reducing poverty, feeding the world's burgeoning population, and protecting the environment. This transformation will have to occur at the level of small-holder farmers so that their complex farming systems can be made more productive and efficient in the use of resources.

The challenge is both technological (requiring the development of new high-productivity, environmentally sustainable production systems) and political (requiring policies that do not discriminate against rural areas in general and against agriculture in particular), and it will have to be accomplished at a time when attention to agricultural development and rural well-being is diminishing. An essential aspect of the response to this challenge is to harness all instruments of sustainable agricultural growth.

THE ROLE OF CGIAR

A major responsibility falls on the Consultative Group on International Agricultural Research (CGIAR), the only organization in the world that exists solely to mobilize the best in agricultural science on behalf of the world's poor and hungry. The CGIAR, created in 1971, is an informal association of 58 public and private sector members supporting 16 international agricultural research centers.

The United States was a founding member of the CGIAR and plays an important role in formulating its policies.

The international centers develop advanced breeding material for adoption and use by national agricultural research systems (NARS) in developing countries. The CGIAR works with a range of partners in the public and private sectors. Its research products are international public goods unconditionally available to poor farmers, national programs, and other users.

The CGIAR is ideally positioned to address the next compelling challenge that agricultural scientists must confront: combining conventional research with the promise of the genetic revolution. Just as the Green Revolution has fed millions and served as the basis of economic transformation, we have to ensure that the gene revolution leads to a "doubly green revolution" in which increased productivity and natural resource management are in balance. The poor will thereby be enabled to begin their ascent from poverty.

THE PROMISE OF BIOTECHNOLOGY

The revolution in the biological sciences — molecular genetics, informatics, and genomics research — has opened up all sorts of possibilities. The promise of biotechnology as an instrument of development lies in its capacity to improve the quantity and quality of plants and animals quickly and effectively. The time required to identify and combine favorable traits through traditional crop breeding is greatly reduced. Increased precision in plant breeding translates into improved predictability of the resulting products in performance and survival.

The application of biotechnology can create plants that are more drought resistant, more salt tolerant, more resistant to pests — without pesticides. Plant characteristics can be genetically altered for earlier maturity, increased transportability, reduced post-harvest losses, and improved nutritional quality. Vaccines against diseases afflicting livestock are already important products of biotechnological research.

In the past few years, there have been continuing increases in the area planted to transgenic crops. In 1998 the global area of transgenic crops more than doubled over that of 1997, with the United States leading the field with 20.5 million hectares (one hectare is equal to 2.47 acres), 74 percent of the global area. The five principal crops grown are soybeans, maize (corn), cotton, canola/rapeseed, and potatoes. In terms of transgenic trait, the largest area was occupied by herbicide-tolerant crop varieties (71 percent), followed by insect-resistant varieties (28 percent).

Most of the early products of agricultural biotechnology focus on crop protection. In 1998, transgenic crops that are herbicide tolerant covered about 19.8 million hectares. Use of herbicide-tolerant varieties greatly facilitates weed control using certain types of herbicide. It also enables farmers to employ soil conservation practices such as minimum tillage, which reduces soil erosion.

As for increased plant resistance to pests, in 1998 an estimated 7.7 million hectares were planted to transgenic crops with introduced genes that produce substances toxic to target insect pests. This has resulted in the reduced use of insecticides, a positive impact not only on farm income but also on the environment.

Research is under way, as well, to improve the nutritional quality or value of some food crops in developing countries. For instance, Swiss scientists have developed genetically modified rice that has higher levels of Vitamin A and iron. With some 2.4 billion people consuming rice as their staple cereal, this "new" rice can potentially prevent cases of blindness and anemia, particularly among millions of children in developing countries.

ISSUES AND CONCERNS

The revolution in the biological sciences has both promise and problems. We are confronted by profound ethical and safety issues, complicated by the issues of proprietary science. Some of the concerns come from scientists who wonder if the results of these scientific efforts could produce "super weeds" or "super viruses." Many protests have been made by civil society institutions on ethical or ecological grounds. The dominance of the private sector in the North, where the bulk of developments in agro-biotechnology have so far taken place, raises fears that this will create a new phase of comparative disadvantage and increased dependency in the South.

Very much at issue are patenting and intellectual property rights (IPR). Supporters of patenting point out that if the private sector is to mobilize and invest large sums of money in research and development in agro-biotechnology, it has a powerful claim to protecting and recouping what it has put into the exercise. On the other side of the argument is the fear that patenting and the exercise of IPR will lead to a monopolization of knowledge, restricted access to germplasm, controls over the research process, selectivity in the focus of research, the development of science and technology apartheid, and, thereby, the increased marginalization of the majority of the world's population.

These concerns cannot and must not be ignored. In October, the CGIAR and the U.S. National Academy of Sciences held an international conference ("Ensuring Food Security, Protecting the Environment, and Reducing Poverty: Can Biotechnology Help?") to examine the full range of issues connected with the development and use of agro-biotechnology, and in particular to discuss safeguards against its perceived hazards. The conference, held at the World Bank in Washington, brought together scientists, governments, the civil society, and professional communicators for an open discussion of the issues. (For further information, see the CGIAR Web site available at http://www.cgiar.org).

The critical issue is that every instrument of agricultural transformation should be mobilized in our efforts to feed the hungry, help the poor, and protect the environment. We cannot accept the notion that deprivation is imprinted on the genes of the poor and destitute, with misery their inevitable destiny. The ethical dimension of depriving them of the advantages that biotechnology with adequate safeguards can bring must be weighed against other ethical concerns. Both sets of issues need to be confronted boldly. We must find ways of realizing the promise of biotechnology while avoiding the pitfalls. ❑

Note: The opinions expressed in this article do not necessarily reflect the views or policies of the U.S. government.

❑ WHY U.S. FARMERS ARE ADOPTING GENETICALLY MODIFIED CROPS

By Janet Carpenter, Research Associate, and Leonard Gianessi, Senior Research Associate, National Center for Food and Agricultural Policy

Genetically modified crops that have employed the innovations offered by agricultural biotechnology have provided growers with higher yields, lower costs, and ease of management, according to recent research by Janet Carpenter and Leonard Gianessi. "Understanding these benefits is critical in an evaluation of the impact that the introduction of this technology has had on U.S. agriculture," the authors say. Regardless, the future in terms of benefits to farmers remains uncertain.

U.S. farmers have rapidly adopted genetically modified crops since their introduction over the past few years. The benefits to growers have been higher yields, lower costs, and ease of management. An additional impact of these varieties is the potential to reduce pesticide use.

While acreage planted to these new varieties has increased, so too has public awareness of and opposition to the growing prevalence of these crops in the food supply, both in the United States and abroad. In response, demands for mandatory labeling of genetically modified crops destined for Europe and Japan has been met with recent requests by U.S. food processors such as Archer Daniels Midland for growers to segregate their genetically modified crops from conventional varieties. The additional costs of product segregation for genetically modified crops may cut into potential profits, and growers may choose not to plant genetically modified varieties in the coming years.

Three major crops in the United States have been planted to genetically modified varieties: corn, cotton, and soybeans. A newly available potato variety has also been planted on a limited acreage. The adoption rates for these crops are given in the accompanying table. Each of these crops delivers a unique set of benefits to growers who adopt them, depending on pest control issues particular to the crops and whether other effective and affordable pest control options are available. This article illustrates the benefits of the genetically modified crops by examining three of the cases in which the technology has been introduced: Roundup Ready soybeans, Bt corn, and Bt cotton.

ROUNDUP READY SOYBEANS

Roundup Ready soybean varieties were introduced in 1996. The main advantage of Roundup Ready soybeans is the simplicity of weed control, which relies on one post-emergence herbicide to control a broad spectrum of weeds without crop injury or crop rotation restrictions.

