# Lesson 1:
## Challenges to Biotechnology

Some people view biotechnology as an answer to problems like world hunger, but others see it as a source of social, economic, environmental, and ethical concerns. Critics of modern biotechnology express a fear that biotechnology may be advancing too rapidly, without adequate safeguards. This lesson will examine several issues surrounding modern biotechnology.

### The Issues

Although many issues have emerged from recent scientific research in biotechnology, most of them can be categorized into one of five groups. The first group deals with the safety of consuming genetically engineered foods. Are there any negative effects from eating these foods? Is it possible that modified foods will trigger allergies? What are the long-term effects of a diet containing genetically modified foods? The second set of issues concerns consumer choice and the labeling of genetically modified foods. Should genetically engineered food products be labeled so that consumers who prefer not to eat them will know which ones to avoid? What are the problems associated with mandated labeling of foods? The third group of issues involves the safety of releasing genetically modified organisms into the environment. What are the consequences of allowing modified plants or animals to mix with closely related organisms? Is the release of these organisms reversible? The fourth group of issues involves questions about whether using biotechnology on animals to produce more meat, milk, or other products or to yield human health products jeopardizes the welfare of the animals. The fifth set of issues includes moral questions about whether genetic engineering of plants and animals is ethical.

### Food Safety

The Food and Drug Administration (FDA) is the federal government agency in charge of making sure that the food supply is safe. The FDA states that genetically engineered foods are as safe as or safer than foods already on store shelves. The basis of their claim is that genetically modified foods must meet the same standards as other foods. Most of the research done on the safety of genetically engineered foods confirms that they are as safe as nonengineered foods. Many scientific studies show that modified crops do not differ in chemical composition from foods that have not been modified. The government, most researchers, and many consumers accept genetically modified crops as safe.

Questions persist about the safety of modified foods for humans, however. Some consumers, including some restaurants and chefs, have stated that they will not use any food that has been genetically engineered. They claim that the government has done very little to ensure the safety of these foods. Some scientists caution that since no long-term studies have been done on the effects of genetically modified foods on human health, no hard evidence exists on which to base statements about their safety over a long period. Some people who are concerned about food safety are calling for long-term testing to determine the effects of genetically engineered foods on humans.

Other consumers have more specific concerns about food safety. They fear that genes that cause allergic reactions may be introduced into a food that was previously safe to consume. They are also concerned that antibiotic-resistant genes (which are used during the process of genetic engineering) in modified food products may reduce the effectiveness of antibiotics used by people who consume the products.

### Labeling of Genetically Modified Foods

Some people argue that genetically engineered foods should be labeled because the public has the right to know if a food has been modified. Individuals can then make an informed decision about whether to buy the product. Some people view genetic modifications as unacceptable for religious reasons. Vegetarians may

want to avoid modified foods because they may contain genes taken from animals. Other people may simply wish to avoid eating genetically engineered foods.
The FDA has stated that since genetically engineered foods are no different from other foods, no need exists for labeling foods as modified. The FDA has two exceptions to this policy. The first is that if a gene that has the potential to cause an allergic reaction is placed in a food, the label must identify the allergen. The second exception is that if a significant change is made in the food's composition, a label must identify this change. A significant change in composition includes any change in a food's nutrient or chemical content. The FDA states that it does not have the power to mandate that companies label foods to explain how they were developed.

**Releasing Genetically Modified Organisms**

Now that companies are marketing genetically modified crop seed such as insect-resistant cotton seed, the risk of releasing genetically modified organisms into the environment is again under debate. The governments of some countries, including the United States, Japan, and Australia, have stated that if nations follow voluntary precautionary policies, the environment is not at risk from modified plants and animals. The United States Department of Agriculture (USDA) had approved more than 25 genetically modified plants for commercial use by the end of 1996. Other governments, such as those in the Philippines and many European nations, have refused to allow genetically modified crops to be imported or grown in their countries. They fear the release of genetically modified plants and animals into the environment. Unless these countries can work out their differences, international trade may be affected.

Some scientists say that releasing genetically modified organisms into the environment is dangerous because they may introduce altered genes into native populations, giving them undesired traits. For some plants, the risk of modified genes entering a wild population is nearly nonexistent; for example, no plants with which cotton can cross pollinate grow in the wild. However, the yellow crooked-neck squash, which has been modified to resist disease, can cross pollinate with a closely related weed, the Texas gourd. The modified plant is now nearing the marketing phase. The squash could possibly pass on the DNA that allows it to resist disease to this noxious weed. Weeds that do obtain the advantage of genetically modified traits could potentially choke out other plants.

