*Agriculture, Natural Resources and Rural Enterprise Division*
*Office of Sustainable Development*
*Bureau for Africa*
*U.S. Agency for International Development*

# Agricultural Biotechnology:
# A Review of Contemporary Issues

**Catherine L. Ives**
**Michigan State University**

**Andrea Johanson**
**Michigan State University**

**Josette Lewis**
**USAID Global Bureau**

**June 2001**

*Agriculture, Natural Resources and Rural Enterprise Division*
*Office of Sustainable Development*
*Bureau for Africa*
*U.S. Agency for International Development*

# Agricultural Biotechnology: A Review of Contemporary Issues

**Catherine L. Ives**
**Michigan State University**

**Andrea Johanson**
**Michigan State University**

**Josette Lewis**
**USAID Global Bureau**

**June 2001**

Publication services provided by **The Mitchell Group, Inc. (TMG)**
pursuant to the following USAID contract: AFR/SD Support Services
Contract Number AOT-C-00-99-00224-00

Contents

# ACRONYMS

| | |
|---|---|
| **ABSP** | Agricultural Biotechnology Support Project |
| **ADS** | Automatic Directive System (USAID) |
| **Bt** | Bacillus thuringiensis |
| **CBD** | Convention on Biological Diversity |
| **CGIAR** | Consultative Group on International Agricultural Research |
| **CIAT** | Centro Internacional de Agricultura Tropical |
| **CIMMYT** | Centro Internacional de Mejoramiento de Maiz y Trigo (maize and wheat) |
| **COTR** | Contracting officer technical representative (USAID) |
| **CRSP** | Commodity-oriented Collaborative Research Support Project |
| **EPA** | U.S. Environmental Protection Agency |
| **EU** | European Union |
| **FAO** | Food and Agriculture Organization (UN) |
| **FDA** | U.S. Food and Drug Administration |
| **GM** | Genetically modified |
| **GMO** | Genetically modified organism |
| **IARC** | International agricultural research center |
| **IEE** | Initial Environmental Examination |
| **ILRI** | International Livestock Research Center |
| **INSORMIL** | International CRSP for sorghum and millet |
| **IP** | Intellectual property |
| **IPR** | Intellectual property rights |
| **IRRI** | International Rice Research Institute |
| **ISNAR** | International Service for National Agricultural Research |
| **OECD** | Organization for Economic Cooperation and Development |
| **PARC** | Pan-African Rinderpest Campaign |
| **PBRs** | Plant breeder's rights |
| **PVP** | Plant variety protection |
| **R&D** | Research and development |
| **SPS** | Sanitary and phytosanitary |
| **TBT** | Technical Barriers to Trade |
| **TRIPS** | Trade-Related Aspects of Intellectual Property Rights (WTO agreement) |
| **UK** | United Kingdom |
| **UPOV** | International Union for the Protection of New Plant Varieties |
| **USAID** | United States Agency for International Development |
| **WHO** | World Health Organization |
| **WTO** | World Trade Organization |

# 1. INTRODUCTORY OVERVIEW

Our goal in this document is to engage the U.S. Agency for International Development (USAID) and its development partners in a broader discussion of contemporary agricultural biotechnology, in order to:

- increase awareness of the issues and opportunities surrounding this technology.
- explore options for new programmatic approaches on a national, regional and global basis.

To establish a basic foundation for the subsequent discussion, we will begin with an overview of biotechnology: what it is, what policy issues it raises and its relevance to USAID and other development organizations. To keep this manageable, we do not attempt to be comprehensive, but rather to give a sense of the "why" and the "what" that this discussion will explore.

**What is biotechnology?**

Modern biotechnology is an applied science based on molecular biology. It seeks to understand biological processes, such as drought tolerance in plants or human diseases like diabetes, on the genetic level. That knowledge can then be used to engineer traits into crops, create diagnostic tools or develop human pharmaceuticals.

Biotechnology can be applied in a number of ways, most of which are not controversial:

- *Genetic engineering of crops*—often called GMOs (genetically modified organisms)—such as corn, potatoes and cotton.
- *Molecular markers to enhance traditional crop breeding*—a research tool described in the example below. The resulting crops are not genetically engineered or GMOs.
- *Molecular diagnostics*—used in agriculture to more accurately diagnose crop/livestock diseases or, in medicine, to diagnose human diseases such as HIV/AIDS.
- *Vaccines*—used in both livestock and human health. They may hold efficacy or safety advantages over traditionally formulated vaccines.
- *Tissue culture*—reproduction of disease-free planting material for crops such as tubers, tree crops and coffee. While not "modern" biotechnology, this activity is included in the definition of biotechnology used by most developing countries.
- *Pharmaceuticals*—more than 30 biotechnology-derived drugs have been approved, some widely used for years. Examples include insulin, hemophilia drugs and heart disease drugs.
- *Industrial applications*—these include food processing (enzymes used in making cheese, high-fructose corn syrup), mining, textiles, paper industry, etc.

To provide a couple of simplified examples of how biotechnology works:

- In traditional crop breeding, plants are selected based on *phenotypic* or visible traits. Using analytical tools developed through biotechnology, breeding becomes more precise through selection of molecular traits on crop DNA rather than phenotypic traits.

- It has been known for many years that the common soil bacterium *Bacillus thuringiensis* (called Bt) produces substances that are toxic to specific insect larvae. In fact, topical sprays of whole Bt bacteria have been used in organic farming for about 40 years. Now scientists have isolated from bacteria the genes that code for those toxic substances and have engineered them into crop plants such as corn, potatoes and cotton. The expression of different variations of that toxin in crops makes them resistant to the European corn borer, the potato tuber moth (or, using a different Bt gene, to the Colorado potato beetle) or the cotton boll worm, respectively.

**Status of global agricultural biotechnology**

- While the United States is the leader in both research and commercial applications, biotechnology research is also conducted by many European and Asian research institutions and industry, as well as in more advanced developing countries and by the International Agricultural Research Centers (IARCs).
- The private sector dominates agricultural biotechnology, funding over 50% of the research and development in the United States. The strength of the private over the public sector introduces important issues that must be addressed when considering the needs of developing countries.

In terms of commercial applications, the following statistics regarding global production of genetically engineered crops are noteworthy:

- Global area of transgenic crops in 1998 is estimated at 27.8 million hectares, a 2.5-fold increase over 1997.
- The United States is the global leader, with 74% of the total global acreage, followed by Argentina (15%), Canada (10%), Australia (1%) and finally Mexico, Spain, France and South Africa, each with less than 1% of the global total.
- The following crops predominate, in this order: herbicide-tolerant soybeans, insect-resistant corn, insect-resistant cotton and herbicide-tolerant canola (rapeseed).
- More than 48 crop varieties have been approved for commercial production worldwide.
- Research has primarily focused on production traits for temperate grains (where the largest commercial sales will be) but has also included vegetables, rice, potatoes, forestry trees, and tropical crops such as coffee, cocoa, papaya, banana, ornamental flowers, cassava, sweet potato, etc.

