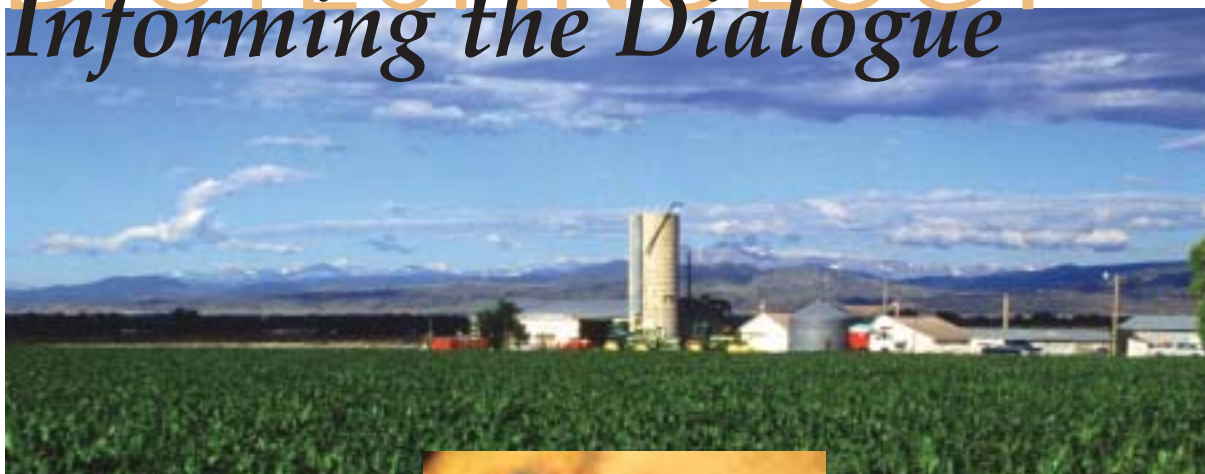


AGRICULTURAL BIOTECHNOLOGY

Informing the Dialogue



College of Agriculture and Life Sciences

New York State
Agricultural
Experiment Station
Geneva, NY



Cornell University
Agricultural
Experiment Station
Ithaca, NY

AGRICULTURAL BIOTECHNOLOGY

From the Dean

The faculty and administration of the College of Agriculture and Life Sciences at Cornell University recognize that there is a public dialogue on agricultural biotechnology. The development of this publication is part of our continued commitment to educate the public and facilitate informed public discussion of the issues surrounding agricultural biotechnology.

Anytime a publication is published on a controversial issue, legitimate questions may arise. I would like to be clear on our College's position and provide answers to some of the most commonly asked questions.

Who funded this publication?

Costs for producing this publication came from discretionary funds of the Dean of the College of Agriculture and Life Sciences (CALs) at Cornell University. It was not funded by private sector or government funds.

Why was this publication developed?

It is important that Cornell participate in the dialogue about the various technical and social issues of biotechnology that affect agriculture, the environment, and human health. Our aim is to present information in a thoughtful, balanced way. However, we recognize that not everyone will agree with what is written. This is part of the dialogue.

Where does Cornell get funding for biotechnology projects and who sets Cornell's research agenda?

For 2000-2001, the College of Agriculture and Life Sciences had a budget of \$183,974,800 dedicated to teaching, research and outreach. Of that total, less than 25% was devoted to research in the social and biological sciences: \$42.8 million. Private companies supplied about 5.4% of the research budget, or about \$2.3 million. The main sponsors of research were federal government agencies (U.S. Department of Agriculture, National Science Foundation, U.S. Department of Health and Human Services), New York State agencies and foundations. These research funds were used in diverse areas in the social and biological sciences, including biotechnology. All funding must be approved by the college and university administrators who enforce guidelines to ensure that information produced by research is not inappropriately restricted by corporate or other interests.

Does Cornell conduct research on products of biotechnology?

Yes. This research includes work on animals, food components, and plants. For example, researchers at Cornell University test biotechnology plants in the laboratory, greenhouse and field according to federal and state regulations, which may require regulatory permits and inspections. Cornell has a system to ensure compliance with these regulations, which can be seen at <http://oeh.cals.cornell.edu/transgen.html> under "Transgenic Procedures and Flow Chart."

How can I find out what is being tested?

Information about what biotech products are being tested and what permits have been issued is available through the U.S. Department of Agriculture's website and through other locations such as Virginia Tech's "Information Systems for Biotechnology" <http://www.nbiap.vt.edu/>.

The purpose of this publication is to help you become more knowledgeable about the issues surrounding biotechnology, and develop a common understanding of agricultural biotechnology. I invite you to participate in the dialogue about this important issue and hope you find this brochure useful in forming your opinions on agricultural biotechnology.

If you have questions or need further information on these issues, please refer to the following web sites which provide more detail than can be covered in this publication: <http://www.nysaes.cornell.edu/agbiotech> and <http://www.geo-pie.cornell.edu/>.

Susan A. Henry, Ph.D.
The Ronald P. Lynch Dean of Agriculture
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AGRICULTURAL BIOTECHNOLOGY

What is Agricultural Biotechnology?



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A field of insect-resistant field corn: In 2001, nearly 25 million acres of biotech field corn were planted worldwide. In the U.S., over 25% of the corn is biotech.

Societies have always been concerned with a safe and abundant food supply. Many scientists see biotechnology as a natural progression from traditional breeding techniques, and believe that the fundamental issues are the same, whether food is produced with or without biotechnology. Is the food safe and nutritious? Does it taste good? How does its production affect the environment and the economic well-being of the public? What regulatory policies are needed to ensure the safety of foods?

It is most important that scientists and the public at large discuss these issues. With less than 2% of the American public now directly involved in agricultural production, many may feel left out of the dialogue about the issues involved in agricultural biotechnology.

Food production systems are complex whether they are conventional, organic, or involve biotechnology. They entail questions of technology and society, and fundamental values for each of us. It is important to understand the issues and become engaged in the dialogue.

What is biotechnology?

Biotechnology, or biotech, are techniques of modern biology that employ living organisms (or part of organisms) to make or modify products, improve plants or animals, or develop microorganisms for specific uses. Biotechnology can involve the use of genetic engineering, as well as many other technologies commonly used for decades.

What is genetic engineering and how does it relate to biotechnology?

Genetic engineering is one form of biotechnology. It involves copying a gene from one living thing (bacteria, plant or animal) and adding it to another living thing. Today's breeders define a genetically engineered organism as an organism that has been improved using genetic engineering techniques in which only a small piece of one organism's genetic material (DNA) is inserted into another organism.

Products of genetic engineering are commonly referred to as "genetically engineered organisms" or "GE products" or "genetically modified organisms" or "GMOs." Since plants and animals have been selectively bred for more than 10,000 years, they have all been "modified." Products developed through genetic engineering are often referred to as simply "biotech" or "biotechnology-derived products." We use these terms in this brochure.

Why use biotechnology methods like genetic engineering?

Genes are the instructions all living things use to build and maintain their cells. Adding a new gene to a crop plant can give it traits that may be of greater benefit to farmers, consumers, and the environment.

- Farmers have adopted biotechnology-derived herbicide resistant crops to manage weeds more efficiently and

conserve soil by using no-till and minimal-till farming practices.

- In the case of biotechnology-derived insect-protected plants, farmers achieve better insect control and often reduce the use of synthetic chemical insecticides.
- Biotechnology-derived virus-resistant plants are, in some cases, the only reliable means for protecting the crop against destructive plant viruses.
- Biotechnology-derived products are being developed to allow more efficient processing of foods, drugs, and other products.
- Biotechnology-derived crops may, in the future, include specific nutritional or health benefits, such as enhanced vitamin or lower fat content.

What types of biotechnology-derived products are used today?

- Medicines (e.g. diagnostic tools and drugs such as insulin)
- Plants (e.g. insect-, disease-, and herbicide-resistant plants)
- Enzymes for food production (e.g. cheese, etc.)
- Yeasts for baking
- Fuels and solvents (e.g. ethanol)
- Protein hormones that allow for more efficient milk production
- Plants that produce medicines or novel materials

Risks and Benefits of Agricultural Biotechnology

Products derived from biotechnology are evaluated on a case-by-case basis through research to resolve questions about biotech risks and benefits compared to current production practices. Prior to the introduction of these products into the market, they are evaluated for food and environmental safety by our federal agencies.

Some degree of hazard is associated with every technology and all activities of our daily lives. It is important to assess the likelihood and consequences of these risks and compare them to the potential and actual benefits of the technologies. Risk assessment is an ongoing process for all technologies, even for ones that have been in existence for decades.

While most of us understand a benefit, understanding a hazard and a risk is more complex. We can imagine everything that could possibly go wrong and call this a list of potential hazards. The next step is to find out which, if any, of these hazards will occur – this is how to assess risk. This leads us to ask questions about a risk, such as: "how often?," "how much?," and "how badly?" In this brochure, we provide some discussion points on the risks and benefits of agricultural biotechnology to consumers, farmers, the environment, and society.

AGRICULTURAL BIOTECHNOLOGY

Agriculture 101

WELLS/USDA-ARS

The plant and animal products we consume today are very different from those consumed by our ancient ancestors, and even by our great grandparents. In the last 10,000 years, our ancestors became food producers instead of hunters and gatherers. During this time, they increased the numbers of domesticated plants and animals and modified them through selective breeding. This provided



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Wallpainting in the tomb of Mennah depicts early Egyptian farmers harvesting grain.

more dependable sources of food, which allowed people to live together and develop larger communities and more complex societies. By reducing the time a society devoted to agricultural production, this

allowed the arts, education, and trade to flourish. Our ancestors improved plants and animals for desired characteristics such as taste, yield, color, or pest resistance. This process continues today. Nature provided our ancestors with the initial material for selective breeding of many different types of plants. We would not recognize many of these ancient plants today because, after domestication and selective breeding, they bear little resemblance to what is available in modern grocery stores.

For example, potatoes originated in South America — their “center of origin.” Wild varieties of potatoes still exist in countries like Peru and exhibit tremendous variation in shape, color, nutritional value, and chemical content. Many wild varieties of potatoes have a bitter taste due to a family of

chemicals called glycoalkaloids, which are toxic to humans. Over time, the levels of these toxic chemicals have been reduced through selective breeding. Shapes and colors have been modified to suit consumer preference.

Exemplifying crop diversity in nature, many varieties of corn serve as a principal grain for much of the world’s population.



Most of the foods we consume daily did not have their origins in wild crops from the U.S. In fact, with the exception of sunflowers and some small fruits, all our present-day food products originated in other parts of the world: for example, corn originated in Mexico, wheat in the Middle East, apples and citrus in Asia, and tomatoes and potatoes in South America.

Plants and animals have evolved over time and taken on new characteristics, but also retain most of the genes from their past heritage. In fact, as we learn more about the genetic makeup of plants, we find tremendous similarity among all plant species. Even more remarkable are recent studies in biology, which demonstrate that plants share many of their same genes with organisms as diverse as bacteria and humans. (For more information, see “Biology 101,” pp. 4-5.)

While natural selection and selective breeding by humans have been the two main methods of plant and animal improvement in the past, biotechnology offers new options. Since their commercialization in 1996, farmers have used biotech plants that resist attack by insects and disease-causing organisms as well as plants that allow new options for weed management. The rate of adoption of biotech plants has arguably been faster than any other agricultural development in the last 50 years. Increasing from an initial planting of 4.3 million acres in 1996, these “pest management” biotech crops were grown on over 123 million acres globally in 2002.

Other plants that provide more “consumer-oriented” benefits are being developed — plants that stay fresh longer, plants that provide health benefits, such as lower fats or higher vitamin and mineral content, and even plants that can deliver safe and effective vaccines when eaten. Biotech carnations that display blue-violet



INTERNATIONAL POTATO CENTER, LIMA, PERU

Over thousands of years of selective breeding, the modern potato scarcely resembles ancestral varieties like the ones shown here.



