

UNIT II - ISSUES IN BIOTECHNOLOGY

Lesson 1: Challenges to Biotechnology

Competency/Objective: Explain the major issues associated with agricultural biotechnology.

Study Questions

1. **What are the major issues associated with the use of biotechnology in agriculture?**
2. **What are the food safety issues associated with genetically modified foods?**
3. **What are the labeling issues associated with genetically modified foods?**
4. **What are the issues related to releasing genetically altered plants and animals into the environment?**
5. **What are the animal welfare issues raised by agricultural biotechnology?**
6. **What are other moral issues concerning agricultural biotechnology?**

References

1. *Biotechnology: Applications in Agriculture (Student Reference)*. University of Missouri-Columbia: Instructional Materials Laboratory, 1998, Unit II.
2. Transparency Masters
 - a) TM 1.1: Results of the Community Survey
 - b) TM 1.2: Summary of Data
3. Activity Sheets
 - a) AS 1.1: Community Survey (Instructor)
 - b) AS 1.1: Community Survey (Student)

UNIT II - ISSUES IN BIOTECHNOLOGY

Lesson 1: Challenges to Biotechnology

TEACHING PROCEDURES

A. Introduction

New technology has always sparked controversy, and biotechnology is no exception. Many ethical issues are emerging as genetic manipulation is used more frequently. This lesson will outline some current issues in biotechnology.

B. Motivation

Bring in two glasses of milk, types of cheese, carrots, tomatoes, or other vegetables. Ask students to taste them to see if they can tell a difference. Tell the students that one sample could be a product of biotechnology. Ask students if they think that both of the samples are safe. How would they know if a food was genetically modified? Would they even care?

C. Assignment

D. Supervised Study

E. Discussions

1. Ask students for examples of issues in biotechnology that they have seen in the news.

What are the major issues associated with the use of biotechnology in agriculture?

- a) Safety of genetically modified food
 - b) Labeling of genetically modified foods
 - c) Safety of releasing genetically modified organisms into the environment
 - d) Animal welfare issues
 - e) Morality of genetic engineering
2. Ask students how they felt when told that the one of the samples of milk, cheese, or vegetables might be a product of biotechnology. Discuss the difference between perception of safety and actual safety.

What are the food safety issues associated with genetically modified foods?

- a) The Food and Drug Administration (FDA) states that genetically engineered foods are as safe as or safer than other foods, since they must meet the same standards; many scientific studies show no differences in the chemical composition of modified and unmodified foods.
 - b) Some consumers, including some restaurants and chefs, have refused to use genetically altered food, because they claim the government has not done enough to ensure their safety.
 - c) Some scientists caution that since no long-term studies have been done on the effects of modified foods on human health, their long-term safety is unknown.
 - d) Other consumers fear that modified foods may have genes that cause allergic reactions or reduce the effectiveness of antibiotics (through the use of antibiotic-resistant genes during the process of genetic engineering).
3. Discuss the pros and cons of labeling food as genetically modified.

What are the labeling issues associated with genetically modified foods?

- a) Some people argue that the public has a right to know if food has been genetically engineered to be able to make an informed decision about whether to buy it.
 - 1) Some people view genetic modifications as unacceptable for religious reasons.
 - 2) Vegetarians may want to avoid modified foods because they may contain genes taken from animals.
 - b) The FDA's policy is that since genetically modified foods are no different from other foods, no need exists for labeling them as modified, with two exceptions.
 - 1) The FDA requires a label for foods with a gene that could cause an allergic reaction.
 - 2) The FDA requires a label if genetic engineering makes a significant change in a food's composition.
4. Ask students if they have seen vegetables in a garden cross-pollinate and produce different fruit. Discuss the possible problems associated with releasing genetically altered organisms.

What are the issues related to releasing genetically altered plants and animals into the environment?

- a) Releasing genetically modified organisms into the environment may introduce altered genes into native populations, giving them undesired traits.
 - b) Releasing modified organisms may reduce biodiversity, if unmodified organisms are unable to compete.
5. Ask students to discuss what treating animals humanely means.

What are the animal welfare issues raised by agricultural biotechnology?

