

GENES, TECHNOLOGY AND POLICY

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e-ASEAN Task Force

UNDP-APDIP

PREFACE

One the many challenges facing the countries in the Asia-Pacific today is preparing their societies and governments for globalization and the information and communication revolution. Policy-makers, business executives, NGO activists, academics, and ordinary citizens are increasingly concerned with the need to make their societies competitive in the emergent information economy.

The e-ASEAN Task Force and the UNDP Asia Pacific Development Information Programme (UNDP-APDIP) share the belief that with enabling information and communication technologies (ICTs), countries can face the challenge of the information age. With ICTs they can leap forth to higher levels of social, economic and political development. We hope that in making this leap, policy and decision-makers, planners, researchers, development practitioners, opinion-makers, and others will find this series of e-primers on the information economy, society, and polity useful.

The e-primers aim to provide readers with a clear understanding of the various terminologies, definitions, trends, and issues associated with the information age. The primers are written in simple, easy-to-understand language. They provide examples, case studies, lessons learned, and best practices that will help planners and decision makers in addressing pertinent issues and crafting policies and strategies appropriate for the information economy.

The present series of e-primers includes the following titles:

- The Information Age
- Nets, Webs and the Information Infrastructure
- e-Commerce and e-Business
- Legal and Regulatory Issues for the Information Economy
- e-Government;
- ICT and Education
- Genes, Technology and Policy: An Introduction to Biotechnology

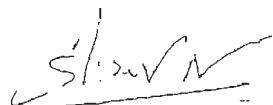
These e-primers are also available online at www.eprimers.org. and www.apdip.net.

The primers are brought to you by UNDP- APDIP, which seeks to create an ICT enabling environment through advocacy and policy reform in the Asia-Pacific region, and the e-ASEAN Task Force, an ICT for development initiative of the 10-member Association of Southeast Asian Nations. We welcome your views on new topics and issues on which the e-primers may be useful.

Finally, we thank all who have been involved with this series of e-primers-writers, researchers, peer reviewers and the production team.



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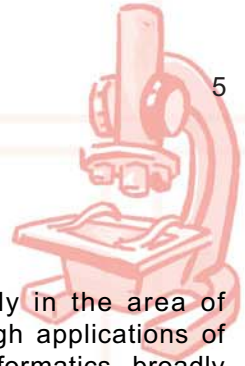
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INTRODUCTION

Rapid advances in information technology, particularly in the area of bioinformatics, have played a critical role in breakthrough applications of modern biotechnology in medicine and agriculture. Bioinformatics, broadly defined as the use of computers to handle biological information, has made possible the genomic era. Bioinformatics provides the computer tools and databases to search, store, analyze and compare these data and to use them to develop, among others, safer and more effective medicines as well higher-yielding, more stress-resistant crops that have the potential for accelerating human development.

However, as the Human Development Report 2001 points out, this potential cannot be realized unless two conditions are met. First, modern biotechnology has to be utilized to address the key health and agriculture challenges facing poor countries. Second, modern biotechnology has to be utilized through a systematic approach that allows potential risks to human health, environment and social equity to be effectively assessed and managed.

This primer discusses the science and policy issues surrounding the use of modern biotechnology. It provides a snapshot of its benefits as well as concerns regarding its potential negative impact on the environment and on human health. The primer is divided into four parts. The first part is on the science behind modern biotechnology. The second part discusses the various issues relating to the application of modern biotechnology to medicine. The third part focuses on the benefits and concerns relating to the use of modern biotechnology in agriculture. Finally, the fourth part discusses ownership and access issues viewed from the perspective of developing countries.

This primer is by no means comprehensive. It is intended merely to introduce readers to the various perspectives in the ongoing debate on the use of modern biotechnology. Readers are therefore encouraged to consult the list of references at the end of the primer.

I. THE SCIENCE

What is biotechnology?

In its broadest sense, “biotechnology” refers to “any technique that uses living organisms, or parts of such organisms, to make or modify products, to improve plants or animals, or to develop microorganisms for specific use.”¹

Biotechnology combines disciplines like genetics, molecular biology, biochemistry, embryology and cell biology, which are in turn linked to practical disciplines like chemical engineering, information technology, and robotics.

Figure 1 shows how biotechnology has evolved through the years. On one end of the development pole are techniques of *traditional biotechnology* like microbial fermentation, used as early as 10,000 years ago in fermenting beer, wine and dairy products. At the other end of the development pole are the continuously evolving techniques of *modern biotechnology*, such as genetic engineering. Using genetic engineering techniques, the genetic makeup of an organism may be modified by inactivating or altering some of its genes and introducing other natural or artificial genes, usually from another organism.

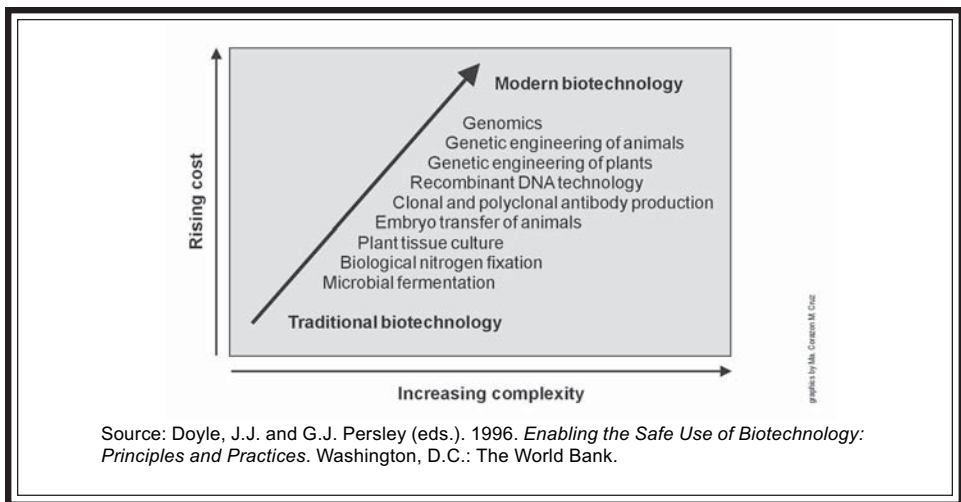


Figure 1. The Gradient of Biotechnology

Recently, the term “biotechnology” has come to be identified with modern biotechnology, specifically the use of genetic engineering techniques in medicine and agriculture. Hence, unless the context requires otherwise, this primer uses “biotechnology” to mean “modern biotechnology”.

What definition of biotechnology is widely accepted not only by scientists but also by governments and multilateral institutions?

The Cartagena Protocol on Biosafety defines modern biotechnology as referring to any process that involves the

application of (i) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid and direct injection of nucleic acid into cells or organelles, or (ii) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination of barriers and that are not techniques used in traditional breeding and selection.² (emphasis supplied)



Although the Protocol is not yet in force (because less than the required 50 States have either ratified or acceded to it), the Protocol's definition of modern biotechnology has gained currency in international circles.

However, while there may be an emerging international consensus on the above definition, strictly speaking it is a definition that is applicable only when one uses the term "modern biotechnology" for purposes of interpreting or implementing the Protocol.

What technical terms should a policy maker know to understand biotechnology?

There are at least four such technical terms: genetics, genes, genome and genetically modified organisms.

Genetics is the branch of biology that deals with the principles of heredity and variation in all living things. It is the study of why and how parents pass on some of their distinguishing features to their offspring. Its focus is on genes and their functions.

The **gene** is the basic unit of heredity and the ultimate arbiter of what we are. It carries instructions that allow cells to produce specific proteins. (It should be noted, however, that only certain genes are active at any given moment and environment.³)

A gene is a part of the deoxyribonucleic acid ("DNA") molecule.⁴ DNA, which is present in all living cells, contains information coding for cellular structure, organization and function.⁵ It is made up of two strands twisted around each other in a helical staircase.⁶

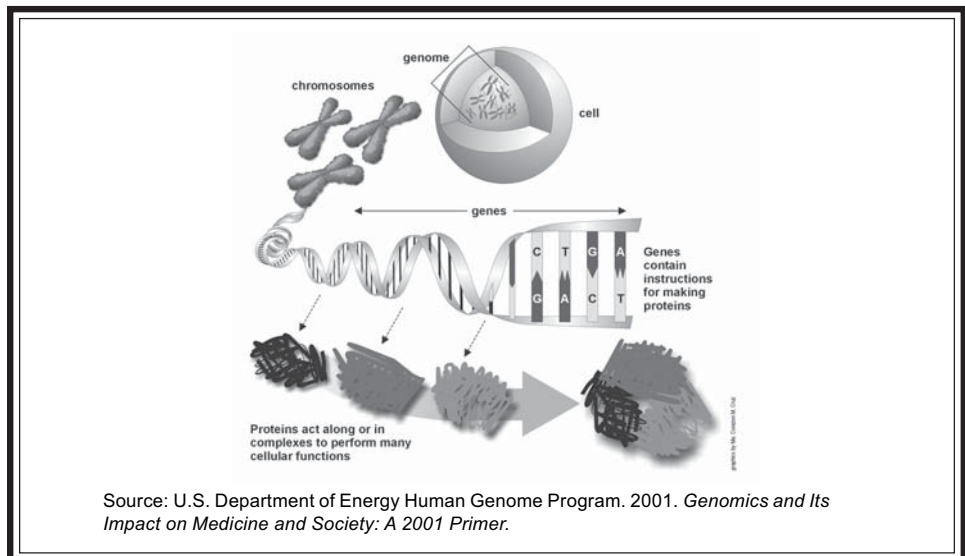


Figure 2. DNA, Genes and Proteins

Each cell in an organism has one or two sets of the basic DNA complement, called a **genome**. The genome is itself made up of one or more extremely long linear array of molecules of DNA that are called chromosomes. Genes, as explained earlier, are the functional regions of the DNA. They are the active segments of the chromosomes.⁷ Figure 3 shows how the genome, chromosomes, DNA and genes relate to each other:

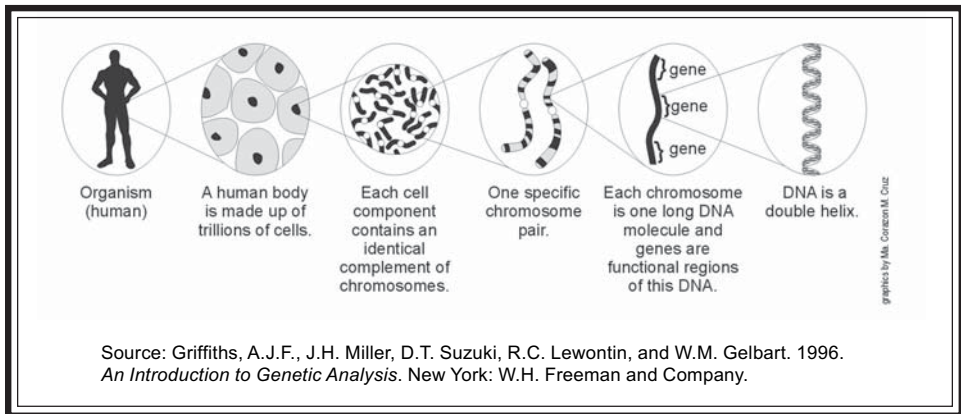


Figure 3. Successive Enlargements of an Organism with Focus on Genetic Material

In modern biotechnology⁸, the genome of an organism is altered by exposing cells to fragments of “foreign” DNA carrying the desirable genes, often from another species. This DNA is taken in and inserts itself into one or more of the recipient’s chromosomes at a location where it is inherited like any other part of the genome. The cells so modified are called transgenic cells. It is from transgenic cells that a GMO can be produced. All of the GMO’s cells contain the additional foreign DNA.⁹