DURE/USDA-ARS

This map depicts the centers of origin of some of the world’s major vegetable crops.



DUKE/USDA-ARS

This map depicts the centers of origin of some of the world's major fruit crops.

coloring are available from florists in Australia. Plants that produce biodegradable plastics and fuels are being developed as alternatives to petroleum-derived products, and animals are being modified to produce less waste and/or grow more quickly than traditional breeds.

The first food products of biotechnology appeared in the market in 1990: an enzyme used in cheese production and yeast for baking. In the case of cheese, a biotech enzyme replaced an enzyme derived from animals, thereby providing a safer, more consistent method of cheese production. Today, this technology is used to produce nearly all the cheese in the U.S. and much of the cheese in Europe, although neither labels their cheese as products of biotechnology. In 1994, a biotech tomato with a longer shelf life was introduced into the market but did not fare well because of production and distribution problems.

Because of the widespread cultivation of biotech crops for pest control, an estimated 60% to 70% of processed foods in the U.S. contain at least one ingredient from a biotech plant — largely due to biotech corn and soybean which are ingredients for many processed foods (see "Food, Food Safety and Human Health," pp. 8-9).



DUKE/USDA-ARS

This map depicts the centers of origin of some of the world's major grain and bean crops.

Controversies in Agriculture

Agricultural biotechnology, like many other technologies in the past, has often been the focus of controversy. Prior to the introduction of pasteurization, for instance, milk was a major cause of disease and death in the American population. In a survey conducted in 1900, 28% of infant mortality was estimated to be due to gastro-intestinal diseases, largely caused by consumption of raw milk. Adoption of milk pasteurization, a process using heat to reduce pathogenic



Louis Pasteur: the father of pasteurization, a major food safety innovation.

microorganisms, quickly and dramatically reduced infant mortality to the point where, today, contaminated milk is no longer a major issue in the U.S. However, when it was introduced, pasteurization was an extremely controversial technology. Opponents claimed it was an unnatural and deceptive technology that adversely affected food

quality and the economics of production.

Other technologies such as freezing food, using microwave ovens, and food coloring have also been hotly debated. Food irradiation has been a topic of controversy but is being increasingly used to reduce the risk of disease-causing organisms in foods.

New technologies like biotechnology, pasteurization, and irradiation are based on scientific research. Often, their introduction has been met with public scrutiny and controversy.

AGRICULTURAL BIOTECHNOLOGY

Biology 101

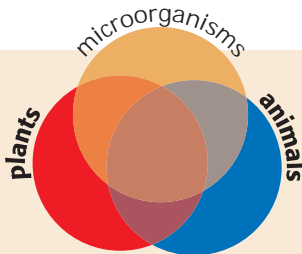
To understand the term “biotechnology,” it is important to review a basic concept of biology — the gene. Genes are contained in all living cells. They provide instructions on cell function, and are passed from generation to generation to enable a species to survive. The wonders of all living things, from the smallest one-celled protozoan to the multi-billion-celled human, are manifested through their ability to use a similar genetic code of life. All the fruits, vegetables, and meat products we eat contain genes and the proteins produced by genes.

DNA is a molecule which is the basis of heredity. Each gene is a section of DNA that occupies a specific place on a particular chromosome and represents the code for the inheritance and development of some characteristic.

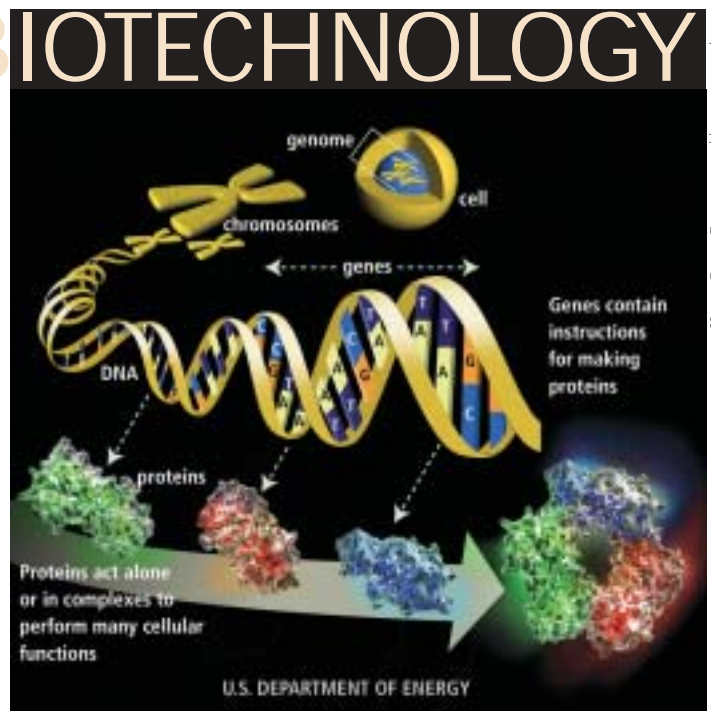
A 19th century monk, Gregor Mendel, used pea plants to determine that genes in plant pollen (the male part of a plant) and the plant ovule (the female part of the plant) pass certain characteristics from one generation to the next. Mendel’s ideas became the basis of our present general understanding of heredity and genetics, and soon led to more fundamental studies on the nature of the gene.

In 1953, James Watson and Francis Crick proposed the structure of DNA (deoxyribonucleic acid), the carrier of genes. They described the structure of the DNA molecule as a complex three-dimensional double helix structure that resembles a ladder (see diagram at the top of this page). The sides of the ladder alternate sugar and phosphate molecules, and the rungs are nitrogenous bases between the sugar molecules. There are four different bases in DNA known as thymine (T), cytosine (C), adenine (A), and guanine (G). The sequence of bases differs from gene to gene, and thus defines the gene. DNA is contained on chromosomes (humans have 23 pairs of chromosomes) and serves two functions: it is the genetic material (genes) that controls heredity, and produces RNA that directs the synthesis of proteins which make cells function.

But genes are not static; they change over time by chance or are selected for by evolutionary processes called “natural selection.” For example, some plants develop the ability to grow in dry climates or fight off insects by producing certain chemicals. As genes continue to change, the characteristics they create in plants and animals are passed to subsequent generations.



Biological organisms share most of the same genes common to all life forms in addition to many other genes for specific traits.



DNA replication and protein production: From DNA instructions, cells make and use proteins to perform the basic functions of life — metabolism, reproduction, and growth — as well as provide an individual’s unique characteristics.

The long road

The discoveries of Watson and Crick revolutionized our understanding of how cells work and how genes are passed from generation to generation, but were really part of a longer scientific process. Even before Mendel conducted his work, for thousands of years farmers had been making crosses of plants and animals to develop lines with desirable characteristics. Charles Darwin also saw the diversity of life and, while not knowing the structure of a gene, recognized the fundamental concept of advantageous characteristics that are passed from one generation to the next because of natural selection.

In the 1970s, scientists began using the discoveries of people like Darwin, Mendel, Watson and Crick, and applying them to modern biology. Paul Berg delineated the key steps by which DNA produces proteins, an important step in recombinant DNA work, which led to his Nobel Prize for Chemistry in 1980. Once scientists realized that the traits of an organism resided within DNA, they began taking segments of DNA that carried information for specific traits (genes) and moving them into single-celled bacteria so the bacteria would begin to express the gene and manufacture a protein.

Herbert Boyer, a biochemist at the University of California at San Francisco, and Stanley Cohen, a professor of medicine at Stanford University, were the first to demonstrate that this technology would work. Their collaborative effort led to the first direct use of biotechnology — the production of synthetic insulin to treat people with diabetes.

Taking a section of genetic material from the DNA of one organism and “splicing” it into another organism is one type of genetic engineering. Genetic engineering is one of the techniques of biotechnology.

The similarity of life

The uses of biotechnology are far reaching, not only in medicine and foods but in our understanding of life itself. Over the last two decades, scientists have unraveled the genetic code of several different organisms only to find they have much in common. The highly publicized “Human Genome Project” <<http://www.ornl.gov/hgmis/>> was a coordinated international effort to identify all the genes in

human DNA. At the same time, a similar project was underway to map the genome of a small flowering plant commonly used for research, *Arabidopsis thaliana* <<http://www.arabidopsis.org/info/agi.html>>.

The Human Genome Project
 Humanity has been given a great gift. With the completion of the human genome sequence, we have received a powerful tool for unlocking the secrets of our genetic heritage and for finding our place among the other participants in the adventure of life.
Science, Feb. 16, 2001

Arabidopsis is not a major agricultural plant, but is directly relevant to other important crops and human biological functions.

Scientists have studied the genetic code of *Arabidopsis* to learn its many fundamental life processes at the molecular and cellular levels, processes common to all higher organisms, including humans. *Arabidopsis* contains numerous genes equivalent to those in humans. Likewise, this simple plant also contains genes which have their counterparts in wheat, corn, rice, cotton, and soybean. The information about the *Arabidopsis* genome is entirely in the public domain so it can be used by anyone at no charge. Similar mapping studies are underway in rice, mice, cattle, and microorganisms.

All living organisms share the same code for DNA and the synthesis of proteins and other basic functions of life processes. At the molecular level, all living things are more alike than different. That is one of the reasons genes can be moved so successfully between such seemingly different organisms, such as plants and bacteria. Genes are not unique to the organisms from which they came. There aren't really “tomato genes,” but there are genes from tomatoes that are the same as genes from very different organisms.



CORONICK/NYSAES/CORNELL

Arabidopsis is a small flowering mustard plant whose genes have been identified. Many of its genes are identical to those of other plants and animals.

The Path to Biotechnology



NATIONAL HISTORY MUSEUM, LONDON

Charles Darwin (1809-1882) was a naturalist on the *H.M.S. Beagle*, which departed on a five-year scientific expedition to the Pacific coast of South America on December 31, 1831. Research conducted on this trip formed the basis of his famous book, *On the Origin of Species by Means of Natural Selection*, which challenged the contemporary beliefs about life on earth.



Gregor Mendel (1822-1884) was an Austrian monk whose experiments on garden peas unraveled the basic laws of heredity. He hypothesized the existence of factors that determine the inheritance of traits from two parents to their offspring. We now know that those factors are genes.



CSHL ARCHIVES

Rosalind Franklin (1920-1958) was a physical chemist who used X-ray diffraction techniques to produce high-resolution photographs of single fibers of DNA. Her work gave experimental backing for the double helix model of DNA presented by Watson, Crick, and Wilkins.



TIME FX

James Watson and Francis Crick published a paper in 1953 on the structure of deoxyribonucleic acid, DNA. That structure — a “double helix” that can make copies of itself — confirmed suspicions that DNA carries life’s hereditary information. For their discoveries, they shared a Nobel Prize in 1962 with Maurice Wilkins.



CSHL ARCHIVES



STANFORD UNIVERSITY

Stanley Cohen and Herbert Boyer developed the techniques that allowed a single gene to be moved between organisms. Their collaboration began in 1972 and, within four months, they succeeded in replicating DNA in bacterial cells.



TIME FX

Their work initiated the advent of genetic engineering and modern biotechnology.

AGRICULTURAL BIOTECHNOLOGY

Techniques of Traditional Plant Breeding and Modern Biotechnology



Prior to modern biotechnology, pollen was the main source of DNA available for making crosses between plants.

Prior to the early 1900s, traditional plant breeding relied only on man-made artificial crosses in which pollen from one species was transferred to another sexually compatible plant. The purpose of a cross is to bring desirable traits such as pest resistance, increased yield, or enhanced taste from two or more parents into a new plant. Plant breeding depends on the existence of genetic variation and desirable traits. Often, desirable characteristics are present in wild relatives that may not be sexually compatible with one of the parent plants, so other means of transferring the genetic material are needed.