- a) Some people question whether it is morally right to genetically engineer an animal to alter its natural ability to produce.
 - b) Some people argue that altering animals to produce pharmaceuticals and other health products for humans is inhumane.
6. Ask students about other ethical reasons that people oppose genetic engineering. Have students complete AS 1.1. Use TM 1.1 to tabulate the results of the surveys. TM 1.2 can be used to further illustrate the results.

What are other moral issues concerning agricultural biotechnology?

- a) Some people view genetic manipulation as "playing God," which oversteps the boundaries of what is appropriate for humans.
- b) Genetic manipulation may permanently alter the balance of nature.

F. Other Activities

- 1. Have a spokesperson who favors genetic engineering and one who is against it speak to the class. The Union of Concerned Scientists is a possible source of speakers opposed to biotechnology. University research programs and biotechnology companies such as Monsanto are good sources of biotechnology speakers in favor of genetic engineering. An Internet search may help locate speakers.
- 2. Have students debate the issue of labeling genetically altered foods. Divide the class into two groups, with one group favoring labeling and the other group opposing it. Have each group collect information that supports its position and then hold a formal debate in class.

3. Have students conduct an Internet search to identify additional issues connected to biotechnology.

G. Conclusion

Agricultural biotechnology promises to raise food production to a new level, but concerns held by the public may slow its acceptance. Food safety and labeling, environmental concerns, and moral issues all need to be addressed so that the public has confidence in the use of biotechnology in agriculture.

H. Answers to Activity Sheet

AS 1.1

Answers will vary.

I. Answers to Evaluation

1. d
2. c
3. Students may give either of the following answers: some people question whether it is morally appropriate to genetically engineer an animal to exceed its natural ability to produce, or some people argue that altering animals for pharmaceuticals and health products for humans is inhumane.
4. Some scientists argue that releasing genetically modified organisms into the environment is dangerous because they may introduce altered genes into native populations, giving them undesired traits. Others argue that releasing modified organisms will decrease biodiversity, because unmodified organisms will be unable to compete.
5. Answers may be either of the following: genetic engineering is “playing God,” or genetic engineering could alter the balance of nature.

EVALUATION

Circle the letter that corresponds to the best answer.

1. Which of the following is not a major issue associated with the use of biotechnology?
 - a. The safety of genetically engineered foods for human consumption
 - b. The welfare of animals on which biotechnology is used
 - c. The labeling of modified foods as products of biotechnology
 - d. The exploitation of the microorganisms used in genetic engineering
2. When does the FDA require products of biotechnology to be labeled?
 - a. Whenever foreign genetic material is introduced into a plant
 - b. Whenever a gene from an animal is introduced into a plant
 - c. Whenever a gene that could cause an allergic reaction is used
 - d. Whenever a gene that is antibiotic-resistant is used