Before the introduction of Roundup Ready soybeans, growers generally applied a pre-emergence herbicide before or at planting to control early season weeds, followed by either mechanical cultivation or selective post-emergence herbicides applied over the growing crop. The use of post-emergence herbicides has been increasing since these materials became available in the 1980s. This has facilitated the adoption of conservation tillage practices and narrow row spacing, which limit the opportunity for cultivation.

Although soybean growers have many post-emergence herbicide options, none has the broad spectrum of weed control of Roundup. Further, many conventional herbicides cause injury to the crop, including stunted growth, while Roundup may be applied over Roundup Ready varieties at any stage of growth without causing damage. Crop injury may not reduce yield, but it can delay canopy closure and increase weed competition with the crop.

Another limitation to conventional programs is the development of herbicide-resistant weeds. Several commonly used conventional soybean herbicides share a common mode of action, and weed populations resistant to these materials have developed in many areas of the U.S. Midwest. Finally, some of the herbicides that are used in soybeans can cause damage to subsequent rotation crops due to the persistence of the materials in soil. There are no crop rotation restrictions using Roundup, as it has no residual activity.

The costs of Roundup Ready soybeans compared to conventional varieties are expected to be roughly the same, although little field-level data exist for comparison. Growers may have realized cost savings by switching from a program using more than one herbicide treatment to a single application of Roundup. In 1998, a program using one application of Roundup over Roundup Ready soybeans cost under $20 an acre, compared to a conventional program using a combination of herbicides that cost around $30. However, the prices of competitive herbicides have been reduced to make alternative programs more competitive with the Roundup Ready system.

Yields of Roundup Ready soybeans are expected to be about the same as conventional varieties. Although state university variety trials have shown that the yield potential of the Roundup Ready varieties has been lower than the highest yielding conventional varieties, this lag is narrowing and is expected to disappear as the herbicide-resistant trait is introduced into the best conventional varieties.

Bt CORN

Field corn varieties altered to express an insecticidal protein from the soil bacterium *Bacillus thuringiensis* were also introduced for the 1996 growing season. Bt sweet corn varieties were introduced for the 1999 season. The main advantage of the Bt field corn varieties has been increased yields. For sweet corn, which is treated much more frequently with insecticides, the impact is expected to be a dramatic decrease in insecticide use. The Bt protein is selectively active against lepidopteran, or caterpillar, insects. Bt corn varieties have provided control of one of the major insect pests in corn, the European Corn Borer. Due to the difficulty in scouting for this pest and the importance of timing insecticide application before the caterpillar bores into the corn stalk and is protected from insecticides, it is estimated that less than 5 percent of field corn acreage in the U.S. "Corn Belt" was being treated with insecticides for the European Corn Borer prior to the introduction of Bt corn varieties.

Researchers have sought alternative methods to control the corn borer, although none has proven effective on a wide scale. Traditional breeding efforts to select for natural resistance to the corn borer resulted in the development of varieties with intermediate levels of resistance that were widely used into the mid 1970s. However, acreage planted to these varieties decreased dramatically due to the introduction of much higher-yielding susceptible hybrids, which could produce higher yields than the resistant hybrids, even after sustaining high levels of damage from the corn borer. Another extensive research program was undertaken by the U.S. Department of Agriculture (USDA) to identify natural predators of the corn borer. The program resulted in the introduction of 24 species of parasites in U.S. corn production areas, of which only six became established. While these beneficial insects have provided control of the corn borer in some years in some areas, their impact has been limited.

Losses due to the corn borer vary each year with infestation levels, and they are generally unpredictable from one year to the next. Largely uncontrolled until the introduction of Bt corn varieties, the European Corn Borer has caused production losses that have ranged from 33 million bushels to over 300 million bushels per year. Bt corn varieties have been shown to provide a very high level of protection from the corn borer. Plants sustain only minute damage as the corn borer larvae attempt to feed. The benefits that growers will realize from planting Bt corn varieties depend on the level of infestation. In light infestation years the benefits may not be great, while in heavy infestation years growers will realize substantial yield increases. An average of available research results comparing yields from Bt and non-Bt corn fields indicates that growers experienced a yield advantage of approximately 12 bushels an acre (2.47 acres are equal to one hectare) in 1997 and four bushels an acre in 1998. The price premium for Bt corn was approximately $10 an acre in 1997 and 1998. Assuming corn prices of $2.43 a bushel in 1997 and $1.95 a bushel in 1998, the average income changes for Bt corn were an increase of $18 an acre in 1997 but a decrease of $1.81 an acre in 1998. It is expected that in 10 of the 13 years from 1986 to 1998, corn borer infestations in the Corn Belt were such that corn growers would have realized a gain from planting Bt corn.

Bt COTTON

Bt cotton varieties were introduced in 1996 and were adopted very rapidly in some cotton production areas. Alabama growers planted Bt cotton varieties on 77 percent of the state's cotton acreage in the first year the new technology was available. The U.S. adoption figures (17 percent in 1998) mask what are actually high adoption rates because some major production areas, such as Texas and the San Joaquin Valley of California, do not face infestations of the pests the Bt cotton varieties control and do not need the technology. The primary benefit to growers of adopting Bt cotton varieties is controlling insect pests that have grown resistant to commonly used insecticides. Growers have also reduced the number of insecticide treatments and insecticide treatment costs.

In 1998, 71 percent of cotton acreage was treated with insecticides to control pests that would otherwise reduce yields. In most states, over 90 percent of the acreage was treated, while in Texas only 47 percent was treated due to low pest pressure in some areas. Bt cotton varieties control three of the primary insect pests of cotton: tobacco budworm, cotton bollworm, and pink bollworm. The Bt cotton varieties are most effective in controlling tobacco budworm and pink bollworm and provide lesser control of cotton bollworm due to its greater ability to survive on more mature cotton plants. Budworm and cotton bollworm cause yield losses in most cotton production areas of the United States outside of California and some areas of Texas. The pink bollworm is prevalent in southern California production areas, as well as Arizona, New Mexico, and far west Texas. Several of the commonly used insecticides for these cotton pests are pyrethroids, which have provided low-cost, effective control. However, in many areas, pyrethroid-resistant populations of tobacco budworm have developed, diminishing the usefulness of these insecticides. In 1995, a year with high tobacco budworm infestation in many areas, Alabama growers sustained nearly 30 percent yield losses due to the ineffectiveness of the pyrethroids in face of high levels of budworm resistance.

Growers who adopt Bt cotton varieties have been able to achieve effective insect control of the three target pests with a reduced number of insecticide applications. USDA pesticide use data show a reduction of 2 million pounds of the insecticides that are recommended for the control of these insects since the introduction of Bt cotton varieties. Insect control costs, including the $32-per-acre technology fee, are expected to be lower than for conventional varieties. In addition, growers in boll weevil eradication zones have adopted Bt varieties at a higher rate than in other areas in order to achieve control of bollworm/budworm in the face of treatments that destroy their natural predators. It is expected that growers will also experience increased yields using Bt varieties compared to conventional varieties.

CONCLUSION

The reasons U.S. growers are adopting genetically modified crops vary. The fact that new genetically modified varieties are capturing a large portion of the very competitive pesticide markets for major crops indicates that the new technology is delivering benefits to growers. Understanding these benefits is critical in an evaluation of the impact that the introduction of this technology has had on U.S. agriculture.

Soybean growers have adopted Roundup Ready soybeans largely due to the simplicity and efficacy of weed control provided by the program. Bt corn varieties have provided insect control for a destructive insect pest that was mostly uncontrolled previously, which has resulted in increased yields. Cotton growers have been able to control insect pests with fewer insecticide treatments.

