What is Agricultural Biotechnology?

For about 10,000 years , farmers have been improving wild plants and animals through the selection and breeding of desirable characteristics. This breeding has resulted in the domesticated plants and animals that are commonly used in crop and livestock agriculture. In the twentieth century, breeding became more sophisticated, as the traits that breeders select for include increased yield, disease and pest resistance, drought resistance and enhanced flavor. Traits are passed from one generation to the next through genes, which are made of DNA. All living things—including the fruits, vegetables and meat that we eat—contain genes that tell cells how to function. Recently, scientists have learned enough to begin to identify and work with the genes (DNA) that are responsible for traits.

DNA is the key to biotechnology

WHAT IS AGRICULTURAL BIOTECHNOLOGY?

Agricultural biotechnology is a collection of scientific techniques used to improve plants, animals and microorganisms. Based on an understanding of DNA, scientists have developed solutions to increase agricultural productivity. Starting from the ability to identify genes that may confer advantages on certain crops, and the ability to work with such characteristics very precisely, biotechnology enhances breeders' ability to make improvements in crops and livestock. Biotechnology enables improvements that are not possible with traditional crossing of related species alone.

HOW IS AGRICULTURAL BIOTECHNOLOGY USED?

Genetic engineering: Scientists have learned how to move genes from one organism to another. This has been called genetic modification (GM), genetic engineering (GE) or genetic improvement (GI). Regardless of the name, the process allows the transfer of useful characteristics (such as resistance to a disease) into a plant, animal or microorganism by inserting genes (DNA) from another organism. Virtually all crops improved with transferred DNA (often called GM crops or GMOs) to date have been developed to aid farmers to increase productivity by reducing crop damage from weeds, diseases or insects.

Molecular markers: Traditional breeding involves selection of individual plants or animals based on visible or measurable traits. By examining the DNA of an organism, scientists can use molecular markers to select plants or animals that possess a desirable gene, even in the absence of a visible trait. Thus, breeding is more precise and efficient. For example, the International Institute of Tropical Agriculture has used molecular markers to obtain cowpea resistant to bruchid (a beetle), disease-resistant white yam and cassava resistant to Cassava Mosaic Disease, among others. Another use of molecular markers is to identify undesirable genes that can be eliminated in future generations.

Molecular diagnostics: Molecular diagnostics are methods to detect genes or gene products that are very precise and specific. Molecular diagnostics are used in agriculture to more accurately diagnose crop/livestock diseases.

Vaccines: Biotechnology-derived vaccines are used in livestock and humans. They may be cheaper, better and/or safer than traditional vaccines. They are also stable at room temperature, and do not need refrigerated storage; this is an important advantage for smallholders in tropical countries. Some are new vaccines, which offer protection for the first time against some infectious illnesses. For example, in the Philippines, biotechnology has been used to develop an improved vaccine to protect cattle and water buffalo against hemorrhagic septicemia, a leading cause of death for both species.

Tissue culture: Tissue culture is the regeneration of plants in the laboratory from disease-free plant parts. This technique allows for the reproduction of disease-free planting material for crops. Examples of crops produced using tissue culture include citrus, pineapples, avocados, mangoes, bananas, coffee and papaya.

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Irrigated genetically engineered cotton field in South Africa.

HOW LONG HAS BIOTECHNOLOGY BEEN USED IN AGRICULTURE AND FOOD PRODUCTION?

The first food product of biotechnology (an enzyme used in cheese production and a yeast used for baking) appeared on the market in 1990. Since 1995, farmers have been growing GE crops. In 2003, 7 million farmers in 18 countries—more than 85 percent of them resource-poor farmers in the developing world—were planting biotech crops. Almost one third of the global biotech crop area was grown in developing countries.

WILL AGRICULTURAL BIOTECHNOLOGY HAVE ECONOMIC AND SOCIAL IMPACTS?