**Biotechnology policy issues**

*Intellectual Property Rights (IPR)*

- Patent protection has played a very significant role in the commercial development of biotechnology. This is in part the result of deliberate U.S. federal policies aimed at stimulating U.S. technological competitiveness. Europe has recently followed in this direction. Many developing countries oppose the application of patents to plants but have other forms of IPR policy options.
- Several international agreements deal with IPR and will be discussed in more detail in chapter 4: the WTO Agreement on Trade Related Aspects of IPR (TRIPS), International Union for the Protection of New Plant Varieties (UPOV), Convention on Biological Diversity (CBD) and FAO International Undertaking on Plant Genetic Resources.

*Biosafety*

- The term biosafety is shorthand for regulatory systems designed to ensure that applications of biotechnology are safe for human health, agriculture and the environment. We will discuss these concerns and how they are regulated in later sections.
- Several international agreements deal with biosafety: the WTO's Sanitary and Phytosanitary (SPS) Agreement, its Technical Barriers to Trade (TBT) Agreement, and the Biosafety Protocol of the Convention on Biological Diversity.

**Biotechnology's relevance to USAID and its partners**

We expect these discussions to help in redefining the goals of our current approach to biotechnology. There are also some ways in which biotechnology might impact or contribute to USAID objectives and our dialog with developing country partners. For example, it may:

- Meet the growing food-production demands created by population growth and changing diets associated with economic development.
- Offer a new tool for improving agricultural productivity in relation to either food security (better food staple crops) or economic development (including export crops such as flowers, coffee and cocoa).
- Improve child survival and nutritional status through crops such as high-iron rice, high–Vitamin A rice and maize, etc.

With these goals in mind, USAID and other development organizations might particularly focus on:

- Promoting developing-country access to this new technology. Developing countries have expressed concern about being left behind by the so-called "biotechnology revolution," particularly because current market-driven private-sector biotechnology applications are not broadly applicable to developing-country needs.
- Helping developing countries analyze the costs and benefits of biotechnology for meeting their food needs (cost, quantity and quality), environmental goals, and economic development opportunities.
- Helping developing countries comply with trade and other international agreements. The increase in science-based agreements will require both improvement of developing countries' scientific capacity and development of science-based trade policies.

# 2. AGRICULTURAL BIOTECHNOLOGY RESEARCH AND COMMERCIAL TECHNOLOGIES: INPUT TRAITS

## Introduction

To date, the worldwide impact of plant biotechnology has been almost exclusively on crops of high economic importance to the developed world. In 1998, for example, the five principal transgenic crops were (in decreasing order of area) soybean, corn/maize, cotton, canola/rapeseed, and potato. Transgenic soybean alone made up over 50% of the acreage; wheat, sunflower and rice were also important. The most common transgenic traits were herbicide resistance (71%) and insect resistance (28%).

Since most multinational seed and biotechnology companies rely on profits, crops that are important to developing countries have attracted less attention. The result is that genetic and biotechnological improvement of these 'neglected' food species is confined to local and specialized research at specific crop centers within those countries, either at international agricultural research institutions and/or in specific collaborations with national agricultural research institutions in the developed world.

Fortunately, one of the major advantages of plant biotechnology is that it can generate generic strategies for crop improvement. Once developed, these strategies can then be applied to many different crops.

## Goals of agricultural biotechnology

These are essentially the same as those of conventional plant breeding, with one or two exceptions. In general terms, the goals fall into two major categories:

- Improving crop performance in the field (so-called input traits).
- Developing new products with enhanced value (output traits).

So far, most commercially grown transgenic crops feature input traits, but in the next few years the commercial release of many more crops with output traits is anticipated. Input traits will be discussed here and output traits in the next section.

*Pest and disease resistance*
Losses of agricultural crops to pests and disease can be very high, particularly in developing countries. Genetic transformation with genes that confer resistance to pests and disease has the potential both to reduce crop loss and to reduce or eliminate the application of agrochemical pesticides.

- *Virus resistance*. Plant viruses of varying kinds often destroy up to 80 percent of many crops. Fragments of DNA from plant viruses can be genetically engineered into crops to give natural protection against those viral diseases. This 'immunity' is passed on to future generations of plants. Transgenic plants from over 20 different plant species, and resistant to more than 30 different viral diseases, have now been produced using variations of this strategy.

One example is a new Hawaiian papaya that is genetically resistant to the devastating papaya ringspot virus. Developed by Cornell University, the University of Hawaii and the Pharmacia-UpJohn Company, this virus-resistant papaya is now widely grown.

- *Insect pest resistance.* The most common approach used to increase plant resistance to insect pests is the 'Bt' strategy. The gene for a protein toxic to many insect pests—and naturally present in the soil bacterium *Bacillus thuringiensis*—is inserted into plants. The plants then produce the toxin themselves and are resistant to insect attack. Different types of Bt toxin with slightly different modes of action and specificity for different species of insects have been identified.

  Varieties of Bt insect-resistant corn, cotton and potatoes are now in commercial production, and sunflower, soybeans, canola, wheat, and tomatoes are expected soon. Other crops being investigated include tobacco, walnut, sugar cane and rice.

- *Resistance to other diseases.* Transgenic solutions to other types of plant pest and disease are now being addressed, and the search for disease-resistance genes in many plant species is now underway. For example, genes which produce antifungal proteins have been inserted into various plants, including banana, giving protection against the damaging Sigatoka disease caused by the fungus *Mycosphaerella fijiensis.*

*Herbicide resistance*

Developing transgenic plants with resistance to herbicide may seem an unlikely goal, but this particular genetic modification accounted for 70% of all transgenic crops grown worldwide in 1998. The modification permits the use of simplified weed management strategies attractive to farmers.

Genes for herbicide resistance occur naturally in bacteria and can be inserted into plants. Herbicide-resistant crops allow farmers to spray their fields with chemical herbicides without harming the crop, a feature that can promote conservation tillage. One such herbicide, Roundup™, is broad-spectrum, has low toxicity to mammals and is rapidly biodegradable.

Herbicide-resistant varieties of soybeans, cotton, corn, canola and rice are now in commercial production. Herbicide-resistant wheat and sugar beet are anticipated soon. Research is ongoing on many other crops.

*Tolerance of environmental stresses*

An important goal of agricultural biotechnology is the development of crops better able to tolerate:

- extreme environmental conditions such as heat, cold and water stress.
- adverse soil conditions, such as high salinity, acidity and alkalinity, and various types of toxicity (aluminum, heavy metals).

The goal is to increase crop yields in such environments, thus reducing the risks to food security in regions where farmers must deal with extreme weather or problem soils.

# 3. AGRICULTURAL BIOTECHNOLOGY RESEARCH AND COMMERCIAL TECHNOLOGIES: OUTPUT TRAITS

**Improved post-harvest life**

It is possible to genetically engineer fruit and vegetables with improved taste and post-harvest qualities. Genetic modification has been used to slow down softening in many fruits (apple, raspberry and melon), thereby increasing shelf life during shipment and storage, although these fruits are not yet grown commercially. This technology is likely to be transferable to other crops, including bananas, pineapples, sweet peppers, peaches, nectarines, mangoes and strawberries. Attempts are also being made to modify some fruit and vegetables, such as tomato, chicory, lettuce and potato, to make them sweeter and more palatable. For example, FLAVR SAVR™ tomatoes, genetically modified for longer shelf life, do not go soft during transport and thus can be left on the plant longer to develop their full flavor. These tomatoes are currently grown in Mexico.

