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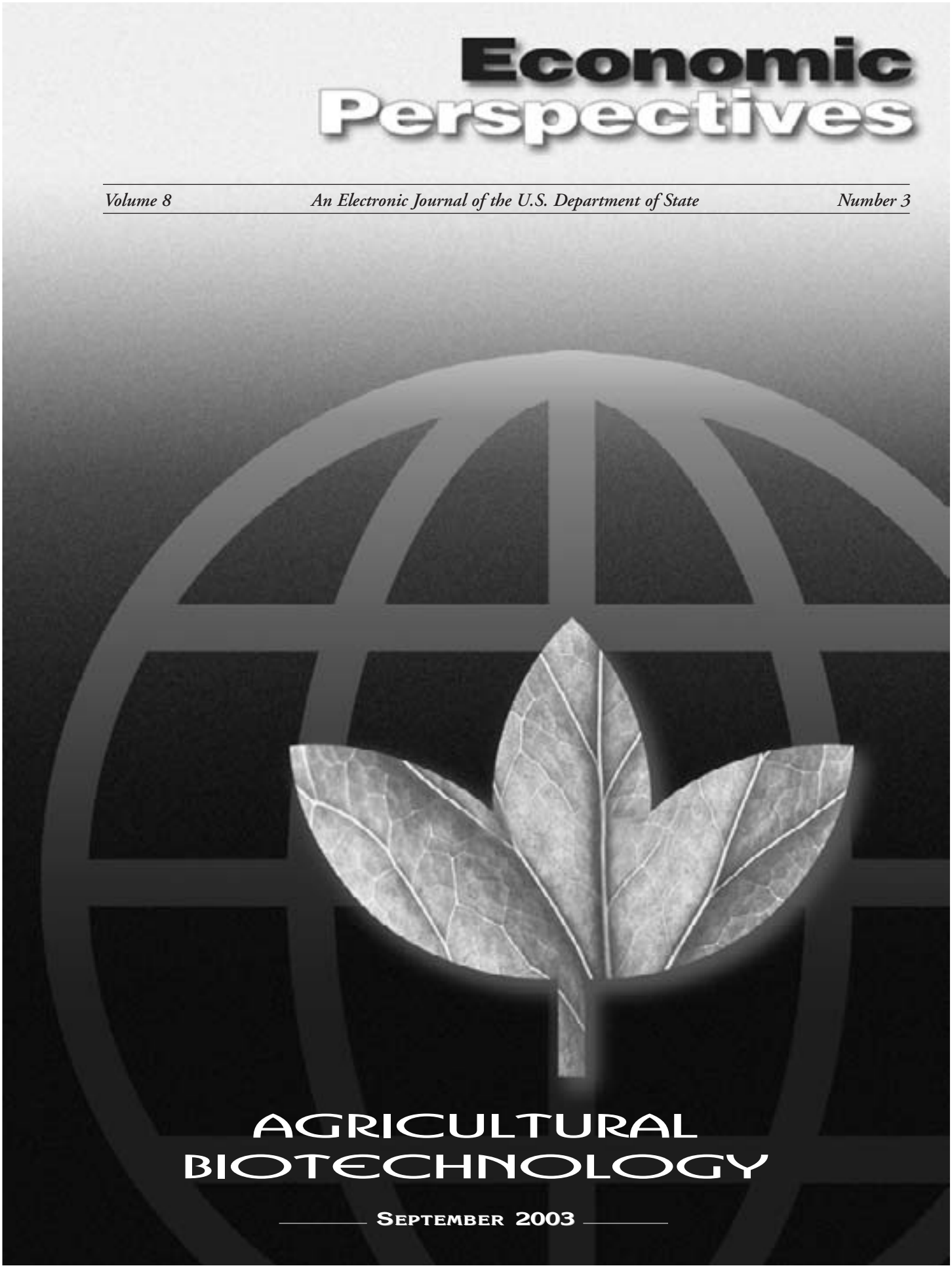

AGRICULTURAL BIOTECHNOLOGY

SEPTEMBER 2003

ECONOMIC PERSPECTIVES

Agricultural Biotechnology

U.S. DEPARTMENT OF STATE *ELECTRONIC JOURNAL* *VOLUME 8, NUMBER 3*

Science and technology helped revolutionize agriculture in the 20th century in many parts of the world. This issue of *Economic Perspectives* highlights how advances in biotechnology can be adapted to benefit the world in the 21st century, particularly developing countries.

Increasing yield potential and desirable traits in plant and animal food products has long been a goal of agricultural science. That is still the goal of agricultural biotechnology, which can be an important tool in reducing hunger and feeding the planet's expanding and longer-living population, while reducing the adverse environmental effects of farming practices.

In a supportive policy and regulatory environment, biotechnology has enormous potential to create crops that resist extreme weather, diseases and pests; require fewer chemicals; and are more nutritious for the humans and livestock that consume them. But there is also controversy surrounding this new technology. The journal addresses the controversies head on and provides sound scientific reasoning for the use of this technology.

In June 2003, agriculture, health and environment ministers from over 110 countries gathered in California and learned first hand how technology, including biotechnology, can increase productivity and reduce global hunger. By sharing information on how technology can increase agricultural productivity, we can help alleviate world hunger.

Contributors to this journal include Under Secretary of State Alan Larson, Under Secretary of Agriculture J.B. Penn, Deputy Food and Drug Administration Commissioner Lester Crawford, and Ambassador Tony Hall, U.S. Representative to the U.N. Agencies for Food and Agriculture, who address a broad range of topics from the basic science of biotechnology to food safety and labeling issues. Their articles are complemented by essays from an internationally respected group of researchers and academics, a State Department fact sheet on the Cartagena Biosafety Protocol and additional resource information.

Ann M. Veneman
Secretary
U.S. Department of Agriculture

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

CONTENTS

AGRICULTURAL BIOTECHNOLOGY

❑ FOCUS

❑ COMMENTARY

RESOURCES

ECONOMIC PERSPECTIVES

An Electronic Journal of the U.S. Department of State *Volume 8, Number 3, September 2003*

The Bureau of International Information Programs of the U.S. Department of State provides products and services that explain U.S. policies, society and values to foreign audiences. The Bureau publishes five electronic journals that examine major issues facing the United States and the international community and that provide information about U.S. society and values. The journals — *Economic Perspectives, Global Issues, Issues of Democracy, U.S. Foreign Policy Agenda, and U.S. Society and Values* — provide statements of U.S. policy together with analysis, commentary and background information in their thematic areas.

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Current or back issues of the journals, and the roster of upcoming journals, can be found on the Bureau of International Information Programs' web site at http://usinfo.state.gov/journals/journals.htm. They are available in several electronic formats to facilitate viewing on-line, transferring, downloading and printing.

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❑ TRADE AND DEVELOPMENT DIMENSIONS OF U.S. INTERNATIONAL BIOTECHNOLOGY POLICY

By Alan Larson, Under Secretary of State for Economic, Business and Agricultural Affairs

Science-based regulation of agricultural biotechnology contributes to the free trade of safe biotech applications and to the appropriate use of this technology to promote development, writes Alan Larson, under secretary of state for economic, business and agricultural affairs. Larson adds that biotechnology — one of the most promising new technologies of our times — is too important for the future prosperity of the world to ignore.

Biotechnology is one of the most promising new technologies of our times. The expanding use and trade of agricultural biotechnology-derived products is enhancing prosperity and well-being both in developed and developing countries. Unfortunately, while the United States and many other nations around the world are expanding the development and use of safe biotechnology-derived products, some countries have imposed unjustified restrictions on them. Such restrictions threaten the international trading system and are preventing developing countries from exploring the enormous potential of biotechnology to improve the lives of their people.

BIOTECHNOLOGY AND DEVELOPMENT

In 2000, the world's population was about 6 billion. It is expected to increase to 9 billion by 2050. As a result, there will be more people to feed on an increasingly crowded planet. Food production will have to increase, and it must increase in an environmentally sustainable way. Since 1980, 50 percent of the increased agricultural productivity in the developing world came through improved seed technology. Better seeds can come from improving traditional methods, developing conventional hybrids, and through biotechnology. Biotechnology, while not a panacea, can make an important contribution.

Agricultural biotechnology achieves enhanced crop productivity in a more environmentally sustainable way. In the United States, the growing use of agricultural biotechnology is resulting in reduced use of pesticides and increased adoption of environmentally friendly farming practices such as "no-till" farming, which reduces soil erosion and fertilizer run-off. Enhanced productivity means that more food can be raised on the same amount of land. As population pressure grows in the coming years, the ability to grow enough food for the world's burgeoning population without encroaching on vital habitats such as tropical rainforests will be of enormous benefit to the environment.

The United States is not the only country that is reaping the benefits of biotechnology. New crops derived from biotechnology are being used in developing countries such as Argentina, South Africa, China, the Philippines and India. The attraction of biotechnology in these countries lies in the direct benefits these varieties bring to the developing country farmer. In China, for example, where small farmers grow biotechnology-derived insect-resistant cotton varieties in great numbers, these varieties require fewer pesticides, which not only reduce costs, but also significantly reduce exposure to dangerous chemicals. As a result, farmers are healthier and have expanding incomes that let them buy better food for their families or send a child to school rather than have that child work in the fields. Such results, spread over the population of an entire country where farmers are by far the largest percentage of the population, provide the opportunity for development and improved prosperity.

The challenge is to make tried and tested biotechnology varieties available to more developing countries and to help develop new varieties specifically adapted for their conditions. This is why the United States supports the development of biotechnology-derived staple food crops that will fight disease such as insect-resistant cowpeas, disease-resistant bananas, cassava and sweet potatoes. Biotechnology may also offer a quicker route for under-nourished populations to get access to a better diet. For example, a Vitamin A enriched rice variety known as "golden rice" is under development to help fight blindness caused by malnutrition.

The potential benefits of this new technology should not be thrown away or delayed unnecessarily. Last year a few African nations balked at receiving badly needed food aid — food most Americans eat every day — because of unscrupulous and unscientific fear mongering. This must

stop. Rather, the international community should reach out to developing countries — as the United States is doing — to explain how safe biotechnology-derived products can be regulated, used domestically, and traded abroad to the benefit of all.

BIOTECHNOLOGY AND TRADE

Despite the benefits of biotechnology for both the developed and developing world, biotechnology-derived crops are at the center of a number of contentious trade disputes. This is the case even though more than 3,200 esteemed scientists around the world — including 20 Nobel Laureates — have concluded that the biotechnology-derived products currently on the market do not pose greater risks to human health than their conventional counterparts.

The only way to maintain a free and fair trading system is for products traded in that system to be regulated in a logical, objective and science-based manner. When such a system is in place, we can have confidence in the safety of the products we trade. How biotechnology-derived crops are treated in the international system will have consequences not just for biotechnology, but also for all new technologies. It is important that we get this right.

The rules governing the trade of biotechnology-derived products, and indeed all products, must be based on scientific risk assessment and risk management. The World Trade Organization (WTO) Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) requires that measures regulating imports be based on "sufficient scientific evidence" and that countries operate regulatory approval procedures "without delay."

When science is the basis of decision-making, countries find it easier to agree on rules. For example, the Codex Alimentarius Commission recently approved science-based guidelines for biotechnology food safety assessments relating to human health. These guidelines were approved unanimously by the Commission, which is composed of 169 members, including the U.S., EU (European Union) member countries, and the vast majority of developing nations.

Three international standard setting bodies, including Codex, are specifically recognized by the WTO SPS Agreement. The Codex Alimentarius Commission develops food safety standards. The International Plant Protection Convention (IPPC) focuses on preventing the spread and introduction of pests in plants and plant products. The Office of International Epizootics (OIE) performs a similar function for animal health. All three organizations base their work on scientific analysis. It is essential for the integrity of the international trading system that the WTO continue to refer to the work of these bodies in assessing biotechnology products and that these organizations continue to perform science-based work.

The U.S. supports workable, transparent and science-based regulations for agricultural biotechnology applications. In fact, the U.S. government provides technical assistance to countries to help them develop their own capacity to regulate this technology and put it to use for the benefit of their citizens. When countries adopt a science-based approach to biotechnology, fair rules for the regulation and trade of biotech products can be established. The U.S. is committed to pursuing such a science-based approach to biotechnology with its trading partners and is convinced that this approach is the best way to ensure a fair and safe trading system for agricultural biotechnology products.

CONCLUSION

Agricultural biotechnology can help both the developing and developed world enhance productivity while preserving the environment. Science-based regulation of agricultural biotechnology applications contributes to the free trade of safe biotech applications and to the appropriate use of this technology to promote development.

