

UNIT II - ISSUES IN BIOTECHNOLOGY

Lesson 2: Agencies Involved in Biotechnology

Competency/Objective: Identify government agencies involved in biotechnology.

Study Questions

1. **What is the role of the Environmental Protection Agency (EPA) in biotechnology?**
2. **What is the role of the United States Department of Agriculture (USDA) in biotechnology?**
3. **What is the role of the Food and Drug Administration (FDA) in biotechnology?**
4. **What is the role of the Occupational Health and Safety Administration (OSHA) in biotechnology?**
5. **What is the role of the National Institutes of Health (NIH) in biotechnology?**
6. **What is the role of the Nuclear Regulatory Commission (NRC) in biotechnology?**
7. **How is the international trade of biotechnology products regulated?**

References

1. *Biotechnology: Applications in Agriculture (Student Reference)*. University of Missouri-Columbia: Instructional Materials Laboratory, 1998, Unit II.
2. Activity Sheet
 - a) AS 2.1: Solving the Regulatory Puzzle

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TEACHING PROCEDURES

A. Review

The first lesson of this unit discussed several issues concerning biotechnology. These issues may be addressed by federal agencies. Federal agencies have been given the responsibility of overseeing areas such as food and environmental safety. This lesson reviews the roles that each of these agencies plays in monitoring biotechnology.

B. Motivation

1. Ask students "Have any of you ever been concerned about buying or eating food that was unsafe?" Remind the students of instances when meat was contaminated with the *E. coli* bacteria. How does one know that America's food supply is safe? The federal government has answered this question by giving the responsibility of safeguarding America's food supply to a federal agency known as the Food and Drug Administration (FDA).
2. Write the following acronyms on the chalkboard and have students identify the agency: FDA, EPA, USDA, OSHA, NIH, and NRC. Ask students to describe the role of each agency in biotechnology.

C. Assignment

D. Supervised Study

E. Discussion

1. Ask students for examples of areas that the EPA regulates. Explain the EPA's role in overseeing biotechnology.

What is the role of the Environmental Protection Agency (EPA) in biotechnology?

- a) The EPA regulates any pesticidal quality that might be present in plants that have been genetically engineered.
 - 1) The EPA must issue an experimental use permit before approving a field test for a modified plant.
 - 2) The applicant for the permit must submit a detailed plan of the proposed field test.
 - b) The EPA regulates the use of pesticides on genetically modified plants.
 - c) All genetically modified microorganisms are regulated by the EPA.
2. Discuss examples of the areas of biotechnology that the USDA oversees.

What is the role of the United States Department of Agriculture (USDA) in biotechnology?

- a) Funds research in biotechnology
- b) Regulates agricultural research and products through its Animal and Plant Health Inspection Service (APHIS)
 - 1) APHIS requires permits for the field testing, shipping, and delivery of any seed or plant modified through biotechnology. In 1993 an exception to the prior approval requirement was made for six crops (corn, soybeans, cotton, potatoes, tobacco,

- and tomatoes) that have a history of safe genetic modification. Only notification 30 days prior to field testing modified crops is required.
- 2) APHIS reviews how research was conducted and its results and outlines possible concerns posed by the release of the new crop or product.
3. Discuss with students the important role that the FDA plays in regulating biotechnology.

What is the role of the Food and Drug Administration (FDA) in biotechnology?

- a) The FDA, which is responsible for ensuring the safety of the nation's food supply, issued a statement in 1992 that is the basis of its policy concerning plant biotechnology.
 - 1) Genetically modified food products or food additives will be regulated in the same way as food products or additives produced by other means; only the characteristics of the food are important.
 - 2) The FDA allows foods to be introduced to the commercial market with notification of its planned introduction.
 - 3) The FDA has the power to remove a food from the market if it suspects the food is unsafe.
 - 4) Approval prior to marketing is required for some genetically modified foods; they may have to be labeled as well.
 - (a) Foods containing a substance known to cause allergic reactions
 - (b) Foods in which the nutritional value has changed
 - (c) Foods that contain genetic material from a source not currently in the food supply
 - b) The FDA also regulates all drugs and drug delivery systems, including genetically engineered animal vaccines.
4. Ask students to describe what they know about OSHA. Explain that most companies are required to follow OSHA safety regulations.

What is the role of the Occupational Safety and Health Administration (OSHA) in biotechnology?

OSHA's mission is "to save lives, prevent injuries, and protect the health of American workers." OSHA's involvement in agricultural biotechnology is primarily to ensure that workers in biotechnology work in a safe environment.

5. Ask students to describe the NIH and to explain its role in biotechnology.

What is the role of the National Institutes of Health (NIH) in biotechnology?

- a) NIH is a federally funded agency whose mission is "to uncover new knowledge that will lead to better health for everyone;" it is involved in biotechnology in many ways.
 - 1) Conducts research in biotechnology in its own laboratories
 - 2) Supports the research of nonfederal scientists in various public and private institutions within and outside of the United States
 - 3) Helps in training of research scientists by funding graduate student research efforts
 - 4) Fosters biomedical communication
 - b) NIH regulates the research that it funds through a set of guidelines, but has no control over other research.
 - c) Many researchers in both public and private institutions voluntarily follow NIH guidelines.
6. Ask students if they know when the NRC was established (1974). Note that the primary role of the NRC is regulating nuclear reactors. Discuss the NRC's role in overseeing biotechnology.

What is the role of the Nuclear Regulatory Commission (NRC) in biotechnology?

