Lesson 1:
An Overview of Biotechnology

The word "biotechnology" probably brings to mind an image of scientists in a laboratory, but it is much more than pure scientific research. Biotechnology is as old as making wine and as new as gene- splicing. It is applied to crops in the field and livestock in the barn.

Defining Biotechnology

The term "biotechnology" is often regarded as highly technical and scientific. Most members of the general public have heard of biotechnology, but they do not know how to define it. "Bio" refers to living things, and "technology" involves the application of science. Biotechnology can therefore be defined as the application of scientific principles to living things. It involves harnessing the natural biological processes of cells from microorganisms, animals, and plants to develop useful products. This broad definition of biotechnology includes processes such as fermentation and the use of yeast to cause bread to rise. These processes have been used for centuries.

A narrower definition of biotechnology includes only those processes that involve the recombination of genes from living things in a laboratory setting. The recombination of genes involves cutting and relinking a DNA strand. Modern biotechnology dates from the 1970s, when scientists first developed a way to splice genes from the DNA of one organism into the DNA of another organism.

When animals or plants reproduce sexually, DNA is transferred from the two parents to the offspring. This transfer of DNA is a natural process. Selective breeding of animals or plants can be considered biotechnology because a natural biological process is being harnessed to produce a useful product. Modern biotechnology, however, allows a scientist to transfer specific genes from one organism to another. The new organism will have a predetermined trait based on this genetic information.

The Past Role of Biotechnology

Biotechnology has played a vital role in crop production throughout history. One of the earliest examples of biotechnology was the development of fruit tree grafting techniques by the Greeks around 300 B.C. Crop biotechnology was greatly advanced by Gregor Mendel's experiments with garden peas in 1865 and his discovery of the foundations of genetics. The development of the first hybrid corn plant in 1879 is another example of how biotechnology has affected agriculture. In 1933, fewer than 1 percent of the U.S. corn crop came from hybrid plants, but by 1943, more than 70 percent of the crop was produced with hybrid corn. Crop production was again enhanced by the international development of improved wheat and rice varieties between 1946 and 1965.

Biotechnology has also been important in animal production. Selective breeding of livestock was practiced by people in the Middle East as early as 18,000 B.C. Animal crossbreeding and purebreeding were practiced in Europe as early as 1500 A.D. A procedure for artificial insemination was first developed in Italy in the late eighteenth century.

Biotechnology has also affected the food processing industry. The use of bacteria to make cheese, bread, and alcohol began in Egypt between 4,000 and 2,000 B.C. The food processing industry was boosted by the invention of the modern distillery in the United States in 1830, which optimized the process of fermentation to produce alcohol. In the 1860s, Louis Pasteur discovered that fermentation was carried out by bacteria and confirmed the existence of microorganisms, leading to applications such as the large scale brewing of beer and wine.

Emerging Applications of Biotechnology

The modern era of biotechnology began with the first successful recombination of DNA in 1973. This achievement was the first step in the development of genetic engineering. Genetic engineering (also referred to as genetic modification or genetic manipulation) is the alteration of the genetic material of living cells by incorporating different genes to produce organisms with new characteristics.

In the late 1970s, scientists developed the technique of plant tissue culture. Tissue culturing has been important in the development of nearly all transgenic plants, or plants that incorporate genes from some other source. This process allows a plant breeder to grow an entire plant from only a few plant cells.

New technologies have been developed in animal biotechnology as well. After years of using artificial insemination, the livestock industry gained another application of biotechnology with the development of embryo transfer techniques in the early 1980s. Methods of cloning animals have also been developed. In 1981, a Chinese scientist first cloned a fish. In Scotland in 1997, a ewe named Dolly was the first animal to be cloned from the cells of an adult mammal. Also in 1997, a calf named Gene was cloned from cells taken from a 30-day-old fetus.

The ability to alter DNA through genetic engineering has made many new products possible. The first genetically modified food product, an enzyme used in making cheese, was approved for use in the United States in 1990. Today, this enzyme is used to process most of the hard cheese produced in the United States. The first genetically modified crop plant was approved in the United States in 1994. This plant was the FlavrSavr™ tomato, which was engineered to taste better and have a longer shelf life. Insect-resistant and herbicide-tolerant crops were approved for use in the United States in 1995 and 1996. Animal vaccines produced from genetically modified bacteria were developed in the mid-1990s.

The future applications of biotechnology are not easy to predict. Several biotechnology products are currently being researched. Some of these products include environmentally tolerant crops and plants genetically modified to be used for biofuels. The future applications of biotechnology will address specific problems or obstacles preventing higher yields and higher quality agricultural products.

Consumer Perspectives toward Agricultural Biotechnology

Agricultural biotechnology is typically viewed by consumers as both positive and negative. Consumers in developed countries such as the United States like the idea of lower food costs, increased nutrient content, and having fresh fruits and vegetables available year-round. In developing countries, the interest is mainly in increased and cheaper food supplies.

However, some consumers in both developed and developing countries have concerns about the use of biotechnology. Some people fear that foods produced in this manner may not be safe to eat, even though U.S. regulatory agencies have stated that genetically modified foods are as safe as unmodified foods. Consumers also fear that agricultural biotechnology could harm or endanger the environment if genetically altered organisms are released.

The perspective of the consumer is an important factor in determining the market potential for products developed through biotechnology. Whether their fears are valid or not, consumers make the final decision about whether to purchase biotechnology products. Therefore, their concerns must be addressed.

Producer Perspectives toward Agricultural Biotechnology

Producers of agricultural products may also have both positive and negative feelings toward biotechnology. Producers see the potential for increased profits due to higher yields or lower input costs. Producers also see a benefit in reducing the amount of chemicals applied to their crops through the use of pest-resistant plants, since water supplies on their land would be better protected from contamination. Profitable new “customized”

crops will benefit producers as well. Examples of customized crops are corn developed specifically for the production of ethanol or carrots developed for carrot stick snacks. Producers will receive premium prices for these types of crops.

Agricultural biotechnology does raise concerns among producers. Producers fear that small farms may not have the opportunity to use biotechnology and that large corporate farms may become more competitive and force them out of business. They also fear that a genetically modified crop could create a "super weed." The genetically modified plant could cross pollinate with a wild plant species to produce a plant that is nearly impossible to control. The debate continues as to whether there is any justification for these fears.

Nonagricultural Impacts of Biotechnology

Agriculture is only one of the areas affected by biotechnology. The human health industry, and particularly the producers of pharmaceuticals, have been greatly affected by biotechnology. Insulin for diabetics, for example, is now produced by genetically modified bacteria. It was the first product made by genetic engineering to be approved for sale in the United States. Many human vaccines have been developed using the same method, including a vaccine for rabies. Some human antibiotics and human growth hormones can be produced using modified bacteria. Biotechnology has also affected the health industry through the development of tests that detect genetic disorders. Huntington's disease, Down's syndrome, Tay-Sachs disease, and cystic fibrosis can all be detected much earlier because of tests developed through biotechnology.

Another industry that is benefiting from biotechnology is the mining industry. Bacteria are being genetically modified for biomining. They will break down poor quality heavy metal ore. The metal can then be extracted much more easily. The bacteria will allow ore to be used that was once too costly to process.

Law enforcement and the criminal justice system have begun to use DNA for forensic purposes. A process called DNA fingerprinting can help to identify individuals who have committed a crime. It can also be used to match a child with its biological parents in cases where they have been separated due to war, kidnapping, or other circumstances.

The waste treatment industry and companies that clean up pollution are testing the use of genetically modified bacteria to treat sewage, clean up oil spills, and improve soil contaminated with organic compounds such as DDT. These bacteria literally feed on the undesired compound. Solid waste sites like landfills are examining the use of modified bacteria that will feed on the waste and give off methane gas, which can be burned as a fuel.

Summary

Biotechnology is the application of science to living things. Biotechnology has affected plant and animal production and the food processing industry, but it is also very important in many other areas, such as human health, mining, law enforcement, and waste disposal. Consumers and producers of recent products of agricultural biotechnology view them from different perspectives. These perspectives will influence the direction and pace of research in biotechnology in the future.

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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

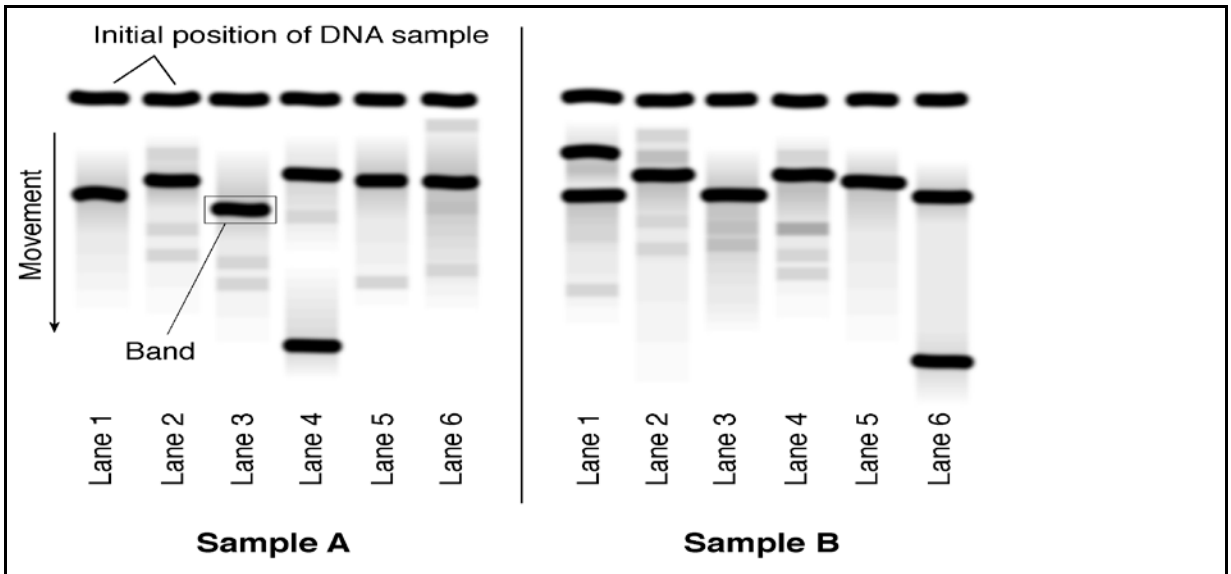
One of the issues surrounding biotechnology patents is the question of ownership of the genetically modified organism. Should genetically modified plants and animals be deemed the property of the individual or corporation responsible for modifying them? The answer to this question is controversial. Some 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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Lesson 1:
The Scientific Method

Agricultural biotechnology is a rapidly expanding area of research. This growth makes the documentation of research methods, procedures, and results vitally important. With so many researchers exploring the applications of agricultural biotechnology, proper research methods and proper documentation of those methods is necessary. The scientific method helps researchers organize their experiments and allows other researchers to duplicate their work, which adds credibility to the results. Patent applications have been rejected or slowed due to poor documentation of research or poor research methods, both of which make replicating the research difficult. This lesson will outline the proper method of designing biotechnology research efforts.

The Scientific Method

The scientific method is a way of addressing scientific questions that provides a rational and structured system for research. A single biotechnology research effort may cost hundreds of thousands of dollars or more. A solid research approach is necessary to ensure the wise use of funds. Biotechnology researchers use the time-tested structure of the scientific method when conducting research.

The scientific method used by biotechnology researchers has six major parts. The first step in using the scientific method is to identify the problem to be investigated in a problem statement. The problem statement expresses the general purpose of the research. Knowledge about the problem or question for which an answer is being sought is required. The problem must be stated in such a way that it will lead to experimentation that will solve the problem. A sample problem statement is “Some plants in a corn field have yellow leaves.”

After the problem has been identified, the second step is an investigation into previous research to identify alternate explanations or solutions to the problem. This activity leads into the third step of the scientific method, which involves formulating a hypothesis, or educated guess, about the anticipated outcome of the research. The hypothesis is essential, since experiments are developed to validate or invalidate this statement. It must be a focused and detailed statement that can be tested for accuracy. A hypothesis for the problem statement in the preceding paragraph is “Nitrogen deficiency causes the corn plants’ leaves to be yellow.” Since the hypothesis will direct the methods of experimentation, the hypothesis is the most important statement made by the researcher.