Scientists around the world, including those in the European Union, agree that there is no evidence that approved biotechnology-derived foods pose new or greater dangers to the environment or to human health than their conventional counterparts. Indeed, any alleged downsides to agricultural biotechnology lie in the realm of the theoretical and potential. The upsides have already been demonstrated. Biotechnology is too important for the future prosperity of the world to ignore.❑

❑ AGRICULTURAL BIOTECHNOLOGY AND THE DEVELOPING WORLD

By J. B. Penn, Under Secretary of Agriculture for Farm and Foreign Agricultural Services

Biotechnology has the potential to play a large role in more rapidly advancing agricultural productivity in developing countries while protecting the environment for future generations, writes J.B. Penn, under secretary for farm and foreign agricultural services at the U.S. Department of Agriculture. Penn says biotechnology is simply another crop improvement tool in the long history of cultivation.

Agricultural biotechnology has been changing the face of agriculture since its commercial introduction in 1996 and the widespread adoption of bioengineered crops by farmers in the United States and other countries. However, this technology is not without controversy and is causing political reverberations around the world. While it holds enormous promise for significantly increasing food production and relieving already strained land and water resources, it has become an emotional issue among some consumers and environmental groups. As the science continues to be developed, it clearly will present both opportunities and challenges to participants throughout the food chain.

BACKGROUND ON CONVENTIONAL PLANT BREEDING

Almost all plants can be considered “genetically modified.” Genetic modification occurs when plants within a species simply produce offspring. The offspring is not exactly like either of the parents; it is a genetic combination of both. For centuries, plants have been cultivated and cross-bred by man to produce offspring with specific, desired traits. For example, maize as we know it today barely resembles its ancestor, teosinte, or Zea mexicana, a tall grass that produces finger-length "ears" containing a single row of a few grains. Maize produced today has been cultivated for many years to serve as a food crop, with far different traits than those of its predecessors.

When varieties are cross-bred to produce a hybrid plant, millions of genes are combined in the process. Scientists must select and continually cross-breed the plants, often over a period of several years, to obtain plants with the largest number of desired traits and the least number of undesirable traits.

HOW IS BIOTECHNOLOGY DIFFERENT?

Modern biotechnology is a tool that allows scientists to select a single gene for a desired trait, incorporate it into plant cells, and grow plants with the desired trait. In many ways it is simply a “high-tech” version of traditional plant breeding. This more efficient process prevents millions of genes from being crossed and possibly producing undesirable traits. Biotechnology is also different because it allows scientists to incorporate genes from other species — something that cannot be done via conventional plant breeding. This makes biotechnology a very powerful and useful tool for plant breeders.

Some people fear this tool because it is perceived as “unnatural.” However, most people forget that the food crops we have today would not exist without man's intervention, whether through plant breeding, fertilizer application, delivery of irrigation water or use of modern tractors and equipment. Without cultivation by man over the years, we would still have teosinte instead of conventional maize. The same is true for wheat, tomatoes, potatoes, watermelon and any product on today's supermarket shelf. Thus, biotechnology is simply a modern, additional tool in the long history of plant cultivation and agriculture.

AGRICULTURAL BIOTECHNOLOGY TODAY

While the focus of the first “generation” of biotech crops has been on the considerable economic benefits to farmers, more and more evidence is accumulating that significant food safety and environmental benefits are beginning to accrue.

Farmers have indicated their acceptance of biotech varieties by the unprecedented pace in which they have

been adopted. According to the U. S. Department of Agriculture (USDA), in the United States approximately 80 percent of soybeans, 38 percent of maize and 70 percent of cotton were planted to biotech varieties in 2003. The United States is not alone in experiencing this evolution in agriculture. Adoption rates in other countries, such as Argentina, Canada and China, where biotech varieties are approved, have been similarly rapid.

According to the National Center for Food and Agricultural Policy in Washington, D.C., U.S. farmers have realized the following benefits through the use of biotech varieties:

- Roundup Ready soybeans: 28.7 million lbs. (13,018.3 metric tons)/year decrease in herbicide use; $1.1 billion/year savings in production costs.

- Bt cotton: 1.9 million lbs. (861.8 metric tons)/year decrease in insecticide use; 185 million lbs. (83,916 metric tons)/year increase in cotton production.

- Bt maize varieties: Over 16 million lbs. (7,257.6 metric tons)/year decrease in insecticide use; 3.5 billion lbs. (1,587,600 metric tons)/year increase in production volume.

- Papaya: Virus-resistant biotech papaya saved the Hawaiian papaya industry $17 million/year in 1998 from the devastating effects of ringspot virus.

These results illustrate enormous decreases in pesticide use, with corresponding environmental enhancement, along with equally dramatic increases in production and savings in production costs. While biotech results vary by farm, the economic benefits obviously have been significant. These benefits are realized not only by farmers, but also by the environment and to consumers in general.

- The reduced reliance of biotech varieties on chemical inputs means less water pollution.

- Reduced chemical usage results in safer water supplies and higher quality drinking water as well as a better environment for wildlife.

- Higher yielding biotech crops can help ease the strain on land resources, reducing the need for expansion onto more fragile areas and thus allowing for greater conservation of natural habitats.

- Energy usage on biotech crops is lower because there are fewer passes through fields in applying chemicals. Less fuel use means less carbon entering the atmosphere as carbon dioxide (CO_2).

- Herbicide-resistant crops encourage the adoption of conservation tillage, especially no-till, which reduces erosion of topsoil.

WHAT'S NEXT?

Current research will lead to food crops that are resistant to environmental pressures such as drought, temperature extremes and salty soil. Scientists around the world are also investigating the "second generation" of biotech products — those with direct consumer benefits such as enhanced nutrition levels. Many of us have heard of “golden rice,” which contains higher levels of beta carotene — an important component in vitamin A production. Scientists in India are working to develop a biotech potato variety with higher levels of protein. Edible vaccines could also be produced by plants to provide low-cost, low-maintenance medicines. These are just a few of the numerous examples of cutting edge research that will further the changes we have already witnessed in the global food chain. The possibilities are enormous.

IMPLICATIONS FOR THE DEVELOPING WORLD

Global population projections suggest an additional 725 million mouths to feed in just 10 years. By 2020, this will grow to 1.2 billion more people to feed — equivalent to the populations of all Africa and South America combined. This expansion comes despite the fact that today some 800 million people — nearly one in seven — face chronic hunger. This is especially devastating to the world's children, where one in three is undernourished, and a child dies every five seconds due to hunger.

Biotechnology alone will not feed tomorrow’s world. However, this far-reaching agricultural technology, in combination with political and economic reforms, can increase crop productivity by increasing yields and improving the nutritional content of crops in developing countries. It will also help provide lower-cost food to low-income consumers. Bringing such benefits to developing countries would have far-reaching results, indeed.

An annual increase of 3 to 4 percent in African crop and livestock yields would almost triple per capita incomes while reducing the number of malnourished children 40 percent. Increased agricultural productivity will drive economic growth and expand opportunities to trade, bringing more and better jobs, better health care, and better education.

Consumers in developing countries spend a high proportion of their disposable income on food, which could be reduced with a more efficient food system, thereby leaving more of their income for other products to enhance their quality of life.

The most critical areas in the world for bringing economic prosperity and stability are the developing countries. Agricultural productivity in these countries must advance more rapidly to meet growing food demand and raise incomes while protecting the environment for future generations. Biotechnology has the potential to play a large role in this achievement. ❑

❑ UNDERSTANDING BIOTECHNOLOGY IN AGRICULTURE

By Lester M. Crawford, Deputy Commissioner, U.S. Food and Drug Administration

Bioengineering provides distinct advantages over traditional breeding technologies because the risk of introducing detrimental traits is likely to be reduced, says Deputy U.S. Food and Drug Administration Commissioner Lester Crawford. Crawford, a doctor of veterinary medicine by training, argues that there are no scientific reasons that a product should include a label indicating that it, or its ingredients, was produced using bioengineering. He also outlines draft guidelines to strengthen controls that would prevent biotech products in field trials from inadvertently getting into food or feed.

Based on two decades of experience with bioengineered foods and overwhelming scientific data that these foods are safe to eat, we believe that biotechnology can offer a safe and important tool for both exporting and food-deficit countries. This paper describes some of the basic science behind biotechnology, the U.S. regulatory structure for ensuring safe foods and U.S. policy on the issue of labeling.

CROSS-BREEDING, HYBRIDIZATION AND BIOENGINEERING

Scientists have been improving plants by changing their genetic makeup since the late 1800s. Typically, this has been accomplished through cross-breeding and hybridization, in which two related plants are cross-fertilized and the resulting offspring have characteristics of both parent plants. In the breeding process, however, many undesirable traits often can appear in addition to the desirable ones. Some of those undesirable traits can be eliminated through additional breeding, which is time consuming. Breeders can then further select and reproduce the offspring that have the desired traits. Many of the foods that are already common in our diet are obtained from plant varieties that were developed using conventional genetic techniques of breeding and selection. Hybrid maize, nectarines, which are genetically altered peaches, and tangelos, which are a genetic hybrid of a tangerine and grapefruit, are all examples of such breeding and selection.

Today, by inserting one or more genes into a plant, scientists are able to produce a plant with new, advantageous characteristics. The new gene splicing techniques are being used to achieve many of the same goals and improvements that plant breeders historically have sought through conventional methods. They give scientists the ability to isolate genes and introduce new traits into foods without simultaneously introducing undesirable traits. This is an important improvement over traditional breeding. Because of the increased precision offered by the bioengineered methods, the risk of introducing detrimental traits is actually likely to be reduced.

FOOD SAFETY CONCERNS

The U.S. Food and Drug Administration (FDA) has found no evidence to indicate that either ordinary plant deoxyribonucleic acid (DNA) or the DNA inserted into plants using bioengineering presents food safety problems. Nor are the small amounts of the newly expressed proteins likely to change dramatically the safety profile of the plant. If safety concerns should arise, however, they would most likely fall into one of three broad categories: allergens, toxins or anti-nutrients. FDA has extensive experience in evaluating the safety of such substances in food. It is important to note that the kinds of food safety testing typically conducted by developers of a bioengineered food crop to ensure their foods meet all applicable requirements of the Food, Drug and Cosmetics Act (FD&C Act) address these potential concerns. In the event that something unexpected does occur, this testing provides a way to detect such changes at the developmental stage and defer marketing until any concern is resolved.

As aforementioned, some of the food safety concerns that could arise include:

Allergens: Foods normally contain many thousands of different proteins. While the majority of proteins do not cause allergic reactions, virtually all known human allergens are proteins. Since genetic engineering can introduce a new protein into a food plant, it is possible

that this technique could introduce a previously unknown allergen into the food supply or could introduce a known allergen into a "new" food.

Toxins: It is possible that a new protein, as introduced into a crop as a result of the genetic modification, could cause toxicity.

Anti-nutrients: It is possible that the introduction of anti-nutrients, such as molecules like phytic acid, could reduce essential dietary minerals such as phosphorus.

The use of genetic engineering techniques could also result in unintended alterations in the amounts of substances normally found in a food, such as a reduction of Vitamin C or an increase in the concentration of a naturally occurring toxicant in the plant food.

LEGAL AND REGULATORY ISSUES

One important component in ensuring food safety is the U.S. regulatory structure. The FDA regulates bioengineered plant food in conjunction with the United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA). FDA has authority under the FD&C Act to ensure the safety of all domestic and imported foods for man or animals in the United States market. The exceptions to this are meat, poultry and certain egg products, which are regulated by USDA. The safety of animal drug residues in meat and poultry, however, is regulated by FDA. Pesticides, including those bioengineered into a food crop, are regulated primarily by EPA. USDA's Animal and Plant Health Inspection Service (APHIS) oversees the agricultural and environmental safety of planting and field testing bioengineered plants.

Bioengineered foods and food ingredients must adhere to the same standards of safety under the FD&C Act that apply to their conventionally bred counterparts. This means that these products must be as safe as the traditional foods in the market. FDA has the power to remove a food from the market or sanction those marketing the food if the food poses a risk to public health. It is important to note that the FD&C Act places a legal duty on developers to ensure that the foods they market to consumers are safe and comply with all legal requirements.

FOOD ADDITIVES

A substance that is intentionally added to food is a food additive, unless the substance is generally recognized as safe (GRAS) or is otherwise exempt, such as a pesticide whose safety is overseen by EPA. The FD&C Act requires premarket approval of any food additive regardless of the technique used to add it to food. Thus, substances introduced into food are either new food additives that require premarket approval by FDA, or GRAS and are therefore exempt from the requirement for premarket review. Generally, foods such as fruits, vegetables and grains are not subject to premarket approval because they have been safely consumed over many years. Other than the food additive system, there are no premarket approval requirements for foods generally.

Under FDA policy, a substance that would be a food additive if it were added during traditional food manufacturing is also treated as a food additive if it is introduced into food through bioengineering of a food crop. Our authority permits us to require premarket approval of any food additive and, thus, to require premarket approval of any substance intentionally introduced via bioengineering that is not generally recognized as safe.