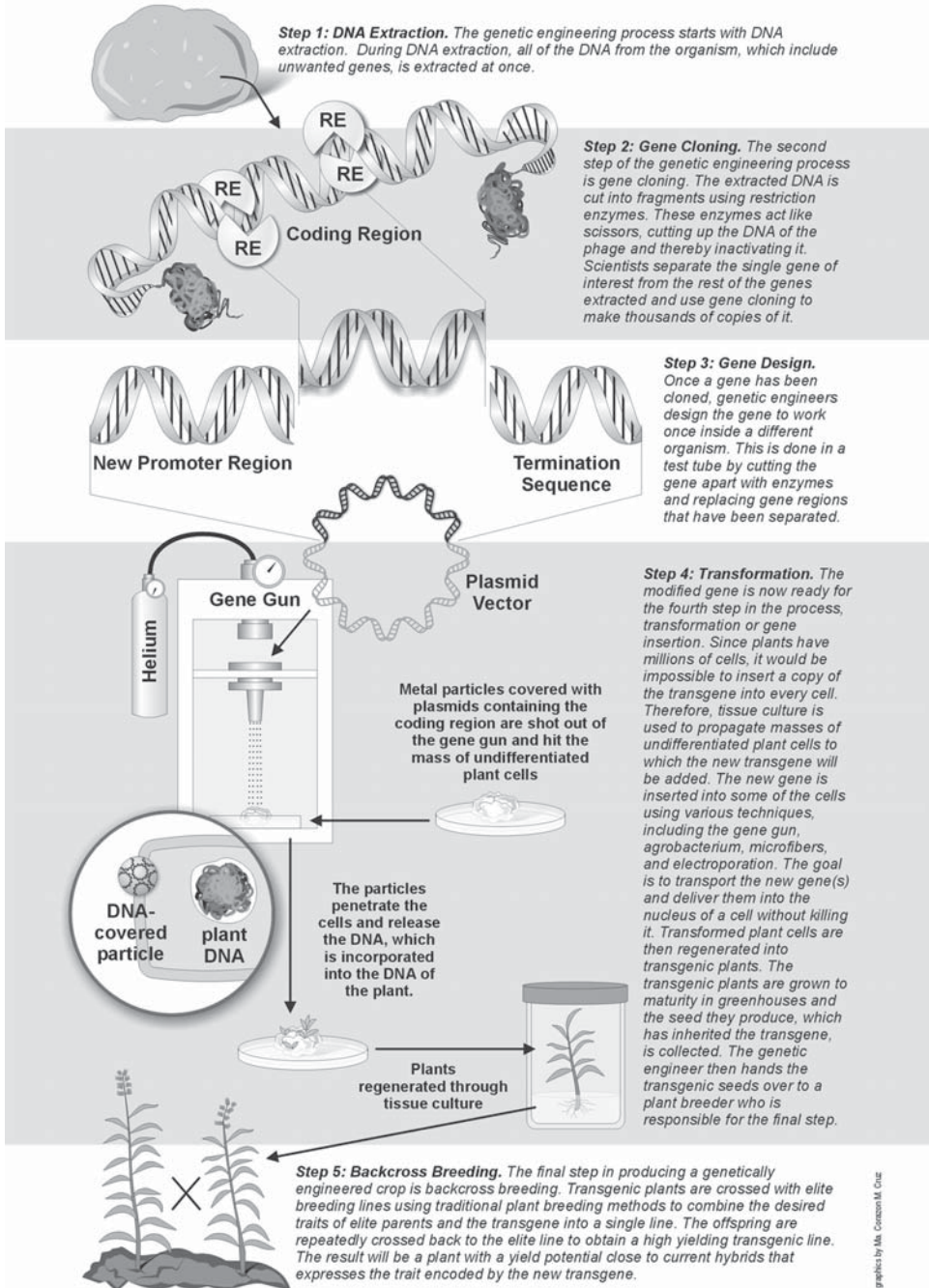
There is no universal definition for **genetically modified organism** (also called “transgenic organism” or “living modified organism”). However, it is generally understood to be a plant, animal or microorganism that contains genes that have been altered or transferred from another species or from the same species by means of genetic engineering techniques.

What role does information technology play in the development of modern biotechnology?

Our knowledge of biology has grown in such a way that we need powerful tools to organize that knowledge. Information technology, through the field of bioinformatics¹⁰, makes possible the rapid organization and analysis of biological data. Bioinformatics merges biology, computer science, and information technology to manage and analyze genomic data, with the ultimate goal of understanding and modeling living systems.¹¹



Box 1. How to Genetically Engineer a Plant. The process of genetic engineering in plants requires the successful completion of a series of five steps.



Why do we have to familiarize ourselves with the science of and issues surrounding modern biotechnology?

There are at least two reasons. The first has to do with the potential benefits that modern biotechnology offers humankind. The European Commission (2002)¹² refers to modern biotechnology as the “next wave of the knowledge-based economy” after information technology, and the “most promising of the frontier technologies.”¹³ It has identified applications in the following areas:

1. **Health care.** Biotechnology can be used to arrive at novel and innovative approaches to meet the needs of ageing populations and poor countries.
2. **Crop production.** Biotechnology can deliver improved food quality and environmental benefits through agronomically improved crops. It may be used to produce foods with enhanced qualities like higher nutritional benefits.
3. **Non-food uses of crops.** Biotechnology can also improve non-food uses of crops as sources of industrial feedstock or new materials such as biodegradable plastics. For example, canola is now being used to produce high-value industrial oil. Under the appropriate economic and fiscal conditions, biomass can contribute to alternative energy with both liquid and solid biofuels (e.g., biodiesel and bioethanol) and processes such as bio-desulphurisation.¹⁴
4. **Environmental uses.** New ways of protecting and improving the environment are possible with biotechnology, including bioremediation of polluted air, soil, water and waste, as well as the development of cleaner industrial products and processes like biocatalysis.¹⁵

The second reason why knowledge of biotechnology is important is that with more biotechnology-derived products being placed on the market, chances are these products will find their way into most countries, even those that do not use biotechnology for production. A government needs to be familiar with modern biotechnology if it is to effectively regulate biotechnological products and ensure that any adverse effects, if any, on the environment, human health, and social structures are properly managed, if not avoided.

II. APPLICATIONS IN MEDICINE

What are the applications of modern biotechnology in the medical field?

In medicine, modern biotechnology finds promising applications in:

- pharmacogenomics;
- drug production;
- genetic testing; and
- gene therapy.



What is pharmacogenomics? What are its anticipated benefits?

Pharmacogenomics is the study of how the genetic inheritance of an individual affects his/her body's response to drugs. It is a coined word derived from the words "pharmacology" and "genomics". It is therefore the study of the relationship between pharmaceuticals and genetics. The vision of pharmacogenomics is to be able to design and produce drugs that are adapted to each person's genetic makeup.¹⁶

Pharmacogenomics results in the following benefits:¹⁷

1. **Development of tailor-made medicines.** Using pharmacogenomics, pharmaceutical companies can create drugs based on the proteins, enzymes and RNA molecules that are associated with specific genes and diseases. These tailor-made drugs promise not only to maximize therapeutic effects but also to decrease damage to nearby healthy cells.
2. **More accurate methods of determining appropriate drug dosages.** Knowing a patient's genetics will enable doctors to determine how well his/her body can process and metabolize a medicine. This will maximize the value of the medicine and decrease the likelihood of overdose.
3. **Improvements in the drug discovery and approval process.** The discovery of potential therapies will be made easier using genome targets. Genes have been associated with numerous diseases and disorders. With modern biotechnology, these genes can be used as targets for the development of effective new therapies, which could significantly shorten the drug discovery process.

Box 2. Selected Recombinant Products for Disorders Affecting Large Patient Populations

<u>Diabetes</u>	<u>Acute myocardial infarction</u>
Humalog (insulin lispro)	Retavase (reteplase)
Lantus (insulin glargine)	TNKase(tenecteplase)
NovoLog (insulin aspart)	
<u>Hepatitis B</u>	<u>Rheumatoid arthritis</u>
Engerix (recombinant hepa- B vaccine)	Enbrel (etanercept)
Intron A (interferon- α 2b)	Kineret (anakinra)
Recombivax (recombinant hepa-B vaccine)	Remicade (infliximab)
<u>Stroke</u>	
Activase (alteplase)	

Source: Feldbaum, C. (8 February 2002). *Some History Should Be Repeated*, 295 SCIENCE, at 975

4. **Better vaccines.** Safer vaccines can be designed and produced by organisms transformed by means of genetic engineering. These vaccines will elicit the

immune response without the attendant risks of infection. They will be inexpensive, stable, easy to store, and capable of being engineered to carry several strains of pathogen at once.

How does biotechnology contribute to drug production?

Modern biotechnology can be used to manufacture existing drugs more easily and cheaply. The first genetically engineered products were medicines designed to combat human diseases. To cite one example, in 1978 Genentech joined a gene for insulin and a plasmid vector and put the resulting gene into a bacterium called *Escherichia coli*. Insulin, widely used for the treatment of diabetes, was previously extracted from sheep and pigs. It was very expensive and often elicited unwanted allergic responses. The resulting genetically engineered bacterium enabled the production of vast quantities of human insulin at low cost.¹⁸

Since then modern biotechnology has made it possible to produce more easily and cheaply the human growth hormone, clotting factors for hemophiliacs, fertility drugs, erythropoietin and other drugs.¹⁹ Most drugs today are based on about 500 molecular targets. Genomic knowledge of the genes involved in diseases, disease pathways, and drug-response sites are expected to lead to the discovery of thousands more new targets.²⁰

What is genetic testing?

Genetic testing involves the direct examination of the DNA molecule itself. A scientist scans a patient's DNA sample for mutated sequences.

There are two major types of gene tests. In the first type, a researcher may design short pieces of DNA ("probes") whose sequences are complementary to the mutated sequences. These probes will seek their complement among the base pairs of an individual's genome. If the mutated sequence is present in the patient's genome, the probe will bind to it and flag the mutation. In the second type, a researcher may conduct the gene test by comparing the sequence of DNA bases in a patient's gene to a normal version of the gene.

What are the potential uses of genetic testing?

Genetic testing can be used to:

- Diagnose a disease.
- Confirm a diagnosis.
- Provide prognostic information about the course of a disease.
- Confirm the existence of a disease in individuals.
- With varying degrees of accuracy, predict the risk of future disease in healthy individuals or their progeny.





Genetic testing is now used for:

- carrier screening, or the identification of unaffected individuals who carry one copy of a gene for a disease that requires two copies for the disease to manifest
- prenatal diagnostic screening
- newborn screening
- presymptomatic testing for predicting adult-onset disorders
- presymptomatic testing for estimating the risk of developing adult-onset cancers
- confirmational diagnosis of symptomatic individuals
- forensic/identity testing

Are genetic tests now available in the market?

Some genetic tests are already available, although most of them are used in developed countries. The tests currently available can detect mutations associated with rare genetic disorders like cystic fibrosis, sickle cell anemia, and Huntington's disease. Recently, tests have been developed to detect mutation for a handful of more complex conditions such as breast, ovarian, and colon cancers. However, gene tests may not detect every mutation associated with a particular condition because many are as yet undiscovered, and the ones they do detect may present different risks to different people and populations.²¹

What is gene therapy?

Gene therapy may be used for treating, or even curing, genetic and acquired diseases like cancer and AIDS by using normal genes to supplement or replace defective genes or to bolster a normal function such as immunity. It can be used to target somatic (i.e., body) or germ (i.e., egg and sperm) cells. In somatic gene therapy, the genome of the recipient is changed, but this change is not passed along to the next generation. In contrast, in germline gene therapy, the egg and sperm cells of the parents are changed for the purpose of passing on the changes to their offspring.

How is gene therapy done?

There are basically two ways of implementing a gene therapy treatment:

1. *Ex vivo*, which means "outside the body" – Cells from the patient's blood or bone marrow are removed and grown in the laboratory. They are then exposed to the virus carrying the desired gene. The virus enters the cells, and the desired gene becomes part of the DNA of the cells. The cells are allowed to grow in the laboratory before being returned to the patient by injection into a vein.
2. *In vivo*, which means "inside the body" – No cells are removed from the patient's body. Instead, vectors are used to deliver the desired gene to cells in the patient's body.

How extensive is the use of gene therapy?

Currently, gene therapy use is limited. Somatic gene therapy is primarily at the experimental stage. Germline therapy is the subject of much discussion but it is not being actively investigated in larger animals and human beings.