The fourth step is to design an experiment that will accurately test the hypothesis. This step is also a critical step. If the hypothesis is correct but poor experimental methods are used to test it, the chance of obtaining usable results is reduced. Selecting experimental methods for research requires knowledge of the available testing procedures and their advantages and limitations.

The fifth step of the scientific method is to conduct the experiment and collect data. When experimentation is complete, the final step is to draw conclusions about the success of the experiment by analyzing the information it provides. Based on this information, the researchers will accept or reject the hypothesis. The results of the experiments are examined, and evidence about answers to the original problem is detailed. As a part of this step, the limitations of the research results must also be explained. The conclusions collected must be supported by evidence in order to be valid.

Many researchers must add an additional step to this process. After the experiments have been chosen to test the hypothesis, researchers generally have to write a proposal. This proposal is directed at one or more funding agencies that provide funding to support research efforts. Researchers who work for private companies do not normally write a formal proposal, but they must still convince the company that the proposed research is worthwhile.

Importance of the Scientific Method

A logical question to ask when discussing the scientific method is simply, "Why is the scientific method important for research?" Three main reasons for its importance exist. First, the scientific method provides a logical approach to solving a problem. Scientific research, including research in biotechnology, is essentially a search for the unknown. The search for an unknown requires a basic, comprehensive search beginning from a given point. The scientific method helps researchers to analyze the known information and to select the best way to find the desired answers. Second, the scientific method is important because it helps force researchers to examine their research objectively. The structure of the scientific method aids in identifying alternative answers to research questions since the researchers must carefully examine existing research in the area of interest. A final reason that the scientific method is important is that its use allows other researchers to repeat the experiments. Other researchers need to be able to duplicate the results of an experiment before its validity can be fully established. Research that follows the scientific method is more easily understood than research that does not follow that structure. Research must follow the scientific method to gain professional credibility.

Laboratory Notebooks

Laboratory notebooks serve an important function in biotechnology research. Notebooks provide a detailed account of the day-to-day activities of the experimental process. These notes are vital in examining directions for future research and for proving that specific research was done at a set time, which is required for patent applications. When research is not successful, researchers often review laboratory notebooks so that new research efforts can better address the problem. A notebook should be bound and written using permanent ink. It should also be complete, covering actual activities and all observations made. The laboratory notebook should have a cover that identifies the subject of the research and a table of contents.

Information from individual experiments is recorded on laboratory sheets. These sheets contain six major sections. The first section is for the title of the experiment, the date, and the name(s) of the investigator(s). The second section should briefly describe the purpose of the experiment. A list of materials needed should be included next. The procedures for the experiment should be outlined in the fourth section. These procedures should be detailed and include specific quantities of substances used, as well as the precise methods of using them. The next section should be a record of experimental results in the form of data and observations. Finally, the conclusions drawn from the research are recorded at the end of the laboratory sheet.

Summary

The scientific method is an important tool in research for biotechnology. Without the logical structure of the scientific method, research would involve a blind search for answers. The six parts of the scientific method help researchers organize their research efforts and increase the likelihood of success. The laboratory notebook is an important source of documentation for researchers. This notebook should be a complete, day-to-day account of the research.

Credits

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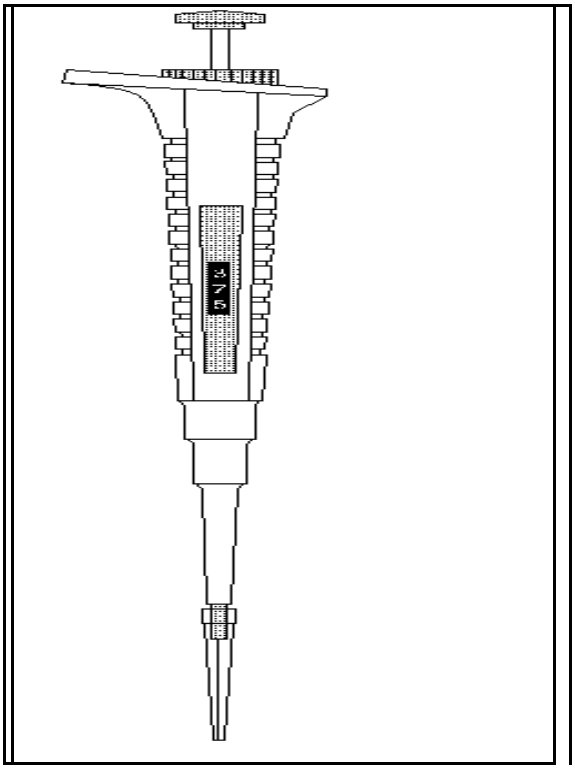
Lesson 2:
Laboratory Equipment and Techniques



The heart of biotechnology is the research laboratory. Biotechnology laboratories are equipped with many types of tools and instruments. Individuals involved in biotechnology should be familiar with the equipment used in these laboratories as well as special procedures for developing and maintaining suitable working conditions that are free of contaminants.

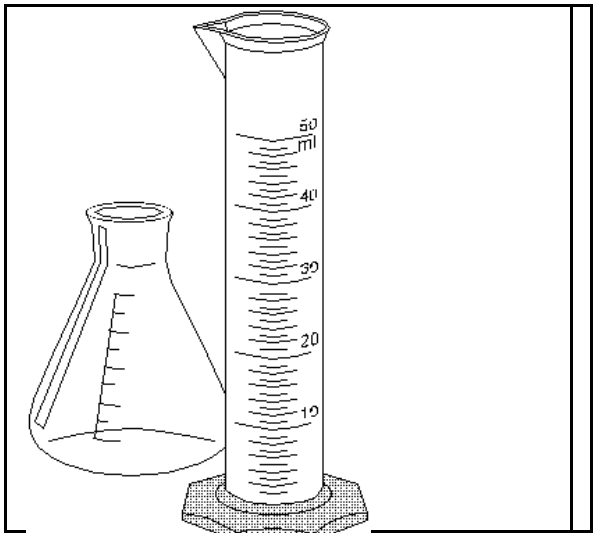
Laboratory Equipment

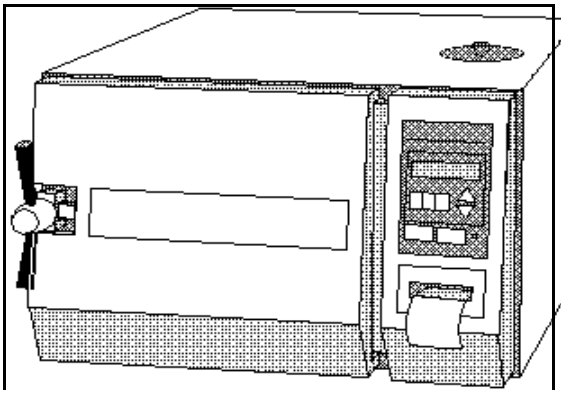
Laboratories where biotechnology research is conducted contain many different types of laboratory equipment. The specific equipment found in a given laboratory will vary based on the type of research being done. However, most laboratories have a basic set of equipment.

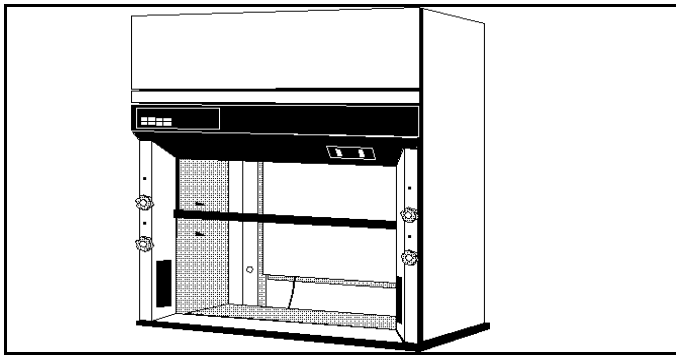
The pipettor (Figure 2.1), which is used to measure and transfer amounts of liquid smaller than one milliliter (ml), is a common tool in biotechnology laboratories. Pipettors are available in three main sizes: zero to 20 microliters (μl), 20 to 200 μl, and 200 to 1,000 μl.

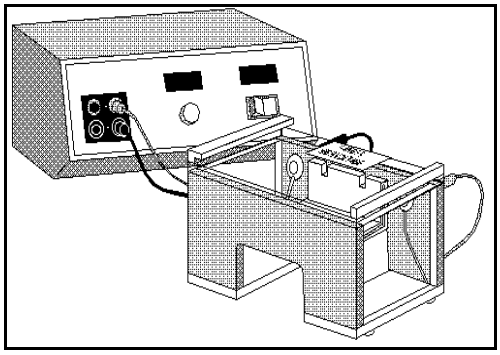
A variety of plastic ware and glassware is used in the biotechnology laboratory. Pipette tips, test tubes, and centrifuge tubes are examples of plastic ware used in a laboratory. Petri dishes made of plastic or glass are the containers most commonly used for growing bacteria or tissue cultures. Glassware used in laboratories includes beakers, flasks, graduated cylinders, and test tubes. Figure 2.2 shows some examples of plastic ware and glassware.

Researchers sterilize most of the plastic ware and glassware in an autoclave, which is illustrated in Figure 2.3. An autoclave uses steam under high pressure for sterilization.









A fume hood (Figure 2.4) is an enclosure that vents air to the outside. Fume hoods allow researchers to use chemicals with dangerous or noxious fumes. They are commonly sterilized with ultraviolet light or a 70 percent alcohol solution when researchers do tissue culture and other sensitive procedures.

Another piece of equipment needed for tissue culture and the propagation of bacteria is an incubator, which is shown in Figure 2.5. An incubator maintains a preset temperature that provides an optimum climate for cell cultures to grow.

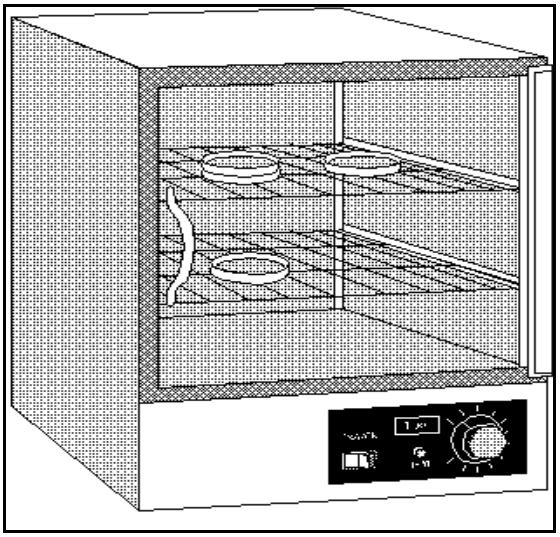
An electrophoresis unit (Figure 2.6) is a common piece of equipment. Electrophoresis separates DNA fragments by size using an electric current. The electrophoresis unit is like a sieve for separating these microscopic fragments. The fragments are shown on an electrophoresis gel.

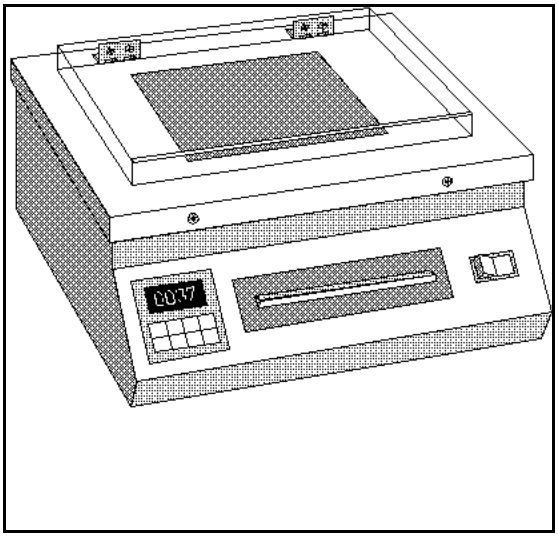
A A transilluminator, shown in Figure 2.7, is used to view an electrophoresis gel. A transilluminator illuminates the gel by passing a shortwave ultraviolet light through it. Regular light will not show the dyes used to stain the gel.