Examples of substances intentionally introduced into food that would be reviewed as food additives include those that have unusual chemical functions, have unknown toxicity, or would be new major dietary components of the food. For example, a novel sweetener bioengineered into food would likely require premarket approval. In our experience with bioengineered food to date, however, we have reviewed only one substance under the food additive provisions, an enzyme produced by an antibiotic resistance gene, and we granted it approval as a food additive. In general, substances intentionally added to or modified in food via biotechnology to date have been proteins and fats that are, with respect to safety, similar to other proteins and fats that are commonly and safely consumed in the diet and, thus, are presumptively GRAS. Therefore, they have not needed to go through the food additive approval process.

PRE-MARKET CONSULTATIONS

FDA has established a consultative process to help companies comply with the FD&C Act's requirements for bioengineered foods that they intend to market. The

results of our consultations are public information and are available on our website at: http://www.cfsan.fda.gov/~lrd/biocon.html. Since the consultation process was created, companies have used the process more than 50 times as they sought to introduce genetically altered plants representing more than 10 different crops into the U.S. market. We are not aware of any bioengineered plant food that is subject to FDA's jurisdiction and is on the market that has not been evaluated by FDA through the current consultation process.

Typically, the consultation begins early in the product development stage, before the product is ready for market. Company scientists and other officials meet with FDA scientists to describe the product they are developing. The agency then advises the company on what tests would be appropriate for the company to assess the safety of the new food. After the studies are completed, the data and information on the safety and nutritional assessment are provided to FDA for review. FDA evaluates the information for all of the known hazards and also for potential unintended effects on plant composition and nutritional properties since plants may undergo changes other than those intended by the breeders. For example, FDA scientists are looking to assure that the newly expressed compounds are safe for food consumption and that there are no allergens new to the food, no increased levels of natural toxicants, and no reduction of important nutrients. They are also looking to see whether the food has been changed in any substantive way such that the food would need to be specially labeled to reveal the nature of the change to consumers.

If a plant developer used a gene from a source whose food is commonly allergenic, FDA would presume that the modified food might be allergenic. The developer, however, is allowed the opportunity to demonstrate that such food would not cause allergic reactions in persons allergic to food from the source.

Our experience has been that no bioengineered product has gone on the market until FDA's questions about the safety of the product have been answered.

LABELING

One of the most important issues confronting the biotechnology industry is that of labeling. Under the FD&C Act, a food is misbranded if its labeling is false or misleading in any particular way.

FDA does not require labeling to indicate whether or not a food or food ingredient is a bioengineered product, just as it does not require labeling to indicate which conventional breeding technique was used in developing a food plant. However, if genetic modifications materially change the composition of a food product, these changes must be reflected in the food's labeling. This would include its nutritional content (for example, more oleic acid or greater amino acid or lysine content) or requirements for storage, preparation or cooking, which might impact the food's safety characteristics or nutritional qualities. For example, one soybean variety was modified to alter the levels of oleic acid in the beans. Because the oil from this soybean is significantly different from conventional soybean oil, we advised the company to adopt a new name for that oil, a name that reflects the intended change.

If a bioengineered food were to contain an allergen not previously found in that food and if FDA determined that labeling would be sufficient to enable the food to be safely marketed, FDA would require that the food be labeled to indicate the presence of the allergen.

FDA has received comments suggesting that foods developed through modern biotechnology should bear a label informing consumers that the food was produced using bioengineering. We have given careful consideration to these comments. However, we do not have data or other information to form a basis for concluding that the fact that a food or its ingredients were produced using bioengineering constitutes information that must be disclosed as part of a bioengineered product's labeling. Hence, we believe that we have neither a scientific nor a legal basis to require such labeling. We have developed, however, draft guidance for those who wish voluntarily to label either the presence or absence of bioengineered food in food products.

STRENGTHENING CONTROLS OVER FIELD TRIALS

In August 2002, President Bush's Office of Science and Technology Policy (OSTP) proposed strengthening controls over field trials to address the potential of material from field trials inadvertently getting into food or feed.

FDA's task is to publish draft guidance for comment on procedures to address the possible intermittent, low-level presence in food and feed of new non-pesticidal proteins

from biotechnology-derived crops that are under development for food or feed use but have not gone through FDA's premarket consultation process. Under this guidance, FDA would encourage sponsors, domestic and foreign, to submit protein safety information when field testing showed that there could be concerns that new non-pesticidal proteins produced in the field-tested plants might be found in food or feed. FDA's focus would be on proteins new to such plants because FDA believes that at the low levels expected from such material, any food or feed safety concerns would be limited to the potential that a new protein could cause an allergic reaction in some people or could be a toxin.

PHARMACEUTICAL CROPS

FDA has the authority and responsibility for regulating pharmaceuticals, whether they are manufactured in a traditional manufacturing plant or manufactured in crops in the field. For crops in the field, however, there are additional issues to be addressed, including issues involving the parts of the plant that do not contain the pharmaceutical and the residual crop left over after a pharmaceutical is extracted.

In September 2002, FDA and USDA published Draft Guidance for Industry on the use of bioengineered plants or plant materials to produce biological products, including medical devices, new animal drugs, and veterinary biologics. This draft guidance outlines the important scientific questions and information that should be addressed to FDA by those who are using bioengineered plants to produce medical or veterinary products. We are currently reviewing public comments on this guidance.

CONCLUSION

After 10 years of experience in this country, there is every reason to conclude that bioengineered foods are as safe as food produced through traditional breeding techniques. Both the U.S. General Accounting Office (GAO) and the National Academy of Sciences (NAS) have issued reports agreeing with this assessment. We are confident that the foods developed using bioengineering that we have evaluated are as safe as their counterparts, and we will continue to follow the development of this technology to ensure that any new safety questions are also resolved prior to marketing. ❑

❑ A GREEN FAMINE IN AFRICA?

By Ambassador Tony P. Hall, U.S. Mission to the U.N. Agencies for Food and Agriculture

Countries facing famine must consider the severe, immediate consequences of rejecting food aid that may contain biotechnology, writes Tony Hall, U.S. Ambassador to the U.N. Agencies for Food and Agriculture. Southern African countries that faced severe food shortages in late-2002 and rejected U.S. food aid, risked the lives of millions of their people. The rejected food, he writes, is the same food people in the United States eat and has undergone rigorous food safety and environmental impact testing.

Last year and the first few months of 2003, Southern Africa was on the verge of a catastrophe. It was on the brink of famine and is not out of the woods yet. The United States Government did everything we could to stop it and, for the most part, we were successful. The causes were, and remain, varied: drought, a rampant HIV/AIDS epidemic that orphans millions and failed governments prepared to play the politics of hunger. Some governments even blocked the delivery of emergency food relief needed to head off starvation. Their excuse was derived from the ongoing debate over biotechnology, spurred in part by certain European bias against biotechnology.

Last October, I went to visit Zimbabwe and Malawi, two of the six nations affected by the crisis. As the newly arrived U.S. Ambassador to the United Nations Agencies for Food and Agriculture, I had to see this crisis first hand. After almost 24 years of fighting hunger as a U.S. Congressman, however, I had a good idea of what famine looked like. I visited hospitals, feeding centers and schools. I saw many malnourished people — mostly children — and when I asked these children "when is the last time you ate?" most replied that it had been two days, and some said five or six days. Hospitals were overflowing with children they struggled to keep alive. This is another result of the HIV/AIDS epidemic that has created almost one million orphans in Zimbabwe alone, and perhaps 800,000 in Malawi, with no means of support or sustenance.

U.S. and international experts agreed that the worsening food crisis in southern Africa placed as many as 14.5 million people at risk. These people did not have enough food then and most do not have enough today. Hunger continues to haunt many of their days. Even though we have done much to assist, they are in different stages of starvation. The situation in Zimbabwe is still headed for major disaster. Zambia could have been even worse.

In 2001, the U. S. Famine Early Warning System (FEWSNET) identified the onset of drought and food shortages. By February 2002, the United States was moving emergency relief into the region with the World Food Program (WFP). In southern Africa, more than 350 thousand metric tons of U.S. food aid had been delivered by November and another 150 thousand metric tons were delivered in the following three months. This still represented only half the food the region needed. But food that should have gotten into Zimbabwe and Zambia with ease was stuck outside these countries, while debate raged inside over the human health and environmental risks posed by the maize millions of Americans eat daily.

Moreover, the Zambian government decided to reject the maize the U.S. had donated. More than 15,000 tons of U.S. maize had to be removed from the country by WFP at a cost of almost $1 million. There were riots when some hungry Zambian citizens learned of their government's plan and some of the food eventually made it back into the country through the black market.

It doesn't take a lot to calculate the impact of these debates, carried out by well-fed experts. As the region headed for famine, vulnerable people perished. While the U.S. respects the rights of countries to make their own decisions about biotechnology, we have no other option but to provide the food we consume ourselves. And other donors simply could not have increased their donations to fill the gap had more U.S. food aid been rejected.

The United States provides between one-half and two-thirds of the food aid needed to meet emergencies around the world. All of this food comes from our own stocks and markets. It is the same food we eat. It is the same food we feed our children. Maize is the staple food of southern Africa and U.S. maize is about one-third biotech. All of the food donated by the United States has passed our rigorous food safety and environmental impact testing. In fact, it is eaten daily and has been for years by millions of Americans, Canadians and South Africans, and millions of other people all over the world. We have the most rigorous food safety testing system in the world. For

this reason, U.S. biotech and non-biotech foods are mixed together. We do not, and see no need to separate them.

At the request of Secretary General Kofi Annan, the World Food Program, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) issued a joint policy on biotechnology in the summer of 2002. It stated that, based on all scientific evidence, genetically modified (GM)/biotech foods now marketed present no known risk to human health. The European Commission also issued a public statement in August 2002, which agreed that there was no evidence that genetically modified maize varieties are harmful. Even strong biotech opponents such as Greenpeace belatedly recommended that African countries accept GM maize as an alternative to starvation.

But years of anti-biotech lobbying, demands for a "precautionary principle" that no amount of science can satisfy, and a mistrustful climate provide a ready excuse. This climate is fostered in part by some nongovernmental organizations (NGOs) that seek to capitalize on repeated scares over food safety regulations in Europe that have nothing to do with biotech.

When I was in Zimbabwe and Malawi, nobody asked me about the safety of biotech food. Nobody. Starving people, of course, simply want to be fed. But civil servants in the governments of Zimbabwe and Malawi did not ask, nor NGO relief workers, nor anyone else. It is vitally important that the countries and the international community carefully consider new and emerging issues such as biotechnology. But it is also important that we realize that our actions, or our inactions, have consequences. People can die, they did die and they will die.

The United States remains ready to help. Leaders in affected countries are, of course, free to choose whether to accept that help. But as Gro Brundtland, former head of the World Health Organization stressed, they must consider the severe, immediate consequences of rejecting food aid that is made available for millions of people so desperately in need. Time could run out. ❑

❑ THE CARTAGENA PROTOCOL ON BIOSAFETY

U.S. Department of State, July 2003

More than 130 countries adopted the Biosafety Protocol on January 29, 2000, in Montreal, Canada. It is called the Cartagena Protocol on Biosafety to honor Cartagena, Colombia, which hosted the extraordinary Conference of the Parties to the Convention on Biological Diversity (CBD) in 1999. The objective of this first Protocol to the CBD is to contribute to the safe transfer, handling and use of living modified organisms (LMOs) — such as genetically engineered plants, animals and microbes — that cross international borders. The Biosafety Protocol is also intended to avoid adverse effects on the conservation and sustainable use of biodiversity without unnecessarily disrupting world food trade.

The Protocol will enter into force on September 11, 2003. Although the United States is not a Party to the CBD and therefore cannot become a Party to the Biosafety Protocol, the U.S. participated in the negotiation of the text and the subsequent preparations for entry into force under the Intergovernmental Committee on the Cartagena Protocol. We will participate as an observer at the first Meeting of the Parties (MOP1), scheduled for February 2004 in Kuala Lumpur, Malaysia.

The Protocol provides countries the opportunity to obtain information before new biotech organisms are imported. It acknowledges each country's right to regulate bio-engineered organisms, subject to existing international obligations. It also creates a framework to help improve the capacity of developing countries to protect biodiversity.

WHAT IT DOES

The Protocol establishes an Internet-based "Biosafety Clearing-House" to help countries exchange scientific, technical, environmental and legal information about living modified organisms (LMOs).

It creates an advance informed agreement (AIA) procedure that in effect requires exporters to seek consent from an importing country before the first shipment of an LMO meant to be introduced into the environment, such as seeds for planting, fish for release or microorganisms for bioremediation.

It requires shipments of LMO commodities, such as maize or soybeans that are intended for direct use as food, feed or for processing, to be accompanied by documentation stating that such shipments "may contain" living modified organisms and are "not intended for intentional introduction into the environment." The Protocol establishes a process for considering more detailed identification and documentation of LMO commodities in international trade.

It also sets out information to be included on documentation accompanying LMOs destined for contained use, including any handling requirements and contact points for further information and for the consignee.