- a) Regulates the use of radioactive materials by academic and industrial biotechnology research laboratories
 - b) Requires a special permit for the transport, handling, storage, and disposal of radioactive materials
7. Ask students if they know of any other agencies that might be involved in overseeing biotechnology. Discuss the international trade of products of biotechnology and how it is regulated. Have students complete AS 2.1.

How is the international trade of biotechnology products regulated?

International committees are meeting to try to establish voluntary guidelines for the movement of genetically modified organisms between nations.

F. Other Activities

- 1. Have a guest speaker (e.g., county health or local environmental employee) discuss biotechnology.
- 2. Have students do research and write a report on different regulatory agencies.

G. Conclusion

Many federal agencies are involved in overseeing biotechnology. Some companies have complained that they are required to complete unnecessary steps to comply with the inflexible rules of these agencies. Some consumer groups complain that the agencies responsible for monitoring biotechnology are not trained in biotechnology and know little about it. Still other people feel that these agencies are doing an adequate job in regulating biotechnology. However, nearly everyone agrees that some regulation is needed.

H. Answers to the Activity Sheet

- 1. Approval/permits: EPA - to obtain an experimental use permit due to pesticidal properties
FDA - due to the change in the composition of the potato
Notifications: USDA - notification required prior to field testing
- 2. Approval/permits: EPA - to obtain an experimental use permit due to pesticidal properties
USDA - to obtain a field test permit
Notifications: FDA - notification required for the planned introduction of a new food product

I. Answers to Evaluation

- 1. b
- 2. c
- 3. b
- 4. c
- 5. a
- 6. d
- 7. d
- 8. The NRC regulates the use of radioactive materials by academic and industrial biotechnology research laboratories. It requires a special permit for the transport, handling, storage, and disposal of radioactive materials.

9. The FDA evaluates genetically modified food products or food additives in the same way as food products or additives produced by other means. Only the characteristics of a food are important.
10. International committees are meeting to try to establish voluntary guidelines for the movement of genetically modified organisms between nations.

EVALUATION

Circle the letter that corresponds to the best answer.

1. The Animal and Plant Health Inspection Service (APHIS) is a part of the:
 - a. Environmental Protection Agency (EPA)
 - b. United States Department of Agriculture (USDA)
 - c. Food and Drug Administration (FDA)
 - d. National Institutes of Health (NIH)

2. The federal agency that regulates the labeling of a food is the:
 - a. Environmental Protection Agency (EPA)
 - b. United States Department of Agriculture (USDA)
 - c. Food and Drug Administration (FDA)
 - d. National Institutes of Health (NIH)

3. What agency regulates the environment in which employees work in agricultural biotechnology?
 - a. Environmental Protection Agency (EPA)
 - b. Occupational Safety and Health Administration (OSHA)
 - c. Food and Drug Administration (FDA)
 - d. National Institutes of Health (NIH)

4. The National Institutes of Health (NIH) performs which of the following roles in overseeing biotechnology?
 - a. NIH plays a major role in regulating the health and safety aspects in all biotechnology laboratories.
 - b. NIH uses a set of guidelines to regulate drug research in all public research institutions.
 - c. NIH can only regulate research that it funds, but its guidelines influence the actions of many other researchers.
 - d. NIH is not involved in regulating biotechnology research.

5. From which agency must a researcher obtain an experimental use permit?
 - a. Environmental Protection Agency (EPA)
 - b. Food and Drug Administration (FDA)
 - c. Occupational Safety and Health Association (OSHA)
 - d. National Institutes of Health (NIH)

6. A new corn plant genetically modified to resist the European corn borer would need approval from which of the following agencies?
 - a. Nuclear Regulatory Commission (NRC)
 - b. National Institutes of Health (NIH)
 - c. Occupational Safety and Health Administration (OSHA)
 - d. Environmental Protection Agency (EPA)

7. A genetically modified bacterium that helps wheat use nitrogen from the air would need approval from which two agencies?
- a. FDA and EPA
 - b. USDA and NRC
 - c. NIH and OSHA
 - d. EPA and USDA

Complete the following short answer questions.

8. What is the role of the Nuclear Regulatory Commission (NRC) in regulating biotechnology?
9. How does the FDA regulate genetically modified foods or food additives?
10. How are nations attempting to regulate the international trade of organisms created using biotechnology?

Lesson 2: Agencies Involved in Biotechnology

Name _____

Solving the Regulatory Puzzle**Objective:** Identify the agencies involved in overseeing biotechnology.

Read the following paragraphs that describe genetically modified agricultural products that are or could be developed. List the agencies that must be notified about the product and those from which approval or a permit must be secured. Explain why each agency must be contacted.

1. Monsanto has developed a potato called the NewLeaf® potato that can protect itself from the Colorado potato beetle. This insect can destroy a field of potatoes in two or three days by stripping the plants of their leaves. If this potato was further modified to produce potatoes with a higher solids content that absorbs less oil when cooked, what are the regulatory requirements that Monsanto would have to meet?

- a) Approval/permits needed:

- b) Notifications needed:

2. *Bacillus thuringiensis (Bt)* is a naturally occurring bacterium found in the soil that is noted for its ability to control pests. Gardeners have been using *Bt* as a biological insecticide spray for nearly 100 years. Many crops are being developed that will contain *Bt* genes. If a carrot was developed containing this gene, what regulatory requirements would its developer need to meet?

- a) Approval/permits needed:

- b) Notifications needed:

