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APPLICATIONS OF BIOTECHNOLOGY TO CROPS: BENEFITS AND RISKS

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INTRODUCTION

The purpose of this paper is to summarize the recent scientific developments that underpin modern biotechnology and to discuss the potential risks and benefits when these are applied to agricultural crops. This introductory paper is intended for a general audience who are not specialists in the area but who are interested in participating in the current debate about the future of genetically modified crops. This debate is particularly timely with the forthcoming discussion of a new round of international trade talks in Seattle in December 1999 where international trade in genetically modified organisms (GMOs) will be an issue. This paper is restricted to genetically modified crops. It is the intention of CAST to produce a series of subsequent papers that will address some of these issues in more detail and in the broader context of genetic modification beyond crops.

TERMINOLOGY

Biotechnology refers generally to the application of a wide range of scientific techniques to the modification and improvement of plants, animals, and microorganisms that are of economic importance. **Agricultural biotechnology** is that area of biotechnology involving applications to agriculture. In the broadest sense, traditional biotechnology has been used for thousands of years, since the advent of the first agricultural practices, for the improvement of plants, animals, and microorganisms.

The application of biotechnology to agriculturally important crop species has traditionally involved the use of **selective breeding** to bring about an exchange of genetic material between two parent plants to produce offspring having desired traits such as increased yields, disease resistance, and enhanced product quality. The exchange of genetic material through conventional breeding requires that the two plants being **crossed** (bred) are of the same, or closely related, species. Such active plant breeding has led to the development of superior plant varieties far more rapidly than would have occurred in the wild due to random mating. However, traditional methods of gene exchange are limited to crosses between the same or very closely related species; it can take considerable time to achieve desired results; and frequently, characteristics of interest do not exist in any related species. Modern biotechnology vastly increases the precision and reduces the time with which these changes in plant characteristics can be made and greatly increases the potential sources from which desirable traits can be obtained.

METHODS

In the 1970s, a series of complementary advances in the field of molecular biology provided scientists with the ability to readily move DNA between more distantly related organisms. Today, this **recombinant DNA technology** has reached a stage where scientists can take a piece of DNA containing one or more specific genes from nearly any organism, including plants, animals, bacteria, or viruses, and introduce it into a specific crop species. The application of recombinant DNA technology frequently has been referred to as **genetic engineering**. An

organism that has been modified, or **transformed**, using modern techniques of genetic exchange is commonly referred to as a **genetically-modified organism (GMO)**. However, the offspring of any traditional cross between two organisms also are "genetically modified" relative to the genotype of either of the contributing parents. Plants that have been genetically modified using recombinant DNA technology to introduce a gene from either the same or a different species also are known as **transgenic plants** and the specific gene transferred is known as a **transgene**. Not all GMOs involve the use of cross-species genetic exchange; recombinant DNA technology also can be used to transfer a gene between different varieties of the same species or to modify the expression of one or more of a given plant's own genes, e.g., to amplify the expression of a gene for disease resistance.

The application of recombinant DNA technology to facilitate genetic exchange in crops has several advantages over traditional breeding methods. The exchange is far more precise because only a single (or at most, a few), specific gene that has been identified as providing a useful trait is being transferred to the recipient plant. As a result, there is no inclusion of ancillary, unwanted traits that need to be eliminated in subsequent generations, as often happens with traditional plant breeding. Application of recombinant DNA technology to plant breeding also allows more rapid development of varieties containing new and desirable traits. Further, the specific gene being transferred is known so the genetic change taking place to bring about the desired trait also is known, which often is not the case with traditional breeding methods where the fundamental basis of the trait being introduced may not be known at all. Finally, the ability to transfer genes from any other plant or other organism into a chosen recipient means that the entire span of genetic capabilities available among all biological organisms has the potential to be genetically transferred or used in any other organism. This markedly expands the range of useful traits that ultimately can be applied to the development of new crop varieties. As a hypothetical example, if the genes that allow certain bacteria to tolerate high external levels of salt can serve the same purpose when transferred into crops such as potatoes, wheat, or rice, then the production of such improved food crops on marginally saline lands may be possible. Given that the acreage of such saline lands is estimated to be equal to 20 to 25% of the land currently under cultivation world wide, this would

SOME USEFUL DEFINITIONS OF BIOTECHNOLOGY AND ITS COMPONENT TECHNOLOGIES

Biotechnology is any technique that uses living organisms or parts thereof to make or modify a product or improve plants, animals, or microorganisms for specific uses. All the characteristics of a given organism are encoded within its **genetic material** , which consists of the collection of **deoxyribonucleic acid (DNA)** molecules that exist in each cell of the organism. Higher organisms contain a specific set of linear DNA molecules called **chromosomes** and a complete set of chromosomes in an organism comprises its **genome** . Most organisms have two sets of genomes, one having been received from each parent. Each genome is divided into a series of functional units, called **genes** , there being 20,000 to 25,000 such genes in typical crop plants like corn and soybean. The collection of traits displayed by any organism (**phenotype**) depends on the genes present in its genome (**genotype**). The appearance of any specific trait also will depend on many other factors, including whether the gene(s) responsible for the trait is turned on (**expressed**) or off, the specific cells within which the genes are expressed, and how the genes, their expression, and the gene products interact with environmental factors.

The key components of modern biotechnology are as follows.

- *Genomics*: the molecular characterization of all the genes and gene products of a species.
- *Bioinfomatics:* the assembly of data from genomic analysis into accessible and usable forms.
- *Transformation*: the introduction of single genes conferring potentially useful traits into plants, livestock, fish, and tree species.
- *Molecular breeding*: the identification and evaluation of useful traits in breeding programs by the use of marker assisted selection, for plants, trees, animals, and fish.
- *Diagnostics*: the more accurate and quicker identification of pathogens by the use of new diagnostics based on molecular characterization of the pathogens.
- *Vaccine technology*: based on the use of modern immunology to develop recombinant DNA vaccines for improved disease control against lethal diseases.

Source: based on Persley and Doyle, 1999.

be a significant contribution toward global food security.

Two primary methods currently exist for introducing transgenic DNA into plant genomes in a functional manner. For plants known as dicots (broad-leaved plants such as soybean, tomato, and cotton), transformation is usually brought about by use of a bacterium, *Agrobacterium tumefaciens*. *Agrobacterium* naturally infects a wide range of plants and it does so by inserting some of its own DNA directly into the DNA of the plant. By taking out the undesired traits associated with *Agrobacterium* infection and inserting a gene(s) of interest into the *Agrobacterium* DNA that will ultimately be incorporated into the plant's DNA, any desired gene can be transferred into a dicot's DNA following bacterial infection. The cells containing the new gene subsequently can be identified and grown using plant cell culture technology into a whole plant that now contains the new transgene incorporated into its DNA. Plants known as monocots (grass species such as maize, wheat, and rice) are not readily infected by *Agrobacterium* so the external DNA that is to be transferred into the plant's genome is coated on the surface of small tungsten balls and the balls are physically shot into plant cells. Some of the DNA comes off of the balls and is incorporated into the DNA of the recipient plant. Those cells can also be identified and grown into a whole plant that contains the foreign DNA.

The ability to easily incorporate genetic material from virtually any organism into many different crop plants has reached the stage of commercial applicability. About 50% of the maize, soybeans, and cotton grown in the United States in 1999 had been modified using recombinant technologies. The major technical limitation on the application of recombinant DNA technology to improving plants is insufficient understanding of exactly which genes control agriculturally important traits and how they act to do so.

The study of genes involves the rapidly developing field of ***genomics***, which refers to determining the DNA sequence and identifying the location and function of all the genes in an organism. It appears that many traits are conserved between species, i.e., the same gene confers the same trait in different species. Thus, a gene for salt tolerance in bacteria may confer salt tolerance if it is transferred and expressed in rice or wheat. The advent of large scale sequencing of entire genomes of organisms as diverse as bacteria, fungi, plants, and animals, is leading to the identification of the complete complement of genes found in many different organisms. This is dramatically enhancing the rate at which an understanding of the function of different genes is being achieved. From the standpoint of agricultural biotechnology, advances in genomics will lead to a rapid increase in the number of useful traits that will be available to enhance crop plants in the future.