A safe and sufficient food supply, grown in an environmentally responsible fashion, is essential for humanity. Like any technology, agricultural biotechnology will have economic and social impacts. Since their introduction, crops improved using biotechnology have been used safely, with benefits such as the reduction of pesticide use. Agricultural biotechnology is only one factor among many influencing the health and welfare of farmers and other citizens in the developing world. As biotechnology continues to evolve, factual and open public discourse is vital to define the role it should play in society.

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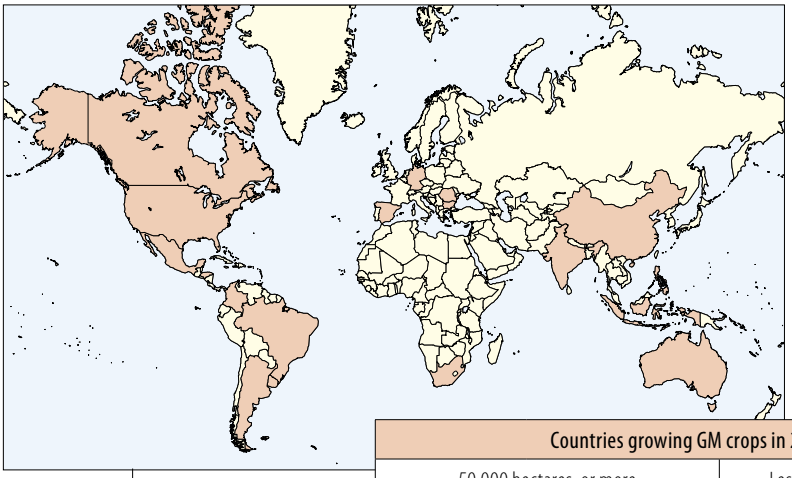
Genetically Engineered (GE) Crops: A Rapidly Expanding Market

ADOPTION IS GROWING

- From 1996 to 2003, the global area of transgenic crops has increased 40-fold, from 1.7 million hectares (mha) in 1996 to 67.7 mha in 2003. These were grown by 7 million farmers in 18 countries.
- In 2003, six principal countries (USA, Argentina, Canada, Brazil, China, and South Africa) grew 99% of the global transgenic crop area. The top 6 countries included 4 developing countries and 2 industrial countries.
- Recently, two new countries, India and the Philippines, joined the global group of countries that are growing genetically engineered crops.

Figure 1. Distribution of transgenic crops worldwide *(James, C. 2003)*



Countries growing GM crops in 2003		
50,000 hectares, or more		Less than 50,000 hectares
USA	42.8 million	Spain
Argentina	13.9 million	Mexico
Canada	4.4 million	Philippines
Brasil	3.0 million	Colombia
China	2.8 million	Bulgaria
South Africa	0.4 million	Honduras
Australia	0.10 million	Germany
India	0.10 million	Indonesia
Romania	>0.05 million	
Uruguay	>0.05 million	

Developing countries increasingly adopt genetically engineered crops. In 2003, more than one quarter of the global transgenic area was grown in developing countries. Figure 2 shows the area of GE crops in industrial and developing countries from 1996-2003. Developing countries account for an increasing proportion of the total area planted to GE crops worldwide, increasing from 14% in 1997 to 30% in 2003.