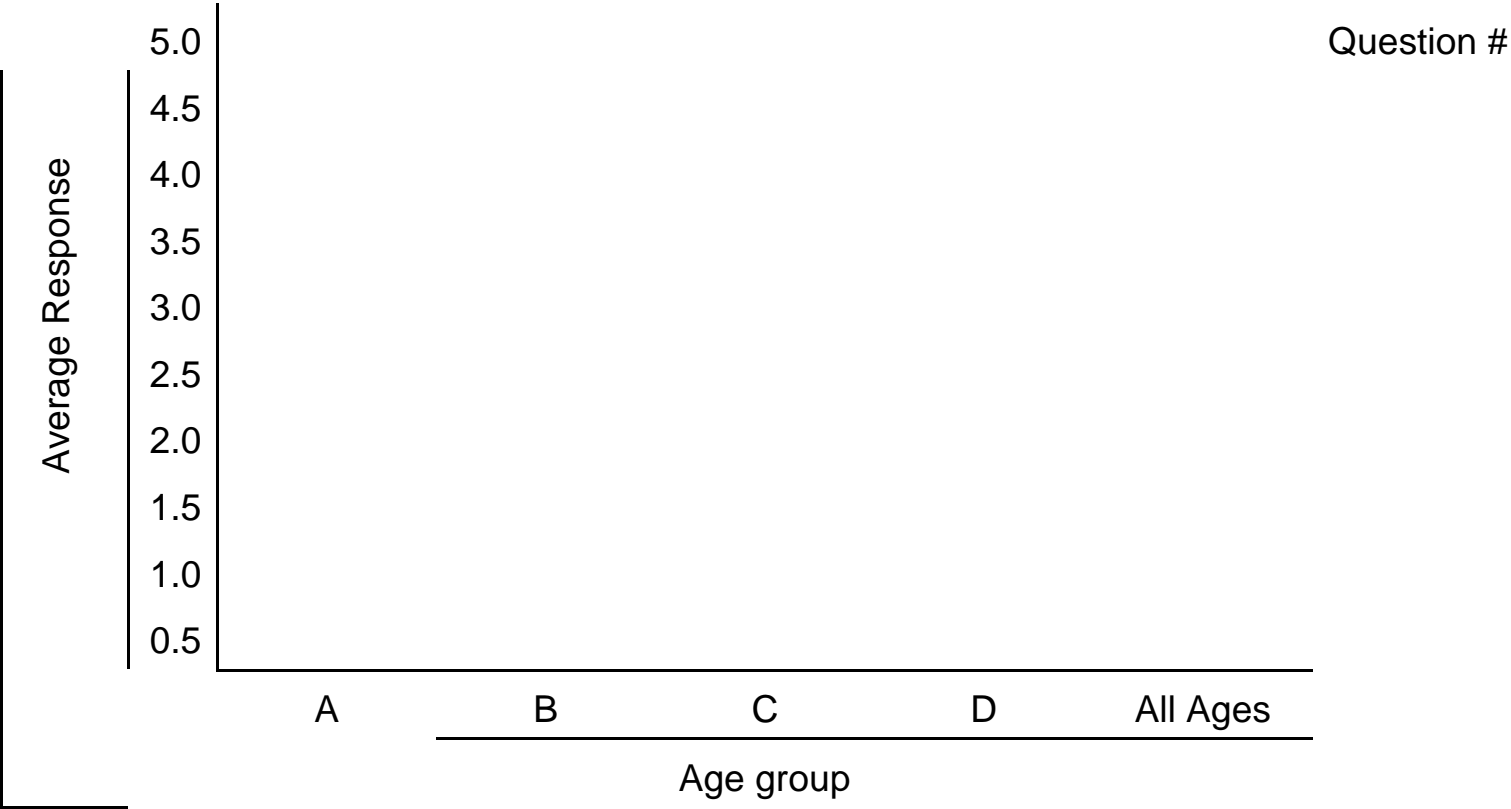
Complete the following short answer questions.

3. What is one issue raised by people who are concerned about the use of biotechnology on animals?
4. What are two reasons that some scientists question the safety of releasing genetically modified plants into the environment?
5. What is one reason that genetic manipulation may be considered morally wrong?

Question Number	Category A <20 yrs old	Category B 20 - 40 yrs old	Category C 40 - 60 yrs old	Category D over 60 yrs old	Overall Score
	Average Score	Average Score	Average Score	Average Score	
1					
2					
3					
4					
5					
6					
7					

Summary of Data

TM 1.2



Lesson 1: Challenges to Biotechnology

Community Survey

Objective: Investigate the reactions of the public to agricultural biotechnology.

1. Give each student four copies of AS 1.1, since they must interview four people.
2. When they have finished, collect the completed surveys from the students and have them assist in sorting, tabulating, and recording the survey results. TM 1.1 is provided to help tabulate the results of the survey. The results of the survey could also be given to a statistics class for further analysis or assigned to an advanced student for further analysis of the differences in responses by gender.
3. Sort the surveys by age group: <20 (Group A), 20-40 (Group B), 40-60 (Group C), and >60 (Group D).
4. Beginning with Group A, write the scores of the first question on the board. Find the average score for the question and record it on TM 1.1. Repeat this process for each age category.
5. Find the average score for each question using all of the surveys, and record the score in the "Overall Score" column of the transparency.
6. A bar graph has been included in TM 1.2 that can be used to compare the response for each question.
7. Interpret the data. An average median score of 2.5 for a statement shows that the community is neutral about it. A score greater than 2.5 shows an attitude that supports the statement. A score less than 2.5 shows an attitude that does not support the statement. Discuss the attitudes revealed by this survey. Is age a factor in the attitudes displayed by the community? What is the overall perception of biotechnology in the community? Discuss the limitations and accuracy of this survey and its results.