Why Are Agricultural Biotechnology Products Being Developed ?

New developments in agricultural biotechnology are being used to increase the productivity of crops, primarily by reducing the costs of production by decreasing the needs for inputs of pesticides, mostly in crops grown in temperate zones. The application of agricultural biotechnology can improve the quality of life by developing new strains of plants that give higher yields with fewer inputs, can be grown in a wider range of environments, give better rotations to conserve natural resources, provide more nutritious harvested products that keep much longer in storage and transport, and continue low cost food supplies to consumers.

After two decades of intensive and expensive research and development in agricultural biotechnology, the commercial cultivation of transgenic plant varieties has commenced over the past three years. In 1999, it is estimated that approximately 40 million hectares of land were planted with transgenic varieties of over 20 plant species, the most commercially important of which were cotton, corn, soybean, and rapeseed (International Service for the Acquisition of Agricultural Biotechnology [ISAAA], 1999). The countries include several of the world's major producers and exporters of agricultural commodities: Argentina, Australia, Canada, China, France, Mexico, South Africa, Spain, and the United States. Approximately 15% of the area is in emerging economies. The value of the global market in transgenic crops grew from US$75 million in 1995 to US$1.64 billion in 1998.

The traits these new varieties contain are most commonly insect resistance (cotton, corn), herbicide resistance (soybean), and delayed fruit ripening (tomato). The benefits of these initial transgenic crops are better weed and insect control, higher productivity, and more flexible crop management. These benefits accrue primarily to farmers and agribusinesses but there are also economic benefits accruing to consumers in terms of maintaining food production at low prices. The broader benefits to the environment and the community through reduced use of pesticides contribute to a more sustainable agriculture and better food security. Crop/input trait combinations presently being field-tested in emerging economies include virus-resistant melon, papaya, potato, squash, tomato, and sweet pepper; insect resistant rice, soybean, and tomato;

disease-resistant potato; and delayed-ripening chili pepper. There also is work in progress to use plants such as corn, potato, and banana as minifactories for the production of vaccines and biodegradable plastics.

Further advances in biotechnology will likely result in crops with a wider range of traits, some of which are likely to be of more direct interest to consumers, e.g., by having traits that confer improved nutritional quality. Crops with improved output traits could confer nutritional benefits to millions of people who suffer from malnutrition and deficiency disorders. Genes have been identified that can modify and enhance the composition of oils, proteins, carbohydrates, and starch in food/feedgrains and root crops. A gene encoding beta carotene/vitamin A formation has been incorporated experimentally in rice. This would enhance the diets of the 180 million children who suffer from the vitamin A deficiency that leads to 2 million deaths annually. Similarly, introducing genes that increase available iron levels in rice three-fold is a potential remedy for iron deficiency that affects more than 2 billion people and causes anemia in about half that number.

The new developments in gene technology also may be useful to solve problems in human health care, agriculture, and the environment in poor countries, given the chance. So far, the major research and development efforts of the private sector in biotechnology have been directed at opportunities for introducing traits useful to producers in the markets in industrial countries, because this is where bioscience companies are able to recoup their investments. New modalities that mobilize both public and private resources are needed if poor people are not to be bypassed by the genetic revolution.

The recent report of the Nuffield Council on Bioethics in the United Kingdom (1999) concluded that there is a compelling moral imperative to enable emerging economies to evaluate the use of new biotechnologies as tools to combat hunger and poverty. Creative partnerships between the developing countries, the international agricultural research centers, and the private sector could provide new means for sharing and evaluating these new technologies. Several emerging economies are making major investments of human and financial resources in biotechnology with the aim of using these new developments in science to improve food security and reduce poverty. These developments were discussed in detail at a conference in Washington, D.C. in October 1999 cosponsored by the Consultative Group on International Agricultural Research (CGIAR) and the U.S. National Academy of Sciences (CGIAR, 1999).

Applications of biotechnology in agriculture are in their infancy. Most current genetically-engineered plant varieties are modified only for a single trait, such as herbicide tolerance or pest resistance. The rapid progress being made in genomics may enhance plant breeding as more functional genes are identified. This may enable more successful breeding for complex traits such as drought and salt tolerance, which are controlled by many genes. This would be of great benefit to those farming in marginal lands worldwide, because breeding for such traits has had limited success with conventional breeding of the major staple food crops.

