

The Future of Agricultural Biotechnology
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Thank you for inviting me to deliver the D.W. Brooks Lecture here at the College of Agricultural and Environmental Sciences at the University of Georgia. It is truly an honor and privilege to be with you today.

For this historic lecture, I have chosen to focus on the most revolutionary technology in the history of agriculture—biotechnology. The technology has proceeded with stunning success during the past five years. However, the technology has also been the center of controversy. This lecture is therefore not only about the many benefits biotechnology offers, but also the issues evolving around the technology.

The Biotechnology Industry Organization (BIO) for which I work is a novel trade association because it is one of the few associations centered on a technology rather than a specific commodity or product. BIO's membership includes over 1,000 companies and universities in North America and around the world. These members are actively involved in research and development of biotechnology for use in new medicines, foods and industrial products to benefit people's lives and the environment.

Agricultural biotechnology is a precise science that enables us to find the most beneficial traits, in terms of added nutrition, increased safety or greater ability to fight pests or diseases, and incorporate them into various organisms. Biotechnology can isolate a particular gene (or trait) in one organism, remove it and then transfer it to another organism, where this same gene replicates itself, creating a stronger and more resilient new variety. Mankind has been doing this for millennia, as far back as the ancient Mesopotamia and early Native American civilizations. On one level, this process is not unlike adding a new ingredient to a recipe or a new shade to a painting. The only real difference is the increased precision, predictability, safety assurance and breadth of genetic material that can be used. Biotechnology is providing practical answers to some of the greatest challenges we face at the dawn of a new millennium, such as hunger and malnutrition, as well as more effective ways to prevent diseases and treat serious illnesses. Biotechnology is an accessible and exciting new development that is already improving the way we live.

Worldwide Rapid Adoption of Agricultural Biotechnology

Discoveries in biotechnology allow some key crops to have their own protection against insects and disease, allowing these crops to be grown using less chemical pesticides. These new

varieties have been adopted by farmers in this country and elsewhere at a rate never before seen in history. Today they are planted on over 100 millions acres around the world. In the United States, in a matter of only five years, over 65 percent of the soybeans, almost 70 percent of the cotton, and 25 percent of the corn are varieties that have been enhanced through the use of biotechnology, according to the U.S. Department of Agriculture. For hybrid corn, one of the most recent technological revolutions in agriculture, it took almost 30 years to reach comparable adoption rates.

In other countries, we see this rapid rate of adoption as well. According to the International Service for the Acquisition of Agribiotechnology Applications (ISAAA) in 2000, over 65 percent of the canola, almost 50 percent of corn and about 20 percent of soybeans planted in Canada are of varieties improved through biotechnology. In Argentina, almost the entire soybean crop consists of Roundup-Ready soybeans. In Mexico, over 30 percent of the cotton is Bt cotton. In Australia, 35 percent of the cotton is Bt cotton. In Brazil, Roundup-Ready soybeans are still not formally approved, but numerous sources agree that at least 20 percent of the soybeans grown in Brazil today are Roundup-Ready soybeans smuggled in from Argentina. China is also entering the picture; approximately 10 percent of its cotton acreage is Bt cotton. It is interesting to note that these unprecedented rates of adoption have wherever governments have established rational, science-based regulations and refrained from erecting barriers to the new products.

The obvious question is, Why has there been such rapid acceptance of these new varieties by farmers around the world? The answer is straightforward: It makes a difference to the farmer's economic bottom line. It either increases yields or decreases input costs, or does both. The most obvious input costs that have declined are for pesticides because in most cases less pesticide is needed. For example, the National Center for Food and Agricultural Policy reports that cotton pesticide usage has declined by over 50 percent. Research is also documenting the fact that fertilizer efficiency has increased, there is more flexible weed control—especially for soybeans—and the technology promotes conservation tillage, protects water quality and aids in soil conservation.