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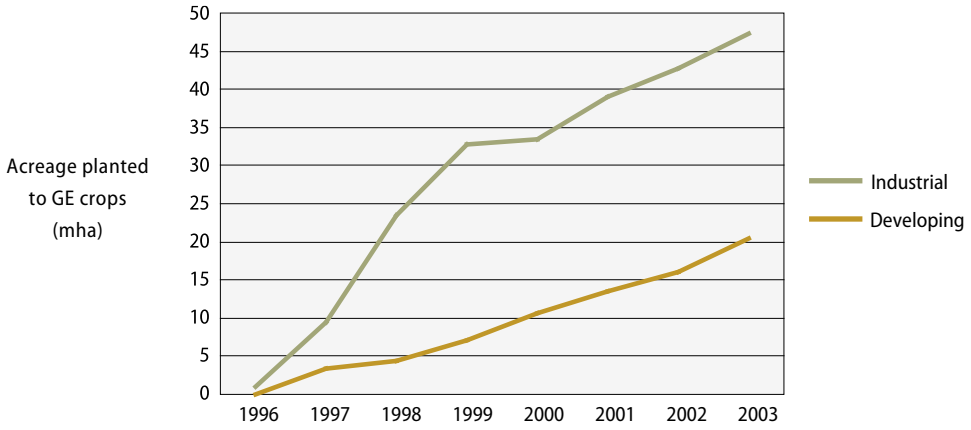
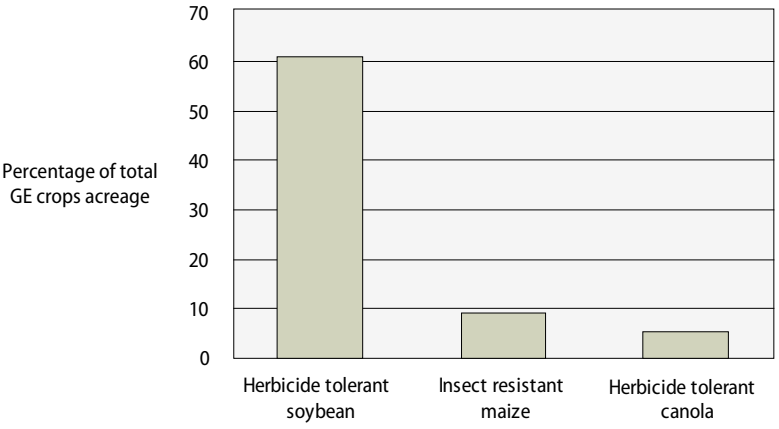
Figure 2. Growth of crops in industrial and developing countries *(James, C. 2003)*



IMPORTANT GE CROPS IN 2003

- **Herbicide-tolerant soybean** was the dominant transgenic crop, grown commercially in seven countries in 2003 (USA, Argentina, Canada, Mexico, Romania, Uruguay and South Africa).
- **Insect-resistant maize** was the second most dominant crop, planted in nine countries (USA, Canada, Argentina, South Africa, Spain, Philippines, Honduras, Uruguay and Germany).
- **Herbicide-tolerant canola** was the third most dominant crop, planted in two countries, Canada and the USA.
- **Bt cotton** is increasingly important in countries such as China, India, and South Africa.

Figure 3. Dominant GE crops in 2003 *(James, C. 2003)*



Sources:

James, C. 2003. Preview: Global Status of Commercialized Transgenic Crops: 2003. ISAAA Brief No. 30. Ithaca, NY.

What are Genetically Engineered (GE) Crops?

Genetic Engineering is the introduction of a specific gene into the DNA of a plant to obtain a desired trait. The gene introduced may come not only from another plant species, but also from other organisms. While traditional plant breeding involves crossing related plants, biotechnology is a new tool that enhances the capability of breeders to be more precise.

WHAT ARE THE GOALS OF GENETIC ENGINEERING?

The goals of genetic engineering are the same as with traditional breeding. They may aim to improve crop performance in the field by conferring pest and disease resistance, herbicide resistance, or tolerance to environmental stresses (such as drought or flooding). They may also aim to develop products with enhanced value, such as improved post-harvest life, nutritional value, or other health benefits.

Insect resistance

In the last few years, several crops have been genetically engineered to produce their own Bt proteins, making them resistant to specific groups of insects. "*Bt*" is short for *Bacillus thuringiensis*, a soil bacterium that contains a protein that is toxic to a narrow range of insects, but not harmful to animals or humans. Applications of *Bt* bacteria have been used to control insect pests for many years, before the advent of the current *Bt* crops made using biotechnology.