Benefits and Risks of Agricultural Biotechnology

In assessing the benefits and risks involved in the use of modern biotechnology, there are a series of issues to be addressed so that informed decisions may be made as to the appropriateness of the use of modern biotechnology when seeking solutions to current problems in food, agriculture, and natural resources management. These issues include risk assessment and risk management within an effective regulatory system as well as the role of intellectual property management in rewarding local innovation and enabling access to technology developed by others. In terms of addressing any risks posed by the cultivation of plants in the environment, there are six safety issues proposed by the OECD that need to be considered. These are gene transfer, weediness, trait effects, genetic and phenotypic variability, expression of genetic material from pathogens, and worker safety (Cook, 1999).

In making value judgments about risks and benefits in the use of biotechnology, it is important to distinguish between *technology-inherent risks* and *technology-transcending risks.* The former include assessing any risks associated with food safety and the behavior of a biotechnology-based product in the environment. The latter emanate from the political and social context in which the technology is used and how these uses may benefit and/or harm the interests of different groups in society.

Technology-Inherent Risks

In terms of technology-inherent risks, the principles and practices for assessing these risks on a case-by-case basis are well established in most Organization for Economic Cooperation and Development (OECD) countries and several emerging economies. These principles and practices have been summarized in a series of OECD reports published over the past decade or more. National, regional, and international guidelines for risk assessment and risk management provide a basis for national regu-

latory systems. Biosafety guidelines are available from several international organizations including the OECD, United Nations Environment Program, United Nations Industrial Development Organization, and World Bank.

Principles, Practices, and Experience

Regulatory trends to govern the safe use of biotechnology to date, include undertaking scientifically based, case-by-case, hazard identification and risk assessments; regulating the end product rather than the production process itself; developing a regulatory framework that builds on existing institutions rather than establishing new ones; and building in flexibility to reduce regulation of products after they have been demonstrated to be of low risk.

The biosafety risk assessments conducted prior to thousands of experimental and field trials in the United States focus on the characteristics of the organism being assessed, including its novel traits, intended use of the organism, and features of the recipient environment. The concept of substantial equivalence between new and traditional products has been used as a basis for determining what safety tests are needed before commercialization of products derived from genetic engineering, and if product labeling is required, and if so, what information would be useful to consumers. Familiarity has emerged as a key biosafety principle in some countries. Although familiarity cannot be equated with safety, it has provided the basis for applying existing management practices to new products, and is premised upon case-by-case and step-by-step risk assessment and management of new products. This approach has been recommended by the OECD and is the basis of the U.S. regulatory system (Juma and Gupta, 1999).

A recent development, partly in response to negative public reactions to the growing use of genetically modified crops in agriculture in some countries, has been the introduction of measures in a number countries, especially in Europe, and most recently Japan, to label some or all biotechnology-based products, with the aim of giving consumers more choice. There is also a view by some regulatory authorities for regulatory requirements relating to GMOs to be based on a more precautionary approach. This approach is based on the proposition that not enough may be known about long-term adverse effects of GMOs, and thus requires prior evidence of the safety of biotechnology based products for human health and the environment. The current debate on labeling includes the issues of whether product labeling should be mandatory or voluntary, what information should be on the label so as to inform consumers as to their choice, and whether labeling is feasible in bulk commodities that may contain a mixture of GMO and non-GMO crops.

Toward an International Biosafety Protocol

During the negotiations to establish the Convention on Biological Diversity in the early 1990s, there was concern expressed by some governments that GMOs may pose a risk to biological diversity. Consequently, intergovernmental negotiations have been in progress over the past several years to negotiate a legally binding biosafety protocol under the Convention on Biological Diversity (CBD). The centerpiece of the draft protocol is an advance informed agreement (AIA) procedure to be followed prior to the transboundary transfer of GMOs (called living modified organisms or "LMOs" in the protocol). LMOs that will come into contact with the environment of an importing country are to be covered under the AIA, to assess them for any potential adverse impacts on biodiversity. There is debate, however, as to which LMOs should be regulated by the protocol and for what purpose. Is the intention to provide international oversight of specific traits in LMOs that may adversely affect human health and the environment and/or impact on biodiversity, or is the AIA procedure to be focused on oversight of the gene technology processes by which the LMOs were produced?