The Protocol includes a "savings clause," which states that the agreement shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreement, including, for example, World Trade Organization (WTO) agreements.

The Protocol calls on Parties to cooperate with developing countries in building their capacity for managing modern biotechnology.

WHAT IT DOES NOT DO

The Protocol does not address food safety issues. Experts in other international fora, such as Codex Alimentarius, address food safety.

It does not pertain to non-living products derived from genetically engineered plants or animals, such as milled maize or other processed food products.

It does not require segregation of commodities that may contain living modified organisms.

It does not subject commodities to the Protocol's AIA procedure, which would significantly disrupt trade and jeopardize food access, without commensurate benefit to the environment.

The Protocol does not require consumer product labeling. The mandate of the Protocol is to address risks to

biodiversity that may be presented by living modified organisms. Issues related to consumer preference were not part of the negotiation. The Protocol's requirement for documentation identifying commodity shipments as "may contain living modified organisms" and "not intended for intentional introduction into the environment" can be accomplished through shipping documentation.

KEY PROVISIONS OF THE BIOSAFETY PROTOCOL

ADVANCE INFORMED AGREEMENT (AIA) PROCEDURE

The Protocol's AIA procedure, in effect, requires an exporter to seek consent from an importing country prior to the first shipment of a living modified organism (LMO) intended for introduction into the environment, e.g., seeds for planting, fish for release and microorganisms for bioremediation.

The AIA procedure does not apply to LMO commodities intended for food, feed or processing, e.g., maize, soy or cottonseed, to LMOs in transit, or to LMOs destined for contained use, e.g., organisms intended only for scientific research within a laboratory.

Importers are to make decisions on the import of LMOs intended for introduction into the environment based on a scientific risk assessment and within 270 days of notification of an intent to export.

COMMODITY REQUIREMENTS/ BIOSAFETY CLEARING-HOUSE

The agreement requires governments to provide the Biosafety Clearing-House with information concerning any final decisions on the domestic use of an LMO commodity within 15 days of making a decision.

DOCUMENTATION

The agreement sets forth different shipping documentation requirements for different types of LMOs. These requirements will be in effect after the Protocol comes into force.

Documentation accompanying shipments of LMOs intended for introduction into the environment, e.g., seeds for planting, must identify the shipment as containing LMOs along with the identity and relevant traits and/or characteristics of the LMO, any requirements for safe handling, storage, transport and use, the contact point for further information, a declaration that the movement is in conformity with the Protocol and, as appropriate, the name and address of the importer and exporter.

Documentation accompanying shipments of LMO commodities intended for direct use as food or feed, or for processing, must indicate that the shipment "may contain" LMOs, that the shipment is not intended for intentional introduction into the environment, and specify a contact point for further information. The Protocol provides for a decision by the Parties on the need for detailed requirements for this purpose, including specification of the identity and any unique identification of the LMOs, no later than two years after the entry into force of the Protocol.

Documentation accompanying LMOs destined for contained use, e.g., for scientific or commercial research within contained facilities, must identify the shipment as containing LMOs and must specify any requirements for safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the LMOs are consigned.

EXISTING RIGHTS AND OBLIGATIONS UNAFFECTED

As evidenced by both the substantive content of the Protocol and its preambular "savings clause," Parties must implement rights and obligations under the Protocol consistent with their existing international rights and obligations, including with respect to non-Parties to the Protocol.

PRECAUTION

Precaution is reflected in the Protocol's preamble objective, with a reference to Principle 15 of the Rio Declaration on Environment and Development, and provisions on an importing Party's decision-making process regarding the import of an LMO:

"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism in order to avoid or minimize such potential adverse effects."

Both the substantive content of the Protocol's precaution provisions and the preambular "savings clause" make clear that a Party's use of precaution in decision-making must be consistent with the Party's trade and other international obligations.

TRADE WITH NON-PARTIES

The Protocol states that the "transboundary movement of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol." Therefore, although the Protocol only requires trade between Parties and non-Parties in LMOs to be consistent with the "objective" of the Protocol, we anticipate that, as a practical matter, firms in non-Party countries wishing to export to Parties will need to abide by domestic regulations put in place in the importing Parties for compliance with the Protocol. ❑

THE ROLE OF AGRICULTURAL BIOTECHNOLOGY IN WORLD FOOD AID

By Bruce Chassy, Professor and Executive Associate Director of the Biotechnology Center at the University of Illinois Urbana-Champaign

Biotechnology has the potential to play a key role in reducing chronic hunger, particularly in sub-Saharan Africa, which missed out on the "Green Revolution" of the 1960s and 1970s, says Bruce Chassy, professor and executive associate director of the Biotechnology Center at the University of Illinois Urbana-Champaign. He urges more public investment in agricultural research, education and training at the local, national and regional levels.

Food aid is one of several global mechanisms created to deal with hunger and food insecurity. The need for food aid around the globe varies from specific responses to acute and episodic shortages to long-term donations of food to abate continuing chronic inability of some regions to become agriculturally self-sufficient. While agricultural biotechnology is not a panacea to food insecurity, it is likely to play a vital role in the delivery of food assistance and reduction of hunger for generations to come.

THE GLOBAL NEED FOR FOOD AID

The U.N. Universal Declaration of Human Rights declares the right of access to food and freedom from hunger as a fundamental right.

Although we live in a world of unprecedented prosperity and technological development, 800-850 million people are malnourished. More than 200 million of these are children, many of whom will never reach their full intellectual and physical potential. Another 1-1.5 billion humans have only marginally better access to food and often do not consume balanced diets containing sufficient quantities of all required nutrients.

The majority of this nutritionally at-risk population lives in developing countries. Most, perhaps 75 percent, live in rural agricultural regions. Most are very poor. There is a well-recognized link between poverty and hunger. In fact, family income is probably the single most important determinant of adequacy of access to food. The World Food Summit in 2002 reaffirmed a commitment made by the international community five years earlier to halve the number of hungry people by the year 2015. That goal will not be met unless agricultural productivity and personal income can be improved in the world's poorest regions.

It is argued by some that eliminating poverty is more important than producing more food since there is more than enough food produced in the world to feed everyone. Economists tell us that there is a surplus of food in the world — or at least a surplus of grain that when tabulated as potential caloric intake could theoretically adequately feed the current global population. But the sad lesson of both recent and ancient history is that adequate food supplies do not reach everyone. The large number of hungry people proves that. It is pointless to argue whether poor agricultural productivity or extreme poverty is more to blame when people are starving. What is clear is that if the rural poor can produce a surplus of food in a more efficient and sustainable manner, there will be adequate food supplies, increasing income and the opportunity for supporting rural development.

While most experts would agree that the only long-term solution to hunger is economic development and the elimination of poverty, people who are food self-sufficient through local or regional agriculture will not go hungry. Unfortunately, neither the required increases in agricultural productivity nor the necessary rural development will happen overnight. The question then becomes “What do we do in the meanwhile?” The short-term solution for the hungry is food aid. But even food aid has become politicized as skeptics have charged that it is simply a way for rich over-producing nations to eliminate the surpluses produced by their heavily subsidized farmers. The skeptics also assert that food aid robs local farmers of markets and makes them hungrier. These arguments ignore the daily reality faced by hundreds of millions of hungry people for whom the immediate alternatives are simple: continued hunger and ultimate starvation or the acceptance of food aid.

ELIMINATING CHRONIC HUNGER: A ROLE FOR BIOTECHNOLOGY

The Green Revolution of the 1960s and 1970s helped India and China and other Asian countries become

agriculturally self-sufficient net exporters of food in the last three decades. The increased productivity has been accompanied by increases in personal income and stimulus to national economies. Similarly, through application of new technology, agricultural productivity per hectare has doubled in most developed countries in the same timeframe. The development of new high-productivity agricultural technologies resulted from investment in agricultural research performed in government laboratories, research universities, and non-governmental institutes such as the Consultative Group on International Agricultural Research (CGIAR) centers scattered around the globe. A crucial element of success has been the deployment of effective systems of outreach education and technology transfer. Research and technology transfer has also taken place in the private sector.

For a variety of complex reasons, improvements in agricultural productivity did not take place in all developing countries. Quite the contrary, some of the least developed countries are now even less able to produce sufficient food. There, the Green Revolution never happened. While civil unrest and political corruption may have contributed greatly to this phenomenon, from an agricultural point of view, the failure lies in the lack of investment in and adoption of new technologies and management practices. Often this occurred because there was not sufficient attention paid or investment made in research to develop effective local or region-specific strategies and technologies.

Sub-Saharan Africa is a region where growth in agricultural production has not kept pace with expanding need. As a whole, the region has some of the poorest and most depleted agricultural soils. Only 4 percent of the farmed land is irrigated. Significant areas of agricultural land are at risk of becoming desert while in some parts of the region excessive humidity and high temperatures contribute to a high incidence of disease and pests. Weeds such as Striga stifle yields. Droughts are commonplace in some parts of the region. Outright crop failure is common and poor yields are endemic. There is clearly a need to develop crop varieties and management strategies that are more productive under these conditions. High on the list of desired traits are crops with enhanced resistance to environmental stresses such as drought, temperature and salinity; enhanced resistance to diseases and pests; and improved agronomic properties and yield potential. The heavy reliance on a few staple crops makes biofortification — the boosting of the vitamin and mineral components of foods to enhance the nutritional value — an attractive strategy as well.

Recent advances in molecular biology and genomics greatly enhance the plant breeder's capacity to introduce new traits into plants. Commercial applications of agricultural biotechnology have already produced crops such as Bt-maize, rice, potatoes, cotton and sweet corn (sweet maize) that can protect themselves against insects; virus-resistant papaya, squash and potatoes; and herbicide-tolerant crops such as wheat, maize, sugar cane, rice, onions and beets that allow more effective weed management.

There is accumulating evidence that these biotech crops can be more productive and profitable for farmers. Major reductions in costs for labor, energy and chemicals have been documented. The crops have also proven to be environmentally-friendly, particularly with regard to biodiversity, reduction of agricultural chemicals in soil and water, and decreased exposure of workers and communities to chemicals.

There is also an emerging international consensus of scientific and regulatory opinion that crops derived through biotechnology are safe to eat as food and feed and beneficial for the environment. These and other promising technologies are now being directed at improving the production and yield of African staple crops: banana, cassava, maize, millets, oil crops, peanut, potato, rice, sorghum, soybean, sweet potato and wheat. Protein-enhanced sweet potatoes and potatoes and carotene-enhanced rice and oilseeds promise to improve the nutritional value of the diet. Thus, over the long term, agricultural biotechnology promises to play a crucial role in improving agricultural productivity and reducing the environmental impact of agriculture leading to agricultural sustainability and food security in many regions of the world. While it would be foolish to say that agricultural biotechnology alone will solve the world's food problems, it would be equally foolish to assert that food insecurity can be eliminated without agricultural biotechnology.

In recent years, there has been a significant change in the organization of agricultural research directed at improving food security. It is now recognized that research needs to be done at local, national and regional levels in order to address specific agricultural challenges and produce new varieties appropriate to local agriculture and customs. This change is particularly focused on utilizing and expanding local scientific and agricultural human and capital infrastructure that can work in partnership with international scientists and funding. Although the path is clear and there are numerous successful examples of these kinds of international partnership, global funding

for such activities falls far short of the level required to achieve global food security in the next decades.

RECENT CHALLENGES POSED BY ACUTE FOOD SHORTAGES

Widespread local or regional crop failure often leads to acute food shortages and hunger. The reason for episodic events can be as varied as flood, droughts or civil war. The United Nations, national governments and an assortment of nongovernmental organizations (NGOs) often respond by mobilizing an immediate food aid program. Food aid distribution can be hindered by lack of infrastructure for storage and transportation of food, and there are often concerns for the security of aid workers.

Recently, a new obstacle to food aid distribution has been identified. Repeated crops failures in Southern Africa have placed millions of people in six nations at risk. In response, the United States offered food aid that included substantial shipments of maize. The maize supply in the United States is approximately 30-35 percent insect-protected Bt-maize developed through biotechnology. This variety of maize had been approved by the U.S. Environmental Protection Agency (EPA), the U.S. Department of Agriculture (USDA) and the Food and Drug Administration (FDA) as safe for consumption as food and feed. It was commingled with conventional maize in the U.S. commodity system. However, since the intended recipient nations did not use biotech seed varieties and imported few commodities such as maize, they for the most part lacked specific laws and regulatory systems with respect to foods produced through biotechnology. Genetically modified (GM) maize was an unapproved food in their regulatory systems. In light of the global scare campaign against GM foods, several countries hesitated to accept the aid. Ultimately, intensive international consultation and fact-finding satisfied all of these countries save Zambia, which continued to refuse GM food aid. One obvious conclusion to be drawn from this experience is that regulatory systems and training need to be in place before the need for food aid arises again.