The Biotech Pipeline

In the next few years, the focus will be on enhancements to “first wave” agronomic traits such as Bt varieties that protect the plant against pests as the corn rootworm, which causes millions of dollars in losses to farmers every year. New varieties will be available with stacked traits that allow the farmer to choose which trait needs to be expressed to combat a specific pest. For example, if the European corn bore is present, the farmer can apply a non-toxic chemical to the plant that will activate a gene to express the protein to which the corn bore is susceptible.

Over the next five years biotechnology will develop many more products that will radically change American agriculture. We'll see a shift in emphasis to “second wave” value products that include enhanced human foods, livestock and industrial products, and pharmaceuticals.

Livestock Products

The use of biotechnology in livestock and associated products is moving forward on three fronts: 1) improved animal health, 2) pharmaceutical production and 3) product improvement. Improved animal health includes vaccines such as the pseudorabies vaccine in hogs already in use and TickGard for cattle. Those technologies could not have been brought to market as quickly nor be as efficacious without biotechnology techniques.

An extremely exciting area of research and development is the use of animals in pharmaceutical product production. To date, the most promising work is in milk and eggs. In particular, sheep milk has been used in treatment of cystic fibrosis, goat milk in cancer therapy, mice milk for rheumatoid arthritis and the chicken egg for influenza. And the production of therapeutic proteins causes no ill effects to the animal involved.

Finally, very promising biotechnology research is focused on improving animal production with respect to nutritional quality and the environment. Reducing the fat in meat is a major research objective. This is being done in a couple of ways. One line of research injects recombinant somatotropin into the animal, which redistributes nutrients and causes the animal to produce more muscle (meat) and less fat. Most work to date in this area has been with hogs. Another way is through research focused on the animal genome and the use of bioinformatics. As more is learned about the genomics of cattle, hogs and poultry, genes can be identified that enhance the production of meat and reduce the proportion of fat.

Animal genomics may be used to protect the environment. Scientists today are genetically engineering hogs to produce less-polluting wastes. A leading source of water pollution is phosphate in animal manure. Hogs and chickens are the primary producers of phosphorous because they lack the enzyme phytase, which is needed to digest phytates, the main source of phosphorous in plant feed. It is now possible through the use of biotechnology to produce the missing enzyme in their saliva. The result is that hogs can digest phytates and excrete 75 percent less phosphorous in their manure.

Enhanced Foods

A great deal of research in food is focused on enhancing its nutritional benefits, improving food safety and producing new vaccines.

Nutritional Benefits—One of the most recent discoveries is with tomatoes. Tomatoes are an excellent source of the carotenoid lycopene, a compound that protects the body against prostate cancer, and flavonols, which are potent antioxidants correlated with lowering the risk of cardiovascular disease. Through the transfer of genetic material from petunia into tomato, the result is a transgenic tomato line with significantly increased flavonols. Similar research is being undertaken to add vitamin E, an anti-oxidant thought to prevent cancer, to vegetable oils; to reduce the harmful saturated fats of cooking oils; and to increase protein quality in vegetables.

Another example is the development of “golden rice.” Rice, a main food staple in developing countries and often the only food available in the dry season, is deficient in vitamin A causing a half million children to go blind every year and making many more vulnerable to a variety of diseases. The World Health Organization estimates that more than 124 million children suffer from vitamin A deficiency and 1 million to 2 million children die each year for lack of vitamin A. Through the use of biotechnology, rice is being developed that contains beta carotene, a source of vitamin A. Giving the plant two genes from the daffodil and one from a bacterium enables it to produce more nutritious rice that is golden in color. Golden rice is a potential solution to vitamin A deficiency and the blindness and disease it causes.

Food Safety—Many people cannot eat foods such as peanuts, milk and bread because they have an allergic reaction to these foods. For example, nearly 3 million consumers cannot eat peanuts. Research is under way to identify and remove the genes producing the protein responsible for the allergic reaction in susceptible people. Nonallergenic peanuts would enable many consumers to eat peanuts, potentially lift bans on serving peanuts in schools and enabling consumers to benefit from the protein, fiber, vitamin E and folate peanuts provide.