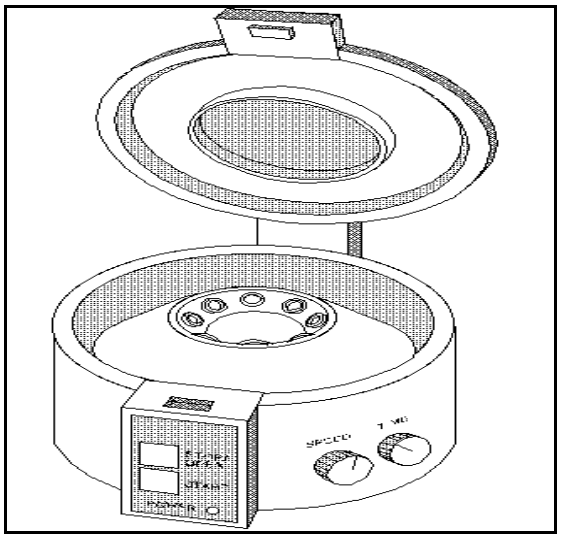
Polymerase chain reaction (PCR) equipment is also found in biotechnology laboratories. PCR is a method of increasing the quantity of DNA in a sample by heating and cooling the DNA to break it down and force it to replicate. PCR equipment takes various forms, from a series of water baths to the newest automated form, the thermocycler (Figure 2.8).

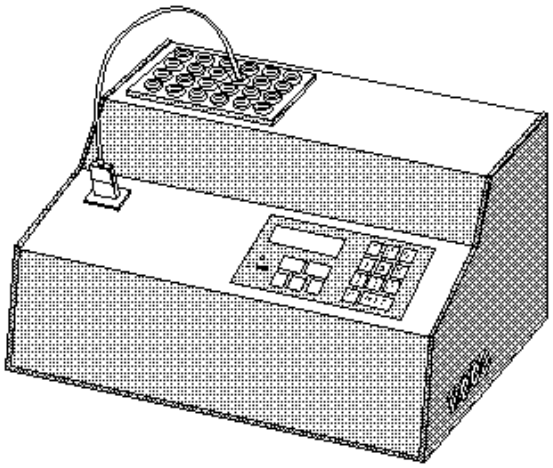
DNA is separated from a liquid by using a microcentrifuge, which is illustrated in Figure 2.9. A microcentrifuge is essentially a high power spinner that uses centrifugal force to separate solids, such as DNA, from a liquid.

A vortex is a vibrating mixer used on test tubes. It mixes a solid or liquid with a liquid. A test tube is placed on a small rubber cap that vibrates in a circular motion, which causes the contents of the test tube to mix.









The microscope is an important device for enlarging and viewing organisms or specimens that are not visible to the naked eye. Two basic types of microscopes are used in biotechnology laboratories. The dissecting microscope is a low-power microscope that magnifies 10 to 100 times. This microscope is used in embryo transfer and tissue culture techniques. The second type of microscope is a general laboratory microscope that magnifies 100 to 1,000 times.

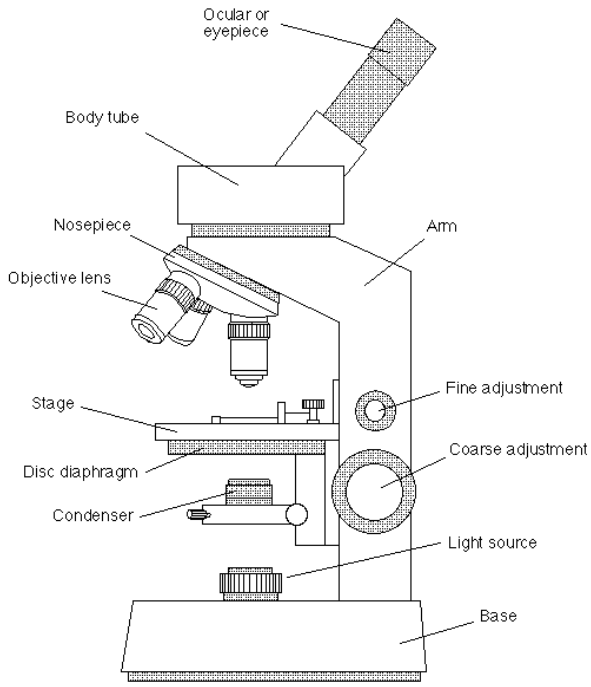
The Microscope

A microscope (Figure 2.10) has many parts. The ocular, or eyepiece, is the initial point for viewing a specimen and contains the first lens system, which normally magnifies the specimen 10 times (10X). The second lens system is called the objective. It projects the magnified image up through the ocular. Most microscopes have two or three objectives that vary in their degree of magnification. A rotating piece called the nosepiece holds the objectives.

The body tube of the microscope holds the ocular and the objectives the correct distance apart. The arm is the curved support that connects the body tube to the base. The base is the stand on which the microscope rests. Slides containing the specimens to be observed are placed on the stage, which has clips to hold the slide in place.

The disc diaphragm contains a series of different sized openings that control the amount of light shining on the specimen. The light comes from a light source like a mirror or small electric lamp. On microscopes with a lamp, a condenser focuses the light on the specimen.

The two main dials for adjusting a microscope are the coarse adjustment and the fine adjustment. The coarse adjustment is the larger of the two dials; it is always used first to focus on a specimen with the low power objective. The fine adjustment refines the focus. With the high-power objective, only the fine adjustment is used to focus the microscope.



Procedures for Manipulating Microscopic Specimens

A specimen viewed under a microscope must be very thin since it is placed, or mounted, on a glass slide. If a wet mount is needed, a drop of water should be added to the specimen. Usually, a cover slip is placed on top of the specimen; gently pressing on the cover slip will remove air bubbles. To view some specimens correctly, they must be stained. The correct staining procedures vary greatly from specimen to specimen.

Once the slide is prepared, it is placed on the stage and secured by the clips. Next, the light source must be turned on and adjusted so that light passes through the specimen. The low-power objective is then selected, and the coarse adjustment is used to focus the specimen's image. If more magnification is needed, the high-power objective is selected, and the fine adjustment is used to focus the image. The fine adjustment should only be used to move the objective up and away from the stage. If either the coarse adjustment is used or the fine adjustment is adjusted toward the specimen slide while using the high-power objective, damage to the objective can result.

Aseptic Techniques

Aseptic techniques are procedures used to create and maintain a work area free of bacteria and other microorganisms that might contaminate delicate experiments. A sterile environment is necessary for procedures such as tissue culture or the propagation of bacteria. Some aseptic techniques are described below.

- *Controlled air movement* - The researcher works in an enclosed chamber that allows the flow of air to be controlled.

- *Disinfection* - The work area is disinfected with a 10 percent bleach solution. Then the instruments and work area are sprayed with a 70 percent ethanol solution and allowed to air dry.

- *Scrubbing up* - The researcher scrubs his or her hands and arms thoroughly and allows them to air dry. He or she then sprays them with a 70 percent ethanol solution.

- *Sterilization* - Researchers use an autoclave to sterilize all materials and instruments. An ultraviolet light kills microorganisms in the work area.

A researcher may maintain an aseptic work area by using a shield to avoid breathing on an experiment. He or she should also avoid sneezing or coughing in the work area. When using a fume hood, researchers should use the rear portion of the enclosed area to reduce exposure to bacteria that might enter the area.

Importance of Aseptic Techniques

Experimental procedures like tissue culture and most DNA analysis techniques require proper aseptic techniques to be successful. Contaminants will destroy many biotechnology experiments, so the work environment must be free of them. Bacteria, viruses, and other microbes can interfere with many laboratory procedures.

Summary

Many different types of laboratory equipment are used in biotechnology research. A basic piece of equipment is the microscope, so understanding its parts and their functions is important. Researchers must also know the procedures for manipulating microscopic specimens. Researchers in biotechnology should practice aseptic techniques to prevent the contamination of their work.

Credits

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Lesson 3:
Biotechnology Laboratory Safety

Biotechnology researchers use many types of equipment, chemicals, and specimens in their work; the correct use of all three is vital to the safety of the researchers. Laboratory safety is a very high priority in biotechnology laboratories. The ability to handle chemicals and specimens safely and to use equipment correctly is necessary for employment. A knowledge of emergency procedures for chemical spills and fires is also critical. This lesson highlights some of the most important safety precautions and concerns.

Common Biotechnology Laboratory Safety Concerns

Common biotechnology laboratory safety concerns fall into five major categories: microorganisms, chemicals, radioactivity, electrical hazards, and physical hazards. The use of bacteria and fungi is common in biotechnology laboratories. Some microbes, called pathogenic microbes, are dangerous because they are capable of causing disease. These types of microbes require special containment laboratories and are not used in school laboratories. However, all microorganisms should be handled properly, since even nonpathogenic microorganisms can be harmful in certain cases. Care should be taken to follow aseptic techniques strictly in order to contain microorganisms.

Many types of chemicals are used in biotechnology laboratories, including solvents, enzymes, dyes, and buffers. These chemicals are safe if handled correctly. Care must be taken to avoid contact with the skin. Many chemicals can be absorbed through the skin or spread onto other surfaces by contact. Most of the dyes and buffers are toxic if ingested. Use of these chemicals should be limited if a suitable alternative is available.

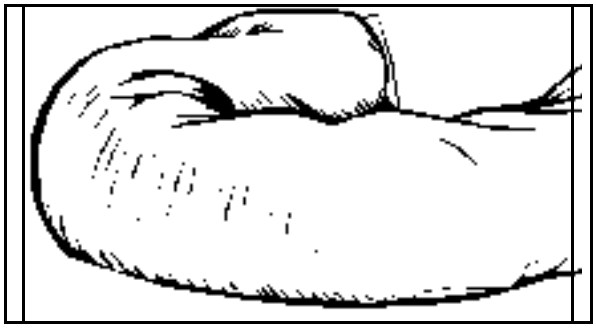
Radioactivity is used in biotechnology laboratories for probes or markers that verify the transfer of DNA segments. A special permit is required to use radioactive materials. To obtain a permit, researchers must complete training about the safe handling and disposal of radioactive substances. Radioactive materials are not used in school laboratory settings.

Electrophoresis equipment can be an electrical hazard. This equipment is safe if used properly. However, if safety precautions are not observed, electrical shock can occur. An individual should never touch the gel solution while the machine is on.

Centrifuges and ultraviolet lamps used in biotechnology laboratories are considered physical hazards. A centrifuge should have a lock that prevents the lid from opening while the machine is spinning. This safety feature prevents fingers from being caught in the rotating machine, which can cause serious injuries. With prolonged exposure, ultraviolet radiation from a transilluminator can damage retinas and bare skin.

Cleaning Up Spills

The possibility of a spill exists whenever chemicals are handled. When the spilled chemical is known, clean up procedures for that specific chemical should be used. The proper procedures are outlined on a Material Safety Data Sheet (MSDS). Chemical suppliers develop these sheets and ship them with all chemicals. The sheets must be kept in a specific notebook or file for easy reference. The MSDS provides a variety of information about the chemical, including its toxicity level, first aid measures, required personal protective equipment, and disposal procedures.



When specific clean up procedures are not available or the content of the spill is unknown, special procedures must be followed. A spill pillow (Figure 3.1) is used to absorb any liquid chemical. The used spill pillow should be regarded as hazardous waste and disposed of

appropriately. If the spill is a solid or a powder, it can be gently swept into a glass container and disposed of as hazardous waste. The spill area should be cleaned with a disinfectant and an ethanol solution to ensure that any remaining traces of the chemical are removed.