Since the 1930s, plant breeders have used various techniques to allow them to create crosses which would not be viable in nature, and these techniques have been used to create new varieties of plants used today. Some of these techniques fall under the broad classification of biotechnology, but are not considered genetic engineering. An example of these techniques includes “embryo rescue,” in which the offspring of the cross would not survive without special help provided in the laboratory.

Beginning in the 1950s, plant breeders also used methods of creating artificial variation in an organism by using radiation and chemicals that randomly caused mutations or changes in the genes of the plant. Plants were then assessed to determine if the genes were changed and whether the change(s) gave the plant some beneficial trait such as disease resistance. If the plant was “improved” by this technique, it was tested further for any negative effects caused by the treatment.



The Asian pear ‘Gold Nijisseiki’ was improved by radiation breeding to be resistant to black spot disease.

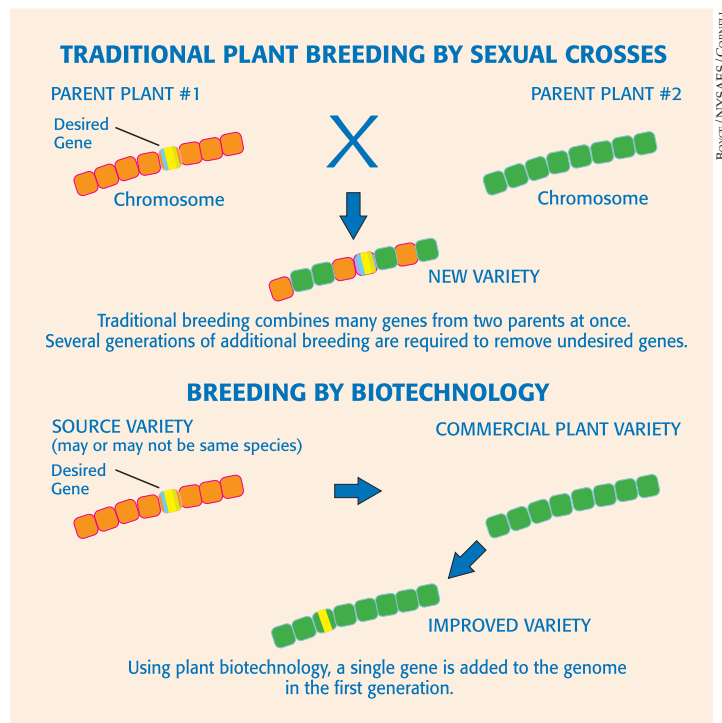
Many of the common food crops we use today — such as insect-resistant corn and herbicide-tolerant soybeans — have been developed with more recent techniques of modern agricultural biotechnology.

The differences

There are two major differences between “traditional plant breeding” (which also includes many techniques involving agricultural biotechnology, as noted above) and “genetic engineering.” The first is the amount of genetic material involved. When two parental plant lines are crossed using traditional breeding methods, the new plant ends up with half the genetic makeup of each

parent. Thus, the desirable gene may be accompanied by many undesirable genes from that same parent. To remove the undesirable genes, continued breeding is required. In the case of genetic engineering, only the few specifically desired genes are moved into the new plant.

A second difference between traditional breeding and modern biotechnology is the source of genetic material. Traditional breeding largely relies on closely related plant species. In modern biotechnology, theoretically, a gene from any living organism may be moved into any other living organism. This permits scientists to move the genes from a bacterium into a plant. In fact, this was done to produce insect-protected biotech plants using genes from a common soil bacterium, *Bacillus thuringiensis* (Bt). This bacterium has been used commercially for more than 50 years as an insecticide spray, but does not provide the same level of control as when Bt is transferred into a biotech plant, like Bt corn or Bt cotton.



How are genes put into crop plants?

Gene transfer using a common soil-dwelling bacterium, *Agrobacterium tumefaciens*, is a powerful tool routinely used to transform plants using modern biotechnology methods such as genetic engineering. Mary-Dell Chilton proved that the crown-galls of plants are caused by the transfer of a small piece of DNA from a plasmid in the pathogen, *A. tumefaciens*, into the host plant, where it becomes part of its genome. This bacterium naturally transfers its genetic material into other



Dr. Mary-Dell Chilton's innovative work has been instrumental in transforming modern biotechnology from concept to reality.

plants so when scientists add a new gene to the bacterium, that new gene is also transferred. While on the faculty at Washington University in the late 1970s and early '80s, Dr. Chilton led a collaborative project using this technology to produce the first transgenic plant. Chilton's work has been essential in transforming modern biotechnology from concept to reality. For her work, she was awarded the Benjamin Franklin Medal in Life Sciences for 2002.

The "gene gun" is another of the tools used worldwide for genetically engineering plant cells. Researchers

at Cornell University's Geneva and Ithaca campuses developed the technology in 1986. A gene gun "shoots" DNA segments into cells at high speed and some of the DNA segments are incorporated into the plant's genome.

Both transformation techniques require an additional step of tissue culture. In this process, the newly transformed plant material is first tested to ensure the gene transfer is successful. Then, because the plant cells



After genetic transformation, plant cells are cultured in growth medium in a jar in the laboratory. Subsequent steps include growth of the plant in a greenhouse and, finally, in trials in the field.

with the newly acquired genes require certain environmental conditions to flourish, they are first grown in tissue culture in the laboratory and then later in the greenhouse and field. Plants that carry a novel gene can be crossed with other plants possessing desirable characteristics and their offspring may then carry the novel gene. A plant carrying a novel gene can also be propagated by taking "cuttings" from the plant, as is done with many woody plants like apples and grapes. In either case, plants are further evaluated under greenhouse trials. Those that prove successful are then evaluated in small, regulated field trials before they are moved into larger trials.

The development of transgenic plants takes years. Regulation of biotechnology-derived plants starts with the product idea and continues with laboratory and field testing. (For a more detailed discussion on regulating biotech, see "Who Regulates the Technology?" on pg. 17, and <http://oes.cals.cornell.edu/transgen.html> under "Transgenic Procedures and Flow Chart.")



Researcher uses a "gene gun" developed at Cornell University to insert DNA segments into another plant cell.

ISSUES DIALOGUE

Is genetic engineering better or worse than traditional plant breeding?

There is some debate about whether genetic engineering techniques are more or less precise than traditional plant breeding, and whether moving genes from one species into another violates "biological boundaries." As in most discussions, the issues are complex. A single cross between two parents using traditional breeding techniques will introduce many new genes simultaneously (half the genes will come from each parent), but the cross can only be made between the same or very closely related species.

Modern biotechnology methods introduce a specific gene but that gene can, in theory, come from any species. Moving a single gene from one organism to another is a more precise form of breeding, but it is not certain where that gene will be placed on the chromosome and how it will function. Thus, it is important for plant breeders using traditional or biotechnology methods to determine not only whether the gene has been moved, but also how it functions.

Clearly, genetic engineering is more powerful than traditional plant breeding since it can utilize genes from other sources to provide the intended effect.

This brings up the issue of biological boundaries between species. Traditional plant breeding, prior to the early 1900s, allowed only crosses within a species or between closely related species. Thus, some argue that traditional breeding offers protection against crossing "biological boundaries." However, others argue that all biological organisms share most of the same genes anyway and that "biological boundaries" are really very fuzzy.

The genetic code is universal — all traits of all living organisms are based on the same DNA code of four "letters" assembled into the instructions (genes) for the development and structure of each organism. Can we classify particular DNA sequences as "foreign" if they have the exact sequence of "letters," but one came from a plant and the other from a bacterium?

Rather than ask whether a DNA sequence is a "plant gene" or a "bacterial gene," perhaps we should simply ask what function it has in the organism.

As we understand more about the total genetic makeup of an organism (its genome), we learn that most organisms share many of the same genes (see "Biology 101," pp. 4-5).

AGRICULTURAL BIOTECHNOLOGY

Food, Food Safety and Human Health



WELLS/USDA-ARS

Fruits and vegetables are important components of a safe and nutritious diet.

Whether a plant has been developed through traditional breeding or modern biotechnology, it is important to assess the potential risk of introducing new characteristics into the plant. Plants naturally contain thousands of chemicals that are used not only to help them develop, but also to protect them from pests. For both biotech and traditionally bred foods, it is important to understand food safety issues. Considerable information exists at the Center for Food Safety and Applied Nutrition <<http://www.cfsan.fda.gov>>.

Allergies and toxins

Most people can eat the plants commonly found in stores in the U.S. without any problem, but some people can't because of food allergies. According to the American Academy of Allergy, Asthma and Immunology (AAAAI)

<<http://www.aaaai.org>>, a food allergy occurs when a person's immune system overreacts to an ordinarily harmless food.

According to AAAAI, an estimated 1% to 2% of adults and 2% to 4% of children have some allergic reaction to some food products. The most common food allergens are proteins from cow's milk, eggs, peanuts, wheat, soy, fish, shellfish, and tree nuts. Allergic reactions vary among individuals and range from mild to severe. An allergenic reaction to a food (as well as to pollen and dust) is due to a naturally occurring chemical in the blood (IgE) that recognizes an allergen and causes the immune system to overreact.

Plants contain what are often termed "secondary plant compounds" — chemicals that are not required for normal plant growth and development which may protect them from insects and diseases, but some may cause toxic reactions in humans if present in high concentrations.

The absolute safety of biotech foods cannot be guaranteed any more than the absolute safety of conventional foods.

Prior to the introduction of a new plant variety, whether bred through traditional or biotechnology methods, it is important to screen it for known allergens or toxins. In traditional breeding, new varieties of potatoes, celery, and cucumbers that had elevated levels of allergens or toxins were

identified through screening and are not commercially available. In the case of biotech plants, whenever a new gene is introduced into the plant, it is also evaluated for the production of potential allergens and toxins (see "Who Regulates the Technology," pg. 17). Recent work has demonstrated that a protein in soybeans that

causes more than half of all soybean allergies can be eliminated through biotechnology.

In March 2002, the American Society of Toxicology <<http://www.toxicology.org>> stated its view on the safety of foods produced through biotechnology: "There is no reason to suppose that the process of food production through biotechnology leads to risks of a different nature than those already familiar to toxicologists or that cannot also be created by conventional breeding practices."

Nutritional disorders

While food allergies and toxins may cause immediate health risks, nutritional disorders generally cause health problems over a longer term. A healthy diet is a balanced diet. Information on proper nutrition and diet can be obtained through the American Dietetic Association <<http://www.eatright.org/>> .

When new varieties of plants are produced through traditional breeding, no long-term studies are undertaken to determine potential nutritional disorders. Traditional breeders have operated under the guidelines that no long-term studies are required for the new plant variety if the breeder has not altered the composition of essential nutrients (e.g. vitamins) or introduced any potential allergens. Biotech plants fall under these same guidelines. From a regulatory standpoint, biotech plants currently on the market are considered "substantially equivalent" to their non-biotech counterparts.

Am I eating biotechnology-derived foods?

Recent estimates suggest that 60% to 70% of processed foods in the U.S. contains at least one ingredient from a biotech plant — largely due to the widespread adoption of biotech corn and soybeans by farmers. Many of these crops eventually

FUTURE APPLICATIONS

In the future, more biotech foods with benefits to the consumer, rather than grower, may be developed — benefits that may include foods with reduced fats or better nutritional composition, longer shelf life, or better taste. More importantly, "functional" foods that have health benefits, such as antioxidants which help prevent cancer, can be developed. As those foods are developed, they will have to be judged on their benefits and risks.



"Golden Rice," developed by Ingo Potrykus, is a transgenic rice that contains beta-carotene and other carotenoids needed for production of Vitamin A, essential in the prevention of blindness.



Biotech bananas can produce edible vaccines to combat diseases.

become processed ingredients, such as corn syrup or soybean oil, and their biotech origin can no longer be detected.

How can consumers be sure that biotechnology-derived products are safe to eat?