Note: Some statements are positive, while others are stated in a negative form. Response scores must be interpreted in the context of the original form of the statement.

Lesson 1: Challenges to Biotechnology

Name _____

Community Survey**Objective:** Investigate the reactions of the public to agricultural biotechnology.

To understand current societal attitudes toward agricultural biotechnology in your community, use the statements below to survey four people. Survey one person from each age group. Record each person's approximate age and gender and their level of agreement or disagreement with each statement.

Age Group (circle one): Under 20 20-40 40-60 Over 60

Gender: Male Female

1. Foods products from genetically modified plants are safe to eat.

1	2	3	4
Strongly disagree	Disagree	Agree	Strongly agree

2. Genetically modified crops pose no real threat to nature or the environment.

1	2	3	4
Strongly disagree	Disagree	Agree	Strongly agree

3. Genetically modified foods sold in a grocery store should carry a label that states that they are genetically modified.

1	2	3	4
Strongly disagree	Disagree	Agree	Strongly agree

4. Genetically modifying animals is inhumane.

1	2	3	4
Strongly disagree	Disagree	Agree	Strongly agree

5. Genetically modifying plants is morally wrong.

1	2	3	4
Strongly disagree	Disagree	Agree	Strongly agree

6. Genetically modifying animals is morally wrong.

1	2	3	4
Strongly disagree	Disagree	Agree	Strongly agree

7. Genetic engineering will significantly increase food production over the next ten years.

1	2	3	4
Strongly disagree	Disagree	Agree	Strongly agree

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

UNIT II - ISSUES IN BIOTECHNOLOGY

Lesson 2: Agencies Involved in Biotechnology

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?

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:

UNIT II - ISSUES IN BIOTECHNOLOGY

Lesson 3: Biotechnology Patents

Competency/Objective: Identify procedures involved in obtaining a patent for a biotechnology product.

Study Questions

1. **What is a patent?**
2. **What are the requirements for obtaining a utility patent for a product of biotechnology?**
3. **What are the issues surrounding the patenting of biotechnology products?**
4. **What is DNA fingerprinting?**
5. **What are the problems associated with the handling of genetic material?**

References

1. *Biotechnology: Applications in Agriculture (Student Reference)*. University of Missouri-Columbia: Instructional Materials Laboratory, 1998, Unit II.
2. Transparency Master
 - a) TM 3.1: Section of a DNA Fingerprint
3. Activity Sheet
 - a) AS 3.1: Patent Debate

UNIT II - ISSUES IN BIOTECHNOLOGY

Lesson 3: Biotechnology Patents

TEACHING PROCEDURES

A. Review

Lesson 2 discussed various regulatory agencies that affect the development of products using biotechnology. Before marketing or even field testing such a product, the developer usually secures a patent to protect the research investment. Patents for biotechnology products have played a major role in shaping the biotechnology industry. Companies have purchased other companies just to obtain certain patents. However, strong opposition to patenting genetically modified life forms has developed. This lesson will discuss patents and the issues surrounding patenting products of biotechnology.

B. Motivation

1. In 1996, biotechnology generated nearly \$13 billion in annual revenues in the United States. The value of biotechnology patents ranges from millions of dollars to less than the patent application fee itself. Many people refer to this search for profitable patents as a high-tech gold rush. Few prospectors will strike it rich, but many will dig for gold.
2. Using an ink pad and small Post-It™ notes, have each student make a copy of his or her fingerprint. Display them to the class to show the differences. Discuss the process of genetic fingerprinting.

C. Assignment

D. Supervised Study

E. Discussion

1. Ask students what a patent is. Discuss examples of products that have been patented (including plants and animals).

What is a patent?

- a) A patent grants property rights that exclude others from making, using, or selling the patented invention throughout the United States for a stated period of time, normally 17 years.
 - b) The U.S. Patent and Trademark Office grants three types of patents.
 - 1) Utility patent - granted for "new and useful" inventions that meet certain statutory requirements; the most common type of patent
 - 2) Plant patent - issued to anyone who invents or discovers and asexually reproduces any new variety of plant, including cultivated spores, mutants, hybrids, and newly found seedlings
 - 3) Design patent - granted for any new, original, and ornamental design for a manufactured article
2. Ask students what is required to obtain a patent. Discuss the requirements for obtaining a utility patent.