Disposal of Biotechnology Laboratory Waste

Biotechnology laboratories commonly produce waste products classified as hazardous waste, which must be disposed of appropriately. Simply dumping everything down the drain is not acceptable. Some of the waste generated by a biotechnology laboratory can be decontaminated and thrown away with other trash to be placed in a landfill. All cultures and equipment that have come in contact with infectious microbes must be autoclaved or disinfected with hospital-type disinfectants before being thrown away. Examples of chemicals requiring special disposal are organic solvents and highly toxic chemicals. The proper disposal method for a chemical substance is found on the chemical's MSDS. Improper disposal of hazardous waste endangers the environment, and a company may receive large fines if OSHA or the EPA discovers that proper disposal procedures are not being followed.

Emergency Fire Procedures

Biotechnology laboratories, like all laboratories, must be prepared for emergencies. A fire exit plan should be posted in the laboratory. In a research laboratory, just as in a classroom laboratory, the fire exit plan should be followed if a fire breaks out and should be practiced during fire drills. Everyone should know the location of the fire extinguisher, the fire blanket, and the fire alarm switch. If a fire occurs in a classroom lab, students should immediately notify the instructor and begin exiting the room.

Personal Protective Equipment

Personal protective equipment (PPE) can help prevent injury to laboratory workers. All laboratories require workers to wear safety glasses or goggles while in the laboratory. They also require latex or other appropriate types of gloves for most laboratory work. Normally, workers use disposable latex gloves. Lab coats or aprons should be worn to protect clothing. Shorts, short skirts, and sandals are not permitted because they expose too much skin to the laboratory environment.

Injuries in the Laboratory

Anyone working in a laboratory should know what to do if an injury occurs. Simple first aid procedures, like applying pressure to stop blood loss or flushing skin or eyes with water if they come in contact with chemicals, should be done immediately. In a classroom lab, the instructor should also be notified without delay so that he or she can follow the school procedure for emergencies. Students should always read and follow any precautions noted in a laboratory exercise to help avoid injury.

Laboratory Ventilation

Most biotechnology laboratories do not require special ventilation. A fume hood vented to the outside is necessary when using chemicals that produce bad odors or harmful vapors. Because it is enclosed, the fume hood may also be used to prevent contamination by serving as a sterile environment for certain laboratory procedures. Some chemicals may only be stored in a lockable ventilated storage cabinet. Ventilated storage cabinets are designed to prevent the buildup of gases that can cause an explosion or fire.

Summary

To work in a laboratory, biotechnology researchers must be able to handle microorganisms, chemicals, radioactivity, electrical hazards, and physical hazards safely. Researchers must wear personal protective equipment and be aware of laboratory hazards.

Credits

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Lesson 1:
The Mechanics of Cells and DNA

Cells are the fundamental units of life. Biotechnology research is usually done on the cellular or subcellular level. Knowing the cellular components and how the parts of a cell work is therefore necessary. Of particular importance is the core component of biotechnology research, DNA.

The Parts of Cells

All cells contain DNA. However, the structures found in the cells may vary. The cells found in plants and animals are similar, but they do have some differences. Bacteria cells are very different from plant and animal cells.

An animal cell (Figure 1.1) has a cell membrane, or plasma membrane, that forms the boundary of the cell. The cell membrane is primarily a lipid (fatty substance), carbohydrate, and protein structure. The membrane's primary function is to control the movement of substances into and out of the cell.

Inside the cell membrane is the cytoplasm, which consists of the contents of the cell, excluding the nucleus. The fluid of the cytoplasm helps control the movement of many substances within the cell. The cytoplasm includes many structures, called organelles, that fill different specialized functions in the cell.

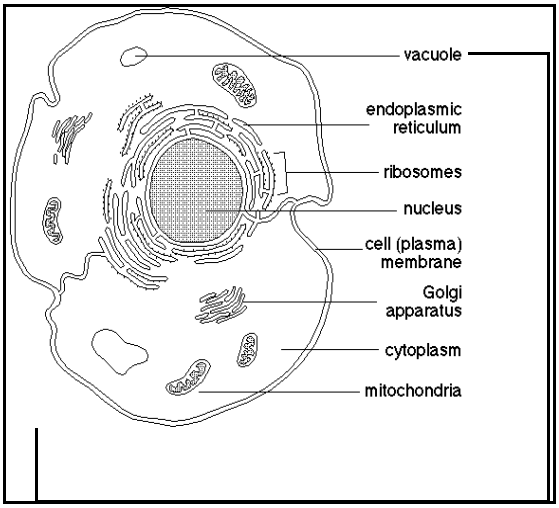
Mitochondria are the powerhouses of the cell. They break down nutrients to provide energy to the cell. Hundreds of mitochondria may be found in a single cell.

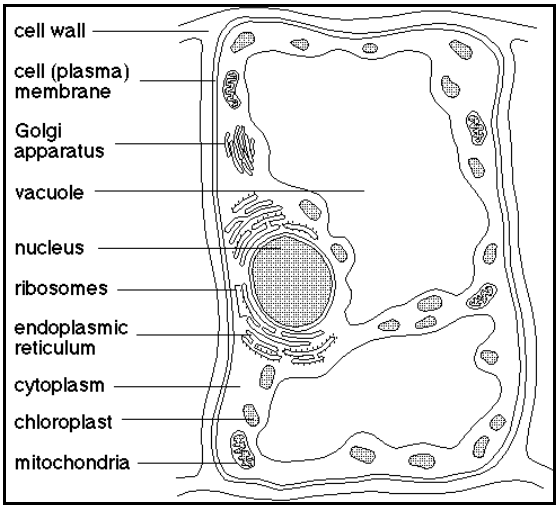
The endoplasmic reticulum is a large network of membranes that transports material within the cell. Ribosomes are found on the endoplasmic reticulum. They are the sites where protein molecules are assembled, or synthesized. These protein molecules are important to the cell and to the organism as a whole because they control the chemical activities of cells.

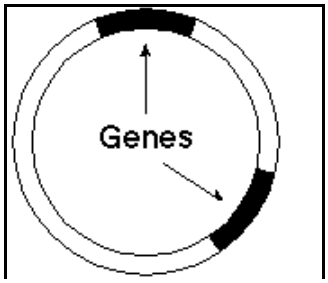
The Golgi apparatus works with the endoplasmic reticulum in transporting proteins. It packages protein molecules for transport within and outside the cell.

Vacuoles are the storage units of the cells. They store water, enzymes, pigments, and other substances.

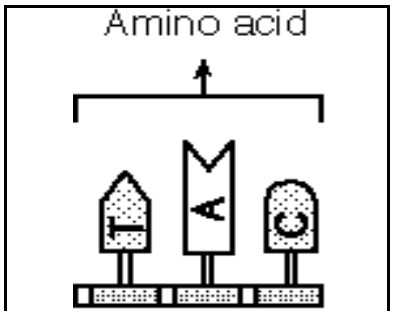
The control center of a cell is called the nucleus, which is defined by a pair of nuclear membranes. Inside the nucleus, chromosomes consisting of DNA can be found. Chromosomes are essentially tightly wrapped pieces of DNA that function as a unit. Genes are segments of DNA on chromosomes that produce a polypeptide (protein). Genes are responsible for the expression of genetic traits because the proteins produced by genes







control the appearance, growth, and functioning of the organism.



Plant cells (Figure 1.2) contain these structures, but they also have a few differences. They have more vacuoles, which can be very large in mature plant cells. Plant cells have chloroplasts; they contain the chlorophyll used in photosynthesis. The cells also have a rigid outside layer called a cell wall that is composed of cellulose. The cell wall provides support for the plant cell and works collectively with the walls of other cells to support the plant. The cell wall has openings that allow substances to pass through it. The cell membrane in plant cells is just inside the cell wall.

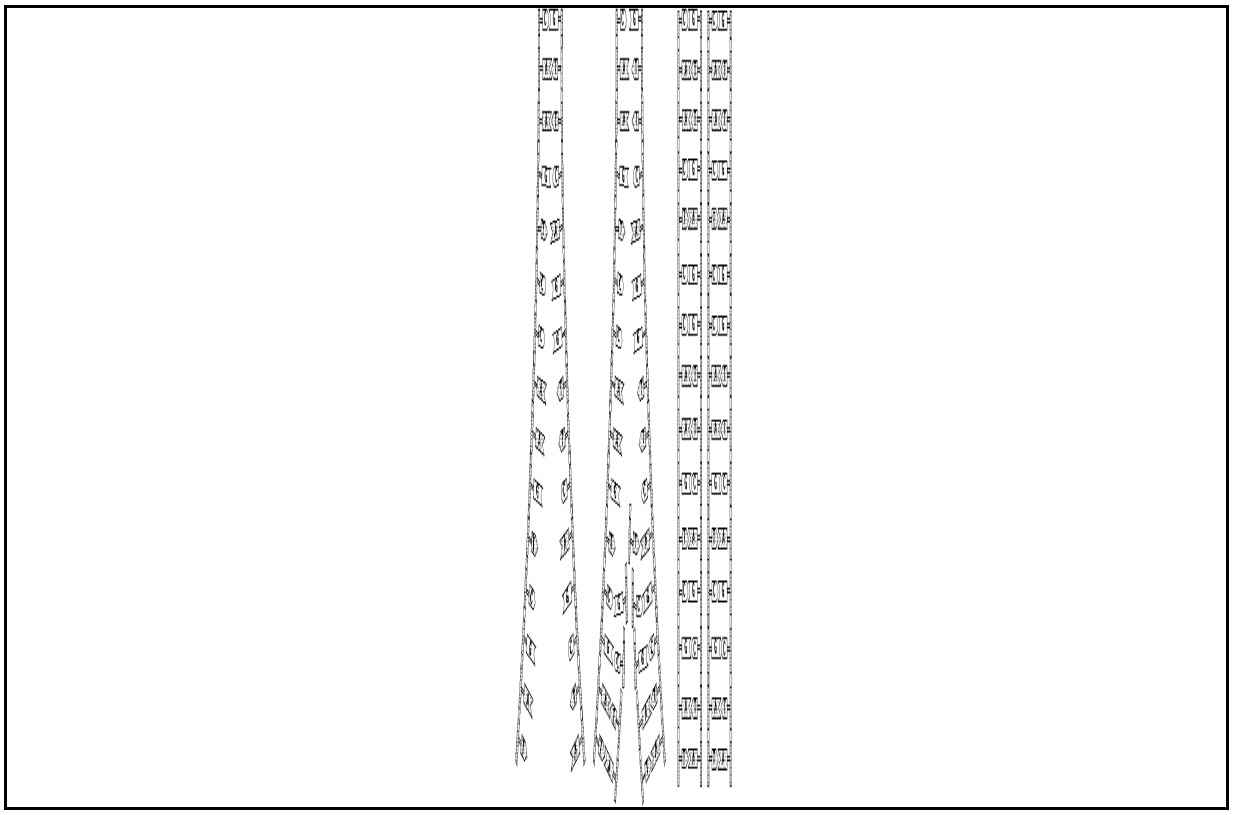
Bacteria have a cell wall and cell membrane. They also have ribosomes that carry out protein synthesis. Unlike animal and plant cells, the chromosomal material is not contained within a nuclear membrane but instead forms a nucleoid region. A unique structure found only in bacteria cells is the plasmid (Figure 1.3). One or more plasmids can be found in a cell. Plasmids are essentially small circular pieces of DNA that code for specific traits and replicate independently of the chromosomal DNA. They normally contain only a few genes. Plasmids play an important role in biotechnology because they can be easily modified to produce pharmaceuticals.

DNA

Genetic modification involves the manipulation of DNA, or deoxyribonucleic acid. DNA is the genetic material of the cell. It is composed of small chemical units called nucleotides. A nucleotide consists of three parts: a phosphate group, a sugar unit (deoxyribose), and a base unit that contains nitrogen. DNA has four different nitrogen bases, creating four different nucleotides. These nucleotides are named after the nitrogen base. The four nitrogen bases are adenine (A), guanine (G), thymine (T), and cytosine (C). The nitrogen base units contain the code used to build proteins. A single strand of DNA may contain more than 100 million base pairs. DNA is not a simple molecule.