Vaccines—Very promising research is resulting in foods that may one day contain vaccines. Transgenic potatoes may carry the vaccine for hepatitis B, bananas may contain a cholera vaccine and lettuce a vaccine for measles. This is especially important for the developing world, where it is very expensive to purchase, transport and store vaccines. Transforming food into a source of these vaccines can be a much more effective and less costly way of providing these needed vaccines to developing countries.

Forestry

The applications of biotechnology in agriculture are not limited to food and feed crops: some research on forestry and trees is also underway. Researchers are exploring ways to make trees grow more quickly and to be more disease and stress resistant. For example, scientists are working on changing the amount of a tree’s lignin – a substance that helps provide rigidity. Reducing lignin could improve the ease and efficiency of processing trees into paper. Alternatively, increasing lignin content could be desirable for lumber and could possibly provide advantages for energy production when wood is used as fuel.

Plant-derived Biologics

Plants are a tremendous source of protein for the development of pharmaceuticals and industrial chemicals. Research is under way in genetically modifying plants to include a protein with potential human or animal therapeutic value. Many laboratories have demonstrated that plants can yield proteins as pure and effective as those manufactured in other ways. Plant-derived biologics have huge advantages: tremendous cost savings, unprecedented large-volume production capacity, reduced capital requirements, relatively fast production and freedom from potential viral and animal protein contamination. Research is showing broad potential application for such illnesses as cancer, inflammatory diseases, autoimmune diseases and cardiovascular disease.

The same is true for the production of industrial chemicals. Research indicates that plants can be modified to produce proteins that become components of detergents, nylon, glue, paints, lubricants and plastics. The potential is very high that plants can be the source of biodegradable plastic polymers that will benefit environmental quality. In essence, plants such as corn, soybeans and tobacco can become “mini factories.”

Policy Issues

The promise of this technology is practically boundless. But as with any new technology, issues do arise. The balance of this paper will survey and briefly describe these issues. I say “survey” because for any one issue, a paper or book could easily be devoted to that topic to do it justice. The controversy associated with agricultural biotechnology covers issues in agricultural production, food safety, labeling, environment, intellectual property, developing countries, food security, research and international trade.

Agricultural Production

Issues of agricultural production include contracting, liability and concentration. Contracting is an issue with farmers because they have witnessed the way contract farming has gone in the broiler and hog industries. Some are concerned that they could become hired labor and lose a good deal of their freedom to operate. However, contracts will be mostly limited to high-value specialty crops. In most cases, contracts for these crops, such as pharmaceutical or industrial use crops, will be on limited acres. And companies will deal only with the very best farmers to produce these valuable crops. The acreage under contract to a pharmaceutical or industrial company will most likely be a small portion of a farmer’s total acreage. This would be in contrast with a broiler or hog producer who is under contract for all the farmer’s production.

Liability may become an issue, especially with organic farmers who have proclaimed that their products are produced without the use of biotechnology. But, this becomes problematic with corn, for example, where pollen could unintentionally be present in an organic field. For marketing purposes, organic farmers have chosen to exclude the use of biotechnology. Therefore, they must take the necessary steps to ensure that they can meet their self-imposed obligation. This issue is more of a problem in international markets where a new crop variety approved for commercialization in this country could be still pending approval in the importing country.

Finally, there is the issue of concentration, in which a few large farm operations account for the vast majority of the food supply and past technology innovations have accelerated the trend to more concentration. However, the technology in products on the market today is captured in the seed, which is about as scale neutral as a new technology can be. The seed is more expensive than traditionally bred seed, but in most cases, the farmer reduces costs on chemical inputs—especially pesticides—which in most cases more than offsets the higher seed costs. So small as well as large farmers can adopt these new varieties.

Environmental and Food Safety Issues

In 1986, the U.S. government put in place the Coordinated Regulatory Framework to regulate food and agricultural products produced through the use of biotechnology. The federal agencies included in the framework are the U.S. Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). The USDA, through its Animal and Plant Health Inspection Service (APHIS), oversees the field-testing of crops. A company or university must request a permit from APHIS before it can field-test its crops. Prior to commercialization, the company must receive USDA clearance. Before approval is granted, APHIS must be satisfied that little if any potential exists for the new plant to cross with a wild relative and become a weed or pest to agriculture. APHIS also must be assured that the new crop variety will have little or no impact on non-target organisms such as beneficial insects and birds.