PUBLIC INVESTMENT IN RESEARCH, EDUCATION AND TRAINING

What the experience of recent decades has taught is that agricultural biotechnology can be a powerful tool in the development of improved crop varieties for developing countries. The promised benefits can only be realized in a permanent and sustainable manner when the countries that benefit play a role in defining the need, developing the solution and implementing the education and technology-transfer systems. Each nation must decide what agricultural goals are in its national interest and what technologies are consistent with consumer acceptance and customs. Shared ownership leads to good stewardship.

Partnerships that lead to shared ownership can solve another challenge to applying technology. One major concern about agricultural biotechnology is that the seeds are owned and sold by large multi-national corporations who might eventually exert external domination and control local seed markets and farmers. An additional problem is that developing countries may have limited access to intellectual property rights that would provide them access to modern agricultural technologies such as new seed types. To help counter these challenges and promote public sector uses in developing countries, a consortium of public universities and public sector institutions has recently announced the formation of the Public Sector Intellectual Property Resource for Agriculture (PIPRA). PIPRA will work to make public-sector research available to more of the people who want it and insure freedom to operate. Multi-national corporations have also demonstrated their willingness to donate their technology and expertise to such efforts.

There is a holistic answer to all these food security needs and concerns. The global community needs to invest more capital in creating agricultural institutions and infrastructure in countries that face food security challenges. Investment must be made in legal and regulatory systems, agricultural research, transportation and processing systems, and education. The success of the Land Grant University system in improving agriculture and contributing broadly to society in the United States over the last 140 years demonstrates that the development of human capital and educational systems is as important as scientific discovery. The creation of institutions and public/foundation funding mechanisms would create a platform for international collaboration that is open to government, university and private-sector collaborators. If the world community is to arrive at its stated goal of food security for every person, it must put aside ideological and political divisions and pragmatically embrace each technology that leads to sustainable food security. ❑

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

THE ROLE OF PLANT BIOTECHNOLOGY IN THE WORLD'S FOOD SYSTEMS

By A. M. Shelton, Professor of Entomology, Cornell University/New York State Agricultural Experiment Station

At the molecular level, different organisms are quite similar, writes Cornell University Professor A.M. Shelton. It is this similarity that allows the transfer of genes of interest to be moved successfully between organisms, therefore, genetic engineering is a much more powerful tool than traditional breeding in improving crop yields and promoting environmentally friendly production methods.

For the past 10,000 years, humans have used the plants nature provided and modified them through selective breeding to have desirable characteristics such as improved taste, enhanced yield and pest resistance. The result is that the plants we consume today would be largely unrecognizable to our ancient ancestors. Scientists consider the techniques of biotechnology to be an aid in the selective breeding of plants and to have far more potential for providing benefits such as enhanced nutritional properties, more environmentally friendly production methods and improved yields. Already, the techniques of biotechnology have produced tremendous benefits in medicine. Virtually all the insulin used to treat diabetes today is produced through biotechnology and genetic engineering, and many of the medicines used to fight cancers and heart problems are produced through these same methods.

DEVELOPMENT OF PLANT BIOTECHNOLOGY

Corn (maize) originated in Mexico from a grass called teosinte that has a small reproductive structure bearing little resemblance to the ear of corn seen in markets around the world today. Tomatoes and potatoes first appeared in South America - tomatoes as small fruits the size of a grape, and potatoes as knobby tubers with high concentrations of a family of bitter chemicals called glycoalkaloids, which are toxic to humans.

Through selective breeding by our ancestors, the shape, color and chemical content of these and hundreds of other plants consumed today have been modified to suit consumer preference or to obtain desired characteristics such as high yield, disease and insect resistance, and tolerance to drought and other plant stresses. Not only have these plants changed in appearance and composition, they also have become distributed worldwide through centuries of human migration and trade. For example, cabbage, which originated in Europe, is now grown on every inhabited continent. When today's consumers walk into a market in many parts of the world, they are witnesses to today's global food system where foods produced in one part of the world are daily shipped to local markets.

We now realize our ancient ancestors were modifying the genetic makeup of plants by transferring genetic material from one plant to another. However, it wasn't until Gregor Mendel, an Austrian monk, conducted experiments in the 1800s with garden peas that the basic laws of heredity were first unraveled. Prior to the early 1900s, traditional plant breeding, like that practiced by Mendel, relied on man-made artificial crosses in which pollen from one plant species was transferred to another sexually compatible plant. The goal was to take a desirable trait from one plant and introduce it into another plant. However, often desirable characteristics either were not present in sexually compatible plants or did not occur in any plant species. This led plant breeders to seek new ways of transferring desirable genes.

Beginning in the 1930s, plant breeders developed techniques to allow them to develop plants from two parent plants that could not normally produce viable offspring. An example is the technique called "embryo rescue," in which the new plant embryo is provided with extra care in the laboratory to enable it to survive during its early growth.

In the 1950s, plant breeders also developed methods of creating variation in an organism's genetic structure through what is termed "mutation breeding." Mutations in the genetic makeup of a plant occur continuously and randomly in nature through such events as the sun's radiation and may lead to the occurrence of new desirable traits. Mutation breeding uses similar random processes to cause changes in a plant's genes. Plants then are assessed to determine if the genes were changed and whether the changes provided a beneficial trait such as disease or insect resistance. If the plant was "improved," then it was tested for other changes that may have occurred. Many of the common food crops we use daily have been developed through techniques such as embryo rescue and mutation breeding and virtually all the foods we consume have genes in them.

It is hard to think of an example of a common food crop in the developed world that has not been improved by some form of modern technology, or what can be

termed “biotechnology.” Simply put, biotechnology is a set of techniques that utilizes living organisms, or parts of organisms, to make or modify products, improve plants or animals, or develop microorganisms for specific purposes. This definition encompasses all human activities conducted on living organisms from the earliest development of plant breeding 10,000 years ago to the present. This is the reason plant breeders consider the term “genetically modified organisms” - or GMOs - to be misnomer since all common food crops of today have been so modified.

THE SCIENCE OF MODERN GENETIC ENGINEERING

Genetic engineering is one form of biotechnology and usually refers to copying a gene from one living organism — plant, animal or microbe — and adding it to another organism. In genetic engineering, a small piece of genetic material (DNA) is inserted into another organism to produce a desired effect. This is in contrast to traditional plant breeding in which all the genes desirable and undesirable contained in the male plant — pollen — are combined with all the genes of the female plant. The progeny resulting from this cross may contain the gene for the desirable character, but it will also contain many of the undesirable genes from both parents.

Genetic engineering has the advantage of being able to transfer only the gene of interest and greatly accelerate plant breeding. But genetic engineering also is more powerful than traditional breeding since it can move genes not only between similar plant species but also from distant relatives, including non-plant species. It is possible to move genes between such seemingly unrelated organisms because all living organisms share the same code for DNA and the synthesis of proteins and other basic life functions. What might seem on the surface to be very different organisms are, in fact, very similar, at least at the molecular level. All living things are more alike than different, and this is one of the reasons that genes can be moved so successfully between such seemingly different organisms as plants and bacteria. Genes are not unique to the organisms from which they came, so there really aren’t “tomato genes” or “bacterial genes.” It’s the collection of all genes in a tomato or a bacterium that makes it a tomato or bacterium, not a single gene. As we learn more about the genetic makeup of all organisms, we see that most plant species differ by only a small percentage of their genes and that even such seemingly different organisms as tomatoes and bacteria have many common genes. These findings suggest that in the long-term evolutionary process even tomatoes and bacteria had some common ancestor.

From the discovery 50 years ago of the structure of DNA, scientists soon came to realize they could take segments of DNA that carried information for specific traits — genes — and move them into another organism. In 1972, the collaboration of Hubert Boyer and Stanley Cohen resulted in the first isolation and transfer of a gene from one organism to a single-celled bacterium where it would express the gene and manufacture a protein. Their discoveries led to the first direct use of biotechnology — the production of synthetic insulin to treat people with diabetes — and the start of what is often called modern biotechnology.

Plants were first transformed through genetic engineering in the late 1970s. Mary-Dell Chilton and colleagues used a common soil-dwelling bacterium, Agrobacterium tumefaciens, that attaches itself to plants and transfers some of its DNA into the plant. Chilton and her colleagues added a gene to this bacterium, which in turn transferred the gene into a plant where it became part of the plant’s DNA. This bacterium is still commonly used in genetic engineering along with another technique that uses a high-velocity mechanism to inject DNA into plant cells. The result from either technique is the same — the plant cells take up the gene and begin to express it as their own.

BENEFITS AND RISKS

Plants developed through genetic engineering were first grown on 1.7 million hectares in 1996 in the United States, but by 2002 they were grown on 58.7 million hectares in 16 countries. By far the major use of the present plants is to manage pests — weeds, insects and diseases. Weed management with genetically engineered plants is accomplished because the plants have a modified enzyme (a protein) that allows them to survive an application of a specific herbicide that normally acts on that enzyme. Growers can plant the herbicide-tolerant seeds, allow the plants to emerge along with any weeds in the field and then treat the field with an herbicide. The result is that the weeds, but not the crops, die. The advantage to growers is that they spend less time on weed management, have enhanced weed control, use safer herbicides, and in many cases use less herbicides. Additionally, this technology allows growers to use soil conservation practices such as reduced or no-tillage, thus helping to retain soil structure and moisture and reduce erosion. Herbicide tolerant crops (soybean, canola, cotton and maize) were grown on 48.6 million hectares in 2002.

Insect-resistant crops developed through genetic engineering utilize the common soil bacterium, Bacillus thuringiensis (Bt), which has been commercially used

for more than 50 years, as an insecticide spray. Although safe to humans and the environment, when a susceptible insect ingests Bt, the Bt protein binds to specific molecular receptors in the gut and creates pores causing the insect to starve to death.

Insecticidal products containing Bt were first commercialized in France in the late 1930s, but even in 1999 the total sales of Bt products constituted less than 2 percent of the total value of all insecticides. Bt, which had limited use as a foliar insecticide, became a major insecticide only when genes that produce Bt toxins were engineered into major crops. The Bt crops available at present are maize and cotton. These were grown on a total of 14.5 million hectares in 2002. Virus-resistant crops were created by inserting a non-infective part of a plant virus into a plant, essentially "vaccinating" the plant to protect it from the virus. This technique is called "pathogen-derived resistance." Squash and papaya have been engineered to resist infection by some common viruses and are approved for sale in the United States. There are fewer than 1 million hectares of these crops.

The bioengineered plants available at present provide growers with better tools to manage pest problems. As with any technology, there are risks and benefits to currently available genetically engineered plants, but the present body of information indicates their use has enhanced pest management, substantially reduced the amounts of pesticides used in some crops, enabled growers to use safer pesticides, and contributed to enhanced safety for humans and the environment. The regulatory process for managing these plants and their effects on the environment and humans has evolved with the technology and the scientific community's knowledge of these tools.

Many of the more controversial issues surrounding genetic engineering of plants — such as pesticide resistance, gene flow and intellectual property issues — are not unique to this new technology but pertain to all types of agriculture. Some species of insects have developed resistance to sprays of Bt, indicating the potential for some species to become resistant to Bt plants. However, despite Bt plants being grown on more than 62 million hectares worldwide from 1996 to 2002, there have been no documented cases of resistance development. The reasons for this lack of resistance appear to involve not only biological factors of the insects and the Bt plant, but also the fact that the regulatory agency (the Environmental Protection Agency) in the United States requires a resistance management plan for growing Bt plants. No other insecticide has such strict regulations. Still, growers, companies and federal regulatory agencies must be vigilant about resistance developing for biotech crops used to manage insects, weeds and viruses as they also must with non-biotech pest management tactics.

It will be important to consider the accrued environmental and health benefits of these biotech crops prior to the development of any resistance and how resistance can be managed if and where it occurs. In addition to pesticide resistance, gene flow from biotech to non-biotech crops may also be a concern. However, the risk of gene flow varies with each crop and each gene. Pollen flow in soybeans is very limited so the risk of a biotech soybean crop crossing with a non-biotech soybean is minimal, but this may be different for another crop. Likewise, if the gene in the biotech crop that provided a pest management trait, such as insect resistance, moved into a non-biotech plant, such as a weed, any selective advantage of the insect-protected weed in the ecosystem should be assessed. These same questions should also be answered with non-biotech crops, but these have not received the same level of attention as biotech crops because of the latter's higher profile.

WHAT'S ON THE HORIZON?

In the future, the potential uses of plant biotechnology are far more wide-ranging than the pest-management biotech crops of today. Plants are being developed that serve as production "factories" for medically important drugs, sources of alternative energy, tools for cleaning toxic waste sites, and biomaterials including dyes, inks, detergents, adhesives, lubricants, plastics and the like. Consumers may see these products as more directly enhancing their quality of life than the pest-management biotech crops of today.