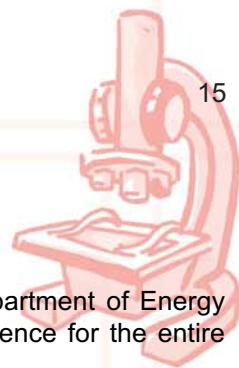
As of June 2001, more than 500 clinical gene-therapy trials involving about 3,500 patients have been identified worldwide. Around 78% of these are in the United States, with Europe having 18%. These trials focus on various types of cancer, although other multigenic diseases are being studied as well. Recently, two children born with severe combined immunodeficiency disorder ("SCID") were reported to have been cured after being given genetically engineered cells.

What are the obstacles to the widespread use of gene therapy techniques to treat patients?

Gene therapy faces many obstacles before it can become a practical approach for treating disease.²² At least four of these obstacles are as follows:

1. **Gene delivery tools.** Genes are inserted into the body using gene carriers called vectors. The most common vectors now are viruses, which have evolved a way of encapsulating and delivering their genes to human cells in a pathogenic manner. Scientists manipulate the genome of the virus by removing the disease-causing genes and inserting the therapeutic genes. However, while viruses are effective, they can introduce problems like toxicity, immune and inflammatory responses, and gene control and targeting issues.
2. **Limited knowledge of the functions of genes.** Scientists currently know the functions of only a few genes. Hence, gene therapy can address only some genes that cause a particular disease. Worse, it is not known exactly whether genes have more than one function, which creates uncertainty as to whether replacing such genes is indeed desirable.
3. **Multigene disorders and effect of environment.** Most genetic disorders involve more than one gene. Moreover, most diseases involve the interaction of several genes and the environment. For example, many people with cancer not only inherit the disease gene for the disorder, but may have also failed to inherit specific tumor suppressor genes. Diet, exercise, smoking and other environmental factors may have also contributed to their disease.
4. **High costs.** Since gene therapy is relatively new and at an experimental stage, it is an expensive treatment to undertake. This explains why current studies are focused on illnesses commonly found in developed countries, where more people can afford to pay for treatment. It may take decades before developing countries can take advantage of this technology.





What is the Human Genome Project?

The Human Genome Project is an initiative of the U.S. Department of Energy (“DOE”) that aims to generate a high-quality reference sequence for the entire human genome and identify all the human genes.

The DOE and its predecessor agencies were assigned by the U.S. Congress to develop new energy resources and technologies and to pursue a deeper understanding of potential health and environmental risks posed by their production and use. In 1986, the DOE announced its Human Genome Initiative. Shortly thereafter, the DOE and National Institutes of Health developed a plan for a joint Human Genome Project (“HGP”), which officially began in 1990.

The HGP was originally planned to last 15 years. However, rapid technological advances and worldwide participation have accelerated the expected completion date to 2003. In June 2000, scientists announced the generation of a working draft sequence of the entire human genome. The draft provides a road map to an estimated 90% of genes on every human chromosome. Already it has enabled gene hunters to pinpoint genes associated with more than 30 disorders.²³

What is human cloning?

Human cloning is one of the techniques of modern biotechnology. It involves the removal of the nucleus from one cell and its placement in an unfertilized egg cell whose nucleus has either been deactivated or removed.

There are two types of cloning:

1. **Reproductive cloning.** After a few divisions, the egg cell is placed into a uterus where it is allowed to develop into a fetus that is genetically identical to the donor of the original nucleus.
2. **Therapeutic cloning.**²⁴ The egg is placed into a Petri dish where it develops into embryonic stem cells, which have shown potentials for treating several ailments.²⁵

The major differences between these two types are shown Table 1.

In February 1997, cloning became the focus of media attention when Ian Wilmut and his colleagues at the Roslin Institute announced the successful cloning of a sheep, named Dolly, from the mammary glands of an adult female. The cloning of Dolly made it apparent to many that the techniques used to produce her could someday be used to clone human beings.²⁶ This stirred a lot of controversy because of its ethical implications.

Table 1. Comparison of Therapeutic Cloning and Human Reproductive Cloning

	Therapeutic cloning (Nuclear transplantation)	Human reproductive cloning
End product	Cells growing in a petri dish	Human being
Purpose	To treat a specific disease or tissue degeneration	Replace or duplicate a human being
Time frame	A few weeks (growth in culture)	9 months
Surrogate mother needed?	No	Yes
Sentient human created	No	Yes
Ethical implications	Similar to all embryonic cell research	Highly complex issues
Medical implications	Similar to any cell-based therapy	Safety and long-term efficacy concerns

Source: Vogelstein, B., Alberts, B. and Shine, K. (15 February 2002). *Please Don't Call It Cloning!*, 295 SCIENCE, at 1237.

What are the concerns regarding the use of modern biotechnology techniques in medicine?

Several issues have been raised regarding the use of modern biotechnology in the medical sector. Many of these issues are similar to those facing any new technology that is viewed as powerful and far-reaching. Some of these issues are²⁷:

1. **Absence of cure.** There is still a lack of effective treatment or preventive measures for many diseases and conditions now being diagnosed or predicted using gene tests. Thus, revealing information about risk of a future disease that has no existing cure presents an ethical dilemma for medical practitioners.
2. **Ownership and control of genetic information.** Who will own and control genetic information, or information about genes, gene products, or inherited characteristics derived from an individual or a group of people like indigenous communities? At the macro level, there is a possibility of a genetic divide, with developing countries that do not have access to medical applications of biotechnology being deprived of benefits accruing from products derived from genes obtained from their own people. Moreover, genetic information can pose a risk for minority population groups as it can lead to group stigmatization.

At the individual level, the absence of privacy and anti-discrimination legal protections in most countries can lead to discrimination in employment or insurance or other misuse of personal genetic information. This raises questions like, is genetic privacy different from medical privacy?²⁸



3. **Reproductive issues.** These include the use of genetic information in reproductive decision-making and the possibility of genetically altering reproductive cells that may be passed on to future generations. For example, germline therapy forever changes the genetic make-up of an individual's descendants. Thus, any error in technology or judgment may have far-reaching consequences. Ethical issues like designer babies and human cloning have also given rise to controversies between and among scientists and bioethicists, especially in the light of past abuses with eugenics.²⁹
4. **Clinical issues.** These center on the capabilities and limitations of doctors and other health-service providers, people identified with genetic conditions, and the general public in dealing with genetic information. For instance, how should the public be prepared to make informed choices based on the results of genetic tests? How will genetic tests be evaluated and regulated for accuracy, reliability, and usefulness?
5. **Effects on social institutions.** Genetic tests reveal information about individuals and their families. Thus, test results can affect the dynamics within social institutions, particularly the family.
6. **Conceptual and philosophical implications** regarding human responsibility, free will vis-à-vis genetic determinism, and the concepts of health and disease. Do genes influence human behavior? If so, does genetic testing mean controlling human behavior? What is considered acceptable diversity? What is normal and what is a disability or disorder, and who decides these matters? Are disabilities diseases that need to be cured or prevented? Where should the line between medical treatment and enhancement be drawn? Who will have access to gene therapy?

III. APPLICATIONS IN AGRICULTURE

What are the applications of modern biotechnology in agriculture?

There are many applications of biotechnology in agriculture.

Improved yield from crops. Using the techniques of modern biotechnology, one or two genes may be transferred to a highly developed crop variety to impart a new character that would increase its yield.³⁰ However, while increase in crop yield is the most obvious application of modern biotechnology in agriculture, it is also the most difficult one. Current genetic engineering techniques work best for effects that are controlled by a single gene. Many of the genetic characteristics associated with yield (e.g., enhanced growth) are controlled by a large number of genes, each of which has a minimal effect on the overall yield.³¹ There is, therefore, much scientific work to be done in this area.

Reduced vulnerability of crops to environmental stresses. Crops containing genes that will enable them to withstand biotic and abiotic stresses may be developed. For example, drought and excessively salty soil are the two most important limiting factors in crop productivity. Biotechnologists are studying plants that can cope with these extreme conditions in the hope of finding the genes that enable them to do so and eventually transferring these genes to the more desirable crops. One of the latest developments is the identification of a plant gene, *At-DBF2*, from thale cress, a tiny weed that is often used for plant research because it is very easy to grow and its genetic code is well mapped out. When this gene was inserted into tomato and tobacco cells, the cells were able to withstand environmental stresses like salt, drought, cold and heat, far more than ordinary cells. If these preliminary results prove successful in larger trials, then *At-DBF2* genes can help in engineering crops that can better withstand harsh environments.³²

Researchers have also created transgenic rice plants that are resistant to rice yellow mottle virus (RYMV). In Africa, this virus destroys majority of the rice crops and makes the surviving plants more susceptible to fungal infections.³³

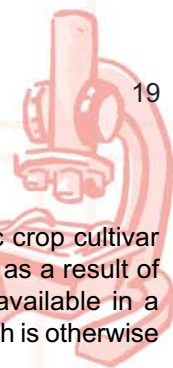
Increased nutritional qualities of food crops. Proteins in foods may be modified to increase their nutritional qualities. Proteins in legumes and cereals may be transformed to provide the amino acids needed by human beings for a balanced diet.³⁴ A good example is the work of Professors Ingo Potrykus and Peter Beyer on the so-called Goldenrice™ (discussed below).

Improved taste, texture or appearance of food. Modern biotechnology can be used to slow down the process of spoilage so that fruit can ripen longer on the plant and then be transported to the consumer with a still reasonable shelf life. This improves the taste, texture and appearance of the fruit. More importantly, it could expand the market for farmers in developing countries due to the reduction in spoilage.

The first genetically modified food product was a tomato which was transformed to delay its ripening.³⁵ Researchers in Indonesia, Malaysia, Thailand, Philippines and Vietnam are currently working on delayed-ripening papaya in collaboration with the University of Nottingham and Zeneca.³⁶

Reduced dependence on fertilizers, pesticides and other agrochemicals. Most of the current commercial applications of modern biotechnology in agriculture are on reducing the dependence of farmers on agrochemicals. For example, *Bacillus thuringiensis* (Bt) is a soil bacterium that produces a protein with insecticidal qualities. Traditionally, a fermentation process has been used to produce an insecticidal spray from these bacteria. In this form, the Bt toxin occurs as an inactive protoxin, which requires digestion by an insect to be effective. There are several Bt toxins and each one is specific to certain target insects. Crop plants have now been engineered to contain and express the genes for Bt toxin, which they produce





in its active form. When a susceptible insect ingests the transgenic crop cultivar expressing the Bt protein, it stops feeding and soon thereafter dies as a result of the Bt toxin binding to its gut wall. Bt corn is now commercially available in a number of countries to control corn borer (a lepidopteran insect), which is otherwise controlled by spraying (a more difficult process).

Crops have also been genetically engineered to acquire tolerance to broad-spectrum herbicide. The lack of cost-effective herbicides with broad-spectrum activity and no crop injury was a consistent limitation in crop weed management. Multiple applications of numerous herbicides were routinely used to control a wide range of weed species detrimental to agronomic crops. Weed management tended to rely on preemergence—that is, herbicide applications were sprayed in response to expected weed infestations rather than in response to actual weeds present. Mechanical cultivation and hand weeding were often necessary to control weeds not controlled by herbicide applications. The introduction of herbicide tolerant crops has the potential of reducing the number of herbicide active ingredients used for weed management, reducing the number of herbicide applications made during a season, and increasing yield due to improved weed management and less crop injury. Transgenic crops that express tolerance to glyphosphate, glufosinate and bromoxynil have been developed. These herbicides can now be sprayed on transgenic crops without inflicting damage on the crops while killing nearby weeds.³⁷

From 1996 to 2001, herbicide tolerance was the most dominant trait introduced to commercially available transgenic crops, followed by insect resistance. In 2001, herbicide tolerance deployed in soybean, corn and cotton accounted for 77% of the 62.6 million hectares planted to transgenic crops; Bt crops accounted for 15%; and stacked genes for herbicide tolerance and insect resistance used in both cotton and corn accounted for 8%.³⁸

Production of novel substances in crop plants. Modern biotechnology is increasingly being applied for novel uses other than food. For example, oilseed is at present used mainly for margarine and other food oils, but it can be modified to produce fatty acids for detergents, substitute fuels and petrochemicals.³⁹ Banana trees and tomato plants have also been genetically engineered to produce vaccines in their fruit. If future clinical trials prove successful, the advantages of edible vaccines would be enormous, especially for developing countries. The transgenic plants may be grown locally and cheaply. Homegrown vaccines would also avoid logistical and economic problems posed by having to transport traditional preparations over long distances and keeping them cold while in transit. And since they are edible, they will not need syringes, which are not only an additional expense in the traditional vaccine preparations but also a source of infections if contaminated.⁴⁰

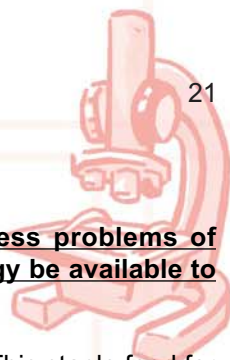
Table 2 provides a panoramic view of other potential applications of modern biotechnology in agriculture.