However, the future of marketing for genetically modified crops remains uncertain. Much depends on the extent of demand for separate marketing channels for non-genetically modified crops and who bears the costs of identity preservation. If marketing agents demand that farmers limit the mixing of these crops with those that have been genetically modified, costs will rise and the benefits farmers have realized using this new technology may disappear. ❑

ADDITIONAL RESOURCES

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Note: The opinions expressed in this article do not necessarily reflect the views or policies of the U.S. government.

U.S. CROP ACREAGE PLANTED TO GENETICALLY MODIFIED VARIETIES IN 1998*

Crop	Acres (millions)**	Percent of Total Acreage
Bt Corn	14.4	18
Bt Cotton	2.3	17.0
Bt Potatoes	0.05	4.0
Roundup Ready Soybeans	19.0	26.0
Roundup Ready Corn	1.0	1.0
Liberty Link Corn	6.0	7.5
Roundup Ready Cotton	2.8	21.0
BXN Cotton	0.7	5.0

*National acreage in genetically modified crops will be less than the sum of acreage in each crop due to the adoption of "stacked" varieties with more than one trait.
**One acre is equal to 0.4 hectares.

❑ THE BIO-PATENT REVOLUTION: ENCOURAGING CREATION OF LIVING INVENTIONS

By Harold C. Wegner, former Professor of Law and Director of the Intellectual Property Law Program at the George Washington University Law School, and currently a member of Foley & Lardner, a Washington law firm

The rapid advances in biotechnology have generated questions about the protection of intellectual property rights and the potential conflict that may result over those seeking to make broad use of the new developments. "The challenge facing society is advancing agricultural science without jeopardizing intellectual property rights and thereby guaranteeing greater food security for emerging economies," says Harold C. Wegner. In this article, he examines some of the critical legal issues involving intellectual property protection and the modern advances in biotechnology.

The persistence of hunger and the accompanying extreme poverty found in many developing economies are indefensible during a period of rapid advances in food production using agricultural biotechnology. The genetically engineered wheat gene, Norin 10, for example, has helped such countries as India and Pakistan increase their wheat harvests by 60 percent. Similarly, Costa Rican scientists have created a new genetically modified rice, one that will help not only Costa Ricans but should be suitable for India, Vietnam, Japan, and other rice-growing countries as well. Biotechnology offers the promise of crops that not only generate their own pesticides to create disease-free products, but also plants with genes that provide improved nutritional content and allow the products to stay on the market shelf longer without rotting.

At the same time, developments in genetically engineered foods are occurring in a proprietary environment, where biotechnology products and the processes are being patented and their release to the public restricted because of the enormous investments by the private sector. Should Costa Rica have exclusive rights to its newly created rice, or should it be shared freely with other countries? Who owns the rights to nature and that which nature produces?

There are no easy answers. The challenge facing society is how to advance agricultural science without jeopardizing intellectual property rights and thereby guarantee greater food security for emerging economies. This article seeks to raise some of the key questions that policy-makers and courts must address and whose outcome will have a profound influence on the development and trade of biotechnology products.

ENCOURAGING INVESTMENT IN BIOTECHNOLOGY

Incentive is vitally important for any innovation that requires a large expenditure of funds and intellectual innovation. To take a bioengineered product out of the laboratory and onto the fields as a commercial crop, the greatest possible care must be exercised to test for the safety of the environment. Large numbers of clinical and field trials are hugely expensive and lengthy, but necessary. The international patent regime is thrust squarely in the middle of the debate because, without an effective international patent regime, there is no realistic possibility that the private sector will invest the significant resources required to advance state-of-the-art genetic engineering.

Without patent protection that would exclude others for a limited period of time, once a product hit the market it could easily be duplicated by everyone. This is particularly true when dealing with "living" inventions. If there is a new strain of rice, all that would be needed to copy the invention and enter into competition with the originator would be a small investment in a modest amount of seed and then the collection of the seed from the resulting crop. Clearly, if the originator of a genetically engineered crop can have no competitive advantage, then what incentive is there to spend the millions of dollars necessary to develop and market a new genetically engineered product? The reality is that without a patent regime, there would be far fewer new products that have the potential to better the human condition.

At the same time, patent law must be structured in a way that not only encourages the original inventor but also provides access to others so that the new product can be improved upon. And it must protect against commercial concerns that obtain patents in the area of biotechnology without carrying through with a concrete product, thus depriving society of a direct benefit.

WHO OWNS AN INVENTION?

Should, however, a patent be granted to something found in nature? One could very well imagine the outcry that would be created if someone enters a rain forest, pulls out a leaf with special medicinal qualities, and then seeks a patent on that leaf. What "invention" was made on the part of man? If the leaf is already known as a native medicinal, then there may not be anything patentable. To be patentable, something must be "new." If someone discovers that a purified extract from that leaf has medicinal qualities, the extract may be patentable. Indeed, Nobel Laureate Sune Bergstrom's isolation of prostaglandin, a class of molecules that help in the control of blood pressure, did not make him the "inventor" of prostaglandin; rather, he was the inventor of a "purified" prostaglandin that had not previously existed in nature.

While someone clearly may be determined to be the "inventor" of a form of the leaf, who owns that invention? A country is free to legislate ownership rights as it sees fit to meet its national policy goals. If the inventor works for a company, in most cases the patent right will go to the company rather than to the inventor.

But merely to discover the active principle involved in the medicinal qualities of the purified form of our leaf does not end the matter of patent ownership. Take, for example, the case of steroids. Decades ago, scientists discovered a basic steroid molecule with its characteristic arrangement of carbon rings. Scientists created synthetic steroids by manipulating chemicals to introduce various atoms onto the steroid's molecular structure. Each of these synthetic modifications, whether made in California or Kyoto, is considered a separate invention and not part of the original invention of the synthetic steroid.

Just as the discovery of the basic steroid molecule has limited benefit to the patent owner, the discovery of a purified leaf extract has limited benefit to the inventor. The real value of the discovery is bestowed on those who produce modifications that lead to needed and valuable products. Since the knowledge of the structure of that purified leaf extract will be in the public domain as part of the scientific literature (and since anyone is also free to use that structure for research even if it is patented), patent law provides little benefit to the "leaf" patent owner unless the structure of the leaf is kept secret. Then the owner of the invention, whether an individual or a company, will have the lead time to first identify the key structure of the purified leaf extract and be able to obtain patents on that structure.

TECHNOLOGY TRANSFER

Obviously, inventions cannot be developed everywhere. Does a company that has the patent on the leaf structure give away the rights to other countries? As I previously stated, that would reduce, and in most cases probably eliminate, the incentive for developing the new product. Consider, for example, a Latin American development of a new crop line that would be suitable in Latin America, Japan, and elsewhere. If the Latin American inventor has not exploited his invention in foreign markets, other countries may be able to take advantage of the technology by providing certain compensations to the investor. Such compensations might include royalty income or an agreement to expend additional resources to improve the initial technology — the possibilities are limitless.

Not all countries have the resources to buy into the new technology. Here there is a role for international development and research organizations such as the Consultative Group on International Agricultural Research and the World Bank. These groups need to consider whether they should allocate additional resources toward the development of genetically engineered products that would be freely shared with the poorest countries.

THE IMPORTANCE OF PATENT PROTECTION

A direct result of the Uruguay Round global trade accord concluded several years ago was the establishment of minimum standards for patent and related intellectual property protection, including those for products resulting from genetic engineering. Such standards are vital not only for protecting products from industrial countries but also for encouraging the creation of and protecting developing country inventions. Countries such as India, with its large number of highly trained scientists and engineers, are well placed for taking advantage of patent protections. Brazil and China are examples of countries that have made great strides in both the creation and implementation of modern patent laws.

Those countries that follow the lead of China and Brazil will have the incentives of the patent system to fuel innovation. Those that fail to move forward with strong patent laws will remain on the sideline, trapped by the lack of an effective patent law, unable to provide the legal setting to foster and encourage innovations in the local economy. ❑

Note: The opinions expressed in this article do not necessarily reflect the views or polices of the U.S. government.

