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.

Credits

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