A key point of disagreement centers around whether LMOs, which are intended for food, feed, or processing rather than for use as seed in the importing country, should be covered under the AIA procedure. These LMOs, called "commodities," would include GM crops such as soya or corn, which form a growing component of the international agricultural commodity trade in these crops. A group of major agricultural exporting countries (the Cairns group) argues that agricultural commodities should be excluded from the AIA procedure, because such LMOs are not intended for release into the environment and therefore cannot pose a threat to biological diversity. This is consistent with current trade in commodities, under existing international agreements, where seed contaminated with plant diseases can be marketed internationally for consumption but not for planting. The Cairns group also contend that providing detailed information on LMOs in bulk agricultural commodity shipments is not feasible, given the commingling of genetically modified and conventional seed, as well as the lack of a direct business link between seed growers and exporters. Other countries are calling for all first time transfers of LMOs, including commodities, to be covered by AIA, as the only way to monitor entry of such LMOs into a country. Some also believe that the protocol should al-

low for consideration of any human health impacts of LMOs as well as their environmental impact. These countries also point out that "intended use" of LMOs for processing (rather than planting into the environment) cannot always be guaranteed once these commodities are within a country's borders.

Another key dispute within the biosafety protocol negotiations is how decisions under AIA can be based on science and precaution. Those calling for sound science to be the basis for decision making note that reliance on an excessively precautionary approach could result in discriminatory or unjustifiable barriers to international trade in LMOs. Those favoring additional precautionary approaches note that unambiguous scientific evidence of harm relating to LMOs may not be forthcoming in the short term. The latter argue, therefore, for the need for precaution in the face of scientific uncertainty to ensure the safety of genetically modified products for human health and the environment. Countries also disagree about whether socioeconomic effects of LMOs, liability and compensation, and pharmaceutical products should be included in the protocol, although these topics fall outside the scope of the protocol, as set by the Conference of the Parties to the CBD in Jakarta in 1994 (Decision 2/5).

The final major issue is how a country's obligations under the CBD and any agreed biosafety protocol should relate to a country's rights and obligations under World Trade Organization (WTO) agreements. The next round of negotiations for the Biosafety Protocol are to be held in Montreal in January 2000.

Effects on Human Health

The health effects of foods grown from genetically modified crop varieties (sometimes called GM foods) depends on the specific content of the food itself and may have either potentially beneficial or occasional harmful effects on human health. For example, a GM food with a higher content of digestible iron is likely to have a positive health effect if consumed by iron-deficient individuals. Alternatively, transfer of genes from one species to another may also transfer allergic risk and these risks need to be evaluated and identified prior to commercialization. Individuals allergic to certain nuts, for example, need to know if genes conveying this trait are transferred to other foods such as soybeans and would labeling be required if such crops were to be commercialized. There is also some concern as to the potential health risks from the use of antibiotic resistance markers in GM foods, although there is no evidence of this.

Labeling also may be needed in some countries to identify other novel content resulting from genetic modification for cultural and religious reasons or simply because the consumers want to know what is the content of the food and how it was produced to make an informed choice, independent of any health risks.

Risks to the Environment

Among the potential ecological risks identified are increased weediness, due to cross pollination whereby pollen from GM crops spreads to non-GM crops in nearby fields. This may allow the spread of traits such as herbicide-resistance from genetically modified plants to nontarget plants, with the latter potentially developing into weeds. This ecological risk may be assessed when deciding if a GMO with a given trait should be released into a particular environment, and if so, under what conditions. Where such releases have been approved, the monitoring of the behavior of GMOs after their release is a rich field for future research in crop ecology.