**Foods with improved nutritional value**

*Enhanced vitamin content*
Genetic modification could be used to produce crops that contain higher amounts of vitamins to improve their nutritional quality. Genetically altered "golden rice," for example, contains three transplanted genes that allow plants to produce beta-carotene, a compound that is converted to vitamin A within the human body. Vitamin A deficiency—the world's leading cause of blindness—affects as many as 250 million children.

*Healthier oils*
Biotechnology is being used to alter the content of many oil crops. A wide range of oil crops has been genetically modified, either to increase the amount of oil or to alter the types of oils they produce: oils of different degrees of 'saturation' have different properties.

- Genetically enhanced soybeans are lower in saturated fats, higher in oleic acid and more stable during frying without further processing.
- Certain oils, such as soybean and canola oils, have been developed to contain less saturated fat.

*Improved protein content*
Biotechnology is being used to upgrade some plant proteins now considered incomplete or of low biological value because they lack one or more of the 'essential' amino acids. Examples include:

- Peanuts with improved protein balance.
- Sweet potatoes with increased total protein content.
- Maize and soybeans with protein content engineered for specific animal feeds.

*Higher starch content for lower fat absorption*
Biotechnology is also being used to develop potato varieties with a higher starch content than normal. Such potatoes absorb less oil during frying and can be used to produce lower-fat potato chips and crisps.

*Non-allergenic foods*
Proteins in certain foods can trigger allergic reactions. Researchers are attempting to genetically modify peanuts, wheat and rice so that they no longer contain the proteins that cause severe allergies.

**Foods with health-related benefits**

In addition to enhancing the nutritional properties of foods, biotechnology is being used to develop foods that have medicinal properties—so-called functional foods or 'nutraceuticals.' Functional foods are products that are claimed to have a positive health benefit beyond 'normal' nutrition. These include:

- Fresh fruit and vegetables with enhanced antioxidant content (vitamins C and E, beta-carotene and selenium).
- Brassicas with increased glucosinolates (anti-cancer substances).

**Plants producing novel products**

Plants can be genetically engineered to produce novel substances—for example, alternative resources for industry, such as starches, fuels, pharmaceuticals, enzymes, antibiotics and vaccines.

- Corn and soybeans could become natural factories for production of ingredients like sucrose, lysine and methionine. These crops would essentially be recyclable and biodegradable and would replace industrial factories.
- Researchers are using biotechnology to develop edible vaccines in plants. These vaccines are genetically incorporated into food plants and need no refrigeration, sterilization equipment or needles. This new technology will be especially useful for delivering inexpensive, safe and highly effective vaccines throughout the world. For example, researchers are developing a vaccine against hepatitis in bananas and vaccines against *E. coli* and cholera in potatoes.
- Oilseed crops could provide farmers with value-added industrial crops that replace petrochemical-sourced industrial materials—e.g., valuable oils, such as gamma-linolenic acid.

**Bioremediation**

Bioremediation (biological remediation) uses the living processes of microorganisms or plants to clean up groundwater, contaminated soils, sludge and industrial waste streams. Genetic engineering techniques are being used to design microorganisms with new abilities to break down these compounds.

**Nitrogen fixation**

Biotechnology is being used to enhance the ability of natural soil bacteria to give plants nutrients, as well as natural fertilizer via nitrogen fixation.

# 4. BIOTECHNOLOGY AND INTERNATIONAL AGREEMENTS

There are several international agreements that impact development, technology transfer and trade in agricultural biotechnology. These agreements focus on the two main policy areas of biotechnology: (1) intellectual property rights (IPR) and (2) biosafety/regulation.

**What are the international agreements that deal with IPR?**

*WTO Agreement on Trade-Related Aspects of IPR (TRIPS)*
TRIPS sets a minimum standard for the protection of plant varieties. Countries have three options to fill this requirement: (1) extend patent protection to plants (as the United States and the EU have done); (2) implement a plant breeders' rights system such as the UPOV system, below; or (3) develop a *sui generis* (unique) system. Most developing countries have been opposed to the use of patent systems in agriculture.

*International Union for the Protection of New Plant Varieties (UPOV)*
UPOV is an international convention on plant breeders' rights or plant variety protection that has been ratified by 44 countries, including a number of developing countries.

*Convention on Biological Diversity (CBD)*
The CBD, an environmental treaty, establishes countries' sovereignty and right to control access to genetic resources and biodiversity. The CBD also promotes the sharing of benefits (monetary and other) derived from the use of genetic resources/biodiversity in areas such as pharmaceuticals and biotechnology. It contains statements promoting the granting of more favorable IPR terms to promote transfer of biotechnology to developing countries. Some developing countries view the CBD as revisiting the terms of the WTO.

*International Undertaking on Plant Genetic Resources*
This FAO-sponsored undertaking focuses on agricultural genetic resources. It is concerned with preserving the genetic resources developed by poor farmers, maintaining access to agricultural genetic resources for international public research, and sharing the benefits derived from them.

**What are the international agreements that deal with biosafety/regulation?**

*WTO Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements*
Part of a suite of agreements establishing the WTO, these agreements help to limit the trade-distorting aspects of sanitary and phytosanitary measures taken by states to protect human and environmental health. Regulations dealing with the phytosanitary, food safety, food labeling, animal health and environmental aspects of biotechnology products thus come under these agreements.

*Biosafety Protocol of the CBD*
This January 2000 protocol to the Convention on Biological Diversity (see above) deals with concerns about the release of genetically engineered organisms into the environment and possible subsequent effects on biodiversity. The core requirement of the Protocol is an Advanced Informed Agreement procedure mandated before shipment of any biotechnology products

(e.g., seeds) to be released into the environment. The Biosafety Protocol also sets forth more limited requirements for shipments of biotechnology-derived agricultural commodities destined for food, feed or processing. The Biosafety Protocol is seen by most developing countries and the European Union as revisiting the SPS and TBT agreements of the WTO.

**Why are these international agreements important to USAID and/or developing countries?**

- If they are parties to the agreements, developing countries will have to amend existing laws and/or draft new ones to meet their obligations. They are likely to need increased technical assistance and capacity building in relevant areas of national policy development.
- The WTO's emphasis on science-based regulatory standards in such areas as biotechnology will require strengthening the scientific capacity of developing countries.
- Access to biotechnology and collaboration with public or private-sector institutions in the United States, Europe or Japan will require the capacity to understand and manage intellectual property.
- Deployment of agricultural biotechnology products will also require adopting a biosafety regulatory system that meets international standards; again, technical assistance and capacity building will be needed.

**USAID/ABSP's experience and issues for discussion**

- As noted, there is tension between the "north and south" regarding the international instruments for IPR (WTO/TRIPS versus CBD) and biosafety (WTO/SPS versus CBD).
- In the past, USAID was able to address these two policy areas from a bottom-up approach—building a hands-on understanding of IPR and biosafety policies in the context of facilitating access to biotechnology. This was done by engaging developing countries in these issues as they arose in the process of developing technology collaboratively. Thus, IPR and biosafety were part of building access to a particular biotechnology application of national interest, rather than seen as solely external issues that served the interests of the United States or of multinational companies. Current pressure to comply with these international agreements means that we now face a top-down environment for policy development, with politics playing a much larger role.
- As was evident from USAID's participation in the Biosafety Protocol negotiations, some developing countries came to the negotiations without previous broad internal discussion of national interests. In some cases, a country's representative knew little of biotechnology research and regulations in his/her country.
- In view of its limited resources, to what extent should USAID directly help developing countries to participate in such international negotiations, versus helping to build the underlying technical capacity needed for scientifically aware policy development and implementation?
- Given the links to trade, it has been easier to build support at the Bureau and mission levels for funding biotech policy work. Past USAID experience has demonstrated greater success in the policy area when policy efforts have been linked to technology access and development, yet funding for technology development is declining. Should USAID maintain such a linkage between research/technology development and policy—and if so, how?