Another concern some environmentalists have about releasing genetically modified organisms into the environment is their effect on biodiversity, or diversity in the numbers of different species of plants and animals. They fear that unmodified organisms will not be able to compete, which will eventually reduce the biodiversity that exists in nature. If this happens, not only would species become extinct, but a potential source of products useful to human beings could be lost. Important sources of genetic information would also disappear with the plants and animals that become extinct.

**Animal Welfare Issues**

As advances in animal biotechnology continue, questions will be raised about whether the genetic engineering of animals is ethical from the standpoint of animal welfare. Some people question whether it is morally right to genetically engineer an animal to alter its natural ability to produce. One concern is that increasing an animal's production capacity may cause poorer animal health. When the FDA approved bovine somatotropin (BST) in 1994, controversy arose over whether the 10 to 20 percent increase in milk production was desirable, since a higher rate of mastitis and a change in the composition of milk might also occur. Studies of BST done in the United States have shown few effects on animal health. However, European countries, under the pressure of animal rights groups, still do not allow the use of BST.

Some people argue that genetically engineering livestock to produce pharmaceuticals and other health products for humans is inhumane. Some animals have already been genetically engineered to produce a desired pharmaceutical in their milk. Pigs that have been modified to produce human blood plasma must be killed to harvest the product. Opponents believe that such uses of animals are unethical.

**The Morality of Genetic Engineering**

Some groups have raised the basic question of the morality of genetic engineering as a whole. People who hold this viewpoint commonly express one of two main moral objections. The first is that humans are "playing God" by manipulating the basic elements of life. Doing so oversteps the bounds of what is appropriate for humans. Counter arguments generally state that human beings should use all the knowledge available to them to improve the human condition. The second moral objection is that genetic manipulation will permanently alter the balance of nature. This view states that human beings should not interfere with natural processes but should learn to live in harmony with their environment. The opposing argument is that humans have manipulated nature in many ways throughout history, and biotechnology is just another way to do so.

**Summary**

Many social and moral issues are associated with biotechnology. These issues include the safety and labeling of genetically modified foods, the safety of releasing genetically modified organisms into the environment, animal welfare issues, and the morality of genetic engineering itself. These issues are being debated in public forums. Coming up with acceptable answers for these tough questions will take time, but many people consider the debate to be healthy and important in shedding light on these issues.

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# Lesson 2:
## Agencies Involved in Biotechnology

In addition to raising new ethical concerns, advances in biotechnology are posing new regulatory questions. Various government agencies are involved in overseeing biotechnology. In 1986, a "Coordinated Framework" was developed to specify which agency has the authority to regulate specific biotechnology research programs or products. The role of each of the federal agencies involved in regulating biotechnology will be briefly described and explained in this lesson.

**The Environmental Protection Agency (EPA)**

The Environmental Protection Agency (EPA) has the broad responsibility of regulating all chemical substances being used as pesticides. The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA), which were enacted by Congress before genetic engineering was discovered, gave the EPA this responsibility. The federal government and the EPA have concluded that any pesticidal quality of a plant is a form of a pesticide and as such is regulated by the EPA. The EPA is therefore involved in overseeing the development and testing of plants genetically modified to protect themselves against pests. In 1995, the EPA approved more genetically engineered pesticide products than traditional chemical pesticides.

The EPA must review and approve applications for plants that are modified to resist pests before they can be field tested. The agency must issue an experimental use permit before approving a field test for a genetically modified plant. The application for the permit requires the submitting party to document the genetic makeup of the organisms from which the new organism was developed, as well as the genetic identity of the new organism itself. This information is often provided through the use of DNA fingerprinting. In addition, the applicant must submit a detailed plan for monitoring and conducting the proposed field test. Results from laboratory tests must be included in the application as well.

Not only must the genetically modified plants be approved, but the EPA must also approve the use of pesticides on the new plant. For example, the EPA would need to approve the chemical Roundup™ made by Monsanto for use with Roundup-tolerant soybeans. EPA approval allows the company to label the product for use on these soybeans.

Because the government has defined all genetically modified microorganisms as "new chemical substances," these organisms are also under the authority of the EPA. Modified organisms include fungi, bacteria, viruses, and protozoa. The EPA must review and approve each of these new "chemical products" before they can be manufactured for commercial use. To help ensure environmental safety, the approval process is complex, because microorganisms are impossible to control once they have been released.

**The United States Department of Agriculture (USDA)**

The U.S. Department of Agriculture (USDA) is involved in agricultural biotechnology in several capacities. The USDA promotes advances in biotechnology by funding a great deal of research in biotechnology. The USDA is also responsible for regulating agricultural research and products.