The EPA regulates the environmental exposure to insect-protected crops (plants that produce their own pesticide) to guard against harm to the environment, beneficial insects and other living things. Before a company receives clearance from EPA, it must demonstrate that the pesticidal protein of the plant is not toxic and that it is safe for human consumption, has no harmful impact on beneficial insects and non-target organisms, and that proper procedures are in place to minimize insect resistance.

The FDA regulates new foods or food ingredients produced through the use of biotechnology by the same rules it applies to safeguard all foods in the marketplace. Nutrition and safety of each product are evaluated at many stages before reaching the consumer. To satisfy the FDA, a company must detail the origin of the new genetic material, a history of its use, a toxicity and nutritional profile, its chemical composition and its allergenic potential. In its evaluation, the FDA applies the concept of substantial equivalence. That is, any safety assessment should show that a new variety produced using biotechnology is as safe as its traditional counterparts. Both intended and unintended effects are taken into consideration. Any differences from the long history of the traditional counterpart are identified. The differences are then studied for safety.

Only after all three federal agencies have signed off on the new crop variety can a company commercialize it. In contrast, new varieties produced through traditional plant breeding have no federal oversight or evaluation of the new plant. The system has worked well for the past 15 years. It has adapted as the technology has changed and will continue to adapt as the technology evolves. Critics of biotechnology like to point to the StarLink episode as a failure of the coordinated framework. But to the contrary, the framework worked very well, especially in containing the potential problem. StarLink was a regulatory compliance issue where a company did not live up to the requirements of its product registration. Those conditions stated that StarLink corn could be commercialized only for industrial use or animal feed. It could not be used in human food. Such a condition is referred to as a split approval by the agency. As a result, the company has had its registration revoked for StarLink so it can no longer sell that variety in this country, and it will cost

the company millions of dollars in damages. In addition, the agency will not grant a split approval for a commodity grain in the future.

Labeling

The FDA established a policy in 1992 that all foods derived through biotechnology be regulated in the same fashion as those developed through traditional methods. This means:

- Products of food biotechnology are subject to the same FDA labeling and safety policies applied to all foods in the U.S. marketplace.
- Different labeling is required when, for example, biotechnology results in a significant change in the composition of a food product. Putting new proteins into a tomato for enhanced processing capabilities may be an example of a substantial compositional change.
- A label also is required if a food is changed so that its nutritional content no longer conforms to the normal expectations. Altering the Vitamin C content of an orange to levels significantly above or below the normal range is a good example.
- FDA requires a label on biotechnology products to inform consumers of any potential health or safety risk, such as if a protein poses an allergy risk, unless scientific data show that the allergen is not present.

Under FDA's current policy, manufacturers also can make voluntary biotech claims about their products such as "contains biotech ingredients" or "does not contain biotech ingredients." These claims, like all claims, must be truthful, clear and non-misleading to consumers..

Consumer surveys repeatedly demonstrate a desire among consumers for more information about the products they purchase from a variety of sources. Information available via brochures, 1-800 hotlines and Web sites help respond to this demand.

Critics of biotechnology want a mandatory label on all foods that have been produced or have ingredients produced through the use of biotechnology. To require, however, that biotech foods bear special labeling to distinguish them from their traditional counterparts would likely mislead consumers into believing that these products are unsafe or otherwise different. Such labeling would be completely inconsistent with the safety assessment framework FDA uses. Ultimately, markets will develop to cater to consumers who are interested in purchasing non-biotech foods and are willing to pay a price for that assurance—just as markets have developed for organic and other specialty foods.