# 5. INTELLECTUAL PROPERTY AND AGRICULTURAL BIOTECHNOLOGY

## What is IP?

Intellectual property (IP) is defined as any new and useful process, machine, composition of matter, life form, article of manufacture, software, copyrighted work or tangible property. It includes such things as new or improved devices, chemical compounds, drugs, genetically engineered organisms, software, or unique and innovative uses of existing inventions. When expressed in a tangible form, IP can be protected by law—under varying conditions and for varying periods of time. This protection includes the right to prevent others from taking advantage of the IP owner's ingenuity.

The granting of intellectual property rights (IPRs) balances public-sector and private-sector interests in that the invention must be disclosed publicly, but inventors possess the limited right to exploit the invention for a pre-defined period of time. This assists the public good because it allows others to improve upon the invention and, after the termination of the monopoly rights, to develop competing products (as opposed to an invention kept as a trade secret).

## Is IP a new concept?

No, the concept of IP is not new; it was developed by medieval guilds in Europe. In the United States, IP is codified in the Constitution. In agriculture, the concept of IP is well established (e.g., patents on farm machinery), while IP is also well established in relation to plants via the plant variety protection (PVP) system.

## Why is IP an issue in agricultural biotechnology?

IP is important in USAID-funded agricultural biotechnology initiatives for a number of reasons:

1. Like other U.S. aid organizations, USAID and its contractors must abide by the Bayh-Dole Act, which permits universities and research institutes to file patents on inventions. This law has led to increased collaborations between the public and private sectors in the United States, but has also complicated transfer of technologies to developing countries.
2. It provides an incentive for private-sector investment in a research-intensive industry.
3. It creates a market for knowledge by providing a legal basis for technology sales and licensing.

## What are the different forms of IP rights (IPRs)?

There are a number of forms of IPRs, including trade secrets (e.g., elite parental lines for hybrid seed production), copyrights, trademarks (e.g., the Pioneer Hi-Bred logo), patents and PVP. The most commonly used types of protection in agricultural biotechnology—and the most controversial—are PVP and patents.

*Plant Variety Protection*
PVP, also referred to as Plant Breeder's Rights (PBRs), allows the plant breeder to protect new plant varieties for a term of 20 years (25 for tree crops). It is considered a *sui generis* system,

i.e., a system of rights designed to fit a particular context and need that is a unique alternative to standard patent protection.

*Patent*
A patent is an exclusive right provided an inventor that excludes all others from making, using and/or selling an invention. Once issued, a patent gives the inventor the legal right to create a limited monopoly by excluding others from creating, producing, selling or importing the invention. This right is of limited duration—for a period of 20 years from the date of filing the patent application. In exchange for the right of exclusion, the inventor must disclose all details describing the invention, so that when the 20-year patent right expires, the public may have the opportunity to develop and profit from the use of the invention.

**PVP versus patents**

Patents are granted provided the invention is novel (new), is non-obvious to one skilled in the field and has a utility (use).

- Patents allow protection of plant genes, rather than just the plant, and allow control of the genetic material of a number of plants for multiple uses such as medicines, pest protection, herbicide resistance, oil production, etc.
- PVPs are less expensive than patents and simpler for both applicants and administrators; hence they tend to be favored by developing countries.
- PVP allows two important exemptions that patents do not: (a) farmer-saved seed and (b) research use.
- Both patents and PVP are enforceable only in the countries for which protection is granted.

**What is TRIPS and how does it relate to agricultural biotechnology?**

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement was adopted by over 100 countries in 1994 and requires that "patents shall be available for any inventions, whether products or processes, in all fields of technology." However, it allowed countries to exclude from protection "plants and animals other than microorganisms." It does require that countries provide for protection of plant varieties either by patents or by an effective *sui generis* system (i.e., PVP) or both. TRIPS permits countries some flexibility in the precise form and the extent of protection. Nonetheless, it promotes the fundamental idea of extending IPR to agricultural genetic resources.

**What are issues/concerns of developing countries in extending IP protection to agriculture?**

- Developing countries often lack the expertise to draft appropriate legislation (PVP or patents) and begin administering such a system.
- Developing countries are concerned that new technology will be held solely in the private sector and will be inaccessible to them; this concern centers around multinational companies in particular.
- Developing countries may question the ethics of protecting, or "owning," living organisms.

- Developing countries are concerned that they may not be able to afford patented technology.
- Developing countries are concerned that farmers, often the traditional innovators, may not benefit from IP protection.

On the other hand, with appropriate IP systems, developing countries:

- Stand to benefit from the protection of their genetic resources.
- May be able to encourage investment in the plant breeding industry.
- May attract international collaborators.

**How has USAID addressed the area of IP?**

While USAID, through the Agricultural Biotechnology Support Project (ABSP), has addressed the development and implementation of national policies and laws, it has focused most of its efforts on developing proper institutional capacity. Because of USAID's emphasis on the development of appropriate agricultural technologies, issues of technology access and management have been critical to the project. This approach demonstrates the benefits of IPR in both international and local arenas. ABSP has:

- Assisted Indonesia in drafting its PVP law.
- Assisted Morocco in implementing its PVP law.
- Assisted Egypt and Indonesia in forming a technology transfer system at their national research institutes to protect endogenous IP and promote research collaborations/ partnerships. Both groups have successfully concluded negotiations with the private sector in developing joint collaborations and/or licensing research results for development into commercial products.

# 6. BIOSAFETY OVERVIEW

Biosafety is probably the most controversial of the issues surrounding biotechnology. Biosafety is shorthand for regulatory systems designed to ensure that applications of biotechnology are safe for human health, agriculture and the environment. As discussed earlier, several international agreements deal with biosafety, including the WTO Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) agreements and the Biosafety Protocol (also known as the Cartageña Protocol on Biosafety) of the Convention on Biological Diversity. We will begin here with a short overview of general principles and terms involved in evaluating and managing risks and perceptions of risks.

**Biosafety regulatory process**

The biosafety regulatory process includes two basic steps:

*Risk assessment*
This step seeks to determine both the probability of particular risks and the consequence if that risk does become a reality. Both factors—probability and consequence—are critical. For example, a risk associated with driving a car is the potential for an accident. Statistically, however, most drives do not end in an accident, and most car accidents do not result in serious harm to human health. Regulation of car manufacturing and use takes this fact into account—cars are not banned or their use highly restricted simply because a risk exists.

*Risk management*
After a risk has been identified, this step looks for ways to manage that risk to reduce the probability of occurrence or to reduce the magnitude of the consequence. Again, returning to the car example, governments manage the risk via manufacturing standards, seat belt laws, speed limits, traffic signals, law enforcement, etc.