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

Bt Corn field at the University of the Philippines, Los Baños

Herbicide tolerance

Chemical herbicides are frequently used to control weeds. Weeds growing in the same field with crop plants can significantly reduce crop yields because the weeds compete for soil nutrients, water, and sunlight. Many farmers now control weeds by spraying herbicides directly onto the crop plants. Because these herbicides generally kill only a narrow spectrum of plants (if they didn't, they would kill the crop plants, too), farmers apply mixtures of multiple herbicides to control weeds after the crop has started to grow.

Researchers realized that if a crop plant is genetically engineered to be resistant to a broad-spectrum herbicide, weed management could be simplified and safer chemicals could be used. It is often argued that such GE varieties reduce soil erosion, because they make adoption of soil-conserving practices such as "no-till" easier. Resistance to synthetic herbicides has been genetically engineered into corn, soybeans, cotton, canola, sugar beets, rice, and flax. Some of these varieties are commercialized in several countries. Research is ongoing on many other crops. One application of this technology is that herbicide could be coated on seed from an herbicide resistant variety (for example, maize) and while the maize would germinate and thrive, weeds and parasites such as *Striga* would be killed.

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Virus resistance

Many plants are susceptible to diseases caused by viruses, which are often spread by insects (such as aphids) from plant to plant across a field. The spread of viral diseases can be very difficult to control and crop damage can be severe. Insecticides are sometimes applied to control populations of transmitting insects, but often have little impact on the spread of the disease. Often the most effective methods against viral diseases are cultural controls (such as removing diseased plants) or plant varieties bred to be resistant (or tolerant) to the virus, but such strategies may not always be practical or available. Scientists have discovered new genetic engineering methods that provide resistance to viral disease where options were limited before.

- In the US, several varieties of squash and zucchini resistant to three important viral diseases have been developed and commercialized.
- Beginning in 1992, a devastating outbreak of Papaya Ring Spot Virus (PRSV) swept through the papaya plantations of Hawaii—papaya production dropped 40% in the course of 5 years. Researchers in Hawaii and at Cornell University developed two GE varieties of papaya resistant to PRSV. Papaya growers in Hawaii have been able to grow GE virus resistant papaya since 1998.
- Scientists are currently developing virus-resistant crops for Africa, including cassava, maize and sweet potato.

Delayed fruit ripening

Delaying the ripening process in fruit is of interest to producers because it allows more time for shipment of fruit from the farmer's fields to the grocer's shelf, and increases the shelf life of the fruit for consumers. Fruit that is genetically engineered to delay ripening can be left to mature on the plant longer, will have longer shelf-life in shipping, and may last longer for consumers.

Foods with improved nutritional value

Researchers are using biotechnology for the development of foods with improved nutritional value. Genetic modification can 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. Biotechnology has also been used to alter the content of many oil crops, either to increase the amount of oil or to alter the types of oils they produce. Biotechnology could also be 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 maize with improved protein balance and sweet potatoes with increased total protein content. Reducing toxicity of certain foods is also a goal of biotechnology. For example, reduction of the toxic cyanogens in cassava has been shown to be possible and could be produced in the future.

Sources:

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How can Africa Gain Access to Genetic Engineering (GE) Technology?

The technology of genetic engineering (GE) includes both the genes of interest and the methods for getting them into plants. Isolating the right genes and then developing plants which contain the new genes has often already been done in other countries by public and private enterprises. The main issue for many developing countries is getting access to the existing technology, rather than re-inventing it.

> *The main issue for many developing countries is getting access to the existing technology, rather than re-inventing it.*

WHO OWNS THE GENES AND THE TECHNOLOGY?

Nobody "owns" genes. However, because it takes time and effort to isolate a gene and discover how to use it for a particular purpose, many genes and the technologies to use them (for example, transferring them into a plant) are protected by patents. Patents are granted for inventions and must show utility; that is, they must have a practical use. Furthermore, this use must be defined specifically in the claims of the patent. Often, the underlying inventions were made at universities, but because of the large investments needed to turn an invention into a product, commercial companies now hold rights to most of the genes and technologies.