FDA has developed labeling guidance for food manufacturers who want to place voluntary claims on label. The guidelines are for food with or without biotech ingredients. They will help ensure that labels are truthful and not misleading

Intellectual Property

The 1980 the U.S. Supreme Court upheld the right to patent living organisms in the now famous *Diamond v. Chakrabarty* case. That decision changed forever the landscape in research, development and commercialization of products produced using biotechnology. Today we have a

very complex patent process, and there are many legal battles over who has the rights to genetic material. The one on the front page of major newspapers today involves the rights over stem cells: A major university that owns the patent on valuable embryonic stem cells is suing a major pharmaceutical company that is seeking exclusive rights to develop therapies using them.

Agricultural biotechnology is not immune from these challenges. A major university wants to genetically engineer soybeans to improve their nutritional value. But university researchers face a scientific hurdle because the research involves a patented technique for inserting genes into the beans. In the celebrated “golden rice” discovery to alleviate vitamin A deficiency, it was covered by as many as 70 patents owned by 31 different companies or universities in various countries. Patent holders have agreed to charge no royalties for rice that is to be given free to poor farmers in developing countries. However, the licensing process has taken about a year to complete.

There are definitely growing pains in this area. Agriculture for decades has been used to having research results freely available. The gene that spurred the green revolution in the 1960s—creating high-yield grain and helping alleviate hunger—was provided to Dr. Norman Borlaug by Washington State University. Today that gene would be patented. However, gene patenting has meant that many more players are involved, and research discoveries have increased at an exponential rate. That is the trade-off before us today.

Food Security and Developing Countries

Developing countries such as India and those in Africa have an overwhelming need to increase food production. Their greatest challenge is to raise the yields of their most widely grown crops, since these are the mainstay of their subsistence farming systems. They must increase their yields because they have no significant room to expand the area of cultivation. The best way to raise yields is through seed-based technologies, which are relatively easily disseminated and which farmers can easily acquire and use. In many cases, conventional breeding to develop improved seeds has hit a plateau, and biotechnology offers the best, if not only way forward.

There are many optimistic signs that the means for developing and delivering biotechnology solutions are or will be in place. Although still under-resourced, most national public-sector research systems in many developing countries are stronger today than they were 25 years ago. A great strength of these systems is their close links with farmers and extension services. Many of the genes for resistance to the stresses that constrain agriculture in developing countries are already present in their crops, either in traditional landraces or in improved varieties. And their farmers will increasingly be able to assert their ownership of the genes found in landraces and other indigenous materials.

To be successful, noted African scientist and author Dr. Florence Wambugu has written that developing countries will need to 1) start with the simple technologies, 2) focus on crops important to poor producers and domestic producers, 3) find out whether biotechnology innovation will meet farmers’ needs before development, 4) make sure products reach farmers’ fields quickly, 5) link their national research system to regional and international networks, 6) establish a credible

regulatory system, 7) stimulate development of a national private sector and 8) be open and transparent. Those make good sense to me.

Public-Sector Research

Government spending for food and agricultural research has slowed. In industrialized countries, public spending has been growing 1.8 percent a year and private spending 5 percent, according to the International Food Policy Research Institute. USDA's research budget of approximately \$2 billion has basically seen no growth in real terms over the last two decades.

In the United States, private agricultural spending surpassed public spending in the early 1980s, and the gap has widened since then. By 1994, two-thirds of American plant breeding was in the private sector. A major fallout from this trend is the inattention to minor crop research. Even in wealthy countries, companies are not likely to devote much effort to minor crops.

Universities find themselves in a tough spot. Unable to obtain any significant real increases in public funding for research, a small but growing proportion of their research funding now comes from the private sector—many times in exchange for first rights to licensing some university discoveries. While critics on campus say this situation threatens academic freedom, universities argue that they get needed funding and access to crop gene databases required for plant research but which they cannot develop on their own. Without significant funding increases from the public sector, this situation will only get more complex and raise more questions.

There is an attempt to reclaim some of the lost ground. A new group, the National Coalition for Food and Agricultural Research, has formed this year, made up of national farm groups and food and agricultural trade associations to lobby the administration and Congress for increased funds. Its goal is to double the public-sector funding for food and agricultural research. But in an atmosphere of perceived plenty, it will be a very tough sell.