Our food supply is among the safest in the world, but that does not mean it is 100% safe. Nothing is 100% safe. The U.S. government works to ensure the highest level of safety possible, but there are still outbreaks of illness due to contamination or spoilage of traditionally produced foods. The U.S. Food & Drug Administration (FDA), Environmental Protection Agency (EPA), and Department of Agriculture (USDA) developed regulations that govern the production and consumption of foods produced through biotechnology. These agencies work with scientists and other individuals to develop data to ensure these regulations are based on sound science. All available evidence shows that foods from biotech crops are at least as safe as foods from non-biotech crops.

What if I don't want to eat food made with biotech ingredients?

By purchasing food products that meet certified organic standards, you have that option. Organically certified producers are not allowed to use biotechnology-derived ingredients or processing aids. In the U.S., organic produce constitutes only 2% of the total market. The FDA is considering labeling standards to assist manufacturers who wish to voluntarily label their foods as being made with or without the use of biotechnology-derived ingredients, while ensuring that the label is truthful and not misleading. The FDA views the terms "derived through biotechnology" and "bio-engineered" as acceptable. Examples of terms that are not acceptable to the FDA are "GM-free," "GMO," and "modified." These standards are being developed for marketing purposes and not because biotech foods are less healthy or less safe to produce.

What other products might contain ingredients from biotech organisms?

Dairy and meat products

No biotechnology-derived fish, cows, pigs, sheep, chickens, or other food animals are on the market as of October 2002. However, livestock routinely eat feed made from biotech crops. Over 70% of the cheeses in the U.S. is made with a biotech enzyme rather than the animal-derived enzyme which it replaced. Milk is commonly obtained from cows treated with a biotechnology-derived version of a naturally occurring hormone called bovine somatotropin (bST) that is used to increase milk production.

Although not required of products from traditional breeding techniques, many studies have been conducted using plants derived from biotechnology fed to livestock and poultry. As summarized by the Federation of Animal Science Societies, scientific studies have documented there are no harmful effects of feeding biotechnology crops to livestock and poultry, and meat, milk, and eggs from these animals are safe and cannot be distinguished from the same products from animals fed non-biotech feed <<http://www.fass.org/>>.

Other foods and products

Modern biotechnology is commonly used in the production of detergents, textiles, pulp and paper manufacturing, leather tanning, metals, fuels, and minerals (see "Biobased



WAY/NYSAES/CORNELL

Chymosin, a biotechnology-derived enzyme, has been used for cheese production for years and replaces the animal-derived enzyme.

Non-food Products," pg. 10). The food industry has used biotechnology-derived bacteria and yeasts for more than 20 years to produce vitamins and nutritional supplements. Biotechnology also has produced medicines to treat a number of human health problems, including arthritis and heart disease. Virtually all the insulin used to treat diabetes is produced by biotechnology methods.

Further information

Because of the importance of having a safe food system, many scientific societies have published information on foods and food safety aspects of crops derived from biotechnology. For more information on the standards and testing procedures for evaluating biotech foods, refer to the Institute of Food Technologists <<http://www.ift.org/govtrelations/biotech/biotechnology.shtml>>.

Which plant products might contain biotech ingredients?

Soybean

More than 70% of the U.S. soybean crop in 2002 is being grown with biotech varieties used for weed management. Soy-based ingredients – including soy protein, soy lecithin, and soybean oil – are present in many processed foods.

Corn

The USDA estimates that farmers planted over 25% of the U.S. field corn crop in 2002 with biotech varieties for insect control and weed management. Corn-based ingredients include corn flour, corn oil, corn syrup, and many more. Some fresh-market sweet corn may be biotech, but almost no canned or frozen corn is presently from biotechnology-derived corn plants.

Canola

Canola oil is extracted from the rapeseed plant – grown mainly in Canada – and more than 50% of the 2002 crop has been grown from biotech varieties used for weed management. Canola is used as a cooking oil and also may be found in many processed foods.

Cotton

Although you might not think of cotton as a food, it often is; cottonseed oil is used in snacks, peanut butter, candies, and many other products. Nearly 70% of the U.S. cotton crop in 2002 was grown with biotech varieties for insect control and weed management.

Other Plants

Biotech disease-resistant papaya and squash are also available. Biotech varieties of potato, tomato, rice, flax, sugar beet, sweet corn, melon, and radicchio are approved for use in the U.S. but are not currently on the market.

AGRICULTURAL BIOTECHNOLOGY

Biobased Non-food Products



In 1935, each Ford car contained components manufactured from two pounds of soybeans.

Biotechnology is not only changing how we grow our food, but also the products we use every day. Naturally occurring enzymes, proteins produced by living organisms which facilitate chemical and biological processes, have been developed through biotechnology and are used extensively worldwide to produce a variety of common foods (e.g. cheeses). Similarly, enzymes play an important role in a variety of processes to manufacture fuels, detergents, textiles, and wood and paper products.

Use of enzymes, or other biologically based (derived from biological material) substances to create useful products, is part of the vision of a biologically based economy being promoted by some scientific organizations, the private sector and federal and state governments. As we learn more about the potential benefits of a biobased economy, this effort is gaining in popularity because many believe it provides more environmentally friendly renewable resources to replace or reduce the use of non-renewable petrochemicals.

The past

Before 1900, many medicines, fibers, plastics, paints, and inks were made from agricultural products. However, because of advances in petrochemical engineering and the availability of inexpensive oil, much of the potential use for raw agricultural products such as corn plants was lost. With advances in genetic and bioprocess engineering, it is now possible to modify plants to serve as efficient, renewable sources of raw materials that can be used for a variety of products. And this is being done.

In 1999, President Clinton signed Executive Order 13134 which had the ambitious goal of tripling the nation's use of biobased products and bioenergy by 2010. Meeting this goal should not only improve the rural economy but also provide an enhanced, sustainable energy policy. Over the last 20 years, exports of agricultural products have stabilized. New

Today there are hundreds of biotechnology-derived products on the market – an estimated 90% of the enzymes used in large scale commercial applications are derived from biotech – including those used in detergents, textiles, pulp and paper manufacturing, leather tanning, metals, fuels, and mineral processing.

opportunities and markets are needed to help agriculture flourish in the future. Furthermore, this Executive Order was conceived as a means to address increasing concerns about the price of gasoline and home heating oil, and many other petroleum-based products. In 1999, oil prices tripled.

In 2000, the National Research Council (NRC), a scientific advisory group to the U.S. government, published a report on the potential impact of biobased products in the 21st century. Much of its focus was on agriculture as the source of raw materials used for production in health, energy, chemical, and material industries.

The future

Various plants are being used to produce biomaterials: inks and dyes, paints and vanishes, soaps and detergents, adhesives and lubricants, biopolymers, film and structural materials such as particle board. Currently there is a \$5.1 billion market for lubricants, \$14.6 billion for composite materials, \$43 billion in paint and \$77 billion in plastics. Biobased products can compete in all these markets.

Additionally, plants serve as energy sources. In some parts of the country, a blend of gasoline and ethanol (commonly produced from corn) is being used. Other plant materials, including grasses and trees, can also be used to produce ethanol and other industrial chemicals. Although we may often hear about the future of ethanol, its success largely depends on the economics of ethanol production and the price of oil, which can shift down to disadvantage ethanol production. Currently, ethanol constitutes only 1% of the total for transportation fuel, but this may rise as biotechnology helps to improve methods of growing and processing corn. Perhaps the future is brighter for more complex fuels that do not lend themselves so easily to petrochemical manufacturing.

Plants may also serve as a source of biochemicals such as vitamins, proteins used in medicine, and specialty chemicals such as activated carbon, phenols or surfactants used in industrial production. The 2000 NRC report targets biobased production from current levels to a 50% increase in energy fuels and greater than 90% increases in biochemicals and biomaterials by 2090. Most of these increases will depend on using agricultural biotechnology, and the rewards can be significant. While no one can foresee all the risks and benefits



Ethanol, a fuel produced using corn, is a growing alternative fuel source.

of a move to a biobased economy, this effort is moving forward because of a recognition that oil is a non-renewable resource with some negative environmental impacts.

What will it take to move from a petroleum-based economy to a biobased economy? Partnerships and new technologies. In recent years, federal and state agencies have begun to recognize the potential of agriculture to contribute to a more sustainable supply of raw materials that can be used for a variety of products currently made using petroleum-based technologies. Executive Orders, scientific advisory panels like the NRC, changes in public policies, developing partnerships with commercial enterprises, and increases in public funding for promoting biobased products are essential. Equally important are new technologies, many of which involve biotechnology. For example, the metabolic pathways of plants such as corn or soybeans will need to be modified so they can efficiently produce materials used in medicines, or developed to perform functions more effectively, thus lowering production costs for fuels and industrial products. Equally important is a required shift in research from petroleum-based chemistry to carbohydrate (plant) chemistry.

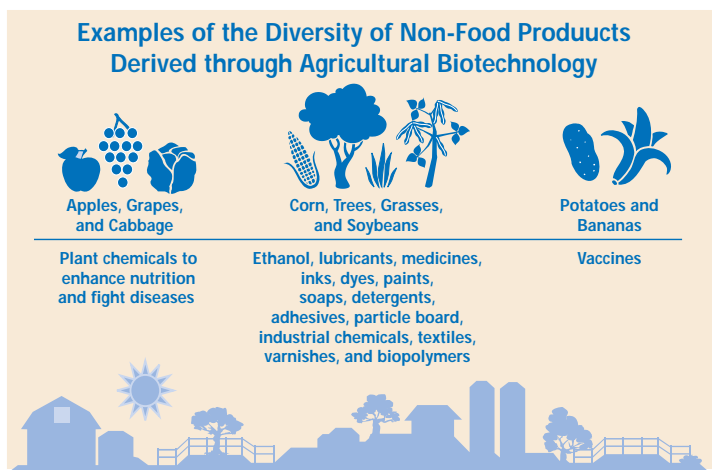
For a more comprehensive discussion on this effort, see National Agricultural Biotechnology Report #12 which can be ordered from <<http://www.cals.cornell.edu/extension/nab>>.

Agriculture and human health

Plants and plant extracts have been the primary source of medicine for thousands of years. For instance, onions and garlic were utilized as herbal medicines by the Babylonians, Egyptians, Vikings, Chinese, Hindus, Greeks, and Romans. Early writings by Hippocrates, the Greek physician often referred to as the “father of Western medicine,” advised followers to chew on willow leaves to reduce pain. Willow trees contain salicin, a member of the class of chemicals called salicylates. In the second half of the 1800s, the pain-relieving chemical from willows was identified and synthesized into acetylsalicylic acid, now commonly referred to as aspirin. More recently, plant chemicals (phytochemicals) from apples, cabbages, grapes, and many other plants have been shown to have positive health benefits, including anti-cancer activity.

With recent advances in biotechnology, plants may now be used to produce medicines in new ways. One promising area is the use of plants to produce antibodies that can treat various human diseases. An antibody is a protein produced in the body in response to contact with a pathogen and which has the capacity to neutralize, and create immunity to, the pathogen. Antibodies may also be directed against proteins associated with the disease process and used to treat the disease directly. Non-plant-produced antibodies are routinely used in organ transplants, cancer therapy and the prevention of infections. Sales of antibodies are projected to be \$4 billion by 2003. Currently, antibodies used for medicines are produced in mammalian cell cultures in the laboratory, and this has limited their availability and increased their costs. As an alternative to the current technology, plants are being developed that will more efficiently produce antibodies on a far larger scale than can be done in mammalian cell culture. In this case, the plants only serve as “production sites” for the antibodies which are later extracted from the plant and then used in treatments.

Another example of the potential for biotechnology to deliver medicines through agriculture is the production of



GOTHAM/NYSAES/CORNELL

plants that, when eaten, will produce immune responses. Potatoes and bananas have been developed through biotechnology to act like vaccines to prevent diseases such as “traveler’s diarrhea.” In addition to the increased capacity for vaccine production, these “edible vaccines” may also prove useful in resource-poor countries where refrigerated storage for traditionally produced vaccines is not available.