Most of the debate surrounding regulation of biotechnology deals with differences in the second step—risk management. As regulators in the United States, Europe and elsewhere point out, there is often very little difference of opinion on the types and probabilities of risks (risk assessment), but political and socioeconomic differences come into play in determining risk management strategies or acceptable levels of risk.

**Science versus socioeconomic risks**

The WTO SPS agreement established a science-based standard for risk assessment and risk management. The SPS does allow for non-scientific considerations in certain cases, such as religious or humanitarian concerns. The United States is among the strongest supporters of science-based standards for regulations dealing with human health, food safety, environment and agriculture.

Several countries have pushed for consideration of economic impact and cultural concerns in the regulatory process. During negotiation of the Biosafety Protocol, developing countries placed a priority on socioeconomic considerations. The counter-argument to the inclusion of these more

subjective criteria has been that they have been abused by some in the past—and will likely be abused in the future—as disguises for protectionist trade policies.

**Standard for acceptable risk**

There are a number of principles that may be used in setting the standard of risk—i.e., establishing whether risks can be sufficiently managed as to be acceptable. While these principles are not necessarily mutually exclusive, much of the current debate surrounding biotechnology deals with the degree of emphasis placed on each principle:

*Substantial equivalence*
This is the standard employed by the United States and supported by OECD and WHO/FAO consensus documents on the safety of biotechnology. Under this principle, biotechnology products should be "as safe as" products produced by alternative means (e.g., conventional foods or conventional farming practices). The focus is on considering the types and levels of risk associated with biotechnology in light of risks of alternative technologies/approaches—and then holding biotechnology products to the same relative risk standard.

This principle embodies the recognition that to hold biotechnology to a higher standard may result in opportunity costs or loss of broader benefits. For example, discouraging the option of using pest-resistant biotechnology crops (through drastic regulations or bans) may sacrifice the opportunity to reduce pesticide use on certain crops for which the main alternative is currently pesticides, with their own well-documented risks.

*Precautionary principle/approach*
Although referenced in several international agreements, the interpretation of this approach is the source of much controversy. In its strongest interpretation, it calls for conclusive proof of safety before allowing new technologies to be adopted.

At the other end of the spectrum, the United States agrees that where questions exist about risk, countries should not be prohibited from permitting use of new technologies while taking precautionary measures, such as establishing regulatory procedures. By this rationale, the establishment of biosafety regulations is in itself a demonstration of the precautionary approach.

The United States has disagreed stridently with the idea that lack of full scientific certainty should be grounds for banning technologies. This was the basis for the dispute between the United States and the European Union over hormone-treated beef, for example. It has been used as a call by some for either banning or greatly adding to the regulation of biotechnology until more research has been done on the risks. This latter approach can conflict with the principle of substantial equivalence when biotechnology is held to a different standard than similar technologies/products.

*Benefit analyses*
In examining environmental impacts of biotechnology, both positive and negative impacts are considered.

Positive impacts may be direct or indirect—e.g., decreased use of pesticides associated with pest-resistant crops, use of less noxious pesticides or impacts accrued from changes in agricultural practices.

*Cost and impact of regulations*
This principle states that as USAID, developing countries and the global community look at increased regulation of biotechnology, a policy consideration should be the cost. Is it commensurate with the risks? And what are the impacts on different sectors: public research, governments, industry, farmers, consumers?

To illustrate, when EPA decided to regulate pest-resistant biotechnology crops under federal chemical pesticide laws, small biotechnology companies objected. The cost it would entail, they argued, would wipe out their ability to bring products to the market, since there was no way they could compete with the deep pockets of the big multinational companies.

Both donor agencies and research institutions in developing countries find it a particular challenge to comply with the increasingly burdensome biotechnology regulatory process. Could the current approach to biosafety indirectly inhibit the development and use of biotechnology by developing countries' research institutions and small farmers?

**Consumer issues and labeling of biotech foods**

The European Union and Japan have adopted requirements that some food products derived from biotechnology must be labeled as such. The rationale for labeling has been consumer concern about the safety of biotechnology products and/or to support consumer choice.

The United States and several other countries have opposed mandatory labeling for several reasons:

- Labeling is required in the United States only for health reasons (e.g., nutritional labeling or notice of contents that can be allergenic or otherwise detrimental to some populations —see Nutrasweet labels on diet soft drinks).
- Consumer concerns about safety should be addressed through non-regulatory means (such as outreach or educational programs).
- Labeling of biotechnology foods would likely send a negative signal to consumers about the safety of these products that the FDA has deemed to be safe.

The United States has supported the idea of voluntary labeling—allowing the market to address consumer choice rather than having the government regulate choice.

Labeling of biotech foods would require strict segregation of biotech crops from non-biotech crops. Segregation would then be followed up by testing and certification systems for "GMO-free" claims. The feasibility of such strict segregation and testing, and associated costs, is a key point of international debate.

**Labeling and developing countries**

It is important to avoid direct transference of the debate over labeling from the United States, Europe and other developed countries to the developing world. Rather, labeling issues should be viewed in the context of the priorities and constraints of developing countries themselves.

Particular questions thus include:

- Are biotechnology labels meaningful in developing countries, given the current state of food-labeling practices and consumer education and priorities?
- If developing countries adopt mandatory labeling laws, how will this affect the costs of foods, both imported and produced locally? The Australia/New Zealand Food Authority and the Japanese government studied the impact of such laws on food prices, with estimates of increases ranging from 6% to 20%. Obviously, increased food prices would have important implications for food security in developing countries.
- Are labeling laws feasible in the context of developing countries' systems of agriculture and food production, distribution and processing? If genetically engineered sweet potatoes, cassava, maize, rice, etc., are introduced in the next two to three years, could developing countries' informal and decentralized production and marketing structures comply with labeling laws, or would such a law in effect be meaningless for locally produced food? In this scenario, the law would at best fail to meet the goal of consumer awareness and at worst establish discrimination between regulation of local and imported food, contravening the WTO requirement for non-discrimination under the SPS and TBT Agreements.
- As developing countries will likely begin to adopt biotech crops in the near future, will labeling laws in export markets such as Europe become additional barriers that must be factored into which crops are targeted for biotechnological research (i.e., non-export crops)?

We are already seeing several cases of concerns with biotechnologically enhanced foods in developing countries:

- Supermarkets in the EU are demanding that beef cattle be fed on GMO-free feed. This threatens the export of Namibian beef fed on South African corn or soybeans, some of which may be genetically modified.
- Canned tuna from Thailand has been questioned for use of GMO soybean oil.
- A British grocery chain is rumored to have warned an Asian rice supplier against use of the nutritionally enhanced "golden rice" due to concern about segregation of GMOs.

**Summary**

Perceptions of the environmental risks of biotechnology, the level of socially acceptable risk and how governments manage risk are to some degree contextual, with significant differences between the United States, Europe and developing countries. The benefits are most certainly different for biotechnology in developing countries.

Both developed and developing countries have tended to import the debate on these issues—and thus the ensuing regulatory systems—directly to developing countries. As we do so, we need to consider carefully what those risks and benefits, and methods of regulating them, will mean in the context of developing countries. Failure to do so may indirectly handicap developing countries in their use of biotechnology to address issues of national importance.