In the meantime, the public sector will continue to tap into the funding and technology of the private sector. Companies in many cases are showing more willingness to enter into partnerships with universities with less restrictions on the technology, especially for assistance in sequencing crop genomes, which is providing too much information for companies to analyze alone. In the end, both sectors need one another, which is a good environment for compromises to occur on the working arrangements of the partnership.

International Trade Issues

Many trade issues could be discussed. For the sake of brevity, I will focus on the main bilateral trade issue—Europe—and the most important multilateral forums important to biotechnology.

This summer the European Commission proposed new measures that would require almost all foods produced using biotechnology to be labeled. The Commission further proposed that biotechnology crops be subject to a traceability system. The Commission believes the new

measures are required to build public confidence in biotechnology for the benefit of consumers and a European industry that has largely been denied the opportunities of the biotechnology revolution.

However, the Commission's proposals would have just the opposite effect. In reference to the BSE crisis, David Byrne, the European Union commissioner for health and consumer protection, said that the Commission actions spring more from a desire to look for "some magic solution or some new measure which will impress the public" instead of an interest in enforcing and using existing regulation. The new Commission proposals fall into the same category and will further undermine, rather than bolster, public confidence. The Commission proposals directly violate the European Union's World Trade Organization (WTO) obligations under the General Agreement on Tariffs and Trade (GATT), the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the Agreement on Technical Barriers to Trade (TBT Agreement). Unless the Commission comes to its senses, the United States will have no choice but to seek sanctions from the EU through the WTO for violating its agreements.

The main multilateral international forums heavily engaged in biotechnology issues are the Biosafety Protocol, Codex Alimentarius and the WTO. The Biosafety Protocol specifically focuses on transboundary movement of any living modified organism resulting from biotechnology that may harm conservation and sustainable use of biological diversity. It is basically a multilateral environmental agreement. Its main impact is on seeds exported for planting purposes; it does not affect the structure for international trade of bulk commodities. A concern is that it could put the use of science-based decisions at risk. It boils down to the United States and a few countries exporting biotech varieties versus Europe, which is trying to impose numerous roadblocks.

The Codex Alimentarius Commission develops the international standards for food safety. It has devoted a great deal of its time in the past few years on food or food ingredients produced through the use of biotechnology. Specific to biotechnology, its committees are working on model safety analysis for plants and microorganisms, food labeling guidelines, traceability and use of the precautionary principle in risk assessment. European Union countries are making serious efforts to turn the commission away from science-based decisions in an effort to slow down and in some cases stop the development of this technology. So far their efforts have been in vain, but it requires close monitoring.

The provisions of the WTO agreement among nations contain no specific reference to food and agricultural products produced using biotechnology. For any disputes related to food safety, its charter directs the WTO to rely on the standards developed by the Codex Alimentarius Commission. Nevertheless, some countries are attempting to include biotechnology in the WTO's provisions. Another issue is the role of the Biosafety Protocol vis-à-vis the WTO. If provisions of one agreement conflict with the other, which has precedent? Some argue that the WTO would take precedent since it contains a clause stating that no other multilateral agreement can take precedent but the Biosafety Protocol contains a similar clause. At some point the issue is sure to be tested.

Closing Comments

Agricultural biotechnology is clearly one of, if not the most dynamic technologies in our history. Time and scientific ingenuity are the only limitations on the ability of biotechnology to improve our lives. But the science is beginning to outrun many policy institutions struggling to keep pace—especially in the international arena. The public and private sectors must renew their efforts to work together with a common goal to achieve the promise of the technology for all. It will require creative and sustained leadership from both sectors to make it happen.

Former President Jimmy Carter summed it up best when he noted recently that agricultural biotechnology was providing real answers to some of the greatest challenges we face at the dawn of a new century, such as hunger, malnutrition and disease. He said, “Responsible biotechnology is not the enemy; starvation is. Without adequate food supplies at affordable prices, we cannot expect world health, or peace.” I can’t say it better than that.

Thank you.