Production of medicines through biotechnology has its challenges, including ensuring these crops do not become commingled with food crops. Several of the companies engaged in developing these technologies are small and do not have the resources to conduct the very expensive clinical trials required, so new partnerships must be formed in order for these products to move through the pipeline. Additionally, federal regulations for the production and utilization of these plant-derived products are evolving. “Pharming” should provide substantial increases in the value of agricultural-derived products in the future.

ISSUES DIALOGUE

How will a biobased economy affect farmers and consumers?

Commodities such as wheat, corn, and soybeans are grown throughout the world. U.S. farmers compete on the world market to sell their products. Depending on the production costs (seeds, fertilizers, machinery, labor, etc.) as well as the value of the U.S. dollar in comparison to other currencies, U.S. farmers may suffer or thrive. In recent years, U.S. farmers have suffered. Without government subsidies, totaling over \$20 billion annually, many U.S. farmers would not survive. But is this sustainable?

Farmers need increased value for their raw products. If farmers grow biotech corn that produces a specific protein used for medicine, this will require more sophisticated production practices by farmers and increased value for the farmers’ raw products.

The important question is how farmers can reap the rewards of these high value commodities? Partnerships with pharmaceutical companies or energy companies and farmers may allow each to gain from the other’s expertise and provide increased income for farmers. Consumers will benefit from less dependence on imported oil used as a base for many products used daily. Consumers will also have access to pharmaceuticals grown in crops for which there is an insufficient supply using traditional fermentation reactors. Plant-based pharmaceuticals may require less energy for production and result in less solid waste, but may have other issues associated with production that must be addressed. These should be done on a case-by-case basis.

AGRICULTURAL BIOTECHNOLOGY

Environmental Issues

The three major biotech crops on the market — soybean, corn, and cotton — have been developed to manage pests such as weeds, insects, and diseases. Since these crops have traditionally been grown using pesticides to control these pests, it is important to compare the effects of traditional pesticide technology with that of biotechnology and the alternatives.

Weed management

Anyone who grows a garden or lawn knows the importance of weed management. Weeds reduce the yield and quality of plants and may also contaminate the product, so most large-scale growers use herbicides. Worldwide, it is estimated that nearly \$14 billion of herbicides are used annually. Depending on the crop, herbicides may be applied prior to planting to reduce weed germination. Additional herbicides may be applied once the crop has germinated in order to kill weeds that escaped the first application.

Although most herbicides are relatively non-toxic to humans and other animals, there is a need to reduce their impact on the environment. One way to do this is to use an herbicide that is less persistent in the environment but still provides good weed control. The rationale for biotech herbicide-resistant crops is that the crop can be planted directly into the field, allowed to germinate with any weeds already present, and then treated with an herbicide that kills only weeds. The common herbicide that a biotech crop is resistant to is called glyphosate (Roundup®). It is considered environmentally safer than other herbicides because it degrades quickly with less risk of contaminating ground water.



BAKER/USDA-ARS

Farmers seek new farming practices and technologies to reduce negative impacts on the environment.

The use of herbicide resistant crops reduces soil erosion and compaction because growers drive over the field fewer times and can use conservation tillage practices (minimal and no-till) more easily. Recent data indicate that their use also results in a substantial reduction of herbicides. Also, conservation tillage practices benefit the environment by preserving soil moisture, soil nutrients and beneficial soil microbes. However, as with any herbicide, there is concern that some weeds may become resistant to glyphosate (see “Resistance to Pesticides,” pg. 21).

Insect control

An estimated \$8 billion is used annually worldwide for control of insects that damage plants and affect human health. In agriculture, an estimated 30% of this market can be served by insect-protected plants, which produce a protein from the bacterium, *Bacillus thuringiensis* (Bt).

Caterpillars, the immature stages of moths, bore into the stalks and ears of corn or feed on the flowers and buds of cotton plants. Crop breeders have not been able to breed high enough levels of caterpillar resistance into corn or cotton by traditional methods. With biotechnology methods, breeders have been able to insert a gene from Bt into cotton and corn to produce a protein that protects the plant against certain economically damaging insects. This protein has been used as an insecticide spray by organic and conventional farmers for over 50 years and is harmless to humans and many beneficial insects. However, it can be only marginally effective when applied as a spray because it breaks down quickly and often does not get to where the insects are feeding.

The area planted to Bt corn and cotton plants has increased dramatically since the introduction of Bt crops in the U.S. in 1996, resulting in reduced pesticide use. In the U.S., 30% of total agricultural insecticide use is on cotton. In 1999, the National Center for Food and Agricultural Policy <<http://www.ncfap.org/>> estimated that the use of Bt cotton resulted in a reduction of 1,200 metric tons of active ingredient of insecticide. Most of the alternative insecticides have a wider spectrum of activity than Bt and are more harmful to the environment and non-target organisms like beneficial insects.



MONSANTO CO.

An insect-damaged cotton boll (left) is contrasted to a healthy insect-protected cotton boll (right).

FUTURE APPLICATIONS

Research is being conducted to develop plants that will be able to clean up waste sites. Plants are also being bred to tolerate salty or dry soils. As with the current biotech plants developed to resist pests, these new plants will have to be evaluated for their benefits and risks to the environment.



BAKER/USDA-ARS

Biotechnology-derived pigs can express salivary phytase and produce low-phosphorus manure that is beneficial to the environment.



MERKLE/UNIVERSITY OF GEORGIA

Transgenic eastern cottonwood (*populus deltoides*) trees are being tested for their potential to remediate soil and water contaminated with mercuric compounds.

It is impossible to foresee all possible impacts, but we can focus on known and probable risks. When risks are characterized as low, based on actual data, then many scientists believe the potential impact should be evaluated proportional to that level of concern. This approach should reduce the chances of rejecting safe technologies simply because they are new and unfamiliar. Other analysts focus on the unknown risks. Ultimately, the goal for scientists and society is to replace current agricultural practices with more economical, sustainable, and environmentally safer practices. A balance between benefits and risks will be developed as a result of this ongoing process of acquiring more information.



Aerial view of a field trial in Hawaii showing healthy transgenic papaya trees (center) surrounded by papaya trees severely infected by papaya ringspot virus.

How should we determine the benefits and risks of these biotech crops on the environment?

From an environmental point of view, it is important to continue to evaluate biotech plants, asking questions such as:

- Do biotech plants reduce the use of pesticides or promote more environmentally friendly pest control methods?
- Do biotech plants unintentionally breed with other plants or weeds and what are the consequences, if any?
- Will biotech plants become hard-to-control weeds?
- Will biotech properties hasten the pest's resistance to pesticides?
- Are biotech plants more hazardous than traditional plants to beneficial insects and other non-target organisms?

These concerns should be examined for all technologies, including biotechnology. Most scientists believe we should examine each of these issues on a case-by-case basis. (More complete explanations and examples are discussed in "Issues in the Media," pp. 20-21.)

However, a primary concern about the widespread use of Bt plants is that insects could become resistant to them. The results of close monitoring have determined there are no cases of insects becoming resistant to Bt plants in the field, but there are instances of insects becoming resistant to Bt sprays. This illustrates the importance of developing a strategy to delay resistance. The Environmental Protection Agency (EPA) mandates a resistance management program for use of Bt plants and this has been very successful. However, it is important that these plants be used in an overall Integrated Pest Management (IPM) strategy. IPM relies on the use of biological and cultural control practices, as well as pest-resistant plants and judicious use of pesticides, to manage pest populations.

Disease management

Traditional breeding has produced plants with resistance to some diseases but not others. Annually, agriculture still relies on the use of fungicides worth \$5.8 billion for control of fungal diseases worldwide. Breeding for resistance to fungi and other microorganisms through traditional methods requires crossing closely related species, one of which has a gene or genes for resistance, but such resistant species often do not exist. Another approach using biotechnology involves taking a gene from the disease-causing organism and inserting it into the plant so that the plant becomes protected (see "The Papaya Story," pg. 20). Squash and papaya with resistance to plant virus diseases have been developed in this manner. Other disease-resistant crops have been developed but are not currently commercialized.

Other traits

When cows are treated with a synthetic version of a naturally occurring hormone, they produce milk more efficiently from the food they consume. This results in reduced animal waste and less impact on the environment. Similarly, if crops are engineered to produce higher amounts of tissue (solids), there will be less waste during processing. This has been achieved with tomatoes grown for processing into paste and sauce, resulting in reduced food costs. Through biotechnology, plants are being developed that require less water and utilize fertilizers more efficiently.

ISSUES DIALOGUE

How does this technology affect the environment?

Every technology has its own set of environmental risks and benefits. In the case of biotechnology, these are being documented through the scientific process, and compared with existing and alternative technologies. Because biotech plants have been used since 1996, some trends have become apparent. As reported by the National Center for Food and Agricultural Policy <<http://www.ncfap.org>>, use of biotech plants has resulted in more than 15 million fewer applications of insecticides and provided control of pests that could not previously be controlled. Use of biotech weed management during 2000 resulted in 19 million fewer herbicide treatments in cotton, and an equal reduction of treatments in soybeans. While there are positive benefits, there is also concern that insects and weeds may become resistant to these biotech crops, as they have to pesticides sprayed on plants (see "Resistance to Pesticides," pg. 21).

Other concerns are that biotech crops may cross-pollinate with wild or cultivated plants (see "Gene Flow," in "Issues in the Media," pg. 21). These concerns vary for each crop species.

Studies are underway throughout the world to assess the environmental risks and benefits of biotechnologies compared to existing or alternative technologies. Scientists will never have full knowledge of any old or new technologies. Biotechnologies were deployed with the expectation that the environmental risks would be lower than the risks of current or alternative technologies. Results to date indicate they are.

AGRICULTURAL BIOTECHNOLOGY

Agriculture and the Global Food System

Agriculture and the world's food system developed over the last 10,000 years, but the pace of change has been most dramatic in the last century. Spices and new seeds were once shipped to the far corners of the world by explorers. Now, hundreds of agricultural products are shipped daily from one country to another. Agriculture has become a global food supply and demand issue. This has gone hand-in-hand with changing demographics throughout the world. For example, in the mid-1800s, the majority of U.S. citizens lived in rural areas and a primary source of income was from



A farm in the Northeastern U.S.

farming. Now, less than 2% of our population is directly involved in farming. In some parts of the world, large rural populations continue to produce the majority of their food. For example, in China, where more than 20% of the world's population lives, it is estimated that 70% of the people live in rural areas and are directly involved in agriculture. In France and Germany, the number of farmers has dwindled by 50% since 1978, to 3-5% of the population.

Agricultural revolutions

It is important to examine the reasons behind the declining number of farmers in the U.S. and other parts of the world. Like any entrepreneur, farmers must constantly develop better management skills and new technologies to survive. In 20th century agriculture, there have been several major technological "revolutions." The *mechanical revolution* began in the early 1900s with the introduction of the farm tractor that allowed one farmer to cover more ground and increase farm size. The *chemical revolution* began shortly after World War II. The production of fertilizer and pesticides increased yields dramatically. In conjunction with the chemical revolution, the *green revolution* utilized new, higher yielding varieties of crops developed through plant breeding to produce more food on less land. Today, we are at the beginning of the *biotechnology revolution*.

While a strong case can be made that the mechanical, chemical, and green revolutions resulted in a decrease in farm numbers and a more efficient use of farmland, it



A U.S. farmer inspects a combine filled with field corn.

is unclear what the overall impact of biotechnology will be on the structure of agriculture in the U.S. and the world.

The global food chain

Along with the decreasing number of farmers in some countries, there is an ever-increasing global food chain. Olive oil may come from Italy or Spain, grapes and citrus from North and South America, lamb from New Zealand and Australia, tomatoes and cucumbers from the greenhouses of Holland, and the list goes on. Products are readily transported from farm to market in developed nations. In many cases, corporations have increasingly taken on the task of organizing and coordinating the production, processing, and distribution of food. If the present trend continues, fewer farms will produce more of the world's food and these farms will be linked to concentrated agricultural supply chains. As the production sector is consolidated, so, too is the retail market sector. Consolidation of the market sector influences the suppliers. In the U.S., consolidation of the market sector lags behind Europe; in Germany, for example, five supermarket chains control nearly two-thirds of the market.