Perhaps an even more dramatic advantage to consumers will be seen when plants are genetically engineered to have enhanced health benefits such as disease-fighting chemicals or increased amounts of essential vitamins and minerals. A healthy and well-informed discussion of the risks and benefits involved in agricultural biotechnology is needed to ensure a proper role for this new technology in our future food and health systems. No one should believe that any technology, including biotechnology, will completely solve the world's agricultural problems. Many people familiar with biotechnology, however, believe it to be an important component of the solution. ❑

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

IMPROVING ANIMAL AGRICULTURE THROUGH BIOTECHNOLOGY

By Terry D. Etherton, Distinguished Professor of Animal Nutrition, The Pennsylvania State University

Livestock feed derived from biotechnology has been shown to increase production efficiency, decrease animal waste and lower the toxins that can cause sickness in animals, asserts Terry Etherton, distinguished professor at The Pennsylvania State University. Genetically modified feed also can improve water and soil quality by reducing levels of phosphorous and nitrogen in animal waste.

INTRODUCTION

Over the past 20 years, biotechnology has lead to the development of new processes and products that have benefited agriculture and society. Between 1996 and 2002 there was a 35-fold increase in acreage planted globally with genetically modified (GM) crops, from 1.7 to 58.1 million hectares, and more than a quarter of GM crops are grown in developing countries. While there has been considerable discussion about the benefits of GM crops in the grains and fruits humans consume, less public debate has been forthcoming about GM crops' profound effects on improving the health of livestock grown for meat products and on reducing some of the environmental costs of livestock wastes.

Adoption of products produced by modern biotechnology will be important to enable the production of food sufficient to feed a growing world population.

Biotechnologies that enhance productivity and productive efficiency — feed consumed per unit of milk or meat produced — have been developed and approved for commercial use in many countries. New biotechnology products have enabled improvements to be made that increase food safety and improve animal health.

Biotechnology also offers considerable potential to animal agriculture as a means to reduce nutrients and odors from manure and volume of manure produced. Development and adoption of these biotechnologies will contribute to a more sustainable environment.

In order to be approved for commercial use in the United States, new agricultural biotechnologies are evaluated rigorously by the appropriate federal regulatory agencies to ensure efficacy, consumer safety, and animal health and well-being. Successful development and adoption of emerging biotechnologies for agriculture require improved public understanding of scientific, economic, legislative, ethical and social issues. The objective of this paper is to provide a brief overview of some of the existing and emerging modern agricultural biotechnologies that affect animal productivity and discuss their current or potential food safety and environmental benefits.

FEEDING LIVESTOCK

Scientific studies evaluating feed components derived from genetically modified (GM) plants have focused on beef cattle, swine, sheep, fish, lactating dairy cows, and broiler and layer chickens, and have included nutrient composition assessments, digestibility determinations and animal performance measurements. These studies have shown that feed components derived from GM plants are equivalent in terms of nutrient composition to non-GM plants. Feeding components derived from GM plants, such as grain, silage and hay, also show results in growth rates and milk yields that are equivalent to those food components derived from non-genetically enhanced feed sources. Studies have reported that GM maize altered for protection against the "corn borer" can have lower contamination by mycotoxins — toxic substances produced by fungi or molds — under certain growing conditions, resulting in safer feed for livestock.

METABOLIC MODIFIERS

Metabolic modifiers are a group of compounds that modify animal metabolism in specific and directed ways. Metabolic modifiers have the overall effect of improving productive efficiency (weight gain or milk yield per feed unit), improving carcass composition (meat-to-fat ratio) in growing animals, increasing milk yield in lactating animals and decreasing animal waste.

The first modern biotechnology to be approved for animal agriculture in the United States was bovine somatotropin (bST) for use in the dairy industry. Application of recombinant bST to dairy cows, by injection every 14 days, increases milk yield and productive efficiency (milk/feed) and decreases animal waste. Milk yield

response to bST in the United States is typically 10-15 percent, approximately 4 to 6 kilograms per day, although larger increases may occur when the management and care of the animals are excellent. Commercial sales of bST began in 1994 in the United States and use has increased in the industry. Presently in the United States, more than 3 million dairy cows are receiving bST supplements. Bovine somatotropin is being used commercially in 19 countries worldwide.

Porcine somatotropin (pST) has been developed for the swine industry. Administration of recombinant pST to growing pigs increases muscle growth and reduces body fat deposition, resulting in pigs that are leaner and of greater market value. Pigs treated with pST use dietary nutrients more efficiently, which improves feed utilization. In the United States, pST is undergoing testing required for FDA evaluation. Worldwide, pST is approved for commercial use in 14 countries.

GM CROPS THAT DECREASE PHOSPHORUS AND NITROGEN EXCRETION

Phosphorus (P) from manure run-off can significantly impact the quality of fresh lakes and streams. P content in swine and poultry manure is high because these species consume diets consisting of cereal grains and oilseed meals in which most, 60 to 80 percent, P is not absorbed in the digestive tract and is excreted in the feces. Consequently, relatively large amounts of dietary P must be fed to pigs and poultry to meet their dietary P requirements. This problem is not observed in ruminants — cattle, sheep and goats — because their digestive tract is more efficient in utilizing dietary P. To solve this problem for pigs and poultry, a special variety of GM maize has been developed that makes the dietary P more available to the animal. Thus, this variety of GM maize offers the potential to further decrease excretion of P by pigs and chickens. A similar GM soybean variety has been developed. Soybean meal derived from this variety of GM soybeans provides more dietary P to pigs and poultry than meal from conventional soybeans. Studies have shown that diets containing GM maize and meal from GM soybeans decrease P excretion in manure by 50 to 60 percent in pigs and chickens. Inclusion of these special varieties of GM maize and soybeans in diets fed to pigs and chickens offers great potential to dramatically reduce P excretion into the environment.

GM crops with improved amino acid profiles have great potential to decrease nitrogen (N) excretion, especially in pigs and poultry. Nitrogen can contaminate ground and surface waters, contribute to “acid rain,” which increases the acids in soils, and be the source of odors. Increased levels of the amino acids lysine, methionine, tryptophan, threonine and other essential amino acids in grains would mean that the essential amino acid requirements of pigs and poultry can be met with lower-protein diets. Such diets contain fewer excesses of other amino acids that eventually must be degraded to urea N and excreted in the urine. Feeding these GM varieties to pig and poultrywould greatly reduce the amount of N — such as urea — from being excreted into the environment.

SAFETY OF FOOD BIOTECHNOLOGIES

In the United States, there is a long history of assessing the safety of foods introduced into the marketplace. The assessment of GM plants and animal biotechnologies is science-based and rigorous. The discovery and development of new animal and plant biotechnologies are part of a continuum leading to the commercialization of agricultural biotechnology products.

Historically, equivalence of composition GM plants, GM animals or animals treated with biotechnology products, such as bST, has been an important component of the regulatory process. Establishing equivalence of composition is evidence that substantive changes did not occur in the plant or animal as the result of the genetic modification event. One endorsement of the robust nature of the comparative safety assessment process used with GM plants is that more than 223 million hectares of GM crops have been commercially grown over the past 10 years with no documented effects to humans, animals or the environment. Likewise, there have been no documented adverse effects of meat and milk derived from cows supplemented with bST, the most rapidly adopted animal biotechnology to date.

CONCLUSION

Agriculture is transiting a remarkable scientific era with respect to the myriad of processes and products that have been developed using biotechnology. Moreover, many new products of biotechnology are being developed that will benefit the food sector. Implicit to approval of these new products is a robust safety assessment process. To date, the approved GM plants and animal biotechnologies have been judged to be as safe as conventionally produced counterparts. Development and adoption of new biotechnologies will be crucial in meeting the challenge of producing enough food for a growing world population while reducing impacts on the

environment. The impact these technologies have on society in the future, however, will be largely dependent on the extent to which they are adopted by producers and the agricultural community and accepted by consumers. Questions about societal impacts and safety often arise as the result of technological change. Inherent to the successful development and adoption of new biotechnologies for agriculture is the need to increase public understanding of the scientific, economic, legislative, ethical and social issues associated with emerging agricultural biotechnologies. ❑

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BIOTECHNOLOGY IN THE GLOBAL COMMUNICATION ECOLOGY

By Calestous Juma, Professor and Director of the Science, Technology and Globalization Project at the Kennedy School of Government, Harvard University

Public debates about the safety of new products introduced in the market go back centuries and were often based less on science than on the politics of the time. Similarly, today, much of the debate about agricultural biotechnology is steered by myths and misinformation and not by science, writes Calestous Juma, professor and director of the Science, Technology and Globalization Project at the Kennedy School of Government, Harvard University. The scientific community, with stronger support from governments, must do more to address science and technology issues with the public, he adds.

Debates over biotechnology are part of a long history of social discourse over new products. Claims about the promise of new technology are at times greeted with skepticism, vilification or outright opposition — often dominated by slander, innuendo and misinformation. Even some of the most ubiquitous products endured centuries of persecution.

For example, in the 1500s Catholic bishops tried to have coffee banned from the Christian world for competing with wine and representing new cultural as well as religious values.

Similarily, records show that in Mecca, in 1511 a viceroy and inspector of markets, Khair Beg, outlawed coffeehouses and the consumption of coffee. He relied on Persian expatriate doctors and local jurists who argued that coffee had the same impact on human health as wine. But the real reasons lay in part in the role of coffeehouses in eroding his authority and offering alternative sources of information on social affairs in his realm.

In public smear campaigns similar to those currently directed at biotech products, coffee was rumored to cause impotence and other ills and was either outlawed or its use restricted by leaders in Mecca, Cairo, Istanbul, England, Germany and Sweden. In a spirited 1674 effort to defend the consumption of wine, French doctors argued that when one drinks coffee: "The body becomes a mere shadow of its former self; it goes into a decline, and dwindles away. The heart and guts are so weakened that the drinker suffers delusions, and the body receives such a shock that it is as though it were bewitched."

BUTTERFLY STORIES AND OTHER MISINFORMATION TACTICS

Today similarly charged stories are told about genetically modified (GM) foods. In addition to claims about the negative impact of GM foods on the environment and human health, there are wild claims that associate GM foods with maladies such as brain cancer and impotence as well as behavioral changes. Some of these rumors are spread at the highest levels of government in developing countries.

The tactics employed in the debates are equally sophisticated. Critics of the technology have used instruments of mass communication to provide the public with information that is carefully designed to highlight the dangers they attribute to biotechnology. Advocates of biotechnology have often been forced to respond to charges against the technology and have only on rare occasions taken the initiative to reach out to the public. This is particularly important because the general public does not readily understand the technical details of biotechnology products and so new communication approaches are needed.

While advocates of biotechnology have often tried to rely on the need for scientific accuracy, critics employ rhetorical methods that are designed to invoke public fear and cast doubt on the motives of the industry. The critics draw analogies between the "dangers" of biotechnology with the catastrophic consequences of nuclear power or chemical pollution. Indeed, they use terms like "genetic pollution" and "Frankenstein foods".

Critics have also relied on the general distrust of large corporations among sections of the global community to make their case. In addition, they have made effective use of incidents, whose risks they have amplified. A much-quoted study by Cornell University researchers indicated that pollen from GM maize producing a Bt toxin killed the larvae of Monarch butterflies. This study was used to dramatize the impact of biotechnology on the environment. Subsequent published peer explanations of the limitations of the study and refutations of the conclusions did not change the original impression created by the critics of biotechnology.

In this case the real environmental issue was not if GM maize killed monarch butterfly larvae or not. The critical question was what impact the maize had on the environment compared to maize grown with chemical pesticides. It is the issue of relative risks that is important; not simply a single event examined outside the wider ecological context. But apparently, this kind of analysis would not serve the cause of critics.

It is notable that the critics of biotechnology have defined the rules of the debate in two fundamental ways.

First, they have managed to create the impression that the onus of demonstrating safety lies with advocates of biotechnology and not on its critics. In other words, biotechnology products are considered unsafe until proven otherwise.

Second, they have been effective in framing the debate in environmental, human health and ethical terms, thereby masking the underlying international trade considerations. By doing so, they have managed to rally a much wider constituency of activists who are genuinely concerned about environmental protection, consumer safety and ethical social values.

There is a general view that concerted efforts to promote public debate will improve communication and lead to the acceptance of biotechnology products. This may be the case in some situations. But generally, the concerns are largely material and cannot be resolved through public debate alone. This is mainly because the root causes of the debate lie in the socio-economic implications of the technology and not mere rhetorical considerations. It is possible that public debates will only help to clarify or amplify points of divergence and do little to address fundamental economic and trade issues.

What then can be done under the circumstances, especially in relation to developing countries that are currently the target of much of the attention of advocates and critics of biotechnology? Operating in the new global communication ecology will require greater diversity of biotechnology products, an increase in the number of institutional players, enhanced policy research on life sciences and society, and stronger policy leadership.