The Animal and Plant Health Inspection Service (APHIS) is an agency of the USDA that is primarily responsible for managing and enforcing all biotechnology-related regulations from the USDA. APHIS has two major functions in regulating biotechnology. They require that prior approval be given in the form of a permit for the field testing, shipping, and delivery of any seed or plant modified through biotechnology. This requirement was suspended in 1993 for six crops that have a history of safe genetic modification. These crops include genetically modified corn, soybeans, cotton, potatoes, tobacco, and tomatoes. APHIS only requires notification 30 days prior to field testing for these crops. The second major function of APHIS is reviewing how research was conducted and its results. This review outlines possible concerns posed by the

release of the new crop or product for the researcher requesting the field test. These concerns must be addressed before the field test can take place.

**The Food and Drug Administration (FDA)**

The Food and Drug Administration (FDA) is the federal agency responsible for ensuring the safety of the nation's food supply. The FDA published a policy statement in May of 1992 that has become the basis of its regulatory policy concerning plant biotechnology. This policy states that the FDA will regulate genetically modified food products or food additives in the same way as food products or food additives produced by other methods. Only the characteristics of the food, not the method of development, are important to the FDA.

The FDA generally allows foods to be introduced to the commercial market with the stipulation that the party introducing the food notify the administration of its planned introduction. The FDA has the power to remove a food from the market at any time if it determines that a "reasonable possibility" exists that the food is unsafe for public consumption. Many new foods, including genetically modified foods, are therefore not required to have prior approval but could be withheld from the market if the FDA suspects that they are unsafe. The responsibility of proving that a new food is safe rests fully on the manufacturer of that food.

Some genetically modified foods, however, must receive approval from the FDA before they are marketed. According to the 1992 policy statement, if a new food contains a substance known to cause allergic reactions, or if introducing or removing a substance causes the product's nutritional value to change, then prior approval is necessary. A food that contains genetic material from a source not currently in the food supply must also be approved prior to marketing. In most cases, this approval requires that the food product be labeled to indicate that a known allergen is present, that the nutritional value of the food has changed, or that a toxin is present in the food.

The FDA also regulates all drugs and drug delivery systems sold in the United States. Genetically engineered animal vaccines must therefore receive FDA approval. The average length of time needed to obtain FDA approval for a new drug is nine years.

**The Occupational Safety and Health Administration (OSHA)**

The mission of the Occupational Safety and Health Administration (OSHA) is "to save lives, prevent injuries, and protect the health of American workers." OSHA is a division of the United States Department of Labor that was created by the Occupational Safety and Health Act of 1970. Nearly 100 million workers and their 6.5 million employers are under the supervision of OSHA. OSHA is involved in agricultural biotechnology primarily to ensure that workers in biotechnology work in a safe environment. Lighting, ventilation, possible exposure to dangerous chemicals or microorganisms, and the presence of safety equipment are all things that OSHA looks at when inspecting a facility.

**The National Institutes of Health (NIH)**

The National Institutes of Health (NIH) is a federally funded agency with a mission "to uncover new knowledge that will lead to better health for everyone." NIH is involved in biotechnology in many ways. For example, NIH conducts research in biotechnology in its own laboratories and financially supports the research of nonfederal scientists in various public and private institutions within and outside of the United States. It also regulates the research that it funds. NIH aids in the training of research scientists by funding graduate student research efforts. It helps foster biomedical communication by linking scientists through newsletters, conferences, and professional publications.

In July of 1994, NIH published a newly revised set of guidelines for research involving genetic modifications. This set of guidelines is very technical and comprehensive. They range from facility requirements for safe containment of microorganisms to explanations of which specific activities require prior NIH approval. NIH does not regulate any field trials of genetically modified organisms but refers researchers to the USDA and

other federal agencies. The agency has no control over research that it does not fund. However, many researchers in both public and private institutions voluntarily follow NIH guidelines.

**The Nuclear Regulatory Commission (NRC)**

The Nuclear Regulatory Commission (NRC) is an independent agency established by Congress under the Energy Reorganizational Act of 1974. Although the primary function of the NRC is the regulation of nuclear reactors and nuclear facilities, it also regulates the possession, use, processing, handling, and export of all radioactive material. Most academic and industrial biotechnology research laboratories use very small amounts of radioactive materials to conduct certain experiments. They must work with the NRC to obtain, use, and dispose of radioactive substances. The NRC must issue a special permit for anyone transporting, handling, storing, or disposing of radioactive materials.