There is no question that the food system of today is far more global and consolidated than in the past. It is important to ask what the benefits and liabilities of consolidation are, and especially how they affect rural populations and smaller farms.

Small farmers in wealthy countries in North America and Europe, especially those who have carved out direct market-



We eat from a global food chain where foods produced in one country are available all over the world.

ing niches, provide an alternative to larger, industrially organized operators. They may produce specialty items that require higher inputs, but also get a higher return. Examples of these include handcrafted cheese, beer, and wine. But, the small farm segment composed of many producers accounts for only a small share of the market in most wealthy countries. As with any small business, a small farm is challenged by the costs of labor, technology, and marketing. Their opportunities for growth are perhaps best in serving niche markets. The proliferation of roadside stands and farm markets are examples. Although small farm production will remain important in wealthy countries, it is unlikely that the urban population will move back to the rural areas to produce food. In the U.S., we have a far more complex and diverse society with jobs in many sectors outside of agriculture. In other parts of the world, especially those with lower incomes where the majority of the population lives in rural



Farmers apply pest control to a vegetable crop in Zimbabwe.

areas, small farms are still the norm and are vital to the economic well-being of the country and its people. For example, in China nearly 50% of the gross domestic product (GDP) is derived from agriculture. Yet farmers in developing countries in Africa, Asia, and Latin America are resource poor compared to farmers in the U.S. and Europe. History suggests that when resources become available to buy new technologies, such as improved seeds or machinery, these farmers are likely to purchase them, increase farm size, and consolidate.

The business of agriculture

Since the mid-1950s, agriculture has become bigger and more specialized and is now one of the world's largest industries, employing 1.3 billion people and producing \$1.3 trillion worth of goods each year. The real value in agriculture no longer rests in the commodities produced by farmers, but instead is captured by input suppliers, processors, and marketers. Farm machinery producers, fertilizer and pesticide manufacturers, and even the world's \$20 billion commercial seed market, are no longer as diversified as they once were. The process of market consolidation began long before biotech crops, but biotechnology, like any innovation, has contributed to this trend. Life science companies with capabilities in biotechnology that were involved in agriculture have purchased seed companies in order to increase the value of the seed itself by making pest-protected crops.

Biotechnology is, perhaps, the most rapidly adopted agricultural technology ever. As with any technology, farmers with small or large operations will decide whether or not to



Asian farmers cultivate rice in paddies.

embrace a specific biotechnology, based on the economics and their markets.

Agriculture and society

Economic forces and government policies have changed the farming landscape in all countries. Federal policies have helped the U.S. food system become efficient and produce very inexpensive food. (The U.S. has one of the lowest food expenditures per capita of any developed country: less than 11% of income, compared to 20% in the European Union.) In the U.S., the historical trend has been to move from an agriculture-based economy to a manufacturing-based economy. Recently, the service sector has become the major part of our overall economy, constituting 73% of the GDP, and employing tens of millions. As farming becomes more consolidated and global, farmers in rural areas may suffer unless they are able to serve specialized markets with value-added products. The introduction of advanced biotechnology into agriculture is only one factor that is transforming the farming sector, rural communities, and society, in general.

ISSUES DIALOGUE

What is the role of biotechnology in the world's food system?

The world's population was over 6 billion in 2000 and there will be an estimated 9 billion people in 2050. Today, nearly 840 million people in developing countries suffer from malnutrition. Biotechnology is often cited as a way to help produce more food for the world, but that is only part of the solution. Any advances in crop technology must be accompanied by more effective distribution channels so foods do not rot on the way to the market. While there are no easy answers to feeding the world's growing population, the use of biotechnology in agriculture is growing in some parts of the world where food scarcity is an issue.

As with other areas of globalization, there are concerns about the loss of local customs in the farming sector. For example, up until the mid-1960s, most farmers saved seed from their harvested crops and planted it the following year. In countries in which farmers have sufficient resources, this practice has been replaced by farmers who purchase and plant high-yielding hybrid seed. In poorer countries, the practice of saving seeds remains important and contributes to plant diversity (see "Gene Flow" in "Issues in the Media," on pg. 21).

AGRICULTURAL BIOTECHNOLOGY

Who Develops and Controls the Technology?



HICKY / NYSAES / CORNELL

A Cornell plant researcher examines biotechnology-derived apple plants in tissue culture that are resistant to a bacterial disease called Fire blight. Later, these plants will be tested in a greenhouse, and then in the field.

Most new technologies come from both the public and private sectors, and, often, through public-private partnerships. This trend also applies to biotechnology. Amid increasingly expensive research technologies and simultaneously declining federal and state support, university scientists have had to search for funding outside the shrinking pool of public support. The result has been closer partnerships between the private and public sectors. The partnership must be carefully monitored by all parties to ensure each partner remains loyal to its mission.

Scientists in publicly funded Land Grant Universities, like Cornell, have an obligation to work first for the public

ISSUES DIALOGUE

What are alternative examples of funding research in biotechnology?

There are examples of private companies donating or sharing their intellectual property in biotechnology to developing countries on a royalty-free basis. Monsanto and Syngenta, both major players in biotechnology, have developed collaborative projects with national and international organizations to bring biotechnology to the developing world. These projects have generally been undertaken in poorer countries that cannot pay for the technology. Some people may consider these efforts as largely humanitarian aid. Others may see them as an example of corporate public relations or as a company's longer term business strategy. Regardless of the motivation, agricultural biotechnology has the potential to benefit developing countries.

One example of companies sharing intellectual property is "Golden Rice," a biotechnology-derived rice containing beta-carotene and other carotenoids, which are needed for production of Vitamin A, a deficiency of which can lead to blindness and death. It is estimated that nearly 500,000 children become blind annually because of this deficiency. Traditional breeding methods have failed to produce a viable solution.

Golden Rice was developed by Ingo Potrykus from the Swiss Federal Institute of Technology and Peter Beyer from the Center for Applied Biosciences, University of Freiburg, Germany. Funding for its development came from the Rockefeller Foundation, the Swiss Federal Institute, the European Union, and the Swiss Federal Office for Education and Science. However, the development of Golden Rice also depended on intellectual property rights (patents) belonging to a number of companies including Monsanto, Syngenta, Bayer, Ornova and Zeneca Mogen. Each of these companies licensed the intellectual property used in the development of Golden Rice free of charge.

Samples of Golden Rice have been donated to the International Rice Research Institute in the Philippines to evaluate its safety and utility in combating Vitamin A deficiency.

No one believes that Golden Rice or any other technology will completely solve malnutrition and disease, but many people familiar with biotechnology believe it to be an important component of the solution.

good. To do so now may require them to work more closely with the private sector to ensure their discoveries make it to the marketplace to produce the intended public good. This must be done without compromising scientific integrity or other strongly held principles.

Discovery and commercialization

University scientists often create new technologies, but commercialization comes primarily through the private sector. Biotechnology, whether in medicine or agriculture, is expensive. Private companies that invest in biotechnology demand return on their investments. They also demand that their investments be protected through patents, trademarks and other legal means. In the U.S. and elsewhere, patent law protects new technologies so investors will feel confident enough of the financial returns to move these ideas into the marketplace. Thus, the patent law has created opportunities for major investments in biotechnology — investments that are often funded by the public through growing participation in savings, stock market, mutual funds, and retirement accounts.

An important issue

An important question is whether there is a downside to the growing presence of corporate money and private investment in the relationship among science, technology, universities and products. If so, what other options are available and what risks and benefits might they entail? One concern that needs to be addressed, especially at universities, is to ensure that the exchange of ideas among scientists, the public and private sector not become limited because of patents and private intellectual rights. This must be balanced against the potential benefit to the public good that comes from a new, useful technology being developed because of the partnership between public and private goals.

One major challenge is to work within existing economic and social orders. Some might propose completely free-market solutions or solutions that operate entirely under public funds without private intellectual property, but neither describes the complex American system for creating and developing science and technology. Exploring existing options and creating public-private partnerships requires a willingness to engage in the complex issues raised in our society.

AGRICULTURAL BIOTECHNOLOGY

Who Regulates the Technology?

CORBIS/INTSALES/CORNELL



A Cornell faculty member discusses pest control issues with federal and state officials.

In the U.S., the Food & Drug Administration (FDA), Environmental Protection Agency (EPA), and Department of Agriculture (USDA) have established regulations that govern the production and consumption of products produced through modern biotechnology. These agencies work with university scientists and other individuals to develop the data to ensure that regulations are based on sound science.

The history

Regulations have been developed over time. In the early 1970s, as modern biotechnology methods emerged, scientists and federal agencies began discussing the relevant safety issues of biotechnology. In 1975, the National Institutes of Health (NIH) sponsored the Asilomar Conference, which was the first step in developing national policies on the safety of biotech organisms. Over the years, federal agencies have developed policies relevant to their particular responsibilities, including agriculture. In 1986, the U.S. Office of Science and Technology Policy published its "Coordinated Framework Notice," which declared the U.S. Department of Agriculture as the lead agency for plants grown for animal feed, while food for humans is regulated by the Food and Drug Administration (FDA). The EPA regulates pesticides, including microbials and, in 1992, the agency was given jurisdiction over biotech plants used for pest control such as corn and cotton.

In January 2001, the EPA formalized existing procedures for regulating biotech crops and plants that produce pesticides or plant-incorporated protectants (PIPs). According to the EPA, "if the agency determines that a PIP poses little or no health or environmental risk, they will be exempted from certain regulatory requirements . . . [and] the rules will exempt from tolerance requirements the genetic material, DNA, involved in the production of the pesticidal substance in the plant."

Currently, there are no global standards for biotech crops.

Recent reports

Additional high-profile reports from federal agencies have been published more recently. A panel of biologists and agricultural scientists convened by the U.S. National Academy of Sciences, an advisory board to the president, examined federal government policies on approving crops produced through biotechnology. Their report was published in February 2002. The panel noted that the "standards being set for transgenic crops are much higher than for their conventional counterparts." Furthermore, they stated that although the USDA had not approved any biotech crops that have posed undue risk to the environment, they did recommend changes in the review process to ensure the environmental safety of products that could be introduced in the future. These recommendations included increased public comment and broader scientific input to enhance the regulatory process.

Biotech crops worldwide

In 2000, biotech crops were produced in a total of 13 countries, and each country had its own regulatory system. In addition to the regulations pertaining to the production of biotech crops, each country may have additional regulations on the importation of biotech crops or on whether products derived from biotech crops must be labeled. Currently there are no global standards for biotech crops. In the European Union (EU), the member countries have not agreed on a standard policy for biotech crops, although some countries such as France, Germany and Spain do grow some biotech crops. A new directive by the EU will become effective in the fall of 2002 requiring more environmental monitoring, as well as labeling and tracking of biotech products through all stages of the food chain. In the past, some countries have not

followed such directives and it is unclear whether all members will recognize this new directive, or how it will be implemented for those countries that do agree to it. The European Commission, which acts on behalf of the EU members, has tried to adopt regulations to facilitate the adoption of biotech crops, and its scientific committees have endorsed the safety of many products derived from biotech crops. However, the complexity of the regulatory process of its EU members has prevented widespread adoption of biotech plants in EU member countries.

While the situation in the EU is perhaps the most complex because of its member states, other countries are developing their own processes. Some of them favor the use of biotech while others do not. The United Kingdom has strengthened its regulatory oversight during the last several years and currently has a moratorium on the commercial release of biotech crops. In Australia, insect-protected cotton is the only biotech crop grown. In March 2002, insect-protected cotton was cleared for commercialization in India, a major producer of cotton on the world market.