The Structure and Function of DNA

James Watson, a biologist, and Francis Crick, a physicist, were the first to discover the structure of DNA. They won the Nobel Prize in 1962 for their work. Watson and Crick found that two strands of nucleic acid are intertwined in a double helix structure. It looks like a twisted or spiraling ladder. The phosphate and sugar units form the sides of the ladder, while the nitrogen base units form the rungs. The nitrogen base adenine will only bond to thymine, and guanine will only bond to cytosine. Hydrogen chemical bonds join the base units.



The DNA in a plant, animal, or bacteria cell is essentially the same except for the sequence of bases it contains. This similarity of DNA makes the manipulation and transfer of DNA between these different life-forms possible. If the structure or function of plant DNA was different from animal DNA, then DNA from a plant could not be spliced into the DNA of an animal.

DNA is the blueprint of a cell. A builder of a house uses a blueprint to see where and how to install the walls, windows, plumbing, electricity, and many other things. In the same way, the cell uses its DNA to determine what types of proteins to build, or synthesize. The proteins produced during protein synthesis by the cells in an organism function as the chemical basis for the development of the organism.

Codons are sections of DNA three nucleotides long (Figure 1.4). Codons code for one of the twenty amino acids that are the building blocks of proteins. The codons are lined up end to end to form the DNA strand. Using this code, amino acids are lined up and linked together to form polypeptides. Two or more polypeptides are then linked together to form proteins. The kind and sequence of amino acids makes the shape of one polypeptide different from another. The shape of a protein is strongly related to how the protein will function.

DNA not only codes for protein production in a cell but also passes this code on to new cells formed by cell division. Essentially, DNA copies itself before a cell divides. This process is called DNA replication.

DNA Replication

Cell division occurs when a cell grows and begins to get too large. When a nonsex cell in a plant or animal divides, the DNA in that cell must first replicate itself so that the two new cells have the same genetic material. Otherwise, each time a cell divided, it would lose half of its DNA. In DNA replication (Figure 1.5), the genetic material copies itself using a strand of DNA as a template. Replication begins when a protein made by a cell undergoing division binds to a section of the DNA called the origin. This event signals an enzyme to begin breaking the hydrogen bonds that hold the two strands of the helix together, causing the double helix structure of the DNA to “unzip.” As the DNA strands come apart, a complex enzyme called DNA polymerase that is

found in the nucleus of cells binds to each DNA strand segment and begins to add a new base unit to the strand. The added base must be compatible with the base on the parent DNA strand. Another enzyme then bonds the new nucleotides together with the parent DNA strand. Each DNA molecule now consists of one parent strand and one newly formed strand. With replication complete, the cell can then divide.

Summary

Cells have many organelles that must function together in order for the cell to survive. Each organelle has one or more functions that help the cell live, grow, and divide. DNA is very important to the cell since the code for building proteins is contained in the cell's DNA. The process of DNA replication allows the genetic code to be passed on to daughter cells.

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Lesson 2:
Cell Reproduction and Genetics

After organisms begin life, they grow and eventually reach maturity and reproduce. Their offspring then begin to grow and develop. A similar life cycle goes on at the cellular level. Young cells grow and mature until they are stimulated to reproduce. Cell reproduction takes place by cell division, in which the material in a cell is divided to produce two new cells. Cell division produces both body tissue cells and sex cells needed to produce offspring.

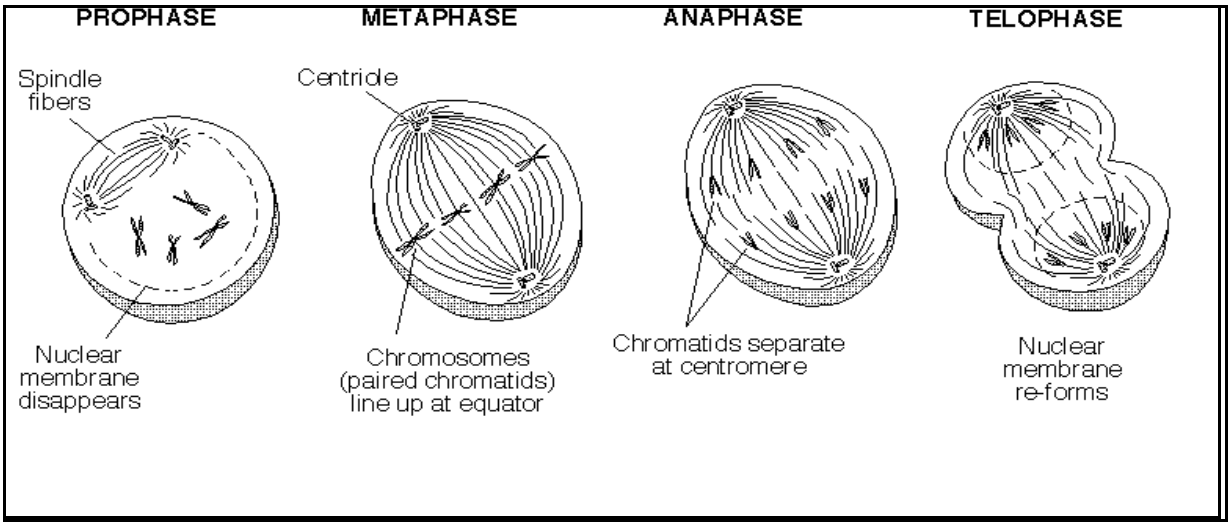
Mitosis

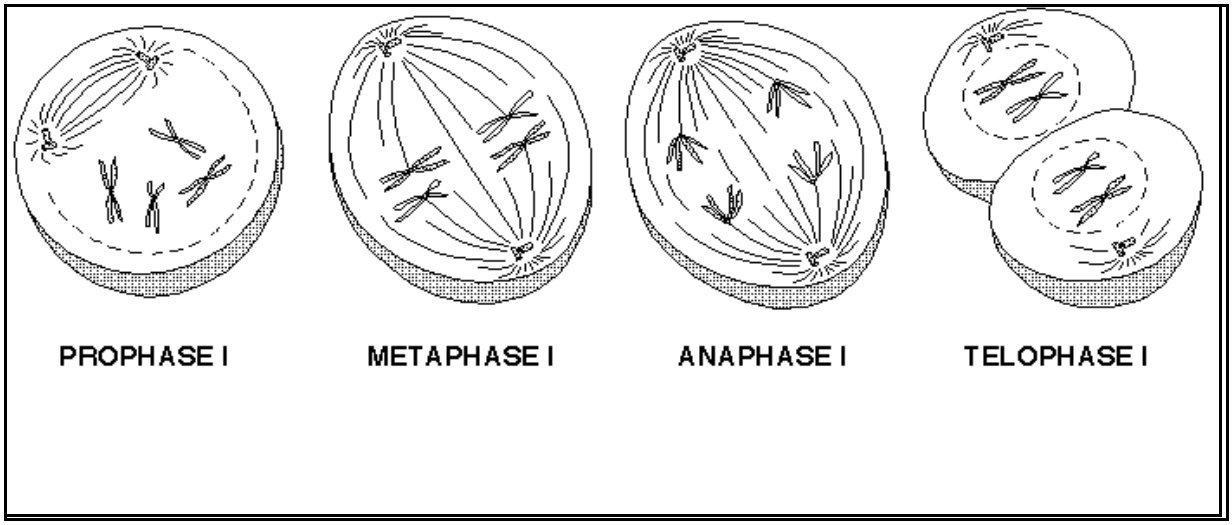
Mitosis is a type of cell division that takes place in somatic cells. Somatic cells include all the cells in an organism except the sex cells, or gametes (ova or sperm). Before mitosis begins, a cell replicates its genetic material. Each of the two new cells created by mitosis will therefore contain the same number of paired chromosomes as the parent cell. They will have two complete sets of chromosomes, or a diploid number of chromosomes. The process of mitosis involves four stages, which are illustrated in Figure 2.1.

The first stage of mitosis is prophase. The chromosomal material coils and condenses, and a double-stranded chromosomal structure becomes visible. This structure consists of two paired chromatids created by the duplication of DNA. Each double-stranded chromosomal unit has a point where the two chromatids connect. This point of connection, which is a body called the centromere, can occur at any point along the chromatids. The nuclear membrane then gradually dissolves. A network made up of complex protein units like hollow tubes, which are known as microtubules, begins forming around structures called centrioles, which start to move to opposite ends of the cell. The centrioles serve as anchors for the network of microtubules. This entire network is called the spindle. Spindle fibers extend from the centrioles toward the center of the cell. At this point, prophase ends.

Metaphase is the next stage of the process. The chromosomal units move to the center of the cell and form a line between the two poles formed by the centrioles. Each spindle fiber attaches to the centromere of one of the chromosomal units.

The third stage is called anaphase. The centromeres break and allow the spindle fibers to pull the two chromatids of the chromosomal unit apart. The chromosomes move toward opposite poles of the cell. The poles move even farther apart, elongating the cell. At the end of anaphase, the two poles of the cell each have a complete set of chromosomes.





The last phase, telophase, begins differently in animal and plant cells. In animal cells, the cell membrane pinches in at the center of the cell until the cell is completely divided into two cells. In plant cells, a structure called a cell plate forms and begins to divide the cell into two cells. A cell membrane forms on both sides of the cell plate, and eventually the cell plate changes into a cell wall. After the cell membrane or cell plate begins to form, a nuclear membrane develops around the two sets of chromosomes. The chromosomes themselves begin to uncoil and lose their distinct outlines. Mitosis ends when this process is complete.

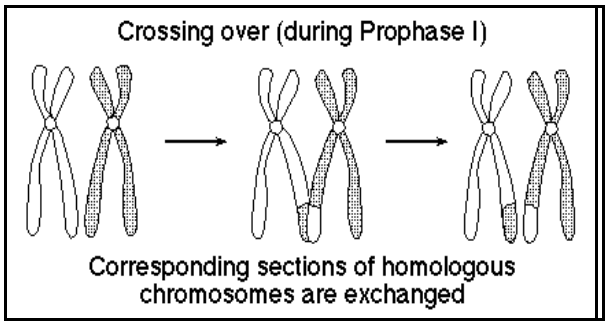
Meiosis

Meiosis is also a type of cell division, but it produces gametes rather than somatic cells. Meiosis produces four gametes, since it consists of two phases of cell division. The gametes produced contain only half the number of chromosomes of the original parent cell, or a single set of chromosomes. It is for this reason that these gametes are referred to as haploid cells.