WHAT DOES IT MEAN WHEN A GENE IS PATENTED?

Patents give the holder the right to prevent others from using the genes in the ways specified in the patent, but only in the countries where the patent is valid. Not only do different countries have different standards over what can be patented, patenting is expensive, so most companies only apply for a patent in countries where they can sell a product for a profit. Many developing countries do not have a system which allows patenting of genes, but sometimes the techniques or the final products may be protected in the context of the national law relating to intellectual property protection.

WHY ARE PATENTS ON GENES ALLOWED?

The idea of patents is to reward inventors not just for having the idea, but for making it public. A requirement of granting a patent is the publication of all of the information needed for someone to repeat the work. It also recognizes that there is a lot of investment needed to make a product out of an invention. A patent is granted for a limited period of time so that the inventor can get a return on that investment. In particular, GE plants take many years to reach the market because of lengthy regulatory approval processes and the time it takes to breed varieties even after new genes have been introduced. It is hard to see how companies would make the long-term investments necessary for research and development related to GE technology if they could not expect a return.

ARE PATENTS THE ONLY METHOD OF OWNERSHIP?

No, plant varieties are often protected under a different mechanism referred to as Plant Variety Protection (PVP) or Plant Breeders' Rights (PBR). This isn't as strict as a patent in terms of needing to be an invention – any plant variety can be protected as long as it is distinguishable from other registered varieties and has not been registered previously, but there are also some limitations to the protection this gives. There is an exemption for farmers to retain seed for re-planting and there is also an exemption for another breeder to use the variety in a breeding program. The idea is to give breeders some return for their time and effort in breeding, but at the same time to encourage more breeding and wide use of new varieties if farmers think they are better.

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HOW CAN DEVELOPING COUNTRIES ACCESS GE TECHNOLOGY?

Patents on genes and GE technology have only rarely been applied for in developing countries. If a product is exported to a country where there is a valid patent, the patents in that country apply and a license would be required. However, since the time needed to develop a GE product is so long, it is usually more efficient to get a license for existing technology even if there isn't a patent locally. What will be needed is an institution (public or private) that can be a license-holder for the technology. As most agricultural research is publicly funded in developing countries, this means that national policies have to allow public institutions to sign commercial licenses.

For instance in Egypt, extensive capacity building in Intellectual Property Right (IPR) and technology transfer led to the establishment of an Office of Technology Transfer and Intellectual Property (OTTIP) in Egypt's Agricultural Research Center. In addition a technology transfer policy was adopted by the Ministry of Agriculture, which makes Egypt one of the first developing countries to have developed a government strategy on the management of IPR in agriculture

WOULD A COMPANY LICENSE THE USE OF A GENE TO A PUBLIC INSTITUTION?

Yes. While companies must make a profit to justify investments, from time to time they will license technology for free. However, payments are commonly royalties on sales or profits. Such amounts may not be easy to determine where the GE product doesn't have a market or isn't sold (often the case for crop plants developed by public institutions for resource-poor farmers). In some recent instances, private companies have been willing to sign a royalty-free license for defined humanitarian uses—sometimes defined as use in a poor country or by poor farmers. This is good public relations for a company, but also may be good business, as raising poor farmers' incomes can make them potential customers in the future.

How are Biotech Crops & Foods Assessed for Safety?

Commercially available foods and crops made using biotechnology have been subjected to more testing and regulation than any other agricultural products, and have all been found safe. This note is an introduction to the assessment processes that have been used in determining the food and environmental safety of these products.

FOOD SAFETY ASSESSMENT

Although biotechnology broadens the scope of genetic changes that can be introduced into plants used for food, it does not inherently result in foods that are less safe than those produced by other techniques. This means that previously established principles for assessing food safety still apply for products of biotechnology. Moreover, these products can be judged on their individual safety, allergenicity, toxicity and nutrition rather than their method of production.

Foods developed with biotechnology are as safe as those developed with conventional practices.