Because of the increasing interest in, and use of, biotech crops in developing countries, it is important that nations develop regulations suitable to their particular situations. The International Service for the Acquisition of Agri-biotech Applications <<http://www.isaaa.org/>> is a not-for-profit international organization that plays a lead role in facilitating the acquisition and transfer of biotechnology and its regulations from the industrialized countries to developing nations.

AGRICULTURAL BIOTECHNOLOGY

Values and Choices

Ethical and religious questions

The term “ethics” means a set of principles of conduct governing an individual, or a set of moral principles or values. Religious beliefs and customs may also dictate a set of values by which one should act. Ethical and religious beliefs and customs may influence how one approaches a discussion of the production and consumption of foods.

In a discussion of the ethical issues raised by the development and application of agricultural biotechnology in world agriculture and food security, it may be helpful to consider three main ethical principles: human welfare, the maintenance of people’s rights, and justice. There are broad differences in the way issues about agricultural biotechnology need to be dissected — from the purely technical aspects to the more complex issues such as whether people have equal access to technology or whether moving genes between organisms is unnatural. Those who have challenged biotechnology as being unnatural are, in turn, challenged by questions of whether treating illnesses such as cancer through chemotherapy or radiation is unnatural. Such questions are complex.

Many of the social and economic issues discussed earlier in this booklet also raise ethical questions. For example, it is important to consider what is lost and what is gained by the trend toward consolidation of the agricultural industry, the decreasing number of people involved in agriculture, and the changes these bring to rural populations. But these issues are not unique to biotechnology.

Agricultural biotechnology is one thread in the complex tapestry of political and economic issues associated with globalization, modernization, and other aspects of an increasingly interconnected world. Resolving these issues requires technical considerations as well as questioning individual and national values and balancing rights and responsibilities.



In today’s marketplace, consumers have choices from around the world in the foods that are available for purchase.

Agricultural sustainability

Sustainability is an important concept for agriculture in the 21st century and implies the creation of food and fiber systems that promote economic vitality within the community, promote food security, and do so in an environmentally responsible manner. Food security implies an abundance of food with adequate nutritional content.

Food sustainability in a global economy means different things to different people, but ensuring economic viability while minimizing environmental damage is fundamental. From an environmental standpoint, it may mean producing food as efficiently as possible with minimal negative impact on the environment.

Some see food sustainability as a battle between agricultural biotechnology and other practices, including organic agriculture, but others disagree. Although organic certification does not allow use of crops developed through some forms of biotechnology, organic farmers do use pesticides. Although these pesticides are not synthetically derived, their use gives rise to the same environmental and human health concerns as all pesticides.

Some organic farmers have expressed an interest in using agricultural biotechnology if it were available to them. On the other hand, conventional agriculture and biotechnology can benefit from some of the practices of organic agriculture. Agricultural biotechnology and organic agriculture practices can both contribute to sustainability.

From an environmental standpoint, sustainable agriculture should be evaluated on production methods that will least harm the environment, not on whether farmers use organic, biotechnology or other methods of production.



Residents of public housing in the South Side of Chicago, Illinois work in a community garden as part of USDA’s urban revitalization program — an example of a local food production system.

Labeling

In the U.S., food labels reflect composition and safety, not the way the food is produced. Presently foods derived through biotechnology do not require labeling because they have been judged to have the same nutritional content with no changes in allergens or other harmful substances. Voluntary labeling for attributes other than allergens,



PHOTOGRAPH BY LONDON
An early example of labeling: The tomatoes used in this tomato puree were developed through biotechnology to have a higher percentage of tomato solids, thus resulting in less waste during processing and lower consumer prices.

nutritional or ingredient information must make true claims — if the labeling is false or misleading, the product is mislabeled. Some ingredients such as oils derived from biotech crops are identical to those from non-biotech

crops, so labeling them as biotech would not really provide useful information on composition or safety.

If currently available biotech foods were to require labels, it would not be on the basis of nutrition or food safety, but on the way they were produced. Should the method of production require labeling? The U.S. courts have ruled “no” because of the endless number of production practices that could be listed, with only arbitrary means to determine which production practices to include or not include. Conventionally produced agricultural products do not require labeling describing how they were produced. If a product is certified as organic it may be labeled as such for marketing purposes, but such a label does not mean that the product is safer to eat or that it was grown in a safer manner. It is estimated that if foods were certified to be biotech-free, it would increase the cost of the food because the product would have to be followed (traced) from the field to the market. The situation is far more complex if processed foods are to be certified. A processed food may contain dozens of ingredients and to certify it as biotech-free would require certification of each ingredient. It is unclear how biotech products would be segregated in a complex food system (see “Who Regulates this Technology,” pg. 17), and who would pay for the additional cost. In the cases of organic, kosher and halal, the consumer who chooses to purchase the specialty product bears the cost. If labeling of biotech foods were mandatory, all consumers would bear the burden. However, future biotech products that have improved nutritional value will have to be labeled as such. The FDA requires any food, including biotech foods, to be labeled if the food changes substantially in its nutrient content, composition, or allergy-causing properties. On January 18, 2001, the FDA published voluntary guidelines on appropriate labeling as to whether foods have been developed using biotech.

From a federal regulatory standpoint, the fundamental question is whether or not labeling would help consumers make an informed choice about the safety or nutritional value of their foods. A number of consumer surveys in the U.S. indicate that most consumers are not concerned about biotech foods. Of those consumers who want labeling, most indicate that the label alone would not provide enough information and they would like more detailed consumer-

oriented information. Some public health professionals have called for labeling so they can track exposure to biotech foods. Other public health professionals have expressed a concern that the cost to consumers does not outweigh the benefits of mandatory labeling — primarily because mandatory labeling of biotech foods would not include information on which transferred genes or gene products (proteins) were present. Current biotech foods contain extremely small amounts of the transferred gene or gene product. People and animals digest proteins from many food sources and all available evidence indicates foods derived from biotech crops are as safe to eat as foods from non-biotech crops.

Truth in marketing

The term “natural” is widely used in agriculture and food production, but requires close scrutiny. Scientists may argue that the fruits, vegetables, grains and animal products we consume are not “natural” since they are the result of deliberate actions of people over thousands of years, rather than the result of nature. Also, “natural” seems to imply “safe,” but many “natural” plants, such as poison ivy, nightshade, and hundreds of others, contain chemicals that are hazardous to humans. The term “natural” is perhaps used more as a marketing strategy than as a guarantee of safety. “Natural” products pose safety concerns similar to those of synthetic products. In the end, each product should be evaluated for safety based on its own benefits and risks, not on whether it was “natural” or “man-made.”

ISSUES DIALOGUE

Is labeling of biotech foods a good or bad idea?

There are a number of questions that could be asked to address this issue. What are the costs of voluntary or mandatory labeling? If labeling is required for export foods, why not label foods intended for sale in the U.S.? If labeling were mandatory, at what level would you begin labeling a product as biotech — if it contains 1%, 5%, or anything above zero of a biotech crop? Are there reliable, inexpensive methods that can be used to detect these levels? (Presently, there are none.) How does labeling impact consumer confidence in the safety of our food supply? Would consumers perceive mandatory labeling as a safety warning? If most processed foods were labeled as biotech, would this provide consumers with meaningful information?

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*These are some of the current issues.
What are the important issues for you?*



BIOTECHNOLOGY

AGRICULTURAL BIOTECHNOLOGY

Issues in the Media

WAY/NYSAES/CORNELL

Following is a discussion of several issues addressed by the media in 1999 through 2002. As additional issues arise, please check the website for updates to this brochure <www.nysaes.cornell.edu/agbiotech>.

The Papaya Story

In 1998, an extensive socio-economic impact survey of 90 Hawaiian papaya farmers was conducted to assess the impact of the papaya ringspot virus (PRSV) and the subsequent introduction of two biotechnology-derived resistant papaya varieties on their livelihoods. PRSV devastated Hawaii's \$45M papaya industry. Production fell from 58 million pounds in 1992 to 24 million pounds by 1998. In the early 1980s, a research team led by Cornell University Professor Dennis Gonsalves characterized PRSV, used recombinant DNA techniques to isolate and clone a gene in the papaya virus that encodes for production of the coat protein of the virus, and introduced the gene into cells of the papaya plant using special technology developed at Cornell University (see "Techniques of Traditional Plant Breeding and Modern Biotechnology," pp. 6-7). The two biotechnology-derived papaya lines were resistant to the virus. In May of 1998, 'Rainbow' and 'SunUp' varieties were commercialized and released to farmers in Hawaii who planted 2000 acres of land previously abandoned because of the disease. As a result, papaya production increased in 1999 for the first time since 1992, and continues to grow.

This survey was one of the first to measure the impact of a biotechnology-derived crop on farmers' lives. The impact was positive, and led to Dr. Gonsalves receiving the 2002 Alexander von Humboldt Award for the most significant contribution to American agriculture in the past five years.

The Monarch Butterfly Story

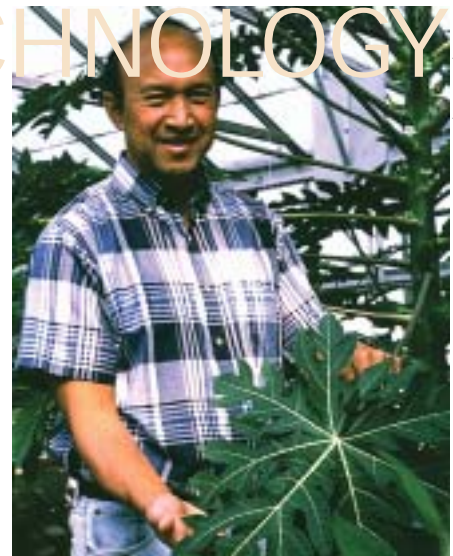
Reports from a small and preliminary laboratory experiment suggested that pollen from a corn plant developed to resist insect attack (Bt corn) could also harm larvae of the Monarch butterfly. This report received worldwide — and some say, sensational — media coverage. Soon the monarch became a symbol for anti-biotechnology activities.

Prior to the registration of Bt corn, the Environmental Protection Agency (EPA) made its assessment of the potential risks of Bt corn to non-target organisms like the Monarch butterfly under field conditions. The agency did not believe that non-target insects like the Monarch would be exposed to sufficient amounts of Bt protein to cause an unreasonable deleterious



The Monarch butterfly, a common symbol for Nature, became a symbol for the anti-biotech movement because of a laboratory experiment with Bt corn pollen.

Dr. Dennis Gonsalves from Cornell University, in cooperation with researchers from the University of Hawaii, developed two virus-resistant varieties of papaya. These biotech crops are credited with saving the Hawaiian papaya industry.



effect, nor that Bt crops would threaten the long-term survival of a substantial number of individuals in the populations of these species. Later, a more thorough study conducted by a consortium of university and government scientists in the U.S. and Canada confirmed the EPA's original judgment by concluding that the effect of Bt corn on Monarch butterfly populations was "negligible."

For a more complete discussion of the subject, see <www.ars.usda.gov/sites/monarch>.

The StarLink™ Story

A soil bacterium, used for decades as a conventional and organic insecticide, was the source of the gene *Cry1A* that was transferred into corn plants to protect them from insect attack (Bt corn). Shortly thereafter, another segment of DNA (*Cry9C*) from another soil bacterium, was introduced into field corn. The resultant variety was called StarLink™. The *Cry9C* product was only registered by the EPA for corn grown for animal feed and industrial uses. StarLink™ was not available for human consumption because all of the studies to assess its potential as an allergen had not been completed, so it was not registered for use in human food. Later studies by the Center for Disease Control indicated *Cry9C* did not pose a health risk to humans.