Other potential ecological risks stem from the widespread use of genetically modified corn and cotton with insecticidal genes from *Bacillus thuringiensis* (the Bt genes). This may lead to the development of resistance to Bt in insect populations exposed to the GM crops. An attempt to manage this risk is being done in the early plantings of GM crops by planting "refuge" sections of Bt-cotton fields with insect susceptible varieties to reduce the opportunity of the insect population to evolve towards resistance to the plants having the Bt gene for resistance (Gould, 1999). There also may be a risk to nontarget species, such as birds and butterflies, from the plants with Bt genes. The monitoring of these effects of new transgenic crops in the environment and the devising of effective risk management approaches is an essential component of further research in risk management.

Technology-Transcending Risks

Technology-transcending risks include the social and ethical concerns that modern biotechnology may increase the prosperity gap between the rich and the poor, both internationally and within individual societies, and that it may contribute to a loss of biodiversity. There also are ethical concerns as to the moral dimensions of patenting living organisms and the cross-species movement of genes. These risks relate to the *use* of the technology, not the technology itself. The management of these risks requires policies and practices that give consumers choices while also promoting environmentally sustainable development through the judicious use of new developments in science and technology.

The reduction of biodiversity is a technology-tran-

scending risk. The reduction of biological diversity due to the destruction of tropical forests, conversion of more land to agriculture, overfishing, and the other practices to feed a growing world population is more significant than any potential loss of biodiversity due to the adoption of genetically modified crop varieties. This is not an issue restricted to transgenic crops. Farmers have adopted new commercially developed varieties in the past and will continue to do so when they perceive this to be to their advantage. On occasion, introduced varieties may enhance biological diversity, as for example for wheat in Turkey and corn in Mexico where new landraces are evolving by genetic introgression of genes from improved varieties into traditional landraces.

To slow the continuing loss of biodiversity, the main tasks are the preservation of tropical forests, mangroves and other wetlands, rivers, lakes, and coral reefs. The fact that farmers replace traditional varieties with superior varieties does not necessarily result in a loss of biodiversity. Varieties that are under pressure of substitution also can be conserved through in vivo and in vitro strategies. Improved governance and international support are necessary to limit loss of biodiversity. Actually or potentially useful biological resources should not be lost simply because we do not know or appreciate them at present (Leisinger, 1999).

Regulatory Systems

Risks and opportunities associated with GM foods may be integrated into the general food safety regulations of a country. The regulatory processes are a matter of continuing scrutiny and debate at the national and international levels as more products of biotechnology come close to market. A science-based, efficient, transparent regulatory system, which enjoys the confidence of the public and the business and farming communities, is essential in enabling the effective use of biotechnology. This system should be closely associated with existing regulatory arrangements for new pharmaceuticals, foods, and agricultural and veterinary products. National regulatory systems are complemented by international technical guidelines. National food safety and biosafety regulations should reflect international agreements, a society's acceptable risk levels, the risks associated with not introducing modern biotechnology, as well as alternative means to achieve the desired goals.

Intellectual Property Management

Trade-related intellectual property rights (TRIPS) also will be an issue related to biotechnology and food at the forthcoming Seattle round of WTO negotiations. There is need for a fair system for intellectual property (IP) management that protects the interests of the inventors while promoting the safe use of the new biotechnologies. All countries who are signatories to WTO have agreed to put in place a system for the protection of intellectual property rights, including protection of new plant varieties, although many have still to do so. These new IP systems need to include ways to reward not only the inventors of new technologies but also those farmers who have been traditional improvers of plant varieties over centuries. There also is a need to devise suitable systems for intellectual property protection that encourage and reward innovation at all levels and for all countries, not only for the technologically sophisticated.

Conclusion

The issues of major concern in relation to the future applications of biotechnology to crop improvement include the evaluation of any risks to human health and the environment; the need for mandatory and/or voluntary labeling of GM foods and/or agricultural commodities for international trade; the relationship between countries' responsibilities under the WTO; and international environmental treaties. These include the international protocol on biosafety being negotiated under the Convention on Biological Diversity, and whether this will provide oversight on traits and/or processes of genetic modification.

Governments and other responsible parties should effectively communicate with the public about the nature of new crop types and new crop varieties, about the unity of life processes in all organisms, and about the risks and benefits of agricultural biotechnology in their own country and internationally. There also is a need to continually improve the transparency and broad participation in the decision making processes in relation to biotechnology, the release of genetically modified organisms into the environment, and the approval of genetically modified foods for commercial use.

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