The safety assessment of biotech foods is based on the principle that they can be compared with traditional foods that have an established history of safe use. This comparison can be based on an examination of the same risks that have been established for traditional foods, keeping in mind that many conventional foods may present specific risks depending on conditions of processing, or to individuals within a population. The intent of this comparative approach is to establish whether the new food is "*as safe as*" its conventional counterpart.

International discussion and expert consultations have resulted in a consensus on the specific safety issues that should be considered when evaluating these new foods. They include the following:

- **The Parent Plant:** Knowledge of the biology of the plant and its history of safe use as a food are important for understanding the natural range and variation of key nutritional components, such as vitamins and minerals; naturally occurring toxicants; anti-nutrients; and potential allergens.
- **The Gene Source:** Information about the natural history of the source organism of a new gene is important in assessing whether it could be a potential source of allergens or toxins.
- **Nutrition:** All plant breeding methods have the potential to change the nutritional value of plants or to lead to unexpected changes in levels of natural toxicants or anti-nutrients. Food safety assessments take into account the potential for any change in nutritional composition, especially in key components that have a significant impact on the diet. Laboratory analyses are used to compare the profile of the new plant with its conventional counterpart for constituents such as protein, fat, fibre, micronutrients, amino acids, fatty acids, vitamins, toxins and anti-nutrients.
- **Allergens:** The potential of accidentally introducing a new allergen (a protein that causes an allergic reaction) into a food is an important safety concern. Fortunately, food allergens have common characteristics, such as remaining stable during digestion and food processing, and they are usually abundant in foods. Internationally accepted approaches for evaluating allergenicity have been established and none of the new proteins present in biotech foods share the properties of allergens.
- **Toxins:** The possibility that new toxins may have been introduced into a food is also tested by comparing any newly produced proteins with known protein toxins using laboratory analyses and animal studies. Like allergens, protein toxins have very well characterized properties, which are not shared by any of the new proteins in biotech foods.

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In assessing these safety issues, the processed version of the food and its impact on specific population subgroups, such as infants or the elderly, is also evaluated.

ENVIRONMENTAL SAFETY

Assessing the environmental safety of a biotech plant requires an understanding of the biology of the plant itself and the practices used in its cultivation. This knowledge is important in identifying and evaluating potential environmental risks and also in designing any appropriate risk management measures. Most countries use similar environmental risk assessment approaches, which include:

- Evaluating the role of the introduced gene in the plant and any changes in the plant's characteristics
- The possible unintended secondary effects on non-target organisms
- The possibility that the modified plant could persist longer in the environment or invade new habitats
- The likelihood and consequences of the potential spread of newly introduced traits to related plants
- Potential impacts on biodiversity

In Hebei province of China, biodiversity of insects appears to have been enhanced by the adoption of Bt cotton.

These environmental safety concerns are not unique to plants produced using biotechnology and are also important when evaluating new varieties produced through conventional plant breeding. The objective of environmental safety assessment is to identify and evaluate any additional risks associated with the release and cultivation of these new plants in comparison with a conventional crop variety that has a history of safe use.

In addition to considering the potential risks associated with the introduction of new biotech crop varieties, consideration must be given to the risks associated with not using biotechnology to achieve desired goals. For example, the biodiversity of tropical rainforests or other ecologically sensitive areas can only be maintained if these natural ecosystems are not destroyed because of the expansion of the agricultural land base. Biotech crops can alleviate pressure to expand agricultural areas by increasing yields with improved pest resistance and increased tolerance to drought or saline soil conditions.

Developing a Biosafety System

All countries with functioning biosafety regulatory systems have developed these systems gradually, usually beginning with voluntary guidelines and standards developed cooperatively by stakeholders in academia, industry, and government. Over time these were incorporated in laws, either under existing legislation covering food and agricultural products or new legislation dealing specifically with biotechnology. Even in countries with long-established systems, biosafety policy and its implementation continue to evolve and it is not unusual to have a mix of voluntary and mandatory measures.