**Regulating International Trade**

All of the above agencies regulate biotechnology in some manner in the United States. However, biotechnology is an international industry and as such must abide by each country's regulatory systems. A movement exists to establish a legally binding international protocol that would set standards by which individual countries could evaluate the possible risks involved with the use of genetically modified organisms. International cooperation in regulating biotechnology is important since food products are frequently imported and exported. International committees are meeting to try to establish voluntary guidelines for the movement of genetically modified organisms between nations.

**Summary**

Several federal agencies oversee the biotechnology industry in the United States. The EPA, USDA, and FDA all have important roles in monitoring biotechnology. These federal agencies work together to ensure that new biotechnology products are safe to use. Other agencies and associations, like OSHA, NIH, and the NRC, play a smaller but vital role. International treaties and agreements could also affect certain aspects of biotechnology. The way biotechnology is regulated may need to change as the science of biotechnology changes.

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# Lesson 3:
## Biotechnology Patents

The biotechnology industry would not be as advanced as it is today if it were not for the ability to patent biotechnology products. While the decision to allow patents for genetically modified plants and animals is controversial, it has stimulated research in genetic engineering in the private sector. Patent applications are made as soon as a discovery or development that promises to have a useful application is verified. The research is kept secret until the patent is granted. This lesson will examine patents for products of biotechnology and the issues surrounding the patent process.

**U.S. Patents**

In the United States, patents are issued by the U.S. Patent and Trademark Office (USPTO). A patent issued by the USPTO grants the holder property rights that exclude others from making, using, or selling the patented invention throughout the United States for a stated period. Normally, this period is 17 years. In exchange for this exclusive right, the public receives the details of the "invention." The purpose of this disclosure is to allow others the ability to develop and market the product after the patent expires. It also stimulates further research by competitors to develop new inventions that are related to, but not covered by, the patent.

The USPTO grants three types of patents. The most common type of patent is the utility patent. The utility patent is granted for inventions that are "new and useful" and that meet certain statutory requirements. The second type of patent is the plant patent. The Plant Patent Act of 1930 permits patent protection for particular types of plants. This patent is issued to anyone who invents or discovers and asexually reproduces any new variety of plant. The new plant variety may consist of cultivated spores, mutants, hybrids, and newly found seedlings. The applicant must be able to prove that the plant is different from other plants to receive the patent. The third type of patent is the design patent, which is issued for a new, original, and ornamental design for a manufactured article. Biotechnology products are not eligible to receive a design patent.

**Patent Requirements**

Many biotechnology products have obtained U.S. patents. For example, the first animal patent was issued in 1988 for a transgenic mouse developed from a fertilized mouse egg cell that had been genetically modified, establishing that modified animals can be patented in the United States under the current patent laws. Other biotechnology products that have been patented include genetically altered microorganisms, seeds, tissue cultures, and altered or nonnatural forms of a molecule, such as a modified protein molecule.

Since most biotechnology products receive a utility patent, an understanding of the requirements of this patent is important. A utility patent has three basic statutory requirements. The first is that the invention must be a new and useful process, machine, manufactured item, or composition of matter. Most biotechnology products fall into the "composition of matter" category since they are essentially rearrangements of DNA. The second statutory requirement is that the invention must be novel and nonobvious. An invention is obvious if it can be readily deduced from information available to the public by a person knowledgeable in the relevant technological field. The final statutory requirement is that the invention must be fully described and clearly claimed in the patent application.

Products must meet the definition of a patentable invention. Laws of nature, physical phenomena, and abstract ideas are not patentable; no one can patent gravity or centrifugal force, for example. For a patent to be granted, other qualifications must be met. A patent cannot remove anything from the public domain. This requirement means that something already commonly used cannot be patented. Not only must the patent not remove anything from the public domain, but it must add adequate information about the invention to the public domain. This information is disclosed as a part of the patent application.