❑ SAFETY AND CHOICE: KEY CONSUMER ISSUES FOR GENETICALLY MODIFIED FOODS

By Lisa Y. Lefferts, Consultant on Food and Environmental Health

"Survey after survey around the world shows that while consumers are generally not opposed to genetically modified foods, they are against allowing such foods to be sold without adequate labeling," says food consultant Lisa Lefferts, who frequently represents Consumers International, a global consumer group with over 230 member organizations in more than 100 countries, at meetings of the Codex Alimentarius Commission. "Genetically engineered foods per se do not worry many consumers as much as the covert manner by which they have crept into the marketplace."

Genetically engineered (GE) foods and food ingredients are widespread in our diet — from infant formula to corn-muffin mix to McDonald's McVeggie Burgers, according to testing in the United States by the publication *Consumer Reports*. Meanwhile, news reports worldwide tell of consumers, farmers, and activists dumping milk, suing governments, destroying GE crops, and persuading supermarket chains and companies to shun GE ingredients.

Why all the fuss? In part, it's fueled by attitudes among regulators and manufacturers that dismiss unanswered questions about the technology; ignore ethical and societal issues, pretending that only science matters; insist that GE foods are "equivalent" to conventional foods, when consumers can and do make distinctions between them; and bully consumers or farmers (for example, through lawsuits designed to stop dairies from disclosing that their cows are not treated with BGH/BST, a genetically engineered hormone).

Sharing power with those affected by biotechnology and addressing their legitimate concerns would help diffuse the controversy; making the risks more voluntary would make them seem smaller.

CONSUMER CONCERNS

Here are some of the issues that matter to consumers.

Allergenicity: Allergic reactions to foods are hard to predict, but they can be life-threatening. Once sensitized, individuals may react more strongly to subsequent exposures to the same allergen. According to the report of a joint Food and Agriculture Organization/World Health Organization Expert Consultation on Biotechnology and Food Safety in 1996, more than 160 foods are associated with sporadic allergic reactions, with children at greater risk than adults.

Genetic engineering can introduce unknown allergens into food. Virtually every gene transfer in crops results in some protein production, and proteins are what trigger allergic reactions. Biotechnology can introduce new proteins into food crops not just from known sources of such common allergens as peanuts and shellfish, but from plants of all kinds, animals, bacteria, and viruses whose allergenicity is largely unknown.

If someone has an allergic reaction to a conventional food, he or she can check the food label, which typically identifies all the ingredients precisely enough that the person can avoid future re-exposure to the allergen. However, if one has a reaction to an allergen in a food on account of a genetic modification, and the label does not disclose the presence of the GE food, one has little clue as to what to avoid in the future. This could very well increase the risk of subsequent exposures to the allergen. Or it could to lead to people needlessly avoiding foods that are actually safe for them.

Environmental Risks: In a study conducted by researchers at Cornell University in the United States, pollen from corn genetically engineered to contain Bt toxin (a toxin from a soil bacterium that kills insect pests) can kill monarch butterfly caterpillars, at least in the laboratory. This recent finding adds to other studies suggesting adverse effects on beneficial insects from genetically engineered plants. This has boosted environmental concerns over genetic engineering, inasmuch as insects, among their multiple roles in living systems, are key pollinators of many plants.

Genetically engineered genes might also accidentally cross over to non-target plants. For example, "terminator" genes might cross over and cause plants to produce sterile seeds, resulting in a significant loss of food and diversity. Similarly, genes from plants engineered to be herbicide resistant could cross over to other plants, creating "superweeds." Studies in Norway and the United States have already demonstrated that the gene for herbicide resistance can move from cultivated canola to wild relatives.

Ethical/Religious Considerations: Some people find genetically engineered foods unacceptable for ethical or religious reasons. Rabbis, ministers, vegetarians, and others can be found on both sides of the debate regarding foods engineered to contain genes from animals or species that are proscribed by certain religions. Labeling allows those consumers to choose according to their conscience without imposing that view on others.

Social/Economic Justice Issues: Many consumers are suspicious of who is controlling a technology that promises to revolutionize agriculture. Biotechnology enables agricultural production to become more vertically integrated, consolidated, and centralized, largely in the hands of multinational corporations. As author and professor Joan Gussow says, "Someone is going to produce and subsequently manipulate the materials out of which each of us is made. Are we really prepared to trust that responsibility to Phillip Morris?"

Probably no GE product has generated as much controversy as the so-called terminator technology, which makes plants produce sterile seeds. Particularly in a country such as India, where farmers routinely save and replant seeds, the prospect of being forced to buy seeds each year from large-scale corporations has generated considerable outrage, leading groups of farmers to burn plots where the seeds were being studied.

Unanticipated Consequences: No technology, no matter how beneficial, is risk free. And with any new technology, there may be unanticipated consequences. The recent revelation that pollen from plants genetically engineered to contain Bt may harm monarch butterflies is a case in point.

Genetic engineering could also bite back by exacerbating the growing problem of antibiotic resistance. Most genetically engineered plants contain a gene for antibiotic resistance as an easily identifiable marker. Hypothetically, antibiotic resistance genes may move from a crop into bacteria in the environment and — since bacteria readily exchange antibiotic resistance genes — move into disease-causing bacteria. In September 1998, the British Royal Society called for ending the use of antibiotic resistance marker genes in engineered food products.

Many consumers know nothing about antibiotic resistance genes used in GE foods, but they do understand the unpredictability of complex systems. Genetically engineering a plant to have a particular trait can have unexpected ripple effects on the ecosystem that cradles it. It is consumers' grasp of this fundamental phenomenon that underlies much of the concern over biotechnology.

MISPERCEPTIONS OF CONSUMER REACTION

GE foods per se do not worry many consumers as much as the covert manner by which they have crept into the marketplace. Here are some common misperceptions I frequently encounter.

Misperception No. 1: Most consumer organizations are anti-technology and oppose all genetically engineered foods. In fact, many independent consumer organizations recognize the potential benefits of biotechnology. Consumers Union, publisher of *Consumer Reports* and the largest and oldest consumer organization in the United States, recognizes that, with proper safeguards, genetic engineering offers the possibility of foods that could benefit consumers. Consumers International, a federation of over 230 consumer organizations from some 100 countries, is pro-labeling, not anti-biotechnology.

The problem is that while consumers have been promised foods that taste better, are healthier, and will help "feed the world," the applications of the technology to date have fallen flat in delivering consumer benefits. BGH/BST, a genetically engineered drug that makes cows produce more milk, has not translated into lower prices. The main benefit of Roundup Ready soybeans and cotton has been to expand the market for Roundup. Bt corn, cotton, and potatoes are spreading pest resistance to this natural and safe insecticide, as well as threatening beneficial wild insects. And most consumers know that there is no such thing as a "magic bullet" solution to the complex problem of world hunger, which has less to do with agricultural production capacity than with political priorities and the distribution of economic resources.

Misperception No. 2: Labels on genetically engineered foods will be viewed by consumers as warning labels. The argument that labeling will stigmatize GE foods in the consumers' eyes as potentially unsafe assumes that only science matters, and that the public is too ignorant to understand the data. Consumers need labeling to make an informed choice based on whatever criteria they wish to use. Labeling with full disclosure would be a positive step toward a more informed citizenry and a way to increase consumers' familiarity with this new technology.

Misperception No. 3: U.S. consumers, unlike consumers in Europe and many other countries, are comfortable with GE foods and don't think labeling is necessary. Actually, only about one-third of Americans interviewed were aware that GE foods are available in the supermarket, according to a recent survey by the International Food Information Council. But many of those who are informed are not going along quietly. Earlier this year, a coalition sued the U.S. Food and Drug Administration (FDA) to block the use of a dozen GE crops as an "imminent" threat to the environment. Last year, a coalition of scientists, religious leaders, health professionals, and chefs filed a lawsuit against the FDA, claiming that the failure to label violates the agency's mandate to protect the public's health and provide consumers with relevant information about the food they eat.