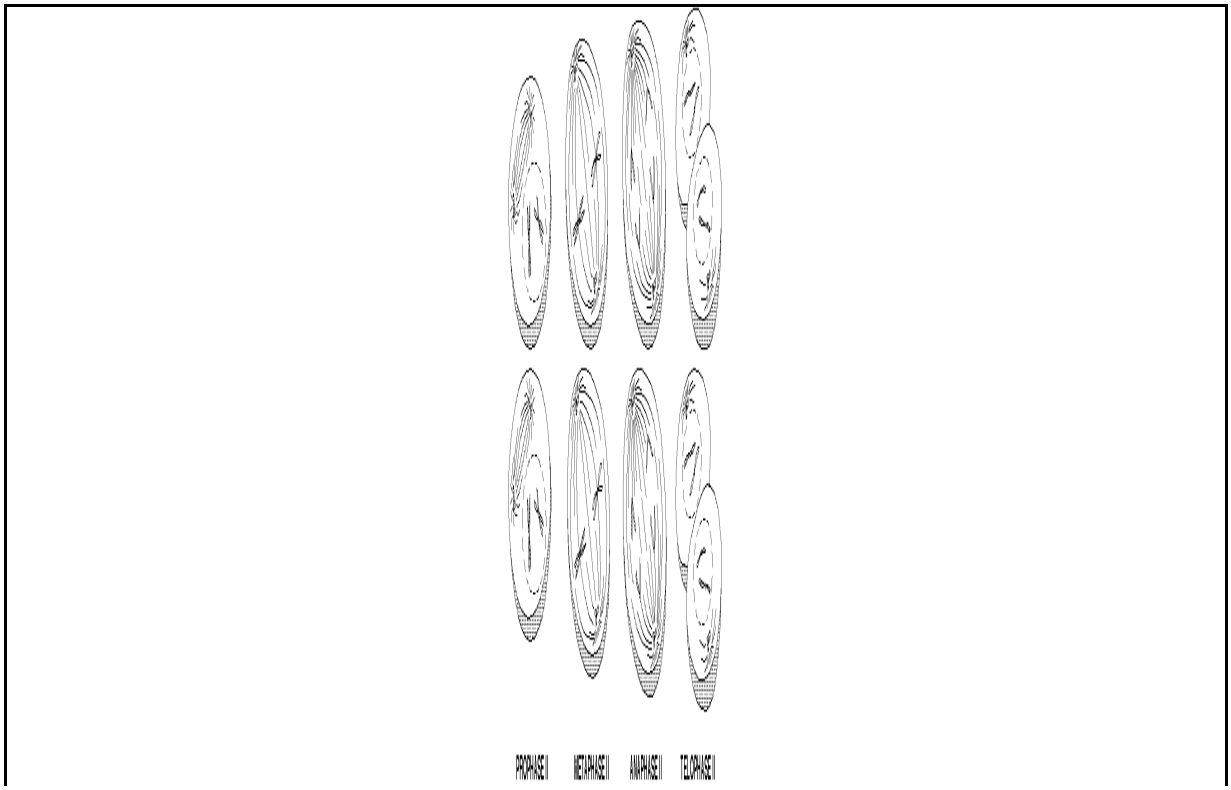
The first cell division process, or meiosis I (Figure 2.2), is somewhat similar to mitosis. The chromosomes replicate before the beginning of meiosis, just as they do before mitosis. During prophase I of meiosis, homologous chromosomes pair together. Homologous chromosomes are paired chromosomes that contain the same set of genes. One of the homologous chromosomes came from one of the organism's parents, and the other came from the other parent. They form a tetrad, a grouping of four chromatids side by side. The nonpaired chromatids may exchange segments through a process called "crossing over," in which a segment from one chromatid breaks off and reattaches to another. The process results in a change in the makeup of the chromosomes (see Figure 2.3). This exchange happens randomly. As in mitosis, the centrioles move apart and the spindle forms. The nuclear membrane dissolves.

Metaphase I is marked by homologous chromosomes lining up in the center of the cell. The spindle fiber ends attach to the centromeres of paired chromatids.

During anaphase I, homologous chromosomes separate and are pulled to different poles of the cell. The two cells formed after telophase will therefore not be genetically identical.



Telophase I can be identified by two distinct events. The first event is the formation of the cell membrane in animal cells or development of the cell plate and cell membrane in plant cells. The second event is the



formation of nuclear membranes around the two new nuclei. The result is two haploid daughter cells.

After meiosis I, the two cells go through a short period of rest and then begin meiosis II, shown in Figure 2.4. Unlike mitosis or meiosis I, the two cells do not undergo DNA replication. Meiosis II begins with the development of the spindle fibers and the movement of paired chromatids to the center of the cell during prophase II. During metaphase II, the chromosomal units line up in a row between the two poles and become attached to the spindle fibers. In anaphase II, the chromatids separate and move toward the opposite poles. In telophase II, the center of each of the two cells closes off with the formation of a cell membrane or cell plate, nuclei form, and the chromosomes uncoil. Meiosis yields four haploid daughter cells that are not identical to the parent cell.

Differences Between Mitosis and Meiosis

Mitosis and meiosis have four major differences. One of the more obvious differences is that mitosis produces two cells from one parent cell, while meiosis produces four cells from one parent cell. Another obvious difference is that mitosis produces diploid somatic cells, while meiosis produces haploid gametes. However, a more subtle difference is that while mitosis produces two identical cells, meiosis produces four nonidentical cells. During mitosis, chromosomes double and contribute an identical chromosome to each daughter cell, while in meiosis homologous chromosomes split and contribute nonidentical chromosomes to each daughter cell. The last major difference between mitosis and meiosis is that in meiosis a tetrad forms and allows "crossing over" of genes to occur between homologous chromosomes.

Dominant and Recessive Genes

Most chromosomes in all species of plants and animals work in pairs. For example, cattle have 60 chromosomes in the nucleus of every somatic cell. These chromosomes function as 30 pairs of chromosomes. Each chromosome has a homologous chromosome that has genes that code for the same information but in a somewhat different way. Each gene in a gene pair is either dominant or recessive.

The interaction between dominant and recessive genes can be seen by looking at coat color in cattle. One section of one of the chromosomes codes for coat color. The gene for coat color is found at the same location on both chromosomes. If one of these genes codes for black and the other codes for white, what will the coat color of the animal be? Since the black gene is a dominant gene in cattle, the animal in question would have a black coat. The dominant gene is expressed, or seen in the animal. A dominant gene masks or covers up the expression of a recessive gene, which will not be apparent as a physical trait of the animal. In this example, the recessive gene is the gene that codes for white.

Homozygous and Heterozygous Gene Pairs

The term allele is used to describe either of the two possible expressions of a gene or multiple genes that code for a specific trait. An allele is usually represented by a letter of the alphabet. If the gene acts as a dominant gene, a capital letter is used to represent it; a lowercase letter is used to represent a recessive gene. If a plant or animal has two dominant alleles or two recessive alleles for a specific trait, it is homozygous for that specific trait. The terms homozygous dominant and homozygous recessive are used to differentiate between the two types of homozygous traits. If, however, a plant or animal has one dominant allele and one recessive allele, it is heterozygous for that trait.

Genotypes and Phenotypes

The genotype of an animal or plant refers to the specific combination of the alleles it possesses for each genetic trait. It is the actual genetic make up of the organism; for the example given above, the genotype would be either BB, Bb, or bb. The phenotype is the expression or appearance of a trait as determined by the genotype.

Mutations

What happens when a base unit is mistakenly inserted, deleted, or miscoded during the replication of DNA? Such a mistake is called a mutation. A mutation is an alteration of the nucleotide sequence found in a DNA molecule. This alteration can happen during replication prior to the beginning of mitosis or meiosis; it affects the organism differently depending on when the mistake occurs. If the mutation occurs just prior to mitosis, the change in the genetic code will be passed on to the daughter cell and any cell descending from the parent cell. Cancer is an example of a somatic cell mutation in which the mutated cell rapidly reproduces. Mutations can also occur just prior to meiosis. In this case, the mutation is passed on to an organism's offspring if the gametes are fertilized. The offspring would have the altered DNA in every one of its cells.

Some mutations can be very beneficial, some can have a negative effect, and others may have no visible effect on an organism. An example of a positive mutation is the mutation that led to the development of the Polled Hereford breed of cattle. This breed was developed in the early 1900s by a rancher who noticed that calves from his Hereford cattle occasionally did not develop horns.

Summary

Cell reproduction is carried out through the processes of mitosis and meiosis. The genetic material passed on through these processes includes dominant and recessive genes and heterozygous and homozygous gene pairs. The genes an organism possesses determine its genotype and phenotype. Sometimes mutations also have an effect on the organism.

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Lesson 3:
Genetic Modification

Genetic modification is a very complicated process performed by highly trained researchers. This lesson will cover the basic procedures used in genetic engineering.

Gene Mapping and Gene Sequencing

Before the driver of a car makes a change in the planned route, he or she should check a road map to find out which roads to add to the route and which roads to avoid. Making changes in the genetic code of a cell is much the same, except that in this case the driver or researcher is driving blind because DNA cannot be seen except under extremely powerful microscopes. The researcher needs a map of the chromosomes of an organism to be able to select specific genes for modification. Gene mapping is the process of finding the location of genes for specific traits on the chromosomes of an organism. An example is a genome map of a corn plant, which shows the parts of the chromosomes that are responsible for plant height.

Gene sequencing is a related process that shows the order of all the base units (A, T, C, G) as they line up on a particular gene. A gene sequence is really a map of a single gene, which may be comprised of 100,000 or more base pairs. Gene sequencing is important to scientists because it allows them to recognize how to cut out a particular gene or gene fragment so that it can be placed into the DNA of the cell being modified.

DNA Extraction

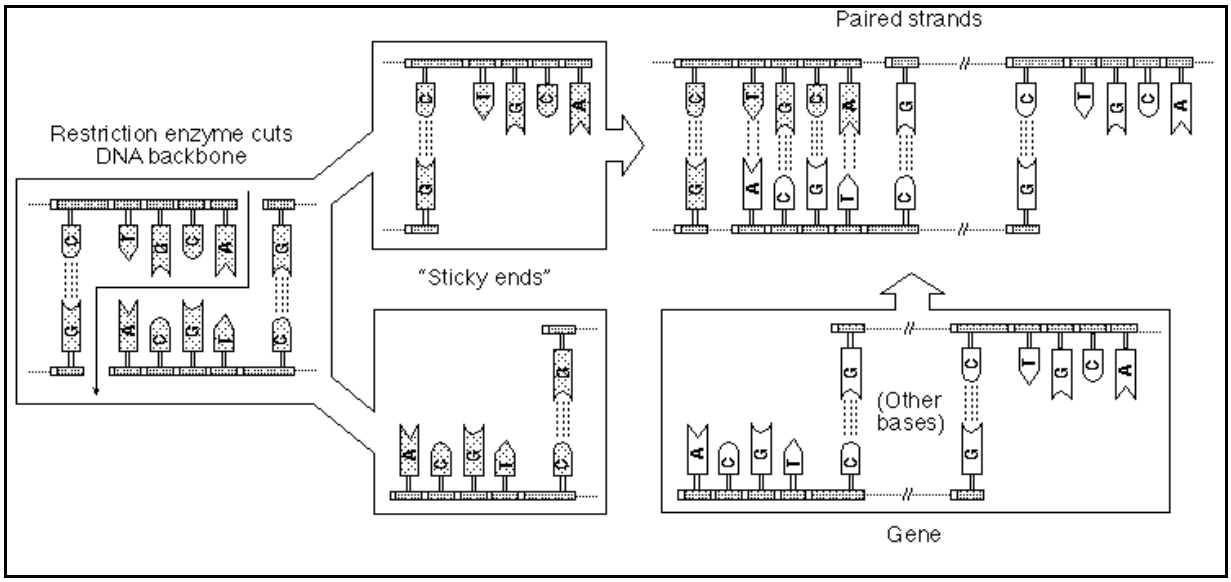
Once a desired gene has been identified, it must be removed from the cell. DNA extraction is a three-step process. The cell membrane or cell wall must first be broken down to release the cytoplasm. The nuclear membrane must also be broken to release the chromosomes. Researchers accomplish this with the use of a surfactant, a fatty acid compound much like a household detergent. These compounds consist of lipids, just like the cell membrane. The surfactant breaks down the cellular membranes at a rate determined by temperature. Heat accelerates this process.

The second step involves the use of a protease, such as the enzyme papain. DNA strands in the chromosome wrap around protein molecules called histones. The protease will split this protein and the other protein contents of the cytoplasm.

The last step involves separating the DNA from the other cell components. Cold alcohol is added to the cellular solution. The DNA strands will clump together and rise to the top of the alcohol, since DNA is insoluble in alcohols. The DNA is then collected for later use.

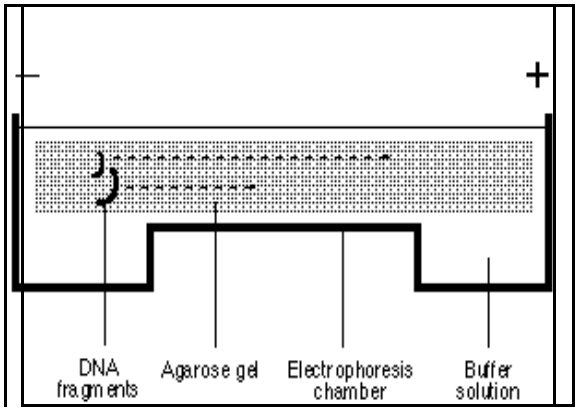
Restriction Digestion

Restriction digestion is the process of cutting DNA into smaller fragments. The DNA is cut by restriction enzymes, which are essentially biochemical scissors. Each restriction enzyme cuts DNA at a specific sequence of nucleotide base pairs, as illustrated in Figure 3.1. The sequence is called a restriction site. All DNA contains natural restriction sites. Researchers use restriction enzymes to cut genes or DNA fragments out of extracted DNA strands. Restriction digestion is useful to researchers in several ways. For example, researchers can identify whether a strand of DNA has a particular gene on it. They can also cut a gene from a strand for gene splicing.