Table 2. Potential Applications of Modern Biotechnology in Agriculture

Subsector	Applications
Crop Production	<p>Diagnostics – to diagnose plant pests and pathogens, contaminants, and quality traits</p> <p>Micropropagation techniques or tissue culture – to multiply disease-free planting materials on a large-scale</p> <p>Development of transgenic crops – to develop commercially new genetically modified crop varieties</p> <p>Modern plant breeding – to develop superior plant varieties rapidly and more precisely</p> <p>Marker-assisted selection – to use genetic markers, maps and genomic information in breeding for high-yielding, disease- and pest-resistant varieties</p>
Biodiversity	<p>Characterizing, conserving, and using biodiversity</p>
Forestry	<p>Gene mapping – to accelerate tree breeding</p> <p>Macropropagation – rapid vegetative propagation by means of cuttings from large plantations of pines and other trees</p> <p>Micropropagation by tissue culture – large-scale multiplication of genetically-superior plantlets</p> <p>DNA fingerprinting – to differentiate species, strains and cultivars accurately</p> <p>Wood security – the selection of genetically superior trees for breeding purposes</p>
Livestock Production	<p>Livestock improvement – to speed up the reproduction process in animals, allowing more generations to be produced</p> <p>Transgenic livestock – development of transgenic lines of virus-resistant poultry and other animals</p> <p>Livestock health – application of diagnostics for the control of major diseases of livestock</p> <p>Vaccine development – development of vaccines for the control of epidemic viral diseases of livestock</p>
Fisheries	<p>Transgenic fish - still being explored</p> <p>Use of molecular markers in biodiversity – research, genomic mapping, and trait selection in fish and other aquatic organisms</p>

Source: Asian Development Bank (2000). *Agricultural Biotechnology, Poverty Reduction and Food Security* (Manila: Asian Development Bank), 16.





There have been reports about modifying rice to address problems of deficiency in Vitamin A. Is this true, and will the technology be available to developing countries?

Yes, there are efforts to improve the nutritional quality of rice. This staple food for two billion people is usually milled to remove the outer layers to prevent their high oil content from causing spoilage. The remaining grains are low in B-carotene, the chemical precursor of vitamin A. Some 400 million people worldwide suffer from vitamin A deficiency while over 3.7 billion people are iron-deficient. Vitamin A deficiency causes five million deaths annually, and blindness in a further 500,000 people, while iron deficiency causes anemia and birth defects.

Golden Rice™ is a transgenic crop created by Dr. Ingo Potrykus and his colleagues to improve the nutritional quality of rice by increasing the quantities of beta carotene (the precursor of vitamin A) and improving the crop's iron content. Several genes have been inserted into the rice genome, including a daffodil gene, allowing the endosperm (the part that remains after milling and polishing) to produce B-carotene. Additionally, a phytase gene (which produces an enzyme to release chemically-bound iron), a gene to increase organic iron, and a gene to aid iron absorption in the digestive tract have been added. The presence of beta carotene in the endosperm of the transgenic rice gives it a golden color. Hence, the name "golden rice".

The research, which was funded by the Rockefeller Foundation, the Swiss government and the European Union, hopes to provide a cheap form of vitamin supplementation. If it is later proven to be viable and safe, Golden Rice will be distributed in developing countries, with no patents blocking access to it.⁴¹ The introduction of vitamin A-producing beta carotene into the rice gene has the potential of addressing the vitamin A problem, especially among those who are too poor to diversify their diets with green vegetables.⁴²

How is modern biotechnology in agriculture different from traditional plant breeding techniques? Is modern biotechnology simply a more advanced stage in the biotechnology development continuum?

Yes and no. Yes, because both traditional and modern biotechnology involve the transfer of genes from one organism to another. Traditional breeding techniques typically involve the repeated mixing of thousands of genes over several years and many generations of plants to achieve a desired trait. Modern biotechnology accelerates this lengthy process by allowing scientists to insert selected genes directly into a plant.⁴³ This makes modern biotechnology less of an iterative process compared to traditional plant breeding techniques. In this sense, modern biotechnology is simply an extension of traditional breeding.

No, because unlike traditional breeding techniques, modern biotechnology can move genes across species, even family, boundaries to produce novel organisms that do not normally occur in nature. To cite a simplistic example, a brown cow

that mates with a yellow cow may produce a calf of a completely new color, but reproductive mechanisms limit the number of new combinations. Cows must breed with other cows or their very near relatives. A farmer cannot breed for a purple cow using traditional sexual reproduction techniques because the necessary purple genes are not available in cows or their near relatives. In contrast, the biological barrier is not as steep, at least in theory, to a genetic engineer. If purple genes are available in another species, say in an iris plant, those genes could be mixed with the genes of the cow to produce purple cows.⁴⁴

How are genes inserted into plants using modern biotechnology?

There are currently two commonly used methods for introducing genes into plants genomes:

1. **Using a plasmid vector.** As previously discussed, a vector, like the plasmids of *Agrobacterium tumefaciens*, may be used to introduce the gene or genes of interest into the plant DNA. The resulting cells are then screened to identify those that have successfully expressed the new trait. The modified seeds are sown in the field and grown like any other crop.⁴⁵
2. **Particle bombardment techniques.** The DNA to be introduced into plant cells is coated onto tiny particles, which are then physically shot into the plant cells. Some of the DNA comes off and are incorporated into the DNA of the target plant.

Are transgenic crops now commercially available?

Yes, genetically modified crops are now available in the market. If you eat corn or soya products, chances are you are consuming genetically modified products. In the United States, it is estimated that 70-85% of all processed/packaged foods contain one or more ingredients that are derived from transgenic crops.⁴⁶

James (2002) estimated the global area planted to transgenic crops in 2002 at 58.7 million hectares. More than one-quarter of this area, or 13.5 million hectares, is in six developing countries, namely, China, India, Indonesia, Argentina, South Africa, and Mexico. India, the largest cotton growing country in the world, commercialized Bt cotton for the first time during the year. However, four countries continue to account for 99% of the global transgenic crop area. The USA grew 66% of the global total, followed by Argentina with 23%, Canada with 6%, and China with 4%. China had the highest year-on-year percentage growth, with a 40% increase in its Bt cotton area.⁴⁷

The adoption rate for transgenic crops is the highest in the history of agriculture.⁴⁸ From 1996 to 2000, 15 countries contributed to a more than 25-fold increase in the global area of transgenic crops, from 1.7 million hectares in 1996 to 44.2 million hectares in 2000.⁴⁹





Which transgenic crops dominate in terms of acreage?

In 2001, the principal transgenic crops were soybean, with 62% of the global area, followed by corn at 21%, cotton at 12%, and canola at 5%. More than three-quarters of the transgenic crops were modified for herbicide tolerance. The balance was mostly for pest resistance,⁵⁰ with a few areas planted to potato and papaya with inserted genes for delayed ripening and virus-resistance.⁵¹

Is genetic engineering in agriculture harmful to the environment?

Most of the concerns revolve around the effect of biotechnology products on the environment and on human health.

Like all new technologies, genetic engineering, if not properly studied and regulated, can adversely impact on the environment. However, we need to review the impact on a case-by-case basis. Biotechnology by itself is not good or bad. As with all technologies, it is how people use it that can be good or bad, risky or beneficial. Each biotechnology product must be evaluated in terms of whether it is useful, beneficial and safe. To date, there is no scientific proof that the use of modern biotechnology has an adverse effect on the environment and on human health.

The major issues that have been raised so far against the environmental impact of genetically engineered agricultural products and the corresponding scientific consensus are summarized below:

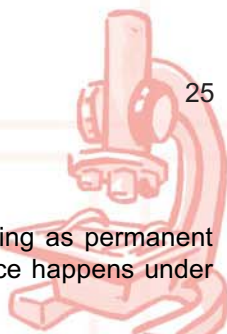
1. **Increased weediness.** One concern is that altered plants may have increased fitness to survive their environments and might grow unaided by human beings in places where they could have unwanted effects. In unmanaged environments, they could displace natural flora and upset entire ecosystems.⁵² However, in a 10-year study to answer the question of whether transgenes conferring herbicide tolerance or insect resistance on crop plants also confer weediness or invasiveness, it was found that genetically modified crops (those that are commercially available) have no more tendency to become weeds than their conventionally bred counterparts. Apparently, more genes are needed to convert a plant into a weed. Another study also showed that biological invasions have extensive time lags that range from 30-150 years and require the chance concordance of favorable conditions before taking off. The question, however, is whether transgenes would hasten this process.⁵³ This is why potential invasiveness of GM plants is evaluated before any decision to release them into the environment is made.
2. **Unintended gene flow.** There is also the concern that if relatives of the altered crops are growing near a field with their conventional counterpart, the new gene could move by means of pollen transfer into the latter. There is merit in this concern. This is why studies have to be done on a case-by-case basis to

determine the potential environmental risks due to unintended gene flow. The European Science Foundation and European Environment Agency (2002) recently released their report on the significance of pollen-mediated gene flow from six major crop types that have been genetically engineered and are close to commercial release in the European Union, namely, oilseed rape, sugar beet, potatoes, maize, wheat and barley. They found, among others, that oilseed rape is high-risk for crop-to-crop gene flow and gene flow from crop to wild relatives. Potatoes, wheat, and barley are low-risk crops. Maize and sugar beet are both medium- to high-risk for crop-to-crop gene flow, with the latter having the same level of risk for gene flow from crop to wild relatives. There are no known wild relatives of maize in Europe with which it can hybridize.⁵⁴

On the other hand, there is much research on developing alternative measures to mitigate unintended gene flow. At present, seed producers of conventional crops can devise mechanisms to isolate their crop lands from related plants in order to maintain the purity of their lines. In addition, several biotechnology measures to prevent horizontal gene flow, such as apomixis, chloroplast transformation, chromosome-specific cytogenetic system, and transgenic mitigation, have been suggested. The most controversial is the Technological Protection System (TPS)⁵⁵ developed by the U.S. Department of Agriculture and Delta & Pine. The technique, commonly called GURT (for Genetic Use Restriction Technology), involves a system of three genes that interact to control the fertility of seeds by the seed producer. The objection to TPS has to do with the possibility of pollen dispersal to adjacent fields of the same crop, inadvertently causing the latter to produce sterile seeds. This would also have a severe impact on the common practice of seed saving among small farmers in developing countries.⁵⁶

3. **Change in herbicide use patterns.** It has been pointed out that widespread use of herbicide-tolerant crops could lead to the rapid evolution of resistance to herbicides in weeds, either as a result of increased exposure to the herbicide or as a result of the transfer of the herbicide trait to weedy relatives of the crops.⁵⁷ However, to date there is no evidence that this phenomenon is taking place.
4. **Squandering of valuable pest susceptibility genes.** Many insects contain genes that render them susceptible to pesticides. Often these susceptibility genes predominate in natural populations of insects. These genes are a valuable natural resource because they allow pesticides to remain as effective pest-control tools. The more benign the pesticide, the more valuable the genes that make pests susceptible to it. It is feared that crops that have been altered to contain the pest-resistance Bt gene can adversely affect the continued susceptibility of pests to the Bt toxin. The continuous exposure of pests to the Bt toxin in altered crops selects for the rare resistance genes in the pest population and in time will render the Bt pesticide useless, unless specific measures are instituted to avoid the development of such a resistance.⁵⁸ It





should be noted, however, that there is really no such thing as permanent resistance to pests and diseases and that insect resistance happens under the current practice of using pesticides or even in nature.