For countries seeking to develop a national biosafety system, it must be emphasized that there is no model for a single best approach. The issues to be considered can be broadly divided into six elements, which are briefly discussed below.

NATIONAL INVENTORY AND EVALUATION

An inventory and evaluation of national priorities, agricultural policies, existing regulatory regimes, and national scientific and technical capacities, is an ideal prerequisite to the development and implementation of biosafety-related policies and regulations. This national appraisal provides a means to identify and characterize available resources and regulatory infrastructures, assess their adequacy for supporting a biosafety system, and identify gaps where capacities need to be strengthened.

NATIONAL POLICIES AND STRATEGIES

A national biosafety policy or strategy provides a set of principles to guide the development and implementation of a biosafety system and should describe the goals and objectives of the regulatory framework. Direction on many of the fundamental issues and public policy choices that must be considered during the development of regulations can be provided by such a strategy. Examples of these issues include the extent to which social, ethical, and economic factors should be considered, the social acceptability of biotechnology and its products, and linkages with other national policies on food, agriculture, and economic development.

SCIENTIFIC KNOWLEDGE, SKILLS AND CAPACITY BASE

The human resource environment that both enables and limits biosafety implementation is shaped by the scope and quality of: competency in the biological sciences; expertise in information acquisition, communications, and management; and, experience in critical thinking, analysis, and decision-making. These capacities have an overriding influence on the development and implementation of a biosafety system. Addressing capacity needs is the top priority for many developing countries.

Building a strong base of scientific knowledge in support of the regulatory system, and development of core competencies in biotechnology product evaluation, are fundamental to any national biosafety system. These activities allow an improved scientific basis for assessments of potential risks and/or benefits, and they strengthen the scientific capabilities for risk management, inspection, and monitoring.

DEVELOPMENT OF REGULATIONS

Decisions on an appropriate regulatory framework should be informed by the national inventory and evaluation, and through extensive consultation with stakeholders, including the public. This is particularly true if a country chooses to incorporate non-safety issues into its decision-making process.

IMPLEMENTATION OF REGULATIONS

The central issues around the implementation of biosafety regulations involve the establishment of appropriate mechanisms for risk assessment, risk management, and risk communication within existing financial, technical, and

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human resource constraints. Decisions made during the implementation phase directly affect the costs associated with assessing and managing risks and ensuring compliance with regulations.

CROSS CUTTING ISSUES

Cross cutting issues are those that are common to each of the five preceding elements and they are often the most challenging factors to address and resolve. They are, however, the issues that will ultimately dictate the scope of a national policy on biosafety, and the conversion of policy into practice. Cross cutting issues affect the implementation of the system designed to assess biosafety, and perhaps more importantly, those non-technical factors that are crucial to public acceptance and confidence in the decisions that are made by government on behalf of the people.

The twin issues of public information and participation have to do with the degree of transparency in a regulatory system, and the degree to which the public has input either into the formulation of regulatory policy or into specific regulatory decisions. Transparency refers to the extent to which governments provide information on why and how certain products are regulated, how risk assessments are performed and decisions made, and as well, the conclusions and decisions that have been reached. Transparency can also involve the perceived independence and objectivity of the regulatory decision-makers.

Human, financial and infrastructure resources largely determine the scientific and administrative capacity of any country; they obviously influence any biosafety related policy or program. Funds must be available to develop and implement a national biosafety system; to support the infrastructure required, such as buildings, labs, equipment, and computers; to facilitate communication and public participation; to train scientific and regulatory personnel; and to foster the research required to assure that risk assessments are sound.

CONCLUSIONS

The development of an effective national biosafety system is important to encourage the growth of domestic biotechnologies; to ensure safe access to new products and technologies developed elsewhere; and to build public confidence that products in the marketplace are safe. The absence of a suitable framework affects the ability of the public and private sectors to invest in biotechnology and to make the products of biotechnology available so that the benefits they afford can be realized.