What are the requirements for obtaining a utility patent for a product of biotechnology?

- a) Statutory requirements
 - 1) 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.

- 2) 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.
- 3) The invention must be fully described and clearly claimed in a patent application.
- b) Additional qualifications
 - 1) The invention must be patentable. The laws of nature, physical phenomena, and abstract ideas are not patentable.
 - 2) A patent cannot remove anything from the public domain. This means that something already commonly used cannot be patented.
 - 3) The granting of the patent must add adequate information about the invention to the public domain.

- 3. Discuss with students whether they think it is acceptable to patent life-forms. Have students complete the debate outlined in AS 3.1.

What are the issues surrounding the patenting of biotechnology products?

- a) The question of ownership of genetically modified organisms
 - b) The patenting of the genetic material of plants and animals native to countries other than the United States
- 4. Ask students what makes fingerprints different. Just as the different line patterns make each fingerprint unique, the different locations of bands on an electrophoresis gel make each DNA fingerprint unique.

What is DNA fingerprinting?

- a) DNA fingerprinting is the process of using laboratory analysis of DNA to generate a pattern that is unique to an individual organism.
 - b) DNA fingerprinting involves several steps.
 - 1) Isolating the DNA
 - 2) Cutting, sizing, and sorting the DNA
 - 3) "Tagging" the DNA with a probe dye
- 5. Discuss some of the problems associated with handling genetic material.

What are the problems associated with the handling of genetic material?

- a) Preventing the theft of genetic material
- b) Flawed results from testing
- c) Preserving the privacy of genetic information

F. Other Activities

Have students further research the controversy surrounding patents on biotechnology by focusing on the issue of whether the government should have the right to grant itself patents. Have the students research cases in which the U.S. government issued a patent to itself for a product of biotechnology. Encourage students to use the Internet in their research.

G. Conclusion

Patents play an important role in the biotechnology industry. Biotechnology companies view patents as vital because they protect their research investments. However, patents on genetic material and products of biotechnology have sparked new debate as to exactly what should be eligible for a patent. Ultimately, U.S. courts will have to decide the answer to this difficult question as lawsuits are filed to challenge certain patent rights.

H. Answers to Activity Sheet

AS 3.1

Answers will vary.

I.

Answers to Evaluation

1. b
2. a
3. c

4. DNA fingerprinting is the process of using the laboratory analysis of DNA to generate a pattern that is unique to an individual organism.

5. The question of ownership of genetically modified organisms and the patenting of the genetic material of plants and animals native to countries other than the United States

6. Preventing the theft of genetic material, flawed results from testing, and preserving the privacy of genetic information

EVALUATION

Circle the letter that corresponds to the best answer.

1. A patent is the:
 - a. Permanent right to the profits received from the marketing of the patented invention.
 - b. Right to exclude others from making, using, or selling the patented invention.
 - c. Right to keep confidential the details of an invention.
 - d. Temporary right to use an invention in the United States.
2. The most common type of patent obtained for an invention using biotechnology is the:
 - a. Utility patent.
 - b. Design patent.
 - c. Plant patent.
 - d. Genetic patent.
3. Which of the following is not a statutory requirement for a utility patent?
 - a. The invention must be a new and useful process, machine, manufactured item, or composition of matter.
 - b. The invention must be novel and nonobvious.
 - c. The invention must be an abstract idea.
 - d. The invention must be fully described and clearly identified in the patent application.