RIGHT TO KNOW, RIGHT TO BE INFORMED, RIGHT TO CHOOSE

The fundamental purpose of ingredient labeling is to tell consumers what is in the foods they buy. For people subject to food allergies, that information is essential to their health.

In the United States, regulators argue that the method by which a plant is developed is not "material" information in the sense of the law. Consumer organizations object that this narrow interpretation gives no weight to material facts that consumers consider important, and that it substitutes the value judgments of regulators for those of consumers. They don't agree with the "it's the product, not the process, that matters" argument. Surely, it would be considered "material" if experimentation on living human subjects was part of the development of crashworthy sports cars.

Survey after survey around the world shows that while consumers are generally not opposed to genetically modified foods, they are against allowing such foods to be sold without adequate labeling. Let the success of biotechnology depend on whether informed consumers "vote" for it in the marketplace. ❏

Note: The opinions expressed in this article do not necessarily reflect the views or policies of the U.S. government.

❑ PUBLIC PERCEPTIONS AND UNDERSTANDING OF AGRICULTURAL BIOTECHNOLOGY

By Thomas J. Hoban, Professor, Department of Sociology and Anthropology, North Carolina State University

Consumer perceptions and understanding of agricultural biotechnology have been strongly influenced by the type of information provided by the media, confidence in governmental safeguards, and cultural preferences, says Thomas J. Hoban. However, research indicates that consumers from different parts of the world have very different perceptions and understanding of agricultural biotechnology. In this article, Hoban, who has studied this issue for the past decade, discusses consumer perceptions about biotechnology in food production and provides guidelines for meeting consumer information needs.

The first agricultural products of biotechnology have reached world markets. These products have received a frosty response in some parts of the world. But despite some recent sensational headlines in the press, North American markets have so far remained calm as foods containing ingredients developed through biotechnology have started arriving in stores. It is clear from a review of consumer surveys conducted in the United States, Japan, and Europe that consumer perceptions about biotech foods are strongly influenced by type of information, confidence in government, and cultural preferences.

VARYING VIEWPOINTS

In general, consumers worldwide see considerable value in human genetic testing, the development of new medicines to combat disease, and the use of biotechnology to develop new types of insect-resistant crop plants. Consumers are less likely to accept the use of biotechnology with animals (even to enhance human health), and they appear less accepting of food products developed through biotechnology, compared to crop plants, which some consumers don't even directly connect with food. The most acceptable applications are those that offer a clear consumer benefit, as well as those that are perceived to be ethical and safe.

However, public attitudes about agricultural biotechnology vary considerably among countries. Consumers from Canada, Finland, Italy, Japan, the Netherlands, Portugal, and the United States are more positive about biotechnology than most other countries. Support for biotechnology is much lower in Austria, Denmark, Germany, and Sweden.

Two countries — the United Kingdom and France — used to be quite positive toward biotechnology but have become more hostile in the past year or so. The United Kingdom has become more negative for a number of reasons, including fallout from mad cow disease, anti-biotechnology comments made by Prince Charles, food retailer panic, and an effective network of activist groups. France has become more negative partly due to French farmers' opposition to American grain imports and a broader French cultural opposition to what they see as the globalization (that is, Americanization) of the food supply.

Surveys in the United States (as recently as the spring of 1999) have consistently shown that between two-thirds and three-quarters of American consumers are positive about biotechnology, and about three-quarters have consistently expressed a willingness to buy insect-protected produce developed through biotechnology. One of the reasons cited for this willingness is that these products require fewer chemical pesticides. Support is highest among men and people with more formal education.

This is not to say that consumers don't have questions. Consumer groups have raised a number of concerns about agricultural biotechnology, particularly that it might somehow involve long-term or unexpected effects. Environmentalists often focus on possible ecological impacts from the use of biotechnology. While these raise important questions, they are not usually on the top of an average consumer's mind. Furthermore, consumers usually associate ethical issues with human or animal genetics, rather than with plants.

AN INFORMED PUBLIC?

Surveys indicate fairly high awareness of biotechnology in Austria, Denmark, Luxembourg, and Sweden. But these are exceptions. In the United States, surveys since 1992 show that only about one-third of U.S. consumers have heard or read much about biotechnology — except for a brief period in 1997, when increased media attention on the cloning of a sheep raised awareness to almost 50 percent. Only about one-third of Japanese consumers reported much awareness of biotechnology in 1995 or 1998. Awareness in France and the United Kingdom (as measured a couple years ago) was comparable to that in the United States, but it has risen for reasons discussed earlier.

Most people get their information on biotechnology from media coverage. If the media do not cover a particular story, the public tends to ignore that issue. The tone of information in the media has an important impact on consumer perceptions. Up until now, media coverage in the United States has tended to be positive and balanced (which helps account for the relatively high levels of acceptance of biotechnology).

This is a sharp contrast to the media coverage in the European Union. In fact, media coverage in the United Kingdom has taken on the characteristics of sensational tabloid journalism. The British media tend to rely on the use of emotional terms such as "Frankenfood." They also have been quick to jump on any negative allegations even when scientific consensus refutes the charge (as was the case with a controversy over the safety of insect-protected potatoes). That accounts for some of the negative consumer and food industry response in the United Kingdom.

Contributing to misinformation on biotechnology is the low knowledge in most countries of basic agricultural and biological sciences. This lack of understanding generates concern, especially when coupled with negative media coverage. There also appears to be a lack of understanding about traditional plant breeding. Countries with the highest levels of knowledge are Canada, the Netherlands, Sweden, and the United States. Countries with the least knowledge include Austria, Greece, Ireland, Portugal, and Spain. Survey results show that providing factual information increases consumer acceptance (at least in the United States, Canada, and Japan).

However, surveys also show that the source of the information may be an important factor in consumer preferences, and that a source trusted in one country is discredited in another. North American consumers have the most trust in independent health and scientific experts. In particular, acceptance increases significantly when American consumers learn that groups such as the American Medical Association, the U.S. Food and Drug Administration (FDA), and others have determined that the foods from biotechnology are safe. Japanese consumers also report high levels of trust in third-party scientific information sources. On the other hand, European consumers express the most trust in consumer and environmental groups. Their trust in government and industry is much lower than in North America.

LABELING FOR WHOM?

The most challenging issues surrounding agricultural biotechnology involve labeling. European consumers have generally been encouraged by consumer activists to demand labels identifying foods that have been developed through biotechnology. Several food retailers (especially in the United Kingdom) have tried to exploit the public concern as a marketing tool. Europe has labeling policies in place, but they have not yet been able to establish workable regulations or procedures. They are now grappling with difficult technical issues such as which methods to use to identify traces of biotechnology-derived ingredients. They also are trying to determine what percent of ingredients in processed foods can be derived from biotechnology and still allow the food to qualify as "biotechnology-free."

For the U.S. consumer, the Food and Drug Administration, an agency within the U.S. Department of Health and Human Services, has determined that a food product should be labeled as a product of biotechnology only if it has been changed in a significant way. FDA policy, supported by over 75 percent of U.S. consumers according to two national surveys, ensures product availability while providing consumers with relevant information about food safety and nutritional changes.

Recent focus groups in the United States also have demonstrated that the wording on labels has a significant effect on consumer understanding and acceptance of biotechnology. Many U.S. consumers are already overwhelmed by the level of detail on food labels and do not really want more information that has no scientific justification. Consumers want to know how a product has been changed and whether it has been approved by a government agency. Any label information needs to be simple, relevant, and clear.