PRODUCTS SPEAK LOUDER THAN WORDS

Much of the debate on the role of biotechnology in developing countries is based on hypothetical claims with no real products in the hands of producers or consumers. Under such circumstances, communication and dialogue are not enough until there is a practical reference point. In other words, rebutting the claim of critics is not as important as presenting the benefits of real products in the market place.

This can best be achieved through collaborative efforts among local scientists, entrepreneurs, policy makers and legitimate civil society organizations. There is ample evidence to suggest that concerns over the safety of new products tend to decline as local participation and ownership in new technologies increase. Similarly, local participation in new technologies increases the level of trust in new technologies, thereby reducing the demand for non-science-based safety regulations. For example, the word of a farmer from South Africa stating the positive impact of GM cotton on her welfare carries more weight than thousands of screaming press releases and empty headlines on both sides of the debate.

This means that spreading the use of biotechnology not only promotes familiarity with the technology, but also generates the information needed to convince the public about the relevance and usefulness of the technology. The broadening of the range of products is therefore a key aspect of the debate. This is particularly important in developing countries interested in using the technology to enhance local products and diversify their food base.

Information on the development of drought-tolerant crops, for example, would be relevant to African countries while other regions might be interested in different products. This view also suggests that general debates about the role of biotechnology are of little utility unless framed in the context of local needs and applications.

The absence of a real stake in the technology creates a vacuum that is often filled with misinformation on the risks and benefits of the technology. Countries such as Kenya and South Africa that have their own biotechnology research programs have a more considered view of the technology.

BROADENING THE CONSTITUENCY

Addressing the issue of biotechnology communication requires an improved understanding of the changing ecology of communication. The ecology includes a complex network of sources of information and opinion leaders as well as new communication tools that were hitherto not available to the public or advocacy groups. In his days, Khair Beg was outraged to learn that coffeehouses

had become an authoritative source of information on what was happening in his jurisdiction. Similarly, the Internet has become a more important communication tool than classical methods such as TV advertising.

But unlike in the days of Khair Beg, the new communication ecology is global in character, making it possible to spread information widely and generate empathy among a diversity of activist organizations, including those that are unlikely to be affected by the technology. These cyber-communities are built around a complex set of mailing lists that are not easily accessible. Correcting misinformation spread through such channels is difficult to do because of the complexity of the networks.

While activists tend to use a diverse array of social movements to advance their cause, advocates have tended to focus on the use of centralized institutions whose impact is largely negligible in the modern communication ecology. But creating the necessary diversity requires a broadening of the base of social movements that champion the role of science and technology in human welfare.

One of the most important aspects of the biotechnology debate has been the role of the popular media. In Europe, for example, the media have played an important role in amplifying claims by critics or creating doubt about positions advanced by advocates of the technology. In contrast, support for the role of science does not usually have the polemical turn that newspaper editors relish.

The traditional view that science is based on immutable facts which can be passed on from an authority to the general public is being challenged by approaches that demand greater participation in decision-making. In other words, scientific information is being subjected to democratic practices.

The debate over biotechnology has pushed the frontiers of public discourse of technical matters. On the one hand, society is being forced to address issues that are inherently technical, and on the other, the scientific community is under pressure to accept non-technical matters as valid inputs to decision-making.

THINKING AHEAD

Policy-oriented research institutions and think tanks play an important role in the war of words. It is notable that critics of biotechnology have made a considerable effort to create alliances with research institutions, including university-based departments. Much of the material used to question the safety of biotechnology often has the legitimacy of a research institution. But non-partisan policy research on the role of biotechnology in society is largely lacking, and so those seeking to provide an alternative view have limited opportunities to obtain credible information.

The lack of systematic research on the interactions between biology and society is a critical bottleneck in efforts to engage the public in dialogue on biotechnology. This is particularly critical given the fact that advances in biology pose new ecological and ethical issues that are not associated with the physical and chemical sciences. For example, concerns over the inability to recall products once released on markets are more pronounced when dealing with the release of biological inventions into the environment.

LEADING THE WAY

Much of the public debate is intended to influence government policy on biotechnology. In this regard, the capacity of governments to assess the available information and use it for decision-making is an essential element of the debate. Political leadership on biotechnology and the existence of requisite institutions of science and technology advice are an essential aspect of the governance of new technologies.

Debates over new technologies will be more pronounced in the future, and governments will increasingly come under pressure to address these issues. But science and technology advice will not be sufficient unless governments view science and technology as integral to the development process. In this regard, enhancing the capacity of leadership to address science and technology issues will contribute to the effective management of public debates over new technologies in general and biotechnology in particular.

On the whole, the nature of emerging technologies — particularly those based on the life sciences — and the changing ecology of communication are making it necessary to rethink strategies for advancing the role of biotechnology in society. The scientific community will need not only to demonstrate a clear sense of leadership, but also to adapt its communication methods to suit the growing complexity and diverse needs of the global community. In the final analysis, it is the range of useful products available to humanity from biotechnology that will settle the debate, not the hollow pronouncements of advocates and critics. ❑

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❑ PRESS RELEASE: U.S. REQUEST FOR A WTO DISPUTE PANEL REGARDING THE EU BIOTECH MORATORIUM

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE
Executive Office of the President

August 7, 2003

WASHINGTON — U.S. Trade Representative Robert B. Zoellick and Agriculture Secretary Ann M. Veneman announced today that the United States is taking the next step in its World Trade Organization (WTO) challenge to the European Union's (EU) illegal five-year moratorium on approving agricultural biotechnology products by asking the WTO for a dispute settlement panel.

The United States, along with Canada and Argentina, initiated the case by requesting formal WTO consultations in May. Canada and Argentina are likewise requesting WTO panels to consider the EU moratorium.

"Delegations from the United States, Canada and Argentina consulted in June with EU officials, but the EU indicated no willingness to comply with its WTO obligations by lifting the groundless moratorium on biotech products," said Zoellick. "The EU's stance leaves us no choice but to proceed with the establishment of a WTO dispute settlement panel. For five years, the EU has kept in place a ban on biotech approvals — a ban which is unsupported even by the EU's own scientific studies. This trade barrier harms farmers and consumers around the world by denying them the benefits of productive, nutritious and environmentally friendly biotech products."

"We have been extremely patient for almost five years," said Veneman. "We have had exhaustive discussions with the Europeans and it now is time to let the dispute settlement process work."

President Bush, in his May 21, 2003, Coast Guard Academy Commencement Address, said that "By widening the use of new high-yield bio-crops and unleashing the power of markets, we can dramatically increase agricultural productivity and feed more people across the continent. Yet, our partners in Europe are impeding this effort. They have blocked all new bio-crops because of unfounded, unscientific fears. This has caused many African nations to avoid investing in biotechnologies for fear their products will be shut out of European markets. European governments should join — not hinder — the great cause of ending hunger in Africa."

The first step in a WTO dispute, which the United States, Canada and Argentina undertook in May, is to request consultations. Other countries who expressed support for the case by joining as third parties to the consultations included: Australia, Chile, Colombia, Mexico, New Zealand and Peru. In addition, El Salvador, Honduras and Uruguay also supported the U.S. position at the announcement of the case and have indicated their intent to join as third parties. Where, as in this case, the consultations do not resolve the dispute, the countries that requested consultations may seek the formation of a dispute settlement panel. Dispute settlement procedures, including appeal, typically take about 18 months.

The WTO agreement on sanitary and phytosanitary measures (SPS) recognizes that countries are entitled to regulate crops and food products to protect health and the environment. The WTO SPS agreement requires, however, that members have "sufficient scientific evidence" for such measures, and that they operate their approval procedures without "undue delay." Otherwise, there is a risk countries may, without justification, use such regulations to thwart trade in safe, wholesome, and nutritious products.

Before 1999, the EU approved nine agriculture biotech products for planting or import. It then suspended consideration of all new applications for approval, and has offered no scientific evidence for this moratorium on new approvals. As EU Environment Commissioner Margot Wallstrom said over three years ago (July 13, 2000): "We have already waited too long to act. The moratorium is illegal and not justified ... The value of biotechnology is poorly appreciated in Europe."

Agricultural biotechnology is a continuation of the long tradition of agricultural innovations that have boosted agricultural productivity, quality and choices by developing new forms of crops. More than 145 million acres (58 million hectares) of biotech crops were grown in the world in 2002. Worldwide, about 45 percent of soy, 11 percent of

corn (maize), 20 percent of cotton and 11 percent of rapeseed are biotech crops. In the United States, 75 percent of soy, 34 percent of corn and 71 percent of cotton are biotech crops.

Numerous organizations, researchers and scientists have determined that biotech foods pose no threat to humans or the environment. Examples include:

- the French Academy of Medicine and Pharmacy;

- the French Academy of Sciences;

- 3,200 scientists from around the world who cosponsored a declaration on biotech foods; and

- a joint study conducted by seven national academies of science: the National Academies of Science of the United States, Brazil, China, India and Mexico, plus the Royal Society of London and the Third World Academy of Sciences.

BACKGROUND

At the May 2003 announcement of the consultation request, Zoellick and Veneman were joined by Dr. C.S. Prakash, (organizer of a pro-agricultural biotech declaration signed by 20 Nobel Laureates and over 3,200 scientists), T.J. Buthelezi, a small farmer of biotech crops from South Africa; Dr. Diran Makinde, DVM, Ph.D., Dean of the School of Agriculture, University of Venda for Science and Technology, South Africa; Dr. Ariel Alvarez_Morales, Principal Scientist, Department of Plant Genetic Engineering, Center for Research and Advanced Studies, Irapuato, Mexico; and representatives from other countries participating in the case.

Since the late 1990's, the EU has pursued policies that undermine agricultural biotechnology and trade in biotech foods. Six member states — Austria, France, Germany, Italy, Greece and Luxemburg— banned modified crops approved by the EU. In 1998, member states began blocking all new biotech applications. This approval moratorium is causing a growing portion of U.S. agricultural exports to be excluded from EU markets and unfairly casting concerns about biotech products around the world, particularly in developing countries. The moratorium had no effect on any previously-approved products, such as corn and soy, which are still used and are available in EU member countries. The U.S. WTO challenge covers both the member state bans and the EU-wide moratorium.

On July 22, 2003, the EU adopted two new regulations on biotech products. The Traceability and Labelling Regulation will require that biotech products be traced throughout the commercial chain, and that food containing biotech products comply with certain labelling requirements. The Genetically Modified Food and Feed Regulation will provide new approval procedures for biotech food and feed products upon its entry into force in about six months. Since neither one of these new regulations lifts the illegal moratorium on biotech products they do not affect the U.S. WTO challenge. ❑

PLANT BIOTECHNOLOGY TIMELINE

Plant biotechnology is a precise process in which scientific techniques are used to develop more plants. Many researchers view plant biotechnology as the next step in the refinement of genetic enhancement techniques that began thousands of years ago with the domestication of wild plants for food production.

4000 BC-1600 AD: Early farmers, like those in Egypt and the Americas, saved seeds from plants that produced the best crops and planted them the next year to grow even better crops.

1700-1720: Thomas Fairchild, the forgotten father of the flower garden, creates Europe's first hybrid plant.

1866: Austrian monk Gregor Mendel publishes important work on heredity that describes how plant characteristics are passed from generation to generation.

1870-1890: Plant researchers cross-breed cotton to develop hundreds of new varieties with superior qualities.

1871-early 1900s: Researcher Luther Burbank develops the Russet Burbank Potato, and later goes on developes several new hybrid fruits, including plums, berries, prunes and peaches.

1908: First U.S. hybrid maize produced by G.H. Shull of Carnegie Institute through self-pollination.

1919: Word “biotechnology” coined by Hungarian engineer Karl Ereky.

1930: Inspired by writings of Luther Burbank, U.S. Congress passes the Plant Patent Act, enabling the products of plant breeding to be patented.

1933: Hybrid maize becomes available commercially in the United States, causing maize yields to triple over the past 50 years.

1953: James Watson and Francis Crick describe the double helix structure of deoxyribonuleic acid (DNA), providing more insight into how DNA carries genetic information.

1960s: After decades of work, Norman Borlaug creates dwarf wheat that increases yields by 70 percent, launching the Green Revolution that helps save millions of lives.

1973: Stanley Cohen and Hubert Boyer successfully splice a gene from one organism and move it into another, launching the modern biotechnology era.

1978: Boyer's lab creates a synthetic version of the human insulin gene.

1982: The first biotech plant is produced — a tobacco plant resistant to an antibiotic. The breakthrough paves the way for beneficial traits, such as insect resistance, to be transferred to plants.

1985: Field trials for biotech plants that are resistant to insects, viruses and bacteria are held in the United States.

1986: The EPA (Enviromental Protection Agency) approves the release of the first crop produced through biotechnology — tobacco plants. A coordinated framework for the regulation of products derived from biotechnology is established.

1991: The USDA's (U.S. Department of Agriculture) Animal and Plant Health Inspection Service (APHIS) publishes guidelines for field trials of biotech crops.