A few years ago, there was a controversy around the effect of genetically modified corn on Monarch butterflies. What was that controversy all about and did it have scientific basis?

Monarch butterfly larvae feed exclusively on the leaves of milkweed plants, which are commonly found in cornfields in the U.S. Pollen from nearby corn can become distributed on the leaves of these plants, and can therefore be eaten by the larvae. In 1999, two studies showed that Monarch butterfly larvae and larvae from related species that were fed leaves dusted with Bt-corn pollen had lower survival rates, compared to those fed leaves dusted with non-Bt corn pollen. These studies were used to suggest that Bt corn was responsible for the recently observed decline in the Monarch butterfly population.

However, subsequent investigations revealed that while a large percentage of Monarch butterfly larvae may feed on milkweed found in the corn belt region of the U.S., there is no overlap between their breeding time and the time of pollen shed through most of this region. Other studies have shown that corn pollen settling on an area decreases rapidly with distance. This and the toxicity studies showing low toxicity of many major Bt-corn strains indicate that pollen densities that could represent significant exposure to feeding larvae are found only within five meters of cornfields, and then rarely.⁵⁹ The current scientific consensus is that the adverse impact of Bt-corn pollen observed in the laboratory does not occur in the fields. Hence, Monarch butterflies are safe from Bt corn.

Are GM foods safe to eat?

At present, there are no studies to indicate that any of the commercially available GM foods are any less safe than their non-modified counterparts. This, of course, does not mean that all products of biotechnology are safe. Hence, the need for regulations. In fact, GM food products are subjected to more tests than their conventionally-bred counterparts.

The concerns raised about the safety of genetically engineered food products fall into the following categories:

1. New allergens in the food supply

There is a concern that transgenic crops could introduce new allergens into foods. However, it is important to keep in mind that eating conventional food is also not risk-free; allergies occur with many new and even known conventional foods. For example, the kiwi fruit was introduced into the U.S. and the European market in the 1960s with no known human allergies; today, there are people allergic to this fruit.⁶⁰

In February 2002, the Royal Society issued a policy report titled *Genetically Modified Plants for Food Use and Human Health—An Update*.⁶¹ The report concluded that there is currently no evidence that GM foods cause allergic reactions and “the allergenic risks posed by GM plants are in principle no greater than those posed by conventionally derived crops or by plants introduced from other areas of the world.”⁶²

2. Antibiotic resistance

Modern biotechnology often uses genes for antibiotic resistance as “selectable markers”. Early in the genetic engineering process, these markers help select cells that have taken up the foreign genes. Although they have no further use, the genes continue to be expressed in plant tissues. Critics of modern biotechnology argue that the presence of antibiotic-resistance genes could have two harmful effects. First, eating food containing these genes could reduce the effectiveness of antibiotics to fight disease when these antibiotics are taken with meals. Antibiotic resistance genes produce enzymes that can degrade antibiotics. If a tomato with an antibiotic-resistance gene is eaten at the same time as an antibiotic, it could destroy the antibiotic in the stomach. Second, the resistance genes could be transferred to human or animal pathogens, making them impervious to antibiotics. If transfer were to occur, it could aggravate the already serious health problem of antibiotic-resistant disease organisms.

However, unmediated transfers of genetic material from plants to bacteria are highly unlikely. Moreover, several strategies have been developed to avoid the inclusion of antibiotic resistance genes in the commercial transgenic variety.

3. Production of new toxins

Many organisms have the ability to produce toxic substances. For plants, such substances help to defend stationary organisms from many predators in their environment. But there is concern that the addition of new genetic material through genetic engineering could trigger the production of toxic substances within plants. This could happen, for example, if the on/off signals associated with the introduced gene were located in the genome in places where they could turn on the previously inactive genes.⁶³

Human beings typically eat several grams of DNA in their diet each day. Hence, the transgene in a genetically engineered plant is not a new type of material to our digestive systems. It is also present in extremely small amounts. In transgenic corn, for example, the transgenes represent about 0.00018 of the total DNA. Decades of research indicate that dietary DNA has no direct toxicity. In fact, exogenous nucleotides have been shown to play important beneficial roles in gut function and the immune system. Likewise, there is no compelling evidence showing the incorporation and expression of plant-derived DNA, whether a transgene or not, into the genomes of a consuming organism.



Defense processes have evolved, including extensive hydrolytic breakdown of the DNA during digestion, excision of integrated foreign DNA from the host genome, and silencing of foreign gene expression by targeted DNA methylation, that prevent the incorporation or expression of foreign DNA. Thus, there is a minimal possibility of adverse effects arising from the presence of foreign DNA by either direct toxicity or gene transfer.

4. Effect on nutrients

Concerns have been raised regarding the possible adverse effect of genetic engineering technology on the nutritional content of food. This is a legitimate concern for regulators. In the U.S., for example, the Food and Drug Administration ensures that the nutritional composition of GM foods is substantially equivalent to that of their conventional counterparts. Studies are performed to determine whether nutrients, vitamins and minerals in the modified food occur at the same levels as in the conventionally-bred food sources. For example, seeds and toasted soybean meal from Roundup Ready™ soybeans have been compared to conventional soybeans in terms of protein, oil, fiber, ash, carbohydrates, moisture content, amino acid and fatty acid composition. The results showed that the composition of transgenic lines is equivalent to that of conventional soybean cultivars, except for the trypsin inhibitors in non-toasted soybean meal, which is not consumed. In addition, the equivalence of the feeding value of the transgenic grains was demonstrated in rats, chickens, catfish and dairy cattle.

5. Concentration of toxic metals

Some of the new genes being added to crops can remove heavy metals like mercury from the soil and concentrate them in plant tissue. The purpose of creating such crops is to make possible the use of municipal sludge as fertilizer. Sludge contains useful plant nutrients but often cannot be used as fertilizer because it is contaminated with toxic heavy metals. The idea is to engineer plants to remove and sequester those metals in inedible parts of plants. In a tomato, for example, the metals would be sequestered in the roots. Turning on the genes in only some parts of the plant requires the use of genetic on/off switches that turn on only in specific tissues, like roots. Such products could pose the risk of contaminating foods with high levels of toxic metals if the on/off switches are not completely turned off in edible tissues. There are also environmental risks associated with the handling and disposal of the metal-contaminated parts of plants after harvesting. Regulations have to address the peculiar functions of GMOs being used as bioremediation agents.

A previous study of the adverse effect of GM potatoes on rats is cited by critics of biotechnology as evidence that GM products are unsafe. What happened to that study?

The study was found to be inconclusive.

Dr. Arpad Putztai, a senior scientist at the Rowett Institute in Aberdeen, Scotland, came to international attention when he announced to the media that eating genetically modified potatoes depressed rat immune systems and caused changes in their intestinal tract. Dr. Putztai and his co-workers compared rats fed genetically modified potatoes with rats fed non-modified potatoes, with and without added GNA. The genetically modified potatoes appeared to cause changes in the rats' immune response and the structure of the intestinal lining.

But there was a flaw in the experiment. While its design was apparently correct for this type of feeding study, rats do not like to eat raw potato. As a result, a standard 110-day trial had to be abandoned after only 67 days because the rats were starving. Starvation affects gut histology, and even the lining of the guts of rats eating unmodified potatoes was shown to be abnormal. The presence of other potato toxins could also have had a confounding effect on cells in the intestine, especially since the potato lines were not substantially equivalent

Does the possible transfer of antibiotic resistance marker genes from ingested GM food to gut microbes pose a significant hazard to human beings?

Organisms that contain DNA encoding for antibiotic resistance proteins are common and are becoming more prevalent in the environment. However, there is no documented evidence that the antibiotic resistance markers in GM foods contribute to antibiotic resistance in gut bacteria. Should there be such a contribution, it is expected to be extremely small for several reasons, including the efficient destruction of the resistance gene in the human gut and the extremely low intrinsic rate of plant-microbe gene transfer.

Furthermore, resistance genes occur quite widely already and the antibiotics involved are not widely used in medical practice. Finally, the technology is now available to omit the use of such selection devices and their use is therefore likely to diminish.

What is the “principle of substantial equivalence”?

The term “substantial equivalence” was first mentioned in 1993 in connection with food safety in a report of the OECD Group of National Experts on Safety in Biotechnology. The members of the group agreed that the most practical approach to determining the safety of foods derived by modern biotechnology is to consider whether they represent a substantial equivalent to analogous traditional products. The term substantial equivalence and the underlying approach were borrowed from the U.S. Food and Drug Administration's definition of a class of new medical devices that do not differ materially from their predecessors and thus do not raise new regulatory concerns.

According to the OECD definition, the concept of substantial equivalence is based on the idea that existing products used as foods or food sources can



serve as a basis for comparison when assessing the safety and the nutritional value of a food or food ingredient that is new or that has been modified by modern biotechnological methods. If a novel food or novel food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety. No additional safety concern would be expected. If a novel food or novel food ingredient is not found to be substantially equivalent to its conventional counterpart, this does not imply that it is unsafe. It must simply be evaluated on the basis of its unique composition and properties.⁶⁴

What is the “precautionary principle”?

The “precautionary principle” traces its origins to Principle 15 of the Rio Declaration on Environment and Development, which provides that:

In order to protect the environment, the precautionary approach shall be widely applied by the States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The use of the precautionary principle is to be based to the fullest extent possible on scientific evidence of a given problem. However, it is not always possible to move towards a decision on a purely scientific assessment; any assessment must also involve economic, social and ethical aspects. The precautionary principle is thus more of a political norm than a clearly defined concept.⁶⁵

Critics of the precautionary principle have argued that it is poorly defined, not sufficiently grounded in science, stifles development of technology, and hinders trade. It is claimed that it is not a valid principle for evaluating scientific evidence as it distorts reality and leads to the acceptance of false beliefs. Opponents are also concerned that the precautionary principle's focus on hypothetical risks will distract consumers and policy makers from the policies needed to address known food-borne threats to human health.⁶⁶

The precautionary principle has been invoked to justify a prohibition of GM crops. The justification for a ban allegedly considers the potential public health and environmental benefits of the banned GM crop. However, it ignores the probable public health and environmental benefits that would necessarily be foregone as a result of the ban. A comprehensive application of the precautionary principle indicates that a GM crop ban, contrary to the claims of its advocates, would increase overall risks to public health and to the environment, especially in developing countries. Thus, it would be more prudent to study, develop, and possibly commercialize GM crops than to ban such crops, provided reasonable caution is exercised through the regulatory agencies.

Should it wish to do so, how should a government regulate the use of modern biotechnology?

The purpose of a biosafety (short for “biological safety”) system is to control the risks associated with the products of modern biotechnology. An integrated national biosafety system has the following elements:⁶⁷

1. **National policy, strategies and research agenda regarding biosafety.** The development of a national biosafety system should begin with the elaboration of a national biosafety policy consistent with a country’s other policy objectives on food, agriculture, the environment and sustainable development. This policy will serve as the basis for the crafting of specific legislation and/or regulations on biosafety. It should articulate a framework where competing goals, such as economic, regional development and environmental protection, may be integrated and communicated as a single national vision.
2. **National inventory and evaluation.** This is a means to identify and characterize the available resources and regulatory infrastructure in a country, assess their adequacy for supporting a biosystem, and identify gaps where capacities need to be strengthened. The inventory should include the following factors:
 - existing regulatory structures and legislation pertaining to the import and export of agricultural commodities, environmental protection, animal and human health safety, and biotechnology
 - existing mechanisms for the development of public policy, legislation, and regulations
 - existing human, financial and scientific infrastructure
 - the current status of biotechnology research and development, including programs for the safe use and handling of GMOs
 - existing mechanisms for regional cooperation and regulatory harmonization
 - existing capacity building programs
 - the role of civil society in policy and regulatory development processes
 - administrative and enforcement capacity
3. **Knowledge, skills and capacity base to develop and implement a biosafety system.** A strong base of scientific knowledge to support the regulatory system and the development of competencies in product evaluation is critical to any biosafety system. A limited knowledge and skills base will tend to produce regulations that are highly protective, at the expense of innovation.