The labeling of processed foods presents a number of logistical challenges and costs for everyone involved. For example, U.S. consumers have reported little need to label a bottle of ketchup that includes tomatoes developed through biotechnology in addition to traditionally bred varieties. In fact, most people don't even understand that different varieties of vegetables or fruits are currently blended during processing. In addition, consumers are not willing to pay extra to have foods labeled as a product of biotechnology (especially when this information has no meaning). Consumers want meaningful choices that are truly different. The "organic" market niche already provides a viable opportunity for consumers who do not want to consume foods developed through biotechnology, for whatever reason.

WHERE TO FROM HERE?

Biotechnology is at a crossroads in terms of public acceptance. Actions and statements by industry, government, and scientists over the next year will have a major influence on the long-term viability of the agricultural biotechnology enterprise. Without a major commitment to consumer education and informed choice, opposition will continue to grow. Such efforts must be based upon ongoing research into the knowledge and attitudes held by consumers and opinion leaders. Different parts of the world clearly require different approaches.

Research results suggest that biotechnology should not become a major issue for most North American consumers. Most U.S. consumers (as well as many others around the world) remain cautiously optimistic about the benefits of biotechnology. They will accept the products if they see a benefit to themselves or society and if the price is right. In fact, we are finding that consumers' responses to foods developed through biotechnology are basically the same as for any other food. Taste, nutrition, price, safety, and convenience are the major considerations. How seeds and food ingredients are produced will be relevant only for a small group of concerned "organic" consumers.

In countries where consumers are more negative about biotechnology — Germany, Austria, Sweden, and Denmark — media coverage and activist opposition have been more pronounced. In these four countries, discussion of the benefits of biotechnology have generally been ignored, while the potential risks have been emphasized. Basic social values and cultural beliefs also explain much of the differences in responses between countries. These are not necessarily amenable to educational efforts.

There also are a number of fundamental cultural differences. For example, consumers' attitudes about biotechnology are closely related to their general beliefs about science, technology, and food. European consumers tend to view farms as public natural areas where they can visit on weekends. Farms in the United States tend to be concentrated in the midsection of the country, far away from the urban population centers. Also in the United States, there has always been strong public support for and appreciation of new technology. Such support has not been as strong in parts of Europe. Some Europeans tend to view their food with an almost spiritual reverence, which is quite different from the common American view of food as fuel. These and other issues need more careful attention.

Another reason for the sustained U.S. support for biotechnology has been a long-term commitment to the education of opinion leaders and consumers. There has been an unprecedented partnership between the government, industry, universities, and third-party groups (such as the American Dietetic Association) to understand and address public concerns well before the products of agricultural biotechnology are released. There is a critical need to renew that commitment to education, information, and social science research.

Our experience in the United States provides some guidelines for a global program of information and education. Consumers need to recognize the existing benefits and future promises of biotechnology. The opportunity that biotechnology provides for feeding the world (while protecting the environment) will be compelling for many consumers. It is also important to build trust in government and scientists to serve the public interest. This requires that farmers, scientists, government officials, and others work together to ensure that consumer decisions are based on balanced information. ❑

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❑ MONARCH BUTTERFLIES AND BT CORN: A REVIEW OF THE RESEARCH

The publication on May 20, 1999, of preliminary research by Cornell University suggesting that the use of genetically modified corn may have toxic effects on larvae of the monarch butterfly has generated a huge amount of publicity and almost as much misinformation. Groups opposing biotechnology have used the preliminary data to argue against production and trade in all genetically engineered crops regardless of the facts. Scientists are now conducting several follow-up studies examining the effects of bioengineered corn pollen on butterflies.

While a review of current research indicates that scientists have found some risk to monarch butterfly caterpillars from Bt corn pollen, very few definitive conclusions can be made at this time, according to British biologist M.J. Crawley. Crawley observes that the data gathered to date are based on preliminary laboratory studies, carried out over a comparatively short period of time under a specific set of conditions. "They do not address the issues over the entire life cycle of the insects," he says.[1] Numerous scientists, industry representatives, and government officials strongly support collecting more definitive data from comprehensive field research in order to resolve what has become a burning issue in the larger biotechnological debate.

Following is a brief review of the Cornell preliminary research and ongoing research.

THE CORNELL UNIVERSITY RESEARCH

The official account of Cornell entomology professor John Losey's preliminary laboratory research was published in *Nature* magazine's May 20, 1999, issue under the title "Transgenic Pollen Harms Monarch Larvae."[2] Losey's research investigated how pollen from genetically engineered corn (Bt corn) affects monarch caterpillars, whose exclusive food source, milkweed, frequently grows in and around corn fields. His one-page scientific correspondence in *Nature* outlined the methodology that he and two researchers used to compare the feeding, growth, and mortality of monarch larvae fed on milkweed leaves dusted either with Bt corn pollen or non-Bt corn pollen, or not dusted with pollen at all.

Losey reported that the larvae "reared on milkweed leaves dusted with pollen from Bt corn ate less, grew more slowly, and suffered higher mortality than larvae reared on leaves dusted with untransformed corn pollen or on leaves without pollen." He wrote: "These results have potentially profound implications for the conservation of monarch butterflies." Noting that the amount of Bt corn planted in the United States is projected to increase markedly, Losey observed, "it is imperative that we gather the data necessary to evaluate the risks associated with this new agrotechnology and to compare these risks with those posed by pesticides and other pest-control tactics." In a Cornell University press release issued on May 19, he described his research as "just the first step" and again called for more research.[3] Losey reports that he has been carrying out follow-up experiments and hopes to publish his latest results this winter.[4]

ADDITIONAL RESEARCH

Another study frequently cited in the media is the ongoing fieldwork by entomologist John Obrycki and graduate student Laura Hansen at Iowa State University. While they have not yet published this research, the abstract they wrote for presentation at an Entomological Society of America meeting describes its focus and preliminary findings.[5] Obrycki and Hansen have been investigating the potential risk that the manifestation and dispersal of Bt toxin in corn pollen poses to monarchs. The first step of their methodology was to place potted milkweed plants at several distances from the edge in both a Bt cornfield and a non-Bt field to determine pollen concentration levels. They then took milkweed leaf samples to assess the mortality of newly hatched monarch larvae exposed to either Bt corn or non-Bt corn pollen. They found that "within 48 hours, there was 19 percent mortality in the Bt corn pollen treatment compared to zero percent on non-Bt corn pollen exposed plants." In evaluating their research, Marlin Rice, an entomologist at Iowa State, writes that both the Iowa State and Cornell studies "suggest that some, but not all, monarch caterpillars may be killed when they eat Bt corn pollen." However, he says, the bottom line is that more research needs to be conducted on the effects of Bt corn on monarchs and other non-target species. [6]

Another team of scientists from Iowa State, the Agricultural Research Service of the U.S. Department of Agriculture, and several other American universities is currently conducting field studies under the sponsorship of the Agricultural Biotechnology Stewardship Working Group (ABSWG). ABSWG is a consortium of biotechnology companies and associations that includes the Biotechnology Industry Organization (BIO), the American Crop Protection Association (ACPA), Monsanto Company, and Novartis Seeds Inc. Through ongoing projects focusing on milkweed distribution, pollen movement, monarch biology, and the biochemistry of Bt pollen, the researchers are studying how the pollen that is transported outside of corn fields affects butterfly larvae in their natural habitat, as they feed on milkweed plants. In a press release, BIO's vice president for food and agriculture states that the consortium's goal was to "assemble a cadre of top-flight, highly reputable and credible public researchers to answer the real questions that grew out the Cornell University laboratory study." [7] According to the executive director of ACPA's Biotechnology Committee, Leah Porter, the researchers plan to present their findings this December at the Entomology Society of America's annual meeting in Atlanta.[8] At the meeting, a symposium on the Impact of Transgenic Corn Pollen on Monarch Larvae will feature the latest results of several high-profile studies.[9]

Also participating on the ABSWG-affiliated research team are scientists from the Agricultural Research Service (ARS). According to an ARS information officer, the USDA scientists are continuing to conduct follow-up studies and have not yet released data from these experiments. An informal meeting to exchange information and discuss the direction of future research is planned for November 2 in Chicago. In a discussion of the Cornell preliminary research, the USDA fact sheet, "USDA and Biotechnology," reports that the department is working to identify useful follow-up information and research to better understand how monarchs and corn pollen interact in the field. The fact sheet lists a number of reasons why the effect of Bt corn pollen on monarchs may prove to be small.[10] These include corn pollen's heavy weight, which may prevent it from being blown a significant distance from the field, and the monarchs' potential capacity to avoid feeding on milkweed plants dusted with Bt pollen. Overall, the document states, "USDA is committed to further research on the potential impacts of new technologies in agriculture." ❑

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Available at (http://www.bio.org/food&ag/bt0813.htm).