1994: A biotech FlavSavr ™ tomato developed to have more flavor and a longer shelf-life than conventionally grown tomatoes, is approved by the Food and Drug Administration (FDA).

1995-96: Biotech soybeans and maize are approved for sale and biotech cotton is commercialized in the United States. Biotech crops become the most rapidly adopted technology in the history of agriculture.

1996: Farmers in six countries plant biotech crops on 4.2 million acres (1.7 million hectares).

1999: German and Swiss scientists develop golden rice, fortified with betacarotene, which stimulates production of vitamin A that can prevent some forms of blindness.

2000: The first entire plant genome is sequenced, Arabadopsis thaliana, providing researchers with greater insight into the genes that control specific traits in many other agricultural plants.

Farmers in 13 countries plant biotech crops on 44.2 million hectares, a 25-fold increase over 1996.

2001: U.S. and Canadian scientists develop a biotech tomato that thrives in salty conditions, a discovery with the potential to create tomatoes and other crops that can grow in marginal conditions.

The European Community releases a 15-year, $64 million study that involves more than 400 research teams on 81 projects. It finds that biotech products pose no more risk to human health or the environment than conventional crops.

EPA renews registration for Bacillus thuringiensis (Bt)maize and cotton, citing that they do not pose any health or environmental risks.

2002: The National Center for Food and Agricultural Policy (NCFAP) study finds that six biotech crops planted in the United States — soybeans, maize, cotton, papaya, squash and canola — produce an additional 1.8 million tons of food and fiber on the same acreage, improve farm income by $1.5 billion and reduce pesticide use by 210,000 tons.

Reprinted from the Council for Biotechnology Information web site. 2003.

GLOSSARY OF BIOTECHNOLOGY TERMS

Agrobacterium tumefaciens: A gram-negative, rod-shaped flagellated bacterium responsible for crown gall tumor in plants. Following infection, the TI plasmid from the bacterium becomes integrated into the host plant's DNA and the presence of the bacterium is no longer necessary for the continued growth of the cell. This bacterium is now used to deliberately transfer genetic material into plants through biotechnology.

Biobased products: Fuels, chemicals, building materials, or electric power or heat produced from biological material(s). The term may include any energy, commercial or industrial products, other than food or feed, that utilizes biological products or renewable domestic agricultural (plant, animal, and marine), or forestry materials.

Biological boundaries: A concept that differentiates one organism from another and suggests that organisms cannot or should not exchange genetic material. An alternative concept is that genes are defined not by the organism from which they came, but by their function. As scientists have identified genes in seemingly non-related organisms such as plants and humans, they have found identical genes in each.

Biotechnology: A set of biological techniques developed through basic research and now applied to research and product development. Biotechnology refers to the use of recombinant DNA, cell fusion and new bioprocessing techniques.

Biotechnology-derived: The use of molecular biology and/or recombinant DNA technology, or in vitro gene transfer, to develop products or to impart specific capabilities in plants or other living organisms.

Bt corn (maize): A maize plant that has been developed though biotechnology so that the plant tissues express a protein derived from a bacterium, Bacillus thuringiensis, which is toxic to some insects but non-toxic to humans and other mammals.

Cell: The lowest denomination of life thought to be possible. Most organisms consist of more than one cell, which become specialized into particular functions to enable the whole organism to function properly. Cells contain DNA and many other elements to enable the cell to function.

Chromosomes: The self-replicating genetic structure of cells containing the cellular DNA. Humans have 23 pairs of chromosomes.

Cry1A: A protein derived from the bacterium Bacillus thuringiensis that is toxic to some insects when ingested. This bacterium occurs widely in nature and has been used for decades as an insecticide, although it constitutes less than 2 percent of the overall insecticides used.

Cultivar: Synonymous with variety; the international equivalent of variety.

Double helix: The twisted-ladder shape that two linear strands of DNA assume when complementary nucleotides on opposing strands bond together.

DNA (deoxyribonucleic acid): The genetic material of all cells and many viruses. The molecule that encodes genetic information. DNA is a double-stranded molecule held together by weak bonds between base pairs of nucleotides. The four nucleotides in DNA contain the bases adenine (A), guanine (G), cytosine (C) and thymine (T). In nature, base pairs form only between A and T and between G and C; thus the base sequence of each single strand can be deduced from that of its partner.

Eukaryote: Organism whose cells have (1) chromosomes with nucleosomal structure and separated from the cytoplasm by a two-membrane nuclear envelope, and (2) compartmentalization of functions in distinct cytoplasmic organelles. Contrast prokaryotes (bacteria and cyanobacteria).

Gene: The fundamental physical and functional unit of heredity. A gene is an ordered sequence of nucleotides located in a particular position on a particular chromosome that encodes a specific functional product, such as a protein or RNA molecule.

Gene flow: The exchange of genetic traits between populations by movement of individuals, gametes or

spores. It involves the spread of new variants among different populations through dispersal.

Gene gun: A device invented at Cornell University that allows genetic material to be introduced into a new organism. The genetic material from the donor is "shot" into cells of the recipient and the material is incorporated into its DNA.

Gene splicing: The isolation of a gene from one organism and then the introduction of that gene into another organism using techniques of biotechnology.

Genetic engineering: The technique of removing, modifying or adding genes to a DNA molecule in order to change the information it contains. By changing this information, genetic engineering changes the type or amount of proteins an organism is capable of producing, thus enabling it to make new substances or perform new functions.

Genetically modified organism (GMO): Often the label GMO and the term "transgenic" are used to refer to organisms that have acquired novel genes from other organisms by laboratory "gene transfer" methods.

Genetics: The study of the patterns of inheritance of specific traits.

Genome: All the genetic material in the chromosomes of a particular organism; its size is generally given as its total number of base pairs.

Herbicide-tolerant crop: Crop plants that have been developed to survive application(s) of one or more commercially available herbicides by the incorporation of certain gene(s) via biotechnology methods, such as genetic engineering, or traditional breeding methods, such as natural, chemical or radiation mutation.

Hybrid: Seed or plants produced as the result of controlled cross-pollination as opposed to seed produced as the result of natural pollination. Hybrid seeds are selected to have higher quality traits, e.g. yield or pest tolerance.

Labeling of foods: The process of developing a list of ingredients contained in foods. Labels imply that the list of ingredients can be verified. The U.S. Food and Drug Administration has jurisdiction over what is stated on food labels.

Minimal tillage practices: Practices that allow farmers to reduce the tilling of the land in order to conserve topsoil and its nutrients.

Mutation: Any inheritable change in DNA sequence.

Mutation breeding: Commonly used practices in plant breeding and other areas in which chemicals or radiation are applied to whole organisms, e.g. plants, or cells so that changes in the organism's DNA will occur. Such changes are then evaluated for their beneficial effects, such as disease resistance.

Natural selection: The concept developed by Charles Darwin that genes which produce characteristics that are more favorable in a particular environment will be more abundant in the next generation.

Nucleotide: A subunit of DNA or RNA consisting of a nitrogenous base (adenine, guanine, thymine or cytosine in DNA; adenine, guanine, uracil or cytosine in RNA), a phosphate molecule, and a sugar molecule (deoxyribose in DNA and ribose in RNA). Thousands of nucleotides are linked to form a DNA or RNA molecule.

Organic agriculture: A concept and practice of agricultural production that focuses on production without the use of synthetic pesticides. The USDA has established a set of national standards which are online at <http://www.ams.usda.gov/nop>.

Ovule: An outgrowth of the ovary of a seed plant that encloses an embryo.

Pesticide resistance: A genetic change in response to selection by a pesticide resulting in the development of strains capable of surviving a dose lethal to a majority of individuals in a normal population. Resistance may develop in insects, weeds or pathogens.

Plant-incorporated protectants: Formerly referred to as plant-pesticides, plant-incorporated protectants (PIPs) are substances that act like pesticides that are produced and used by a plant to protect it from pests such as insects, viruses and fungi.

Pollen: The cells that carry the male DNA of a seed plant.

Prokaryote: Organisms, namely bacteria and cyanobacteria formerly known as blue-green algae, characterized by the possession of a simple naked DNA

chromosome or occasionally two such chromosomes, usually of circular structure, without a nuclear membrane and possessing a very small range of organelles, generally only a plasma membrane and ribosomes.

Protein: A large molecule composed of one or more chains of amino acids in a specific order. The order is determined by the base sequence of nucleotides in the gene that codes for the protein. Proteins are required for the structure, function and regulation of the body's cells, tissues and organs, and each protein has unique functions. Examples are hormones, enzymes and antibodies.

Recombinant DNA molecules (rDNA): A combination of DNA molecules of different origin that are joined using recombinant DNA technologies.

Recombinant DNA technology: Procedure used to join together DNA segments in a cell-free system (an environment outside a cell or organism). Under appropriate conditions, a recombinant DNA molecule can enter a cell and replicate there, either autonomously or after it has become integrated into a cellular chromosome.

Recombination: The process by which progeny derive a combination of genes different from that of either parent.

Resistance management: Strategies that can be employed to delay the onset of resistance. For insect resistance management, this includes the use of a "refuge" in which the insect will not be challenged by the pesticide used in the rest of the field.

Selective breeding: Making deliberate crosses or matings of organisms so that the offspring will have a desired characteristic derived from one of the parents.

Soil conservation practices: See minimal tillage practices.

Splicing: See gene splicing.

StarLink™: An insect-resistant variety of maize that was not labeled for human consumption.

Tissue culture: A process of growing a plant in the laboratory from cells rather than seeds. This technique is used in traditional plant breeding as well as when using techniques of agricultural biotechnology.

Traditional breeding: Modification of plants and animals through selective breeding. Practices used in traditional plant breeding may include aspects of biotechnology such as tissue culture and mutation breeding.

Transgenic: Containing genes altered by insertion of DNA from an unrelated organism. Taking genes from one species and inserting them into another species in order to get that trait expressed in the offspring.

Variety: Subdivision of a species for taxonomic classification. Used interchangeably with the term cultivar to denote a group of individuals that is distinct genetically from other groups of individuals in the species. An agricultural variety is a group of similar plants that by structural features and performance can be identified from other varieties within the same species.

Virus: A noncellular biological entity that can reproduce only within a host cell. Viruses consist of nucleic acid covered by protein; some animal viruses are also surrounded by a membrane. Inside the infected cell, the virus uses the synthetic capability of the host to produce progeny virus.

Vitamins: Various substances that are essential in minute quantities to the nutrition of animals and plants.❑

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KEY INTERNET SITES

UNITED STATES GOVERNMENT

Department of Agriculture
www.aphis.usda.gov/brs/
www.ers.usda.gov/topics/view.asp?T=10100

Department of State
http://usinfo.state.gov/gi/global_issues/biotechnology.html

Environmental Protection Agency
http://www.epa.gov/opptintr/biotech/index.html

Food and Drug Administration
Center for Food Safety and Applied Nutrition
www.cfsan.fda.gov/~lrd/biotechm.html

Office of the U.S. Trade Representative
www.ustr.gov/new/biotech.htm

ACADEMIC AND RESEARCH INSTITUTIONS

AgBios
www.agbios.com/main.php

AgBiotechNet
www.agbiotechnet.com

AgBioWorld
www.agbioworld.org

American Phytopathological Society
www.apsnet.org/media/ps/

Center for Global Food Issues
www.cgfi.com

Cornell University
www.nysaes.cornell.edu/agbiotech/

Council for Agricultural Science and Technology
www.cast-science.org

Information Systems for Biotechnology
www.isb.vt.edu

National Agricultural Biotechnology Council
www.cals.cornell.edu/extension/nabc

National Center for Food and Agricultural Policy
www.ncfap.org

Pew Initiative on Food and Biotechnology
www.pewagbiotech.org

BIOTECH INDUSTRY-SPONSORED GROUPS

Alliance for Better Foods
www.betterfoods.org/promise/promise.htm

Biotech Knowledge Center
www.biotechknowledge.com

Biotechnology Industry Association
www.bio.org/foodag/

Check Biotech
www.checkbiotech.org

Council for Biotechnology Information
www.whybiotech.com

Food for Our Future
www.foodfuture.org.uk

Straight Talk About Biotechnology
www.dupont.com/biotech/

INTERNATIONAL ORGANIZATIONS

Codex Alimentarius
www.codexalimentarius.net/biotech.stm

Consultative Group on International Agricultural Research
www.cgiar.org/biotech/rep0100/contents.htm

Food and Agriculture Organization
www.fao.org/biotech

International Food Policy Research Institute
www.ifpri.org/themes/biotech/biotech.htm

International Rice Research Institute
www.irri.cgiar.org/apec/index.asp

International Service for National Agricultural Research
www.isnar.cgiar.org/kb/Bio-index.htm

Organization for Economic Cooperation and Development
www.oecd.org/topic/0,2686,en_2649_37437_1_1_1_1_37437,00.html

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