**Issues Surrounding the Patenting of Biotechnology Products**

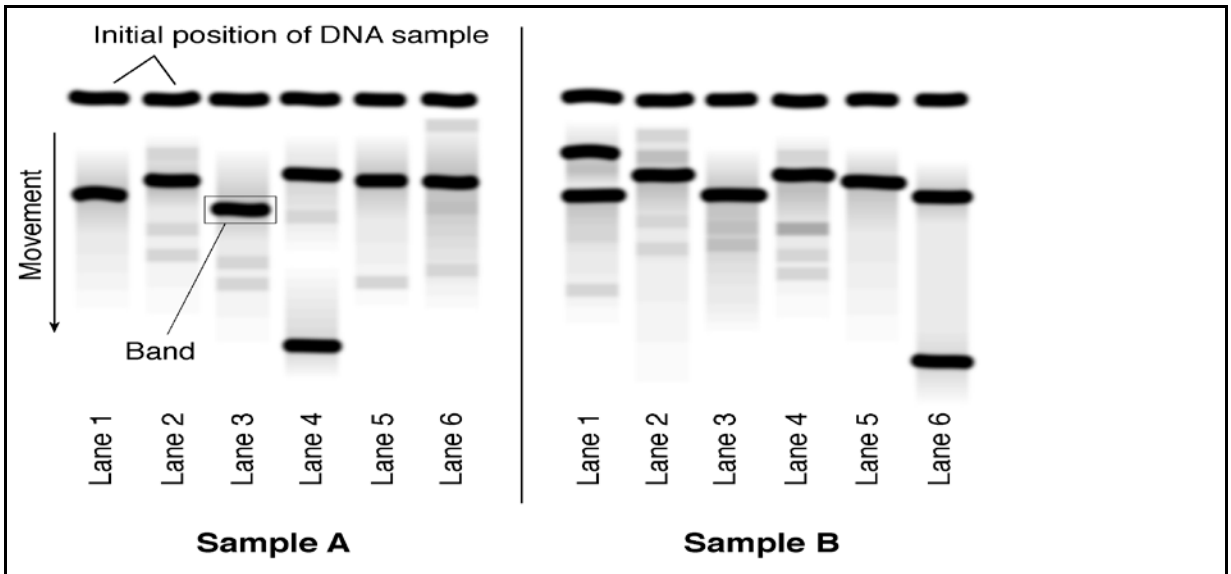
One of the issues surrounding biotechnology patents is the question of ownership of the genetically modified organism. Should genetically modified plants and animals be deemed the property of the individual or corporation responsible for modifying them? The answer to this question is controversial. Some people view genetic material as being owned by everyone and therefore nonpatentable. Those people who believe in the universal ownership of genetic material contend that genetic modifications are not patentable as inventions. However, others disagree, pointing out that genetic modifications constitute a rearrangement of matter. So far the USPTO and the U.S. Supreme Court have confirmed the patentability of genetically modified organisms. Much debate still exists on how broad the patents may be.

Other controversies surround the patenting of the genetic material of plants and animals native to countries other than the United States. Does a country own the DNA of native plants and animals? Should the United States grant patents on plants that have been used for centuries in Third World countries? A patent of this type was granted to a U.S. corporation for the genes producing the insecticidal properties of the seeds of neem trees. Farmers in India have used neem tree seeds as an insecticide for centuries. Even though the patent only covers the use of the insecticidal properties of neem seed in the United States, India would have to honor the patent due to international trade treaties. This patent has sparked an international lawsuit and much international debate.

**DNA Fingerprinting**

DNA fingerprinting is a complicated process involving several steps. The first step is to isolate DNA from an organism. The DNA is cut into many specifically sized pieces using an enzyme in a process called restriction digestion. After a probe dye is added to the DNA, it is sorted by the length of the pieces through a procedure known as gel electrophoresis, in which the pieces are placed in a gel and move through it along paths called lanes when an electric current is applied. Some of the pieces are "tagged" by the dye, which is a marker that attaches to a specific location on the DNA. The result is a pattern that looks like a set of bands (Figure 3.1) that identify the organism from which the DNA was extracted.make a copy of the plant or animal. The owners are therefore vulnerable to the theft of the genetic material by those handling it. For example, ranchers who want to maximize the productivity of a certain animal may choose to use embryo transfer. If a dishonest veterinarian or technician **Problems with Handling Genetic Material**

A major problem associated with the ownership of any genetic material through a patent is that in theory only a



small amount of tissue, blood, or even hair is needed from a plant or animal to make a copy of the plant of animal. The owners are therefore vulnerable to the theft of the genetic material by those handling it. For example, ranchers who want to maximize the productivity of a certain animal may choose to use embryo transfer. If a dishonest veterinarian or technician is hired to perform the procedure, he or she could keep and sell some of the embryos collected.

Other problems associated with handling genetic material are the consequences of flawed test results and the ability to preserve the privacy of genetic information. Flawed results in genetic testing caused by mislabeled samples or experimental error could lead to disastrous decisions about ownership. Breed registrations may be denied or insurance policies made invalid due to flawed DNA fingerprinting results. The privacy of genetic information is also an issue. Controlling access to the genetic information of people, and to a lesser extent animals and plants, is a challenge facing the biotechnology industry.

**Summary**

Products of genetic modification can be patented in the United States if they meet certain requirements. Issues surrounding the patenting of biotechnology products will probably to be debated for many years. However, genetically modified plants, animals, and microorganisms will likely continue to be patented.

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