8. Remarks made by Porter in a telephone conversation with *Economic Perspectives*, September 28, 1999.

9. 1999 ESA Annual Meeting. Entomological Society of America
Available at (http://www.entsoc.org/annmeet.htm).

10. "Questions and Answers: USDA and Biotechnology." United States Department of Agriculture fact sheet.
Available at (http://www.usda.gov/news/bioqa.htm).

❑ BIOTECHNOLOGY LEXICON

The following list of terms is intended to give readers a general understanding of some of the terminology used in the journal articles.

APHIS (Animal and Plant Health Inspection Service): an agency of the U.S. Department of Agriculture responsible for regulating the field testing of genetically engineered plants and certain microorganisms.

Biosafety Protocol: A treaty being negotiated under the Convention on Biological Diversity to set up a process for the safe movement across countries' boundaries of living genetically engineered organisms.

Biotechnology: Broadly defined, the use of biological processes of microbes and of plants or animal cells for the benefit of humans. When used in conjunction with genetic engineering, it is the genetic modification of an organism's DNA such that the transformed individuals have new traits that enhance survival or modify quality. The actual use of biotechnological methods began centuries ago, when plants and animals were selectively bred and microorganisms were used in the production of beer, wine, cheese, and bread. In addition to genetic engineering, biotechnology is concerned with such areas as plant tissue culture, gene splicing, enzyme systems, plant breeding, animal cell culture, immunology, molecular biology, and fermentation. Modern biotechnology is being used in medicine, fuel production, agriculture and food production, and criminal science, as well as in environmental activities.

Bovine Somatotropin (BST/BGH): Known both as BST and BGH (for bovine growth hormone), a naturally occurring protein that has been genetically engineered as a synthetic compound to stimulate milk production in cows.

Bt Crops: Crops that are genetically engineered to carry the gene from the soil bacterium *Bacillus thuringiensis*. The bacterium produces a protein that is toxic when ingested by individual species of insects, thereby providing protection throughout the entire plant.

Bt Cotton: Cotton that is genetically engineered to control tobacco budworms, bollworms, and pink bollworms.

Bt Corn (Maize): Corn that is genetically engineered to provide protection against the European Corn Borer.

CGIAR (Consultative Group on International Agricultural Research): An informal association of 58 public and private sector members supporting 16 international agricultural research centers. The centers develop advanced breeding material for adoption and use by national agricultural research systems in developing countries.

Clone: A group of genetically identical cells or organisms asexually descendent from a common ancestor.

Codex Alimentarius: A World Health Organization body that develops standards for food safety and international food trade.

Convention on Biological Diversity (CBD): An international conference on biodiversity issues. Its objectives are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. This convention is the first comprehensive global agreement to address all aspects of biological diversity. Currently, there are 168 signatories to the convention and 175 members of the Conference of Parties.

DNA (Deoxyribonucleic Acid): The molecule that encodes genetic information. It is constructed of a double helix held together by weak bonds between base pairs of four nucleotides: adenine, guanine, cytosine, and thymine.

EPA (Environmental Protection Agency): A U.S. government agency that issues permits for large-scale testing of herbicides and biotechnology-derived plants containing new pesticidal substances.

FDA (Food and Drug Administration): A U.S. government agency responsible for ensuring that foods derived from new plant varieties are safe to eat. FDA also has legal authority for food labeling.

Genetically Modified Organism (GMO): An organism produced from genetic engineering techniques that allow the transfer of inherited characteristics from one organism to another. Bacteria, fungi, viruses, plants, insects, fish, and mammals are some examples of genetic material that have been artificially changed or altered in order to change some physical property or capability. Living modified organisms (LMOs), genetically engineered (GE) foods, and transgenic crops are other terms often used in place of GMOs.

Genetic Engineering: Very broadly, a technique used to alter or move genetic material (genes) of living cells. In the United States, under guidelines issued by Department of Agriculture's Animal and Plant Health Inspection Service, genetic engineering is defined as the genetic modification of organisms by recombinant DNA techniques. Definitions used in Europe tend to be broader.

Gene Stacking: Combining traits (e.g., herbicide tolerance and insect resistance) in seed.

Genome: The sum of the genetic material in the chromosomes of a particular organism.

Herbicide-tolerant Crops: Crops developed to survive certain herbicides. These crops previously would have been destroyed along with targeted weeds, but now can be used by farmers as an effective weed control. The most common herbicide-tolerant crops (cotton, corn, soybeans, and canola) are marketed under such names as: Roundup Ready (RR), resistant to glyphosate, a herbicide effective on many species of grasses, broadleaf weeds, and sedges; Liberty Link (LL) corn, resistant to glufosinate-ammonium; and BXN cotton, resistant to bromoxynil.

Plant Breeding: The technique of crossing plants to produce varieties with particular characteristics (traits) that are carried in their genes and passed on to future generations.

Recombinant DNA (rDNA): DNA produced using genetic engineering techniques. Such techniques involve transferring a DNA segment from one organism and inserting it into the DNA of another, possibly unrelated, organism.

Transgenic Plants: Plants that result from the insertion of genetic material from another organism, generally through recombinant DNA techniques, to make the plant exhibit a desired trait. ❏

Sources: U.S. Department of Agriculture; Organization for Economic Cooperation and Development; U.S. Congress, Office of Technology Assessment.

KEY CONTACTS AND INTERNET SITES

UNITED STATES GOVERNMENT

U.S. Department of Agriculture (USDA)
14th and Independence Avenue, N.W.
Washington, D.C. 20250 U.S.A.
Key telephone numbers and internet sites:

Animal and Plant Health Inspection Service (APHIS)
Biotechnology and Scientific Services
Biotechnology Evaluation
Telephone: (202) 720-2511
http://www.aphis.usda.gov/biotech/
http://www.aphis..usda.gov/biotech/usda_biotech.html
http://www.aphis.usda.gov/biotech/OECD/usregs.htm
Foreign Agricultural Service (FAS)
Telephone: (202) 720-7115
http://www.fas.usda.gov/
Food Safety and Inspection Service (FSIS)
Telephone: (202) 720-7943
http://www.fsis.usda.gov/
USDA Biotechnology Information Center
http://www.nal.usda.gov/bic/
USDA and Biotechnology
http://www.usda.gov/news/bioqa.htm
Ag Biotechnology Patents and New Technologies
http://www.nal.usda.gov/bic/Biotech_Patents/
Biotech-Related WWW Sites and Documents
http://www.nal.usda.gov/bic/www.html

U.S. Department of Commerce
International Trade Administration (ITA)
Herbert Clark Hoover Building
14th Street and Constitution Avenue, N.W.
Washington, D.C. 20230 U.S.A.
Telephone: (202) 482-2867
http://www.ita.doc.gov/gmo/