Some countries have implemented a system of expert advisory committees, while others have relied primarily on scientists and professionals working within government agencies. The advantage of independent advisory committees is



that they generally have more transparent accountability frameworks because the expertise and academic credentials of their membership are usually published. However, they may suffer from the part-time volunteer nature of their membership. A combination of these two approaches—expert advisory committees *and* government scientists and professionals—may be the best arrangement. Product evaluations performed by competent scientists within a regulatory agency could be supplemented by the results of issue-specific expert panel consultations.

Box 3. Risk Assessment

- *What is risk assessment?*

Risk assessment is a method by which science can be used to address environmental and human health safety concerns. It is broadly defined as the use of scientific data to rank or measure hazards, assess exposure and characterize risks involved in a food-related activity or product. However, risk assessments do not specifically determine whether a product is “safe” or “unsafe”. The use of risk assessment in the development of regulations is related to the expected impact of a particular environmental or food safety problem, the expected impact of protective mitigation measures, and the levels of urgency and controversy surrounding an issue.

- *What are the principles of risk assessment as applied to GMOs?*

There are four basic principles that have found international acceptance. These are embodied in Annex III of the Cartagena Protocol:

1. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.
2. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.
3. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.
4. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

- *What are the limitations of scientific risk assessment?*

In risk assessment analysis, the use of science is not as clear-cut and simple as it may appear initially. First, since scientific knowledge constantly changes and evolves, the best available science about food or environmental issues may be different from one year to the next.

Another complicating factor in the application of science to risk assessment analysis is the disagreement among scientists about conclusions from key influential studies. Ideally, scientists conduct research in a manner that produces precise and accurate results so that study

conclusions are authoritative and nonbiased. However, it is not unusual for scientists to disagree about an experiment's design and conclusions, especially if the results alter the conventional knowledge about a subject. These disagreements may require years of debate and further experimentation in other laboratories before results are accepted by most scientists. Regulations based on professionally disputed scientific studies may not be scientifically defensible once the controversy is resolved through additional data gathering and analysis.

• *Given the above limitations, should one continue to use scientific risk assessment in evaluating biotechnology products?*

Yes, there is no other internationally accepted standard by which one can effectively assess the risks, if any, posed by GM products. One should, however, be cognizant of the above limitations in arriving at a decision involving GMOs.

4. **Development of regulations.** A country may adopt either voluntary guidelines or mandatory regulations. Voluntary guidelines are more quickly put in place and are more flexible for the adoption of revisions incorporating new information requirements. However, the public may not be as confident with voluntary guidelines as they would be with mandatory regulations. Thus, there may be value in adopting mandatory regulations.

If a country elects to develop mandatory regulations, it can do so in one of two ways: (1) it can develop a new act and regulations to specifically address GMOs; or (2) it can regulate GMOs using existing legal instruments such as acts, regulations, and presidential decrees. The former has the advantage of establishing a system that specifically addresses the product or process to be regulated, of being crafted to allow flexibility in the face of new technical advances, and of being perceived by the public as a positive response to addressing the concerns about safety of GMOs. However, it could take long to develop such a new act or regulation, especially with the political controversy that GMOs have generated. Also, this could result in GMOs being regulated in perpetuity even if the scientific basis for the separate regulation has long been eroded.

If a mandatory system is adopted, the policy maker should also decide on whether the system should take any of the following forms:⁶⁸

- *ex ante* regulation in the form of required permits, licenses, regulations, and product approvals before any GM product is used or released, whether for experimental or commercial purposes;
- strict *ex post facto* liabilities in the form of damage payments by the biotechnology research organization or business entities; or
- a *negligence* rule, which is a combination of the *ex ante* regulation and *ex post facto* liabilities.

The biosafety policy developed in most countries emphasizes the *ex ante* regulatory approach. This approach has the major benefit of providing



information to both the producer and consumer of biotechnology products. If a biotechnology organization produces new products according to the regulations, it is less likely to be fined *ex post facto*. Thus, regulation and product standards reduce risk and thereby allow the market to work more smoothly as the participants are better informed about the rules of the game.

Ultimately, the development of biosafety policy will depend on several factors including the nature of risks, the goal of public policy, the institutional and judicial framework, and the involvement of the private sector in biotechnology research.

Regardless of the type of regulatory framework chosen, care must be taken not to overregulate. An unreasonably stringent regulatory system can prevent beneficial products from being made available to the public.

- 5. Implementation of regulations.** The final step of putting the system into operation requires the following elements:
- The regulations or guidelines clearly define the structure of the biosafety system.
 - People are knowledgeable and well trained.
 - The review process is based on up-to-date scientific information.
 - Feedback mechanisms are used to incorporate new information and revise the system as needed.

What international agreements are relevant to modern biotechnology?

Issues related to modern biotechnology have been raised in a number of international fora, including the following:

- Convention on Biological Diversity (CBD)
- Food and Agriculture Organization (FAO)
- Organization for Economic Cooperation and Development (OECD)
- World Trade Organization (WTO)
- World Health Organization (WHO)
- World Intellectual Property Organization (WIPO)
- Asia Pacific Economic Cooperation (APEC)
- Office of International Epizootics (OIE)
- International Plant Protection Convention (IPPC)
- Codex Alimentarius Commission (CAC)
- World Bank

There are also a number of international agreements that relate to modern biotechnology. The most important are the:

- Cartagena Protocol on Biosafety to the United Nations Convention on Biological Diversity

- Agreement on Technical Barriers to Trade
- Agreement on the Application of Sanitary and Phytosanitary Measures
- WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

What is the Cartagena Protocol on Biosafety?

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity is the first international legally binding tool regarding biosafety in biotechnology. It seeks to contribute to ensuring that there is an adequate level of protection in the safe transfer, handling and use of GMOs resulting from modern biotechnology, especially those that may have adverse effects on the conservation and sustainable use of biological diversity. It also takes into account risks to human health, and specifically focuses on transboundary movements.

The Protocol was adopted in Montreal on January 29, 2000, but will take effect only after at least 50 States have ratified it. In summary, the Protocol:

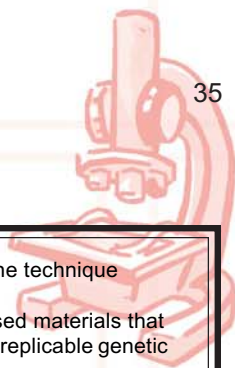
- Establishes an Advance Informed Agreement procedure for imports of LMOs intended for release into the environment;
- Establishes a simplified procedure for notification and information exchange for LMOs intended for food, feed or for processing, such as agricultural commodities;
- Establishes regimes for assessing and managing risks to biodiversity;
- Details information and documentation requirements; and
- Includes provision for capacity-building and financial resources.⁶⁹

Box 4. The Advance Informed Agreement Procedure

A Party¹ exporting a living modified organism (LMO) to another Party for intentional introduction into the latter's environment is required to comply with the advance informed agreement procedure laid down by the Cartagena Protocol. The Advance Informed Agreement, which is the heart of the Cartagena Protocol, is as follows:

1. Prior to the intentional transboundary movement of the LMO, the Party of export should notifies, or requires the exporter² in its jurisdiction to ensure notification, in writing, to the competent national authority³ of the Party of import. The notification should contain the following minimum information⁴:
 - a. Name, address and contact details of the exporter;
 - b. Name, address and contact details of the importer⁵;
 - c. Name and identity of the LMO, as well as the domestic classification, if any, of the biosafety level of the LMO in the State of export;
 - d. Intended date or dates of the transboundary movement, if known;
 - e. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety;
 - f. Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate;
 - g. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety;





- h. Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the LMO;
 - i. Intended use of the LMO or products thereof, namely, processed materials that are of LMO origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;
 - j. Quantity or volume of the LMO to be transferred;
 - k. A previous and existing risk assessment consistent with the risk assessment principles and methodology set forth on the Protocol;
 - l. Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate;
 - m. Regulatory status of the LMO within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the LMO is banned in the State of export, the reason or reasons for the ban;
 - n. Result and purpose of any notification by the exporter to other States regarding the LMO to be transferred; and
 - o. A declaration that the above-mentioned information is factually correct.
2. Within ninety days from receipt of the notification, the Party of import acknowledges such receipt in writing. The acknowledgment should state the following:
- a. the date of receipt of the notification;
 - b. whether the notification, *prima facie*, contained the required minimum information listed above; and
 - c. whether the notifier should proceed according to the domestic regulatory framework of the Party of import (which must be consistent with the Cartagena Protocol) or according to the Decision Procedure laid down by the Cartagena Protocol itself.
- The failure by the Party of import to acknowledge receipt of a notification within the 90-day period does not imply consent to the transboundary movement.
3. If the Party of import requires the notifier to comply with the Decision Procedure of the Protocol, then:
- a. within the same period required to acknowledge the notification, the Party of import informs the notifier, in writing, whether the transboundary transfer may proceed either: (a) only after the Party of import has given its written consent; or (b) after no less than ninety days without a subsequent written consent; and
 - b. within two hundred seventy days from receipt of notification, the Party of import should communicate, in writing, to the notifier and to the Biosafety Clearing-House⁶ of its decision:
 - i. approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same LMO;
 - ii. prohibiting the import; or
 - iii. to request additional information in accordance with its domestic regulatory framework or Annex of the Protocol⁷
 - iv. to extend the 270-day period by a definite period of time.
- Failure by the Party of import to inform the notifier of its decision within the 270-day period does not imply consent to the transboundary movement.

The Advance Informed Agreement applies only for the first intentional introduction of the LMO into the environment of the Party of import, as is the case when, for instance, the LMO is being imported for use in field trials. It does not apply in instances where the LMO is:

- in transit;
- intended for use in a contained facility⁸ (e.g., laboratory and greenhouse); or
- intended for food, feed, or for processing into food or feed,⁹ which is covered by the separate procedure outline in Box 5.

Notes

¹ A State or a regional economic integration organization may be Party to the Cartagena Protocol. A “regional economic integration organization” means “an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by [the] Protocol and which has been duly authorized, in accordance with its international procedures to sign, ratify, accept, approve or accede to it.” (Cartagena Protocol, Art. 4). One, and thus far the only, example for purposes of the Protocol is the European Union.

² An “exporter” is “any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported.” (*Id.*, Art. 3(d)).

³ Each party to the Protocol is required to designate one or more competent national authorities that will be responsible for performing the administrative functions required by the Protocol (Art. 19.1). These functions include the receipt of notifications for purposes of the advance informed agreement procedure.

⁴ *Id.*, Art. 8.1 and Annex I.

⁵ An “importer” is “any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported.” (*Id.*, Art. 3(f)).

⁶ The Cartagena Protocol established Biosafety Clearing-House to “facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms.” It is also meant to assist the Parties in their implementation of the protocol, “taking into account the special needs of the developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centers of origin and centers of genetic diversity.” (Art. 20; emphasis supplied)

⁷ The number of days that the Party of import has to wait for additional relevant information is not included in computing the period within which the Party of import is to respond to the notifier. (*Id.*, Art. 10.3(c)).

⁸ *Id.*, Art. 6.

⁹ *Id.*, Art. 7.2.

Box 5. Procedure for Transboundary Movement of LMOs Intended for Direct Use as Food or Feed, or for Processing

The Cartagena Protocol requires a Party making a final decision regarding the domestic use (including placement in the market) of a LMO that may be subject to transboundary movement for direct use as food or feed, or for processing, to inform the other parties, through the Biosafety Clearing-House, of its decision within fifteen days therefrom.¹ The notification submitted to the Biosafety Clearing-House should contain the following minimum information²:

- a. The name and contact details of the applicant for a decision for domestic use;
- b. The name and contact details of the authority responsible for the decision;
- c. Name and identity of the LMO;
- d. Description of the gene modification, the technique used, and the resulting characteristics of the LMO;
- e. Any unique identification of the LMO;
- f. Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety;
- g. Centers of origin and centers of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate;
- h. Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety;
- i. Approved uses of the LMO;
- j. A risk assessment report consistent with Annex III of the Protocol
- k. Suggested methods for the safe handling, storage, transport and use, including packaging, labeling, documentation, disposal and contingency procedures, where appropriate;

However, a Party may decide to regulate the importation of LMOs intended for direct use as food or feed, or for processing, under its domestic regulatory framework, provided that it is



consistent with the Protocol.³ If a developing country Party has no such domestic regulatory framework, and in the exercise of its domestic jurisdiction, it may declare through the Biosafety Clearing-House that its decision prior to the first import of a LMO intended for direct use as food or feed, or for processing, will be taken according to (i) a risk assessment undertaken in accordance with Annex III of the Protocol; and (ii) a decision made within a predictable timeframe, not exceeding two hundred and seventy days.⁴ Failure by the developing country to communicate its decision within the said period does not imply consent or refusal to the import of the LMO, unless it is otherwise specified by such country.⁵

Notes

¹ Cartagena Protocol, Art. 11.1.