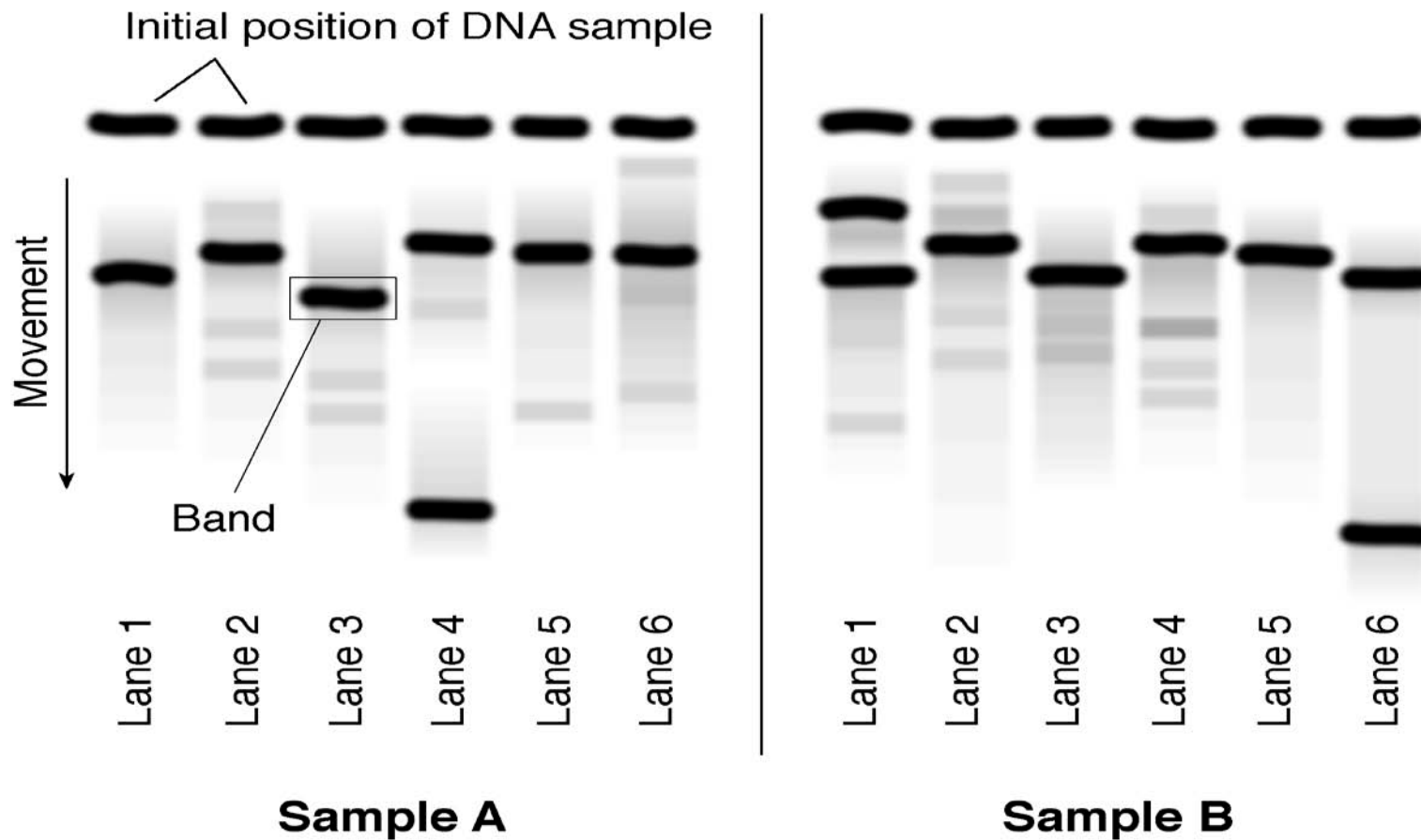
Complete the following short answer questions.

4. What is DNA fingerprinting?
5. What are the issues surrounding the patenting of biotechnology products?

6. What problems exist with the handling of genetic material?

Section of a DNA Fingerprint

TM 3.1



Do the bands in Sample A match the bands in Sample B?

Patent Debate

Objective: Examine issues surrounding the patenting of products of biotechnology.

Your instructor will divide the class into two groups. The first group represents the scientists and the corporations who want to strengthen their right to patent biotechnology products. The second group represents the groups opposed to patenting life-forms. Each group should search the Internet and other sources for information that will support their argument. The questions below should be used to help guide the research. A group must have four major arguments to support its case and be ready to answer the other group's objections. Select one person in each group to record the arguments and answers to possible objections.

- Are patents necessary to protect the monetary investment made by researchers in developing useful products?
- Should plant, animal, or human DNA be patented, since it is not an invention?
- Who owns or controls the genes of plants and animals?
- What international trade problems have arisen or could arise due to patents on genetically modified plants and animals?

Your teacher will moderate the debate. Each side will take turns making a point and then giving the other group the opportunity to raise an objection to the point. This process will continue until both groups have raised their four points. Each group will then be given a short time for closing arguments.