U.S. Department of Energy (DOE)
Office of Biological and Environmental Research and Office of Science
Germantown, Maryland 20974 U.S.A.
Telephone: (301) 903-5805
http://www.er.doe.gov/production/ober/ober_top.html

Oak Ridge National Laboratory
Center for Biotechnology
http://www.ornl.gov/cbt/cbt.htm

U.S. Department of Health and Human Services
Food and Drug Administration (FDA)
Center for Food Safety and Applied Nutrition
200 C Street, S.W.
Washington, D.C. 20204 U.S.A.
Telephone: (202) 205-4943
http://vm.cfsan.fda.gov/~lrd/biotechm.html
National Center for Biotechnology Information
National Library of Medicine
National Institutes of Health
http://www.ncbi.nlm.nih.gov/

United States Department of State
Office of International Information Programs
301 4th Street, S.W.
Washington, D.C. 20547 U.S.A.
Global Issues: Biotechnology
http://www.usia.gov/topical/global/biotech

U.S. Environmental Protection Agency (EPA)
401 M Street, S.W.
Washington, D.C. 20460-0003 U.S.A.
Telephone: (202) 260-6900
TSCA Biotechnology Program
http://www.epa.gov/opptintr/biotech/index.html

Office of the U.S. Trade Representative (USTR)
Winder Building
600 17th Street, N.W.
Washington, D.C. 20508 U.S.A.
Telephone: (202) 395-3230
U.S. Regulation of Products Derived From Biotechnology
http://www.ustr.gov/reports/bioreg.pdf

NON-UNITED STATES GOVERNMENT

Consultative Group on International Agricultural Research (CGIAR)
The World Bank
1818 H Street, N.W.
Washington, D.C. 20433 U.S.A.
Telephone: (202) 473-8951
Fax: (202) 473-8110
E-mail: cgiar@cgiar.org
http://www.cgiar.org/
http://www.cgiar.org/cgnas.htm

Codex Alimentarius Commission
http://www.fao.org/WAICENT/FAOINFO/ECONOMIC/ESN/codex/default.htm

Convention on Biological Diversity
http://www.biodiv.org

European Commission
Science, Research and Development (Biotechnology)
http://europa.eu.int/comm/dg12/biot1.html

Organization for Economic Cooperation and Development (OECD)
http://www.oecd.org/ehs/service.htm

Part I: Biotechnology and Medical Innovation: Socio-economic Assessment of the Technology, the Potential and the Products
http://www.oecd.org/dsti/sti/s_t/biotech/prod/e_97-205.htm
Part II: Biotechnology, Medical Innovation and the Economy: The Key Relationships
http://www.oecd.org/dsti/s_t/biotech/prod/e_98-8.htm
Modern Biotechnology and the OECD
http://www.oecd.org/publications/Pol_brief/9903-eng.pdf
Links to Other Biotechnology or Biosafety Resources on the Web
http://www.oecd.org/ehs/biolinks.htm

United Nations Food and Agriculture Organization
http://www.fao.org

FAO and the Biosafety Protocol to the Convention on BiologicalDiversity
http://www.fao.org/WAICENT/faoinfo/sustdev/RTdirect/rtre0034.htm

Biotechnology and Food Safety
http://www.fao.org/waicent/faoinfo/economic/esn/biotech/tabconts.htm

ACADEMIC AND RESEARCH ORGANIZATIONS

Academic Information: Biotechnology
http:/www.academicinfo.net/biotech.html

Agricultural Biotechnology Support Project
Michigan State University
http://www.iia.msu.edu/absp/

Biotechnology and Biological Sciences Research Council
http://www.cc.bbsrc.ac.uk/

Center for Agricultural Biotechnology
University of Maryland
http://www.umbi.umd.edu/~cab/

Center for Food and Nutrition Policy
Georgetown University
http://www.ceresnet.org

International Centre for Genetic Engineering and Biotechnology
Trieste, Italy
http://www.icgeb.trieste.it/

National Agricultural Biotechnology Council
Cornell University
http://www.cals.cornell.edu:80/extension/nabc/

National Biotechnology Information Facility
New Mexico State University
http://www.nbif.org/indxbdy.html

University of Florida
Biotechnology Resources
http://gnv.ifas.ufl.edu/www/agator/htm/biotek.htm

Virtual Center of Biotechnology for the Americas
Universidad Nacional Autonoma de Mexico
http://www.ibt.unam.mx/virtual.cgi

CONSUMER GROUPS AND INDUSTRY

Alliance for Bio-Integrity
http://www.bio-integrity.org

American Crop Protection Association
Biotechnology Committee
http://www.acpa.org/public/issues/biotech/committee.html

Biotechnology Industry Organization
http://www.bio.org/welcome.html

International Food Information Council
http://ificinfo.health.org/foodbiotech/whatexpertssay.htm

Biotechnology
Union of Concerned Scientists
http://www.ucsusa.org/agriculture/biotech.html

Biotechnology in Scotland
http://www.sebiotech.org.uk/

Web Pages Linked to NBIF
National Biotechnology Information Facility
http://www.nbif.org/About_NBIF/linksto.html ❑

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CALENDAR OF ECONOMIC EVENTS

Currently Under Way and Looking Ahead

Oct 25-29 CGIAR International Centers Week, Washington, D.C.

Oct 29-30 Transatlantic Business Dialogue (TABD), Berlin

Nov 1-2 Southeast Europe: Commercial Opportunities and Partnerships Conference, Sofia

Nov 3-4 Free Trade Area of the Americas (FTAA) Ministerial, Toronto

Nov 18-21 President Clinton visit to Bulgaria, Turkey, Italy, and Greece

Nov 30-Dec 3 Third Ministerial Conference of the World Trade Organization, Seattle, Washington

Dec 5-7 World Economic Forum 1999 India Economic Summit, New Delhi

Dec 6-7 U.S. Secretary of Transportation Rodney Slater to host Beyond Open Skies Global Civil Aviation Ministerial-level conference, Chicago

Dec 6-10 Basel Convention 10th Anniversary Conference of the Parties COP V, Basel

Dec 10 Panama Canal Transfer Commemorative Ceremony

Dec 31 Panama Canal Handover Ceremony

Jan 20-21 Biotechnology: the Science and the Impact, international conference, The Hague

Jan 27-Feb 1 World Economic Forum, Davos, Switzerland

Feb 12-19 UNCTAD X (Quadrennial Meeting), Bangkok

Feb 12-21 APEC Senior Officials Meeting I, Bandar Seri Begawan

Feb 17-20 National Summit on Africa, Washington, D.C.

Jun 3-11 APEC Senior Officials Meeting II, Bandar Seri Begawan

Jul 21-23 G-8 Summit, Okinawa

Sep 18-22 International Atomic Energy Agency General Conference, Vienna

Sep 21-22 APEC Trade Ministerial, Bandar Seri Begawan

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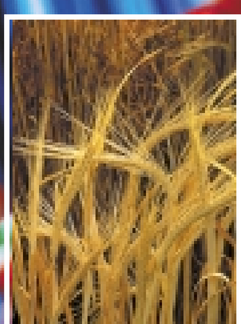

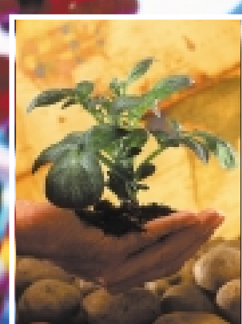
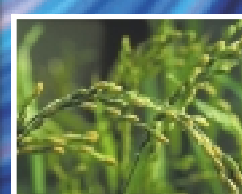
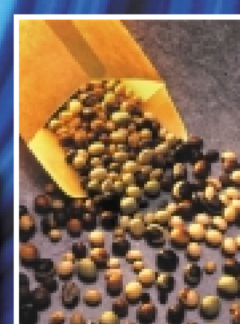

BIOTECHNOLOGY: FOOD SECURITY AND SAFETY

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