² *Id.*, Annex II.

³ *Id.*, Art. 11.4.

⁴ *Id.*, Art. 11.6.

⁵ *Id.*, Art. 11.7.

What is the Codex Alimentarius Commission?

Food standard setting at the international level is done by the Joint FAO/WHO Codex Alimentarius Commission (CAC). This is an intergovernmental body established to protect consumer health and ensure fair practices in the food trade. The 23rd Session of the CAC, held in 1999, agreed to create an *Ad Hoc* Intergovernmental Task Force for Foods Derived from Biotechnology to develop standards, guidelines and recommendations regarding the safety and nutritional aspects of genetically modified foods.

The elaboration of food standards by the CAC follows a step-wise procedure, as shown below:

- Step 1: Authorization of the elaboration of a text as new work
- Step 2: Preparation of a proposed draft
- Step 3: Circulation of the proposed draft for comments by governments and observers
- Step 4: Consideration of the proposed draft by a Committee or a Task Force
- Step 5: Provisional adoption as a draft by the CAC
- Step 6: Circulation of the draft for comments by governments and observers
- Step 7: Consideration of the draft by a Committee or a Task Force
- Step 8: Final adoption by the CAC⁷⁰

Once a text is adopted at Step 8, it is given the status of an international benchmark under the Sanitary and Phytosanitary (SPS) Agreement. While the SPS Agreement requires its Members to base their risk management measures on scientific risk assessment, Members applying recognized international standards such as those of the Codex Alimentarius are deemed to be in compliance with their obligations under the SPS Agreement. There is thus a strong incentive for governments to

use Codex standards as a basis for national regulations. In doing so, they can strengthen their food control system while avoiding unnecessary trade disputes.

The *Ad Hoc* Intergovernmental Task Force for Foods Derived from Biotechnology has recently released, at Step 8 of the Elaboration Procedure, the “Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology” and the “Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants”. Both documents are available at www.codexalimentarius.com, and countries wishing to regulate GM foods are well advised to review them.

What is the Technical Barriers to Trade (“TBT”) Agreement?

The TBT Agreement is one of the agreements under the administrative supervision of the WTO. It recognizes that countries should not be prevented from taking regulatory measures necessary to pursue various “legitimate objectives” such as, *inter alia*, national security requirements, the prevention of deceptive practices, and protection of human health or safety of animal or plant life or the environment. Governments are, however, required to apply technical regulations and standards in a non-discriminatory manner and ensure that they do not restrict trade.

The TBT Agreement incorporates a fundamental principle of general trade law that is relevant to products of modern biotechnology: “like” products should be similarly treated. The intention is to avoid applying different regulatory measures to products with similar characteristics on the ground that they have been produced differently. This is designed to avoid arbitrary and deliberate discrimination against imported products which, although similar, may have been produced with techniques different from those used for domestically produced products. However, there is as yet no formal interpretation as to whether, under the TBT Agreement, products produced using modern biotechnology are “like” their conventional counterparts.

What is the Sanitary and Phytosanitary (SPS) Agreement?

The SPS Agreement, like the TBT Agreement, is one of the WTO agreements. It applies to all sanitary and phytosanitary measures that may affect international trade. Sanitary and phytosanitary measures are domestic standards or regulations established to protect human, animal or plant health on quarantine and food safety grounds and cover such concerns as the presence of microbial contaminants, toxins, heavy metals and pesticide residues in food and quarantine risks posed by pests weeds and pathogens.

In the context of trade in agricultural products, these measures are to be applied only to the extent necessary to protect human life or health and “to protect human life or health from the risk arising from additives, contaminants, toxin or disease causing organisms in foods.” The SPS Agreement removes the right of countries



to arbitrarily restrict access to markets on health and safety grounds. It also calls on members to harmonize sanitary and phytosanitary measures on a global basis by adopting international standard guidelines and recommendations, where these exist. Sufficient scientific evidence must be provided if members wish to maintain SPS measures at levels above relevant international standards.

The scientific requirement of the SPS Agreement is important because it provides a more objective approach in determining what is a justified trade restriction and what is hidden protectionism. On the other hand, the agreement may seem inadequate to tackle restrictions introduced on the basis of consumer sentiments in relation to food production methods such as genetic engineering.

When scientific evidence is unavailable or insufficient for a final judgment about the safety of a product or process to be made, Article 5.7 of the SPS Agreement explicitly allows WTO member states to take precautionary measures based on available pertinent information. Members are, however, obliged to seek additional information so that a more objective evaluation of the risks related to the relevant product or process can be made within a reasonable period of time.⁷¹

IV. OWNERSHIP OF AND ACCESS TO BIOTECHNOLOGY

Do developing countries stand to benefit from the use of modern biotechnology?

Yes, but developing countries should remember that the institutional and economic environment within which modern biotechnology R&D is being conducted differs significantly from that of Green Revolution technologies. The latter was essentially the prerogative of public research institutions and philanthropic foundations. In contrast, the application of modern biotechnology to agriculture is a competitive, commercial endeavor in which powerful private sector interests compete.⁷² Multinational companies in the seed, agricultural chemical, pharmaceutical and food-processing industries play a major role in biotechnology research. Also, as a result of mergers and acquisitions in the past years, the development of new biotechnology applications in agriculture has become increasingly concentrated in the hands of a few companies. The dominant companies that currently operate within the global markets are Monsanto, Syngenta and Pioneer Hi-Bred.

The Food and Agriculture Organization has pointed out that current transgenic crop releases are still “very narrow” in terms of crops and traits, and thus have yet to address the special needs of developing countries. While some 200 crops are currently under field testing in developing countries and other crop-trait combinations are being investigated, focusing mostly on virus resistance, crop quality, and in some cases, tolerance to abiotic stresses, many crops (e.g., vegetables) and traits (e.g., drought- and aluminum-resistance) important to developing countries are still almost entirely neglected.⁷³

Relatively little biotechnology research is being undertaken on the problems of small farmers in rainfed and marginal lands. Neither is there much interest in crops like wheat, sorghum, millet, banana, lentils, cassava, groundnut, and sweet potato. These are considered *orphan crops* because of the private sector's reluctance to work on them.⁷⁴ They have limited appeal because they are grown mainly for personal consumption by poor farmers. Hence, public sector research will have to fill in the void by exploiting the research potential of biotechnology to solve the high-priority problems of the developing world.⁷⁵

What can be done in the global arena to enable developing countries to take advantage of the potential benefits of modern biotechnology?

There is a need to push for a global governance regime for biotechnology that will help to bring a large number of developing countries into the global trading system. The elements of such a governance system should include improvements in market access, development of technological capabilities, access to technology, national regulation of biotechnology, and the management of risks and benefits associated with its use.⁷⁶

Although scientific advances in biotechnology appear to be concentrated in a small number of developed countries, the following factors will allow for the wider participation of developing countries in the new bioeconomy:⁷⁷

1. The growing recognition that the current patterns of globalization are untenable if they do not increasingly include developing country products. Developing countries depend on industries that are based on natural resources and can therefore benefit from the use of modern biotechnology.
2. Many of the techniques used in biotechnology research are becoming readily available because of scientific familiarity, and are therefore relatively easy to acquire through sustained capacity development and enterprise development efforts.
3. Much of the initial R&D expenditures have already been borne by the industrialized countries. What is needed is effective international technology partnerships to enable developing countries to benefit from biotechnology R&D.

However, much will depend on the level of domestic technological capacity in developing countries and the kind of global biotechnology governance system that emerges from the current policy debates. A global governance system that provides opportunities for market access will help to foster the commercialization of new technologies, especially those that threaten to alter the patterns and loci of productions. Resistance to new technologies is likely to be reduced by perceptions of access to the new technologies, as well as to their markets.⁷⁸



Does the current GMO controversy help in clarifying the issues?

Unfortunately, the debate over GMOs has focused on risks to human health and the environment. While these concerns are important, the debate does not adequately reflect the interests of developing countries. This is because the issues are framed in the context of industrialized country concerns.

For instance, the debate ignores the fact that since the rural poor in developing countries are mostly in farming, any technology that helps lighten the load of agricultural workers can free up time to pursue higher-earning occupations. An oft-cited example of the revolutionary potential of modern biotechnology is the harvest in 2001 by Kenyan farmers of the first trial crop of sweet potatoes for resistance to an aphid-borne disease that previously killed up to 80% of their crops.⁷⁹

In addition, one of the main policy goals of developing countries is to enhance food security, a problem that may not be present in many developed countries. While biotechnology cannot solve all of the problems associated with agricultural production, there is no denying the fact that it has the potential to address specific problems such as increasing crop productivity, diversifying crops, enhancing the nutritional value of food, reducing environmental impacts of agricultural productions, and promoting market competitiveness.

Developing countries are hampered in their ability to benefit from advances in modern biotechnology because of the lack of scientific and technological capacity and the low level of enterprise development in most of these countries. While the responsibility for formulating policies and strategies for the wider use of biotechnology lies within the domestic leadership, international cooperation and partnerships are essential in promoting sustainable agriculture in the developing world.⁸⁰

Can modern biotechnology solve the problems of developing countries in agriculture?

Biotechnology is simply one of the instruments that developing countries can use in finding solutions to problems in agriculture. While biotechnology has many potential benefits, it is not—and cannot be—a solution for all of the problems confronting the agricultural sector. After all, technology is only one of many factors for agricultural growth. Hence, while encouraging biotechnology research and development, developing countries should continue to invest in water and soil management, farm-to-market infrastructure, and credit access programs, among others.⁸¹

However, no developing country can ignore the promise of safe and responsible use of biotechnology, whether in the medical or agricultural spheres.

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- ⁸ In the early years, the terms "genetic engineering", "genetic manipulation", "genetic transformation" and "transgenesis" were favored to describe the techniques of genetic modification. R.L. Paarlberg, *The Politics of Precaution* (Baltimore: The Johns Hopkins University Press, 2001), 2.
- ⁹ Griffiths, *supra* note 4, at 4. The following online dictionaries contain further definitions of terms relevant to modern biotechnology: <http://www.fao.org/DOCREP/003/X3910E/X3910E00.htm>, www.hon.ch/Library/Theme/Allergy/Glosaary/allergey.html, www.sciencekomm.at/advice/dict.html.
- ¹⁰ A formal definition is offered by Mark Gerstein of Yale University: bioinformatics as "conceptualizing biology in terms of molecules and then applying informatics techniques to understand and organize the information associated with these molecules, on a large scale." M. Gerstein, "Bioinformatics Introduction"; available from www.primate.or.kr/bioinformatics/Course/Yale/intro.pdf; accessed on 28 February 2003.
- ¹¹ U.S. Department of Energy Human Genome Program, *supra* note 6.
- ¹² Commission of the European Communities (2002), *Life Sciences and Biotechnology*, COM(2002) 27 final, 3. [hereafter "European Commission"]
- ¹³ *Ibid.*, at 4.
- ¹⁴ GMOs can also be used in biomining, or the inexpensive extraction of precious metals from low-grade ores using microbes. Plants are also now being developed to mine precious metals (e.g., Brassica, which is being developed to concentrate gold from the soil in their leaves). *Science and Government*, No. 1, June 2002, 3.
- ¹⁵ European Commission, at 5-6.
- ¹⁶ U.S. Department of Energy Human Genome Program, *supra* note 6.
- ¹⁷ *Ibid.*
- ¹⁸ W. Bains, *Genetic Engineering For Almost Everybody: What Does It Do? What Will It Do?* (London: Penguin Books, 1987), 99.
- ¹⁹ U.S. Department of State International Information Programs, "Frequently Asked Questions About Biotechnology", *USIS Online*; available from <http://usinfo.state.gov/topical/global/biotech>, accessed 21 March 2002. [hereafter "USIS"]. Cf. C. Feldbaum, "Some History Should Be Repeated", 295 *Science*, 8 February 2002, 975.
- ²⁰ *Ibid.*
- ²¹ *Ibid.*





²² *Ibid.*

²³ U.S. Department of Energy Human Genome Program, *supra* note 6.