# 7. Environmental Issues: Benefits and Risks of Biotechnology in Agriculture

**What are the potential benefits to the environment?**

In any risk analysis, it is obviously important to consider any possible benefits. Some potential benefits of biotechnology to the environment can be summarized as follows:

*An increase in the productivity of crops without requiring additional inputs.*
Increasing crop resistance to insects and diseases and reducing weeds will help reduce crop losses. For example, 7–20% of the world's annual maize harvest is destroyed by the European corn borer. If the corn borer can be successfully controlled by Bt, maize yields in Europe and the United States alone could increase by 7–10 million tons—equivalent to the annual food supply in calories for 60 million people.

*A reduction in the amounts of pesticide and herbicide released into the environment.*
Farmers in the United States have reported significant reductions in herbicide and insecticide usage where transgenic crops are grown. For example:

- With one type of insect- and virus-protected potato, no applications of insecticides to control either the Colorado beetle or leaf roll virus were needed.
- In 1,000 fields of herbicide-tolerant soybeans, the reduction in herbicide use ranged from 10–40%, depending on the region and growing conditions.
- Growing insect-resistant GM cotton led to 3 million liters of insecticide saved, compared with non-GM cotton, an 80% reduction in the state of Alabama.
- U.S. trials have shown up to an 87% reduction in sprays on genetically engineered Bt sweet corn.
- In the UK, tests have shown that herbicide-tolerant sugar beet needs to be sprayed only twice during the growing season with glyphosate, whereas non-transgenic beet must be sprayed at least five times with a range of selective herbicides.

*Reduced pressure to exploit additional uncultivated land.*
For example, had Asia's 1961 average cereal yields of 930 kilograms per hectare still prevailed in 1997, nearly 600 million hectares of additional land of the same quality would have been needed to equal the 1997 cereal harvest. Three times more land in China and the United States, and two times more land in India, would have been needed to equal 1992 cereal production.

*Reduced soil erosion.*
With non-transgenic soybean, farmers must clear the weeds before planting their seeds. With herbicide-tolerant soybean, however, the weeds can more easily be controlled at a later stage; farmers can plant the seeds by sowing them directly in relatively undisturbed soil. This conserves moisture and soil fauna and flora, and reduces water and wind erosion.

*The creation of alternative, renewable sources of energy (for example, biodiesel).*

*The creation of new, more environmentally friendly raw materials for industry.*
Examples include biodegradable plastics from plant starches and high-value specialty chemicals.

*Reduction in energy use in farming.*
The evidence so far suggests that fewer chemicals are used on herbicide-tolerant and insect-resistant GM crops. This in turn saves the energy that would have otherwise been used to produce and transport those chemicals. There are potential energy savings on the farm, as well.

**What are the potential risks to the environment?**

*Gene transfer—'genetic pollution' and 'superweeds.'*
One of the concerns about GM crops is that the genes could 'escape' and, through cross-pollination, mix with non-GM crops or their weedy relatives. For example, a herbicide-tolerant gene could be transferred to weeds in wild habitats, turning them into 'superweeds.'

These risks should be assessed case by case, taking into account factors such as:

- Whether a close relative of the crop is present in the area.
- The ability of different species to cross-pollinate with themselves or their weedy relatives—does pollen move any distance from the crop, or does the crop outcross at all?
- Whether the particular genes would provide any 'selective advantage' to the new plants. For example, a gene for delayed ripening would probably not cause an environmental problem.

If a potential risk is identified, various means can be used to manage this risk—for example, by the use of border rows or 'buffer zones' of non-transgenic plants, physical isolation from other cultivated fields, etc. In all cases, monitoring of gene flow can be carried out to assess the effectiveness of these methods.

Most crops are produced as a result of centuries of selective breeding and do not survive well in natural habitats. Hence, most transgenic crops (based on these existing crops and altered for product quality) are unlikely to present a problem to the surrounding ecosystem. Also, although transgenic *superweeds* are referred to, none has yet been shown to exist.

*Effects on non-target species.*
Transgenic crops modified to be resistant to a particular pest or disease may have a negative effect on harmless or beneficial organisms. For example, there are recent reports that Bt corn pollen may be toxic to the Monarch butterfly. Extensive testing is carried out on all transgenic crops to identify such non-target effects.

Such risks, if found to be valid, may still be able to be effectively managed. In the case of the Monarch butterfly, laboratory experiments are continuing to investigate factors such as the actual levels of pollen present in the fields and the timing of pollen release relative to larval feeding.

It is important to remember that the currently available alternative to transgenic crops is often much more harmful to the environment. For instance, the normal practice of routine spraying of broad-spectrum insecticides kills *all* insects, regardless of whether they are beneficial or harmful to the crop.

*Pest resistance.*
The more often any pest control method is used, the more likely it is that resistance to it will emerge in the pest it is designed to control. One current concern is that insects will develop resistance to toxins such as the Bt protein, thus reducing the effectiveness of this control method.

Resistance management is not, however, a new concept to agriculture, and techniques exist that can decrease the likelihood of resistance arising in pest populations. For example, in the United States, areas of susceptible plants (*refugia*) are grown alongside transgenic crops. This is either legally required or a voluntary practice in many areas. Researchers are also looking for new types of Bt toxins that could be alternated, mixed or combined in transgenic crops to reduce the selection pressure on the pests. To date, there have been no confirmed cases of resistant pest populations developing in the field.

*Loss of biodiversity.*
It has been suggested that the very success of transgenic crops could lead to a loss of biodiversity so that less successful crops are not grown and available varieties are reduced; however, the main potential cause of loss of biodiversity is population growth. The needs of a growing global population have largely been met by bringing more land into agricultural production.

Transgenic crops are unlikely to be a significant factor in accelerating biodiversity loss, compared with the enormous problems of habitat loss. In fact, transgenic crops may be able to help preserve uncultivated habitats by increasing yields on land already under cultivation.

# 8. HUMAN HEALTH AND FOOD SAFETY ISSUES

**What are the potential benefits of biotechnology to food?**

Biotechnology alters the chemical composition of plants to provide us with more nutritious as well as better-tasting and longer-lasting food. Some examples of these potential benefits are summarized below:

*Improved nutritional value*

- Enhanced vitamin and antioxidant content (vitamins C, E, beta-carotene, etc.)
- Higher starch content, leading to lower absorption of fat (e.g., potatoes)
- Healthier oils
- Improved protein and amino content
- Non-allergenic
- Increased glucosinolates (in brassicas)
- High polyunsaturated fatty acids

*Improved taste and keeping qualities*

- Sweeter-tasting fruit and vegetables
- Fruit and vegetables with longer post-harvest life

**What are the human health concerns associated with biotechnology in food?**

The primary concern with food produced from transgenic crops is that the genes inserted into food plants, or the proteins subsequently produced in the plant by these genes, may unintentionally create new, and perhaps even unknown, hazards, such as new toxins or allergens.

**What effect do new genes in food have on the people eating them?**

All proteins introduced into transgenic food crops currently on the market have been shown to be nontoxic, rapidly digestible and non-allergenic. Genes themselves are made up of DNA, which is present in all foods, and its ingestion is not associated with human illness.

Occasionally, inserting pieces of DNA into the plant's chromosome can disrupt the function of other genes—for example, affecting the plant's growth. But this can happen with any type of plant breeding (traditional or biotechnological) and is the reason why plant breeders always conduct extensive field testing of new varieties.