Gel Electrophoresis

Gel electrophoresis is a process in which researchers apply an electric current to a gel to separate different lengths of DNA fragments into groups. The researchers can then recover a desired gene or gene fragment. Performing gel electrophoresis requires an electrophoresis box, a buffer solution, a special power supply, and a gel made from agarose or another agent. One end of the electrophoresis box has a positive pole and the other has a negative pole. The gel rests between them. The researcher places DNA fragments that have been stained with a dye in small wells or pockets at the end of the gel nearest the negative pole and applies an electric current to the gel. The buffer solution keeps the gel moist and facilitates the flow of the electrical current. The current causes the DNA fragments, which are negatively charged, to be repelled away from the negative pole and attracted to the positive pole (Figure 3.2). Short lengths of DNA will move through the gel faster than long lengths. The electric current is removed just before the short fragments reach the end of the gel. Fragments of DNA of the same size will be grouped at one spot on the gel. The markings caused by fragments of different sizes are called bands.



Gene-Splicing

Gene-splicing is the process of inserting a piece of DNA into a chromosome of a cell. It is also called ligation because the enzyme ligase is the biochemical glue that joins the pieces of DNA. Gene-splicing involves several steps. The process begins with the researcher cutting out a piece of DNA with a restriction enzyme. The correct restriction enzyme must be used so that the ends of the DNA will be "sticky," meaning that they contain bases that are complementary to the bases of the fragment to be incorporated. Gel electrophoresis must be performed to separate the DNA fragments by size and isolate the appropriate fragment. The

researcher then joins the ends of the selected fragment to the DNA being transformed through a chemical reaction called a ligase reaction. Ligase chemically joins two DNA fragments by causing a bond to form between the phosphate portion of each fragment. The reaction is often done in a test tube. The result is a cell containing DNA from two different sources that forms a new genetic code, which is therefore called recombinant DNA.

This cell is then grown into an organism. In transgenic animals, the gene is spliced into the chromosomes of a fertilized egg, which is then implanted in the female reproductive tract. In plants, the plant cell with the transferred genetic material (often referred to as a transgene) is stimulated to grow into a plant. In each case, the organism has a copy of the new genetic information in every cell.

Summary

Genetic engineering is accomplished through the use of several processes. Gene mapping is used to locate the desired trait. DNA extraction isolates the DNA containing the desired gene. Restriction digestion then cuts the extracted DNA into specific pieces. Electrophoresis separates the DNA fragments into groups of like size. Gene-splicing joins the isolated piece of DNA to the DNA being modified. These basic genetic engineering technologies are used in research laboratories across the country.

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Lesson 1:
Artificial Insemination

Animal biotechnology began when humans began selecting and pairing more desirable animals during breeding to produce offspring of higher quality. Artificial insemination (AI) is an extension of selective breeding that gives livestock managers more options for improving offspring. The advantages and disadvantages of AI must be examined if it is to be used effectively.

Artificial Insemination

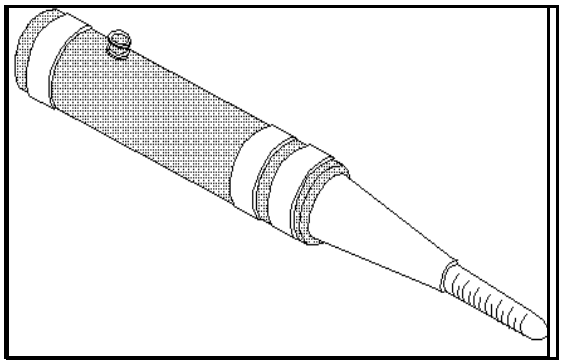
In 1780, an Italian researcher first developed a procedure for impregnating female animals without the presence of a male animal at breeding time. However, artificial insemination was not used by breeders until the late nineteenth and early twentieth centuries. Artificial insemination (AI) is the process of collecting semen from a male animal and placing it in the reproductive tract of a female animal. It is a form of biotechnology that is commonly used by livestock producers across the United States.

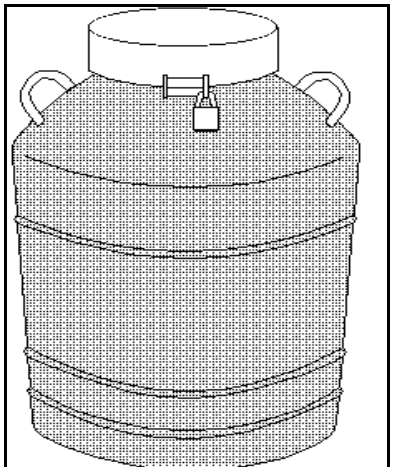
The Benefits of Artificial Insemination

Both artificial insemination and natural breeding have certain benefits. A major benefit of AI is that it allows producers to select and use male animals in their breeding programs that are proven performers, regardless of where the animals are physically located. Another benefit of AI is that reproductive or venereal diseases are not spread between breeding animals. A third benefit of AI is that it can reduce or eliminate the cost of owning and maintaining male animals for breeding purposes. The cost of the semen, the insemination process, and the hormones needed to manipulate the estrous cycle of female animals offset some of the economic benefits, but an AI system can still be more cost effective than a natural breeding system. One of the broader benefits of AI for the livestock industry as a whole is that the genetic improvement of livestock populations through the use of superior animals occurs much more quickly with AI, because of a dramatic increase in the number of offspring a male animal can produce (sire) per year. A single bull can only breed about 60 cows naturally in a year, but that same bull can be used to inseminate nearly 20,000 cows a year with AI.

Equipment for Artificial Insemination

Several different pieces of equipment are used for artificial insemination. Semen collection is most commonly done through the use of a dummy, which is a female replica. Male animals are trained to mount the dummy, and the penis is guided into an artificial vagina. The artificial vagina (see Figure 1.1) is a water-filled plastic sheath and has a collection tube in one end that holds the semen after ejaculation. A microscope is used when analyzing the collected semen. The semen is put into long, thin plastic tubes called semen straws. Each straw holds the amount of semen needed to breed one female. These straws are frozen and stored in an aluminum semen tank (Figure 1.2) containing liquid nitrogen. The straws are placed in an insemination instrument at the time of breeding. The insemination instrument is a long syringe-like tool that





holds the straw and deposits the semen into the female reproductive tract.

The Process of Artificial Insemination

Artificial insemination begins with the collection, inspection, and preparation of the semen. The collection of semen is important, since poor collection techniques will yield poor quality semen. After semen is collected using an artificial vagina, it is analyzed to examine the motility (active movement), shape, and quantity of the sperm. When the semen has been inspected, an extender is added to the semen to increase the volume. Several different types of extenders are used, but the most common are citrate, egg-yolk phosphate, and homogenized milk. These extenders protect and provide nourishment to the sperm when they are frozen. After the extenders have been added to the semen, it is placed in straws and frozen in liquid nitrogen at -320 degrees Fahrenheit.

The next part of the AI process begins when a producer decides to breed his or her animals. Producers must carefully manage the timing of insemination. Good semen and correct insemination procedures will not result in successful fertilization without proper timing. Each animal species has a different estrous cycle, which dictates the timing of insemination. Generally, insemination should occur shortly before ovulation.

When the time is right, the semen is thawed using proper thawing procedures to ensure that the sperm are not damaged. Once the semen is thawed, the straw is placed in the inseminating instrument, which is then inserted into the vagina of the animal being bred. The instrument is guided through the cervix, and the semen is placed just at the end of the cervix or the beginning of the uterus. A trained technician should perform this part of the process.

Manipulation of the Estrous Cycle

Female animals naturally produce the hormones that control the estrous cycle. However, through the injection of certain hormones, a producer can cause females to begin estrous as a group. This process, which is called estrous synchronization, simplifies the management of an artificial insemination program, because the animals in the group can all be bred within one or two days of each other.

Summary

Artificial insemination is an animal biotechnology that has a significant impact on the livestock industry. Artificial insemination is the process of collecting sperm from a male animal and placing it in the reproductive tract of a female animal. AI requires special equipment and close monitoring. The timing of insemination is critical to its success.

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Lesson 2:
Embryo Transfer Technologies

Today's science is tomorrow's applied technology. Embryo transfer is a good example of this trend. Once a complicated procedure requiring surgery, it has become a technology that some livestock producers are using in their own barns. This lesson will describe how embryo transfer is done, as well as some more advanced embryo manipulation methods, such as cloning.

The Process of Embryo Transfer

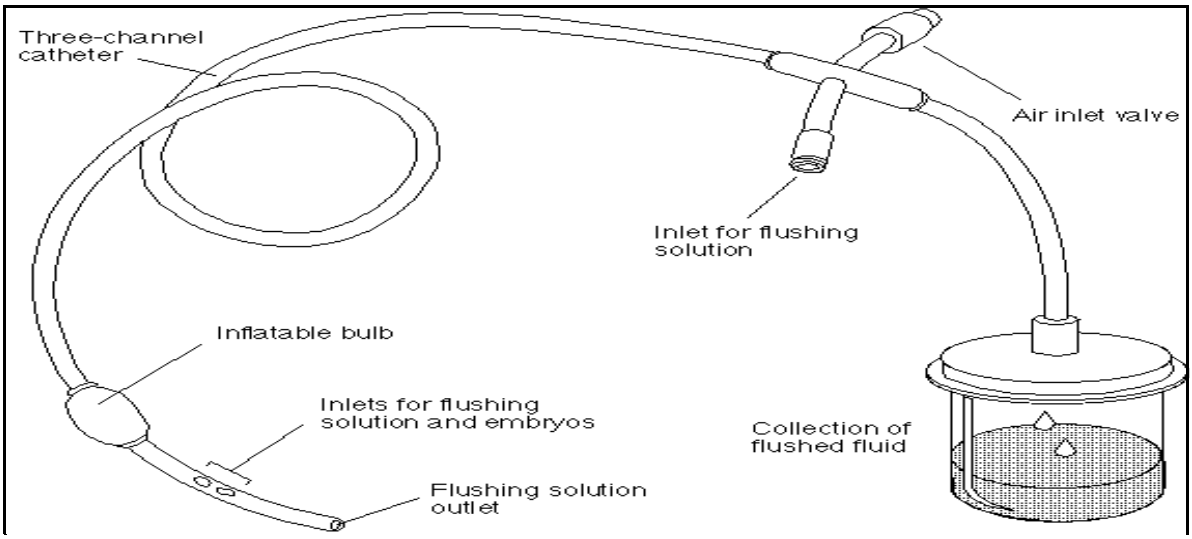
Embryo transfer (ET) is the process of transplanting embryos (fertilized eggs) from a donor female to a recipient female. Although ET is possible in several species of livestock, including sheep, goats, horses and swine, it is most common in cattle, which will be the focus of this lesson. The embryo transfer process has six steps. The first step involves the synchronization of estrous in the donor and recipient, which makes it possible for the collected embryos to be transferred to the recipient without being frozen. Next, the donor must be superovulated. Injecting the donor with a hormone like prostaglandin causes superovulation, or the release of multiple ova. The third step involves breeding the donor cow, either naturally or by artificial insemination. Next, the fertilized ova are collected from the donor through a process called embryo flushing in which fluid is used to wash the embryos out of the female reproductive tract. The fifth step in the embryo transfer process involves isolating and examining the embryos. Healthy embryos are transferred to recipients or frozen for later transfer.