Although StarLink™ represented approximately 1% of the total corn harvested in the U.S. in 2000, it was detected in food products such as taco shells. Registration of StarLink™ for all uses was voluntarily cancelled by its manufacturer, Aventis Corporation. A number of lawsuits resulting from the discovery of unapproved use of StarLink™ are pending. In January 2001, Aventis agreed to pay compensation to farmers across the U.S. Compensation estimates range from \$100 million to \$1 billion. Also, the USDA announced in March 2001 that it would buy back between 300,000 and 400,000 bags of corn seeds that contain traces of *Cry9C*. This may cost the government between \$15 and \$20 million, but was necessary to ensure a stable and predictable market in U.S. and exported corn. In March 2001, the EPA announced it would no longer provide separate registrations for products used for animal feed and human food. This episode demonstrates the need to have appropriate regulation and enforcement for biotechnology products.

Resistance to Pesticides

Pesticides are applied to control pests but, over time, some pests evolve resistance to specific pesticides. Resistance may develop in insects, weeds or fungi and it hasn't mattered whether the pesticide occurs naturally or has been synthesized. Pesticide resistance is an evolutionary process caused by a genetic change in the pest in response to selection pressure caused by a pesticide. The end result is the development of strains of the pest capable of surviving a dose lethal to a majority of individuals in a normal population. There is justified concern that plants expressing pesticidal properties may, over time, lose some of their effectiveness due to resistance, but each case has to be examined individually.

The main herbicide used for weed management in biotech crops is glyphosate. After intensive use over 25 years, only five weed species have developed resistance. (For a more complete discussion of herbicide resistance, see <<http://www.weedscience.org/in.asp>>.) In the case of disease resistance, the only product on the market that has been widely adopted is virus resistant papaya, and there is no evidence that resistance has evolved to these biotech plants.

In the case of commercial insect-protected plants such as corn and cotton, it is a protein from a bacterium, *Bacillus thuringiensis* (Bt), that is toxic to insects. A few species of insects have developed resistance to Bt when it was used as a spray, and this provides a note of caution when using this same protein to protect biotech plants. However, despite the widespread use of Bt plants since 1996, there are no cases of insects developing resistance to Bt plants in the field. This has surprised some while others have seen it as justifying their belief in the effectiveness of this technology when used in conjunction with a proactive resistance management program to delay or prevent resistance. The EPA, the agency responsible for mandating scientifically valid resistance management programs, has relied on advice from scientists knowledgeable about these issues to develop its policies.

Will resistance develop? Will new Bt proteins become available prior to increasing tolerance of the presently available Bt proteins? Will the environmental and human health benefits of Bt plants, prior to the development of resistance, offset the problems that would occur if resistance to specific Bt proteins develops? While these are important questions, what is increasingly evident is that the development of Bt plants provides useful options for managing insecticide resistance and perhaps is an even more effective strategy for managing resistance to Bt than intensive use of Bt as a foliar spray.

Gene Flow

The exchange of genetic traits between populations (i.e. gene flow) has led to tremendous plant diversity in the world. When considering a possible effect of biotechnology on gene flow, it is important to consider the introduced gene and what effect, if any, it may have on overall gene flow. The effects must be judged on a case-by-case basis. When the EPA approved the use of biotech corn, cotton, and potatoes, it did so based on the fact that there were no wild relatives of these crops in the U.S., so cross-pollination would not occur. The exception was cotton in Florida and Hawaii, where wild populations related to cotton species exist. The EPA has prohibited or restricted the use of biotech cotton in these areas. The situation in areas where these crops originated is

far more complex. For example, since Mexico is the center of origin for maize (corn), there are many "landraces" or naturally occurring varieties of maize. In 2001, an article published in the journal *Nature* claimed that Mexican corn landraces had become contaminated by DNA



Biotech crops must be evaluated on a case-by-case basis to resolve questions about risks and benefits compared to current production practices.

from biotech varieties that were banned in Mexico. This paper caused a furor in the scientific community because many scientists believed the researchers used poor techniques. Soon after publication, the editorial board of the journal *Transgenic Research* stated that "no credible scientific evidence is presented to support claims that transgenic DNA was introgressed [*incorporated in the DNA*] into traditional maize landraces in Oaxaca, Mexico" and the journal *Nature* eventually agreed. In the interim, Greenpeace, an activist environmental group, used the original article to petition the Food and Agriculture Organization of the United Nations for a global ban on the production of all biotech plants.

While no conclusions can be drawn from this particular study on Mexican corn, this does not mean that biotech genes may not be detected in Mexican landraces in the future. The important question is whether new genes will provide a selective benefit to a plant that receives them, and what the consequences will be in the long term. This same argument applies to conventionally bred plants as well. Studies to date do not indicate that gene flow from biotech crops will cause any negative consequences to plant diversity, but continued research in this area is important.

One way of restricting gene flow is to not have the gene expressed in pollen. There are also several "gene restriction" technologies that will cause seeds in the next generation not to be viable, thus preventing the spread of the biotech crop. In developed countries, most growers do not save seed to replant the next year because of reduced quality, but saving seed is a common practice in developing countries. Some organizations have opposed gene restriction technologies. However, as biotech crops become more widely planted, there is new interest in technologies that restrict gene flow.

Legal Questions

Another issue is the flow of genes from biotech crops to crops that people wish to protect for marketing (e.g. organic) or personal preference. If biotech corn is grown adjacent to non-biotech corn and both fields shed pollen at the same time, there will be some gene flow between them. This leads to both difficult agronomic and legal issues.

Whose rights are being impinged? Is it the organic farmer who is required by organic standards to have no evidence of biotech crops in a product? Or is it the farmer who is not allowed to grow biotech insect-protected corn because some pollen from the crop may move out of the field? If the farmer does not grow biotech insect-protected corn, some of the replacement insecticides used may have environmental consequences to the farm and neighboring lands. Clearly these are difficult legal questions.

AGRICULTURAL BIOTECHNOLOGY

The Public's Role in the Biotechnology Dialogue

BAKER/USDA-ARS

As part of the ongoing dialogue about biotechnology and other emerging technologies, it is important for the public to stay informed and engaged. The food and agriculture system is complex and dynamic and not something most people think about. In the U.S. and Europe, most people take the availability of food for granted and may not be knowledgeable about how food gets to their plates. The food and agriculture system is difficult to analyze and understand given the many issues and interconnections involved.

Since everyone eats food and consumes agricultural products, everyone is part of the food and agriculture system. And we all have a vested interest in the health of the environment. There are roles and responsibilities for all partners in the food system, including consumers. Consumers may want to know where food comes from, how it is produced, the costs involved, and the consequences associated with each of these considerations. This brochure is intended to help that discussion.



Most crop plants would not survive without the nurturing hands of people.



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The public should become knowledgeable about biotechnology issues and participate in public forums.

The science involved in agricultural biotechnology is the culmination of hundreds of years of discoveries in a variety of fields including genetics, microbiology, optics and laser technologies, immunology, biochemistry, reproductive physiology, and many others. Perhaps the public does not need to understand the details of the technology, but it would be useful to have a broad understanding of the scientific, technological, and human dimensions of agricultural biotechnology. It is equally important to keep asking questions and discussing issues regarding biotechnology. From numerous surveys it appears that people are much more accepting of agricultural biotechnology if there are demonstrated benefits. Documenting those benefits and weighing them against risks is an ongoing process in which the public should be involved.

The common goal is to have a safe, abundant, tasty, high quality, economical, diverse, and nutritious food supply. The means by which this goal is achieved is part of an ongoing dialogue within the context of ever changing variables such as world economies, technology, food security, human health, and many others. New technologies are often surrounded by uncertainty and agricultural biotechnology is no exception.

Because of the complexity of the ethical, scientific, technological and economic questions, no one group of "experts" can resolve the issues. To find ways of integrating the benefits of agricultural biotechnology into our food systems and our society, without being overcome by any risks associated with these new technologies, requires broad-based discussion among many groups. These discussions should include broad education in the science of biotechnology, the system of food production and distribution, the political context in which regulatory decisions are made and other related topics.

Participation should include public meetings, reading media stories, writing letters to the editor, engaging in online discussions, discussing the issues in religious and social settings, and so forth. This should be followed by discussions with policy makers and using the political system to resolve conflicting issues in society.

Ultimately, the complexity of agricultural biotechnology is not about right or wrong answers, but about finding ways to deal with the complexities of the modern world.

This publication can be a starting point for ongoing informed public and scientific dialogues on agricultural biotechnology.

AGRICULTURAL BIOTECHNOLOGY

Glossary of Terms

Listed below are some definitions of biological terms used in this brochure. Many were taken from the on-line dictionary <<http://www.biology-online.org/dictionary.asp>>. For the reader who wants to understand more about biology, there are numerous books and websites, including <<http://www.biology-online.org/default.htm>>

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

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

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

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

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

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

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

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

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

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

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

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

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

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

gene flow: The exchange of genetic traits between populations by movement of individuals, gametes, or spores. It involves the spread of new variants among different populations through dispersal.

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

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

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

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

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

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

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

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

labeling of foods: The process of developing a list of ingredients contained in foods. Labels imply that the list of ingredients can be verified. The U.S. Food and Drug Administration has jurisdiction over what is stated on food labels (see "Labeling," p. 19).

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

mutation: Any inheritable change in DNA sequence.

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

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

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Glossary of Terms, cont.

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

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

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

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

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

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

prokaryote: Organisms, namely bacteria and cyanobacteria (formerly known as blue-green algae), characterized by the possession of a simple naked DNA chromosome, occasionally two such chromosomes, usually of circular structure, without a nuclear membrane and possessing a very small range of organelles, generally only a plasma membrane and ribosomes.

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

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

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

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

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

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

soil conservation practices: See minimal tillage practices.

splicing: See gene splicing.

StarLink™: An insect-resistant variety of corn that was not labelled for human consumption (see "The StarLink™ Story," p. 20).

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

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

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

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

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

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

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For Further Reference

USDA/ARS

Cornell University Web Sites

Informing the Dialogue About Agricultural Biotechnology

<http://www.nysaes.cornell.edu/agbiotech/>

Genetically Engineered Organisms- Public Issues Education

<http://www.geo-pie.cornell.edu/>

Other Sites

These references are provided only as a guide. They include scientific organizations, public interest groups, government agencies, or informed news sources.

American Phytopathological Society
APS Statement of Biotechnology and its Application to Plant Pathology

<http://www.apsnet.org/media/ps/APS%20Biotech%20Statement.pdf>

American Society of Agronomy

<http://www.agronomy.org/>

American Society for Horticultural Sciences

<http://www.ashs.org/>

American Society for Microbiology

<http://www.asmusa.org>

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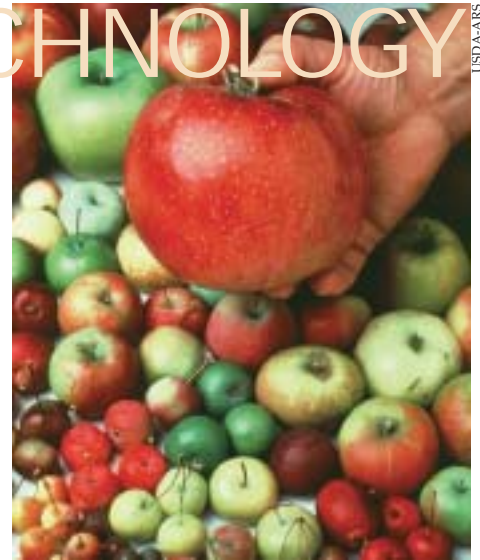
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Food production systems are complex whether they be conventional, organic, or involve biotechnology. They entail questions of technology and society, and fundamental values for each of us. It is important that we understand what the issues are and become engaged in the dialogue.

AGRICULTURAL BIOTECHNOLOGY

Ongoing Dialogue

The public will make decisions about the role of biotechnology-derived products in agriculture. We all should become more knowledgeable about the issues and let our voices be heard. Educational institutions can help shed some light on the dialogue by identifying the issues and presenting information to the public about what we do and do not know about these issues.

We hope the information contained in this publication will help you become engaged in the dialogue because, ultimately, the final decision on biotechnology-derived products rests with the public.

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