If the plant looks normal and grows normally, if the food tastes right and has the expected levels of nutrients and toxins, and if the new protein inserted into food has been shown to be safe, then no safety issues exist.

**Could genetically altered foods contain toxins and allergens?**

In the United States, no matter how a new crop is created—via traditional methods or biotechnology—breeders are required by the U.S. Department of Agriculture to conduct field testing to ensure that only desirable changes have been made. They must also perform analytical tests to observe whether nutrient levels have changed and whether the food is still safe to eat. The results of testing of seeds or crops created using biotechnology have revealed no evidence that any biotechnologically enhanced foods now on the market pose any human health concerns or that they are in any way less safe than crops produced through traditional breeding.

It is always possible to produce unknown effects through any means of plant breeding. Many plants that we routinely eat already contain toxins (e.g., beans contain lectins, potatoes contain alkaloids), and if the amount of these is increased, they may become hazardous to eat. *All* new foods are assessed by appropriate regulatory authorities to ensure that any such changes are detected.

Genetic manipulation permits the more precise transfer of just a few genes whose function is usually known, compared with the transfer of many genes whose function is unknown by conventional breeding. However, before any new transgenic food product is approved for sale, it is assessed by the appropriate regulatory authority.

**Can new foods from transgenic crops contain allergens?**

Genetic engineering does not make a food inherently different from conventionally produced food, and the technology itself does not make the food more likely to cause allergies. Concern about food allergies is genuine, however, and much is known about the foods that do trigger allergic reactions. Ninety percent of all food allergies in the United States are caused by cow's milk, eggs, fish and shellfish, tree nuts, wheat and legumes.

In the United States, the FDA has focused on allergy issues, and companies must state on the food label when a product includes a gene from one of the common allergy-causing foods. Companies are recommended to analyze the proteins they introduce into plants to discover any allergenic properties they may have. So far, none of the new proteins in foods has caused allergies.

**What about the use of antibiotic-resistance 'marker' genes?**

Antibiotic resistance (the ability to be unaffected by an antibiotic) occurs naturally and evolved hundreds of millions of years ago in soil bacteria. The widespread use of antibiotics provides conditions which enable resistant organisms to survive and multiply. As part of the genetic modification process, antibiotic-resistance 'marker' genes are usually linked to the gene of interest in order to more easily ascertain that the plant has been truly genetically modified. There is some concern that the use of antibiotic-resistance genes as markers in transgenic crops may increase antibiotic resistance among diseases affecting humans and animals and worsen the problem of drug-resistant 'superbugs.'

Antibiotic resistance is a serious public health issue, but one primarily caused by the overuse or misuse of clinically prescribed antibiotics. The possibility that antibiotic-resistance marker genes in crops could pose a public health concern has been seriously considered and largely discounted. Nevertheless, to be on the safe side, the U.S. FDA has advised food developers to avoid using marker genes that encode resistance to clinically important antibiotics. Alternative types of marker genes are also being developed, and, in five years' time, it is likely that no new crops using these marker genes will be on the market.

# 9. CURRENT USAID BIOTECHNOLOGY PROGRAMS AND POLICIES

USAID has been involved in the area of agricultural biotechnology for more than 10 years. This section reviews recent and current USAID efforts in agricultural biotechnology research and policy development. It also summarizes internal USAID policies that apply to program activities in biotechnology.

**USAID Research and Technology Development Activities**

*Virus-resistant sweet potatoes*
The Kenyan Agricultural Research Institute and the Monsanto Company have been working together to develop virus-resistant sweet potatoes. ABSP (see below) provided assistance in addressing the biosafety regulations necessary for field testing. While USAID research funding ceased in 1991, collaboration has continued, and field trials are expected this year. These sweet potatoes will be the first genetically engineered crops tested in Kenya, and possibly in sub-Saharan Africa outside of South Africa.

*Agricultural Biotechnology for Sustainable Productivity (ABSP)*
Implemented through Michigan State University in collaboration with other universities and private-sector companies, ABSP integrates research, product development and policy/regulatory development to help developing countries:

- Access and generate biotechnology.
- Establish a regulatory framework for production of biotechnology crops.

To date, ABSP has supported:

- Development of genetically engineered crops with pest resistance traits (viral resistance and insect resistance).
- Tissue culture of tropical crops.

*Commodity-oriented Collaborative Research Support Projects (CRSPs)*
Several CRSPs, such as the Sorghum/Millet (INSORMIL), Bean/Cowpea, Pond Dynamics (aquaculture), and Peanut and Global Livestock CRSPs, are working on development of:

- Molecular markers to enhance traditional breeding programs.
- Crop and livestock disease diagnostics based on biotechnology.

*Rinderpest vaccine*
In support of the Pan-African Rinderpest Campaign (PARC), this University of Calfornia Davis project uses a genetically engineered, heat-stable rinderpest vaccine on livestock, along with an inexpensive field rinderpest diagnostic kit. The program also includes technology transfer and training components that enable African laboratories to produce the vaccine and test kit locally. PARC will conduct field tests of both reagents.

*Heartwater vaccine*
The University of Florida and several southern African partners have been collaborating to develop a genetically engineered vaccine against heartwater, another livestock disease. The vaccine has been approved for testing in Zimbabwe, and mechanisms for commercial production in Africa are being developed.

*CGIAR centers*
In addition to our bilateral programs, USAID is a major contributor to the activities of the Consultative Group on International Agricultural Research (CGIAR). While USAID's support is not earmarked for biotechnology, as much as $5 million of USAID's core contribution to the CGIAR may go to biotechnology research. Among the CGIAR institutions, CIMMYT (maize and wheat), IRRI (rice), CIAT (beans, cassava) and ILRI (livestock disease) are active in biotechnology research. Additionally, the International Service for National Agricultural Research (ISNAR) provides support for policy and regulatory capacity building on biotechnology and biosafety.

**Biotechnology policy and regulatory assistance**

ABSP (see above) provides technical assistance and capacity building in developing the policy framework, which supports private-sector investment in biotechnology as well as its application at the field level. The direct linkage between crop biotechnology research and policy development through ABSP has been important both in providing an incentive to move policy development forward and in closing the gap between research investments and commercial application.

*Intellectual property rights (IPR)*
Several mission-level agricultural policy programs and ABSP have worked toward establishment of national legal systems for IPR protection in agriculture, namely plant variety protection.

*Technology transfer*
ABSP has also provided assistance at the institutional level to improve the ability of public research institutions to negotiate agreements with the local and international private sector and manage IPR issues associated with technology access and technology dissemination.

*Biosafety*
ABSP provides technical assistance at the national and institutional levels to develop and implement biosafety regulations. This has facilitated the field testing of genetically engineered crops in several countries, both crops developed under ABSP and those developed independently by the private sector.

**USAID policies and procedures related to biotechnology**

There are several USAID policies and procedures applying to biotechnology research with which project officers or contracting officer technical representatives (COTRs) should be familiar. In particular, COTRs are responsible for oversight of contractors/grantees regarding procedures for

testing of genetically engineered products (crops and human or livestock vaccines) and procedures for notification of invention of new technologies, described below:

*Biosafety*
USAID-funded projects involving genetic engineering research are subject to federal guidelines and regulatory procedures on laboratory/contained research involving genetic engineering as included in the standard provisions of grants, cooperative agreements or contracts. Field testing or release of genetically engineered products outside of contained facilities falls under the federal environmental regulation (22 CFR 216) requiring environmental impact assessments. Thus, all biotechnology programs must be assessed (generally through an Initial Environmental Examination, or IEE) and cleared by the relevant Bureau/Mission/Agency Environment Officer.