²⁴ A number of scientists have called for the use the term “nuclear transplantation”, instead of “therapeutic cloning”, to help reduce public confusion. The term “cloning” has become synonymous with “somatic cell nuclear transfer”, a procedure that can be used for a variety of purposes, only one of which involves an intention to create a clone of an organism. They believe that the term “cloning” is best associated with the ultimate outcome or objective of the research and not the mechanism or technique used to achieve that objective. They argue that the goal of creating a nearly identical genetic copy of a human being is consistent with the term “human reproductive cloning”, but the goal of creating stem cells for regenerative medicine is not consistent with the term “therapeutic cloning”. The objective of the latter is to make tissue that is genetically compatible with that of the recipient, not to create a copy of the potential tissue recipient. Hence, “therapeutic cloning” is conceptually inaccurate. B. Vogelstein, B. Alberts, and K. Shine, “Please Don’t Call It Cloning!”, *Science*—(15 February 2002), 1237.

²⁵ D. Cameron, “Stop the Cloning”, *Technology Review*, 23 May 2002’. Also available from <http://www.techreview.com>. [hereafter “Cameron”]

²⁶ M.C. Nussbaum and C.R. Sunstein, *Clones And Clones: Facts And Fantasies About Human Cloning* (New York: W.W. Norton & Co., 1998), 11. However, there is wide disagreement within scientific circles whether human cloning can be successfully carried out. For instance, Dr. Rudolf Jaenisch of Whitehead Institute for Biomedical Research believes that reproductive cloning shortcuts basic biological processes, thus making normal offspring impossible to produce. In normal fertilization, the egg and sperm go through a long process of maturation. Cloning shortcuts this process by trying to reprogram the nucleus of one whole genome in minutes or hours. This results in gross physical malformations to subtle neurological disturbances. Cameron, *supra* note 30.

²⁷ *Ibid.*

²⁸ The National Action Plan on Breast Cancer and U.S. National Institutes of Health-Department of Energy Working Group on the Ethical, Legal and Social Implications (ELSI) have issued several recommendations to prevent workplace and insurance discrimination. The highlights of these recommendations, which may be taken into account in developing legislation to prevent genetic discrimination, may be found at <http://www.ornl.gov/hgmis/elsi/legislat.html>.

²⁹ Eugenics is the study of methods of improving genetic qualities through selective breeding.

³⁰ Asian Development Bank, *Agricultural Biotechnology, Poverty Reduction and Food Security* (Manila: Asian Development Bank, 2001). Also available from <http://www.adb.org>. [hereafter, “Asian Development Bank”]

³¹ D. Bruce and A. Bruce, *Engineering Genesis: The Ethics of Genetic Engineering* (London: Earthscan Publications, 1999), 22. [hereafter “Bruce”]

³² S. Abdulla. “Drought Stress” *Nature: Science Update*; available from www.nature.com/nsu; accessed 3 May 2002.

³³ National Academy of Sciences. *Transgenic Plants and World Agriculture* (Washington: National Academy Press, 2001).

³⁴ Bruce, *supra* note 40, at 23. Early attempts to manipulate growth in animals failed due to severe welfare problems. For example, pigs altered with human growth hormone genes suffered deleterious consequences like gastric ulcer, arthritis, dermatitis and renal disease. *Ibid.*

³⁵ For an account of the research and development of Flavr Savr® tomato, see B. Martineau, *First Fruit: The Creation of the Flavr Savr Tomato and the Birth of Biotech Food* (New York: McGraw-Hill, 2001).

³⁶ A.F. Krattiger, *An Overview of ISAAA from 1992 to 2000*, ISAAA Brief No. 19-2000, 9.

- ³⁷ L.P. Gianessi, C.S. Silvers, S. Sankula and J.E. Carpenter. *Plant Biotechnology: Current and Potential Impact for Improving Pest management in US Agriculture, An Analysis of 40 Case Studies* (Washington, D.C.: National Center for Food and Agricultural Policy, 2002), 5-6.
- ³⁸ C. James, "Global Review of Commercialized Transgenic Crops: 2002", *ISAAA Brief No. 27-2002*, at 11-12. [hereafter "James 2002"] Also available from <http://www.isaaa.org>.
- ³⁹ Bruce, *supra* note 37, at 26.
- ⁴⁰ W.H.R. Langridge, W.H.R. "Edible Vaccines", *Scientific American*, September 2000, 49.
- ⁴¹ S. Halos, "Current Concerns and Emerging Issues on Environmental Biosafety" (manuscript), 2001. [hereafter, "Halos"]
- ⁴² R.D. Kryder, S. Kowalski, and A.F. Krattiger. "The Intellectual and Technical Property Components of pro-Vitamin A Rice (GoldenRice™): A Preliminary Freedom-to-Operate Review", *ISAAA Briefs No. 20-2000*, 1-2.
- ⁴³ *Ibid.*
- ⁴⁴ Union of Concerned Scientists, "Genetic Engineering Techniques", *UCS Online*; available from <http://www.ucsusa.org>; accessed 15 June 2002. [hereafter "Union of Concerned Scientists"] There are currently no experiments to produce a purple cow, nor is one likely to be made in the near future. The example given by the Union of Concerned Scientists was adopted only to highlight the possibility of crossing species boundaries.
- ⁴⁵ SEARCA, "Frequently Asked Questions on Biotechnology", *SEARCA Online*, available from <http://www.searca.org>; accessed on 15 June 2002.
- ⁴⁶ B. M. Chassy, "Food Safety Evaluation of Crops Produced Through Biotechnology", *Journal of the American College of Nutrition* 21, no. 3 (2002), 167. [hereafter "Chassy"]
- ⁴⁷ James 2002, *supra* note 47.
- ⁴⁸ Chassy, *supra* note 53, at 167.
- ⁴⁹ James 2002, *supra* note 47.
- ⁵⁰ *Ibid.* at 9-11.
- ⁵¹ L.O. Fresco, "Genetically Modified Crops", *FAO Magazine*, November 2001, *FAO Online*; available from <http://www.fao.org/ag/magazine>; accessed on 15 June 2002. [hereafter "Fresco"]
- ⁵² Union of Concerned Scientists, *supra* note 53.
- ⁵³ Halos, *supra* note 50.
- ⁵⁴ K. Eastham, and J. Sweet, *Genetically Modified Organisms (GMOs): The Significance of Gene Flow Through Pollen Transfer* (Copenhagen: European Environment Agency, 2002), 7-8.
- ⁵⁵ This is the so-called "terminator gene".
- ⁵⁶ Halos, *supra* note 50. For more information on the GURT controversy, please refer to <http://www.comm.cornell.edu/gmo/issues/terminator.html> and <http://www.biodiv.org/doc/meetings/cop/cop-06/information/cop-06-inf-01-rev1-en.pdf>.
- ⁵⁷ Union of Concerned Scientists, *supra* note 53.
- ⁵⁸ *Ibid.*
- ⁵⁹ For an in-depth discussion of the Monarch butterfly controversy, see Pew Initiative on Food and Biotechnology, "Three Years Later: Genetically Engineered Corn and the Monarch Butterfly Controversy", *Pew Initiative Online*; available from <http://pewagbiotech.org>; accessed 15 June 2002.
- ⁶⁰ Society of Toxicology, "The Safety of Foods Produced Through Biotechnology", *US Society of Toxicology Online*; available from <http://www.toxicology.org>; accessed 15 June 2002.
- ⁶¹ Available from <http://www.royalsoc.ac.uk>. The Royal Society is the national academy of sciences of the United Kingdom. It is the oldest scientific academy in existence, having been founded in 1660. Composed of eminent scientists who have been elected for life by peer review as fellows, the Society counts at least 65 Nobel Laureates among its approximately 1300 Fellows and Foreign Members. It is independent of government by





virtue of a royal charter granted in 1663. It produces a series of authoritative statements and reports that provide advice to the UK government and the public on key issues in science and technology. In 1998, it issued the report *Genetically Modified Plants for Food Use*, which it updated in February 2002 with the issuance of—the report *Genetically Modified Plants for Food Use and Human Health — An Update*.

⁶² The Royal Society, “Genetically Modified Plants for Food Use and Human Health – An Update”; available from www.royalsoc.ac.uk; accessed 15 June 2002, 3. The Royal Society noted, however, that in current screening methods, applicable to both conventional and GM foods, there is no formal assessment of the allergenic risks posed by inhalation of pollen or dusts. It recommended that decision trees be expanded to include inhalant as well as food allergies. *Id.*

⁶³ Union of Concerned Scientists, *supra* note 53.

⁶⁴ M. Schauzu, “The concept of substantial equivalence in safety assessment of foods derived from genetically modified organisms” in *AgBiotechNet 2000, Vol. 2 April, ABN 044*

⁶⁵ Danish Protection Agency, “The Precautionary Principle”, *DPA Online*; available from <http://www.mem.dk/faktuelt>; accessed 12 May 2002.

⁶⁶ National Council for Science and the Environment, “Science Behind the Regulation of Food Safety: Risk Assessment and the Precautionary Principle”, *NCSE Online* (27 August 1999); available from <http://www.cnle.org>; accessed 14 May 2002.

⁶⁷ M.A. McLean, *et al.*, “A Conceptual Framework for Implementing Biosafety: Linking Policy, Capacity and Regulation”, *International Service for National Agricultural Research Briefing Paper No. 47*, March 2002.

⁶⁸ M.K. Maredia, “The Economics of Biosafety: Implications for Biotechnology in Developing Countries”, *Biosafety Journal* 3: 1; available from <http://www.bdt.org.br>; accessed 21 May 2002.

⁶⁹ J. Plazinski, “Implications of International Agreements on Agricultural Biotechnology Products for Trading Nations” (manuscript).

⁷⁰ K. Miyagishima, “International Standard Setting in Biotechnology: Role of Codex Alimentarius Commission”, 2001 (manuscript).

⁷¹ Centre for International Economic Studies, “GMOs, Trade Policy and Welfare in Rich and Poor Countries” (May 2000), *University of Adelaide Online*; available from www.adelaide.edu.au/cies; accessed 12 May 2002.

⁷² World investment in public agricultural research grew steadily from the 1950s to the 1980s. This led to the Green Revolution, which spread high-yield seeds to developing countries in the 1960s and 1970s. However, publicly funded research stagnated in the 1990s. This meant that just when modern biotechnology was showing promise in rural agricultural development, the key funders have halted the momentum of investment in agricultural research and extension programs that help train farmers in the latest techniques. Victor, D.G. and Ford Runge, C., *Farming the Genetic Frontier*, 81 FOREIGN AFFAIRS No. 3 (May/June 2002), 115-116. [hereafter “Victor”]

This has adversely affected public research institutes in countries like Kenya and Zimbabwe, which are funded mainly by donor contributions. The donor share in public research funding in Kenya and Zimbabwe accounted for an average of 67% and 50% of total expenditures, respectively. C.A. Falconi, “Agricultural Biotechnology Research Capacity in Four Developing Countries”, *ISNAR Briefing Paper No. 42* (December 1999), 6. [hereafter “Falconi”]

⁷³ Fresco, *supra* note 60.

⁷⁴ Asian Development Bank, *supra* note 39.

⁷⁵ P. Pinstrup-Andersen and E. Schioler, *Seeds of Contention* (Baltimore: The Johns Hopkins University Press, 2000), 92 & 97.

⁷⁶ C. Juma, “Biotechnology and Sustainable Agriculture: Developing Country Perspectives”, 21 January 2000 (manuscript) [hereafter “Juma”].

⁷⁷ *Ibid.*

⁷⁸ *Ibid.*

⁷⁹ Victor, *supra* note 88, at 114.

⁸⁰ C. Juma, *supra* note 92.

⁸¹ L.O. Fresco, *supra* note 60.



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