Since biotechnology requires special technical expertise not possessed by most USAID Environment Officers, USAID has added the following required steps prior to preparation of an IEE or similar assessment:

- Submission of a proposal detailing the testing or release
- External review of proposal
- Written host- (developing-) country approval from the relevant authority

USAID is in the process of formalizing these procedures through the Automatic Directive System (ADS) and the assignment of a biosafety officer to oversee compliance with this process.

*IPR*
USAID must comply with the federal Bayh-Dole Act regarding all intellectual property rights that derive from federally funded research. Also included in the standard provisions of USAID grants, cooperative agreements and contracts, the most salient points of Bayh-Dole are:

- The grantee/contractor can elect ownership of any intellectual property rights rather than ownership being assumed by the federal government.
- The grantee/contractor must report to USAID any inventions, patent filings or licenses, or the lack thereof.
- USAID retains certain rights regarding royalty-free use of patented inventions derived from USAID funding.

# 10. SOCIOECONOMIC AND ETHICAL QUESTIONS

In this last section, we look at the socioeconomic benefits and concerns surrounding agricultural biotechnology.

**Has agricultural biotechnology shown benefits to farmers or to the environment?**

Note that available impact studies are derived primarily from U.S. production systems. Among developing countries, only China has moved into wide-scale production of biotechnology crops. *Ex ante* and field-trial-scale studies allow estimation of impacts for particular biotech crops in developing countries and by smallholder farming systems.

- In 1998, farmers in the United States realized an increased yield of 60 million bushels on 14 million acres of Bt corn. This also resulted in 2 million fewer acres being spread with insecticides.
- In 1998, Bt cotton accounted for 17% of the cotton planted in the United States. Bt cotton boosted total yields by 85 million pounds. Five million fewer acres had to be treated with insecticides, and farmers planting Bt cotton increased their profits by more than $92 million.
- In 1996 and 1997, planting herbicide-tolerant soybean reduced herbicide use by 10–40% and increased yields by an average of 4.7%, leading to a net return of $29.64 per hectare. This is equivalent to a U.S. national benefit of $12 million in 1996 and $109 million in 1997.
- Virus-resistant transgenic tobacco in China is reported to increase the average yield by 5–7% and save 2–3 insecticide applications.
- Estimates of China's Bt cotton acreage for 1999 range up to 1 million hectares. A 1999 study of smallholders (farmers with an average farm size of less than 1 hectare) demonstrated that Bt cotton reduced the cost of production by 14–33% through decreased pesticide and labor costs. Net income benefit from Bt cotton was highest for small-scale producers. Farmers also received the highest percentage of economic benefits from Bt cotton—8 to 17 times that received by Chinese seed companies or Monsanto. Among farms surveyed, pesticide application rates with Bt cotton plunged from an average of 12 to only 2–3 sprayings; this correlated with a reduction in reports of pesticide poisoning by farmers.
- In South Africa, one-hectare farmer trials of Monsanto Bt cotton in 1997–1998 showed a mean yield increase of 453.3 kilograms/hectare and reduction of pesticide use by 5.8 sprays on average. The net economic benefit to farmers in these trials was 33.4% over non-Bt cotton.
- *Ex ante* analysis of virus-resistant potatoes developed jointly by a public Mexican research institution and Monsanto predicted a 32% decrease in production costs over traditional varieties and a larger economic benefit for small farmers over medium- and large-scale farmers. As with Bt cotton in China, this predicted larger benefit for small farmers is associated with improved yields, compared to limited pesticide use on non-genetically engineered crops.

**Are there any benefits to consumers from biotechnology?**

In the public press, significant emphasis is placed on the lack of consumer benefit from biotechnology. Current consumer benefit is accrued indirectly through the decreased use of pesticides on food. A number of products will be available commercially in the next few years that are oriented towards consumer preferences, including "heart-healthy" oils, vitamin-enriched foods, fresher and tastier fruits and vegetables, etc.

It is important, however, to distinguish food systems in developing countries from those in the United States or Europe. Improvements in agricultural productivity in developing countries may more directly benefit "consumers," since they may also be "producers." Increased local food production in developing countries can contribute to lower food costs and enhanced food security. Finally, pesticide use is a larger health problem in developing countries.

**What are the social and ethical concerns surrounding use of transgenic technology?**

The following are some of the most frequently raised objections:

*Biotechnology is "unnatural" and against the will of God.*
The issue of what is "natural" in the context of crops and animals becomes more complex if one considers the thousands of years these crops have been subject to human selection. It is notable that both the Church of England and the Vatican have voiced a "prudent yes" to the genetic engineering of plants and animals.

*Biotechnology will aggravate the prosperity gap between the north and south and will increase inequalities in the distribution of income and wealth.*
Proponents are willing to concede that these are valid concerns, given experience with other agricultural technologies. Three particular issues are:

- *There is an unequal distribution of funding for biotechnology between the public and private sectors.* Given the current situation, in which the private sector is the primary funder and developer of this technology, it is only too likely that many developing countries, small farmers or certain crops will be bypassed, based on market considerations.
- *Access to biotechnology will be challenging for resource-poor farmers, as it has proved with more traditional inputs such as seed, fertilizer and pesticides.* Biotechnology will not necessarily create new challenges in this regard nor overcome traditional inequities in access to resources.
- *Biotechnology innovations may compete with traditional developing-country agricultural exports, as was the case with high-fructose corn syrup (produced using a biotech-derived enzyme) versus traditional sugar exports.* Biotechnology can improve other developing country exports, however—for example, by decreasing spoilage of fruits and vegetables during shipment. Resolution of these issues will depend in part upon how questions of equitable access to and funding of biotechnology are addressed. They are not, however, issues unique to biotechnology.

*Biotechnology primarily benefits multinational companies.*
A complex of factors contributes to the predominance of large private companies in developing and communicating biotechnology.

- Public-sector releases of new crop varieties were decreasing before the advent of biotechnology.
- Regulatory costs associated with commercialization of biotechnology are difficult for the public sector or small businesses to bear.
- The private sector funds more biotech research than the public sector does.

However, large companies' R&D clout does not mean they have monopolized the rewards of biotechnology. Analysis of distribution of economic benefits from Bt cotton in the United States in 1996 and 1998 showed that farmers shared benefits equally with technology companies.

The private sector will likely not be the sole provider of biotechnology applications in developing countries, given market considerations. Public-sector support (nationally and through donors) will be necessary to both balance the public and private good and to realize benefits for many developing countries.

*Patenting of life forms is unethical, and there is inadequate sharing of benefits when companies patent genes derived from developing country sources.*
An FAO undertaking on plant genetic resources is addressing some of these issues. FAO's work has led to the proposition that patent applications require attribution of the geographic origin of derivative materials so as to better allow for claims of inventiveness and sharing of benefits. Two other points to mention are:

- Biotech patents are not exclusive to the private sector; many U.S. universities and the U.S. Department of Agriculture (USDA) also patent biotech inventions.
- Countries have the option under the WTO of excluding plants and animals from patents. Most developing countries have taken this direction.