Advantages of Embryo Transfer

Embryo transfer has several distinct advantages over natural breeding. It can increase the reproductive potential of superior females by allowing the female to produce multiple offspring each year. In addition, embryo transfer increases the rate of genetic improvement in a herd. The average cow can produce four to five calves per year using embryo transfer technology. With a superior cow providing four to five calves per year, high quality herd replacement heifers and bulls accumulate faster. Another advantage of ET involves progeny testing, in which offspring are evaluated for growth characteristics to determine whether an animal produces quality offspring. Using ET, female animals can be more easily and accurately progeny tested since they produce offspring more quickly; in three years, a cow should produce the ten calves needed for progeny rating. Finally, since shipping live animals internationally is a difficult and expensive process, embryo transfer has been employed as a way to use breeding stock from other countries. ET has been used to import and export rare breeds and the offspring of genetically superior animals.

Embryo Transfer Equipment

Embryo transfer requires the use of some specialized equipment. The equipment needed to flush the donor cow includes a special catheter that has three narrow tubes encased in one long tube (see Figure 2.1). One tube inflates the bulb found near the end of the catheter. Another tube injects the flushing solution into the uterine horn to flush out the embryos. The third tube collects the flushing solution and embryos from the donor's reproductive tract. The catheter is inserted into the vagina and through the cervix with a device called a stylet. A collection cylinder holds the flushing solution and embryos after they have been removed from the donor. The technician needs a shoulder-length glove and lubricant to palpate the donor and recipient. Syringes are needed to inflate the bulb in the catheter, inject hormones, and give a local anesthesia. The equipment needed to examine the embryos includes a microscope, a pipette embryo-handling tool, and a gridded search dish. Transferring the embryo to the recipient requires the use of a plastic embryo straw, which holds the embryo for transfer, and an embryo transfer gun, which is used to expel the embryo into the reproductive tract.



Management of Superovulation

When prostaglandin is used to manipulate the heat cycle, preparation of the donor cow begins ten days after she is in standing heat with an injection of the hormone FSH, or follicle stimulating hormone. The injection of large amounts of FSH causes the ovaries of the donor to release multiple ova. These injections are given once in the morning and once in the evening, until a total of seven injections have been given. On the third day of the procedure, prostaglandin is injected into the donor in the morning and evening. These two injections will cause the donor to come into estrus in 48 hours, and she can then be bred either naturally or through artificial insemination. The management of the process of superovulation is slightly different when other hormones are used.

The Embryo Flush Process

The embryo flush process is done seven days after breeding. The technician injects an epidural anesthesia into the space between two cervical vertebrae. The epidural causes the rectal muscles to relax, which aids in the insertion of the technician's hand into the rectal tract to guide the catheter. The technician uses the stylet to insert the special catheter into the vagina, through the cervix, and into the right uterine horn. He or she must palpate the donor carefully to guide the catheter into the proper location. The bulb near the end of the catheter is inflated to block off the uterine horn while it is being flushed.

A sterile flushing solution is allowed to flow into the uterine horn under the force of gravity until 500 milliliters of the solution is in the horn. The technician then starts to massage it to loosen the embryos. When the uterine horn is filled with flushing fluid, the technician opens the outlet tube of the catheter and collects the fluid and embryos in the collection cylinder. This process is repeated with the left uterine horn.

Because of their weight, the embryos settle to the bottom of the collection cylinder. The fluid above the embryos is carefully siphoned off. The embryos are ready to be counted and characterized, or examined for quality. They must be normal in appearance and of the correct size to be usable.

Transferring the Embryo into the Recipient

After the collected embryos have been washed and examined, technicians load embryos that are to be transferred to recipients into embryo straws. They are then prepared to be either transferred into recipient cows or frozen in a container of liquid nitrogen at -320 degrees Fahrenheit. The recipients have already been prepared to receive the embryos through estrous synchronization. A technician loads an embryo transfer gun

with a straw and inserts it into the recipient cow's vagina. He or she guides it through the cervix and into the uterus, where the embryo is expelled.

Cloning

Cloning is the asexual reproduction of an organism in which the resulting organisms are identical. The livestock industry uses two basic methods of cloning. In the first method, the researcher physically splits the embryo into two halves as it is dividing. Each half is transferred to a recipient and develops normally. Embryo splitting doubles the number of embryos available for transfer.

Nuclear transfer is a second method of cloning. Nuclear transfer involves removing the nucleus of an unfertilized ovum. A cell is then extracted from a parent organism and fused into the ovum without a nucleus using an electrical pulse. The new cell has a diploid number of chromosomes and will develop as if it were a natural embryo. However, it must be stimulated to act like a fertilized ova and begin dividing. Nuclear transfer technology can multiply the number of embryos by 16, 32 or even 64, depending on the number of cells available in the parent embryo.

Benefits of Cloning

Cloning has several advantages. It can increase the number of highly prized animals produced because it multiplies the number of collected embryos. Cloned animals are valuable to researchers doing live animal experiments. Fewer animals can be used in these tests because all of the animals--control animals and experimental animals--are identical. Animals genetically altered to produce pharmaceuticals could be cloned as well, which would reduce the cost of producing the animals.

In Vitro Fertilization

In vitro literally means "in glass." In vitro fertilization (IVF) is a process in which immature follicles (ova) are collected from the ovaries of a female animal, stimulated to mature, and fertilized outside the female reproductive tract in a test tube. The fertilized embryos can be transferred to recipient animals.

The process of IVF begins a few days before ovulation. A technician inserts a special probe containing an ultrasound sensor into the vagina and moves one of the ovaries to a position directly above the vaginal wall. The ultrasound equipment is then used to locate the follicles. The technician inserts a needle through the vaginal wall and into the ovary. The needle is attached to a vacuum device that sucks the follicles into a collection bottle. The follicles that are collected are stimulated to mature in the laboratory and are then fertilized.

Summary

Embryo transfer, which has only been in use since the early 1980s, is a relatively new technology in the livestock industry, but the number of dairy and beef cattle producers using it is growing rapidly. Embryo transfer is the process of transplanting embryos from a donor female to a recipient. The procedure involves superovulating a donor, flushing the embryos out of the donor, and transferring the collected embryos to a recipient. More advanced techniques such as embryo splitting, nuclear transfer, and in vitro fertilization are also beginning to be used in the livestock industry.

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Lesson 3:
Applications of Biotechnology in Animal Agriculture

The previous two lessons discussed artificial insemination and embryo transfer. These applications of biotechnology have a direct impact on the genetic makeup of the animals produced. Other forms of biotechnology, such as the use of biotechnology to produce supplemental hormones and animal health products, affect animals more indirectly.

Supplemental Hormones

Supplemental hormones are chemical messengers administered to animals that stimulate them to grow, produce more milk, or improve their performance in another way. Many of the supplemental hormones produced are growth hormones. Human beings and animals naturally produce the growth hormone somatotropin in their pituitary glands, although the somatotropin produced by two species is very different. For example, bovine somatotropin has no noticeable effect when injected into a human being.

Bovine somatotropin (BST) is one of the best known supplemental hormones. In 1993, the FDA approved BST for use as a drug. When injected into a cow, BST causes a secondary hormone to be released that increases blood flow in the mammary glands. This blood flow increases the amount of milk produced by the cow by 10 to 15 percent.

Porcine somatotropin (PST) is another growth hormone. When PST is injected into a pig, it causes the pig to grow about 15 percent faster and consume 20 percent less feed. In addition, muscle mass, including the loin eye area, increases, while backfat is reduced. Researchers are searching for a way to put PST in an implant to eliminate the need for regular injections. The FDA has not yet approved the use of PST.

Growth hormone releasing factor (GHRF) is not itself a growth hormone, but it stimulates the pituitary gland to release larger amounts of growth hormones. Researchers are looking for ways to use GHRF to improve animal production.

Supplemental hormones have shown promise for use in the poultry industry. Research has shown that the use of a chicken growth hormone shortens the time needed for broilers to reach market size by 15 percent. A chicken molting hormone has shown promise in increasing egg production levels.

Producing Supplemental Hormones and Animal Health Products

Before modern biotechnology was developed, the only way to obtain somatotropin was to collect it from the brains of slaughtered animals. However, only a small amount of the hormone could be collected from each animal. The somatotropin was therefore very expensive.

Bacteria can now be engineered to make proteins that they do not normally produce, allowing supplemental hormones like BST to be synthesized. To produce BST, researchers located and isolated the gene that stimulates the production of bovine somatotropin. They inserted it into a plasmid taken from a bacterium. Scientists opened up the plasmid ring with a restriction enzyme and spliced the gene into the opening. The plasmid was reinserted into the bacterium. Modified bacteria are placed in a fermentation tank under ideal conditions for the bacteria to grow and divide. After a substantial number of microorganisms are produced, somatotropin can be purified from the bacteria.

Poor animal health costs the U.S. livestock industry approximately $17 billion annually. Advances in biotechnology have strengthened the fight against animal disease. Biotechnology is used to improve the health of livestock in three major ways.

Monoclonal antibody technology is one way biotechnology is used to produce animal health products. When a virus, bacteria, or parasite attacks an animal, the animal's immune system responds by producing proteins called antibodies. Antibodies are very specific in their function; they are only produced in response to a particular antigen (a substance that triggers an immune response). When an animal is vaccinated with a weakened form of the disease-causing organism, the animal's body produces antibodies that continue to look for the antigen for years after the vaccination. Monoclonal antibodies are produced by fusing a tumor cell to an immune system cell

that produces antibodies against a specific antigen. This process yields a cell that divides rapidly (because of the tumor cell) and produces the desired antibody. Several tests for diseases have been developed from this technology, such as the quick sale barn test for brucellosis and the animal pregnancy test.

The second way biotechnology affects animal health is through the development of therapeutic proteins. In the past, veterinarians have not had a drug to use to fight viruses. When injected into an animal, therapeutic proteins like interferon and interleukin-2 attack viruses. They also stimulate the animal's immune system to attack the viruses. Like growth hormones, therapeutic proteins are produced by genetically modified bacteria. Preventing shipping fever, a disease found in cattle, has been a major focus of the use of therapeutic proteins. Shipping fever is the result of an attack by several viruses that the animal's immune system normally repels; this defense is weakened when an animal is under stress. Injections of therapeutic proteins may help prevent shipping fever.

The third way that biotechnology is influencing animal health is through genetically engineered vaccines. Early vaccines were made from dead or weakened disease-carrying organisms. These vaccines can take a long time to develop, must be refrigerated, and may have side effects. Vaccines developed using genetically modified bacteria contain only the antigen of the disease-causing organism. They stimulate the immune system to produce antibodies against the antigen. Genetically engineered vaccines are safer and can be produced relatively quickly. Examples of vaccines produced through biotechnology include vaccines for scours in pigs, foot-and-mouth disease, pink eye, and tapeworms in sheep.

DNA Fingerprinting in the Livestock Industry

DNA fingerprinting is the result of fragmenting DNA with a restriction enzyme and then segregating the fragments with gel electrophoresis to produce a distinctive pattern. It is being used in the livestock industry to positively identify individual animals. In the past, valuable animals like race horses have been stolen by switching an animal with a look-alike. DNA fingerprinting can accurately identify stolen animals. It can also verify that an animal is the offspring of a particular set of parents. Some breed associations require that a blood sample be submitted with the application for registration for an animal so that a DNA fingerprint can be made. DNA fingerprinting is also being used to identify transgenic animals for patenting purposes.

Emerging Applications of Biotechnology in Animal Agriculture

Research continues into the development of new and expanded applications of biotechnology in animal agriculture. Currently, genetically engineered vaccines for foot rot in cattle and strangles in horses are under development. The livestock feed industry is looking into the possibility of using genetically modified bacteria to produce protein for feeds; the bacteria containing the desired protein would be killed and the contents added to the feed. The feed industry is also researching methods of engineering rumen bacteria so that animals can better use feedstuffs that are normally hard to digest.

The cloning of adult animals is emerging as a new area of animal biotechnology. In early 1997, Dolly, a sheep cloned from a single cell taken from an adult animal, was introduced to the world. Although this type of cloning is possible, it is extremely expensive, and its applications are likely to be limited to a few highly specialized functions. For example, if animals were genetically modified to grow human organs, cloning these animals would allow their numbers to increase more quickly.

Summary

Biotechnology is playing a growing role in animal agriculture. From the use of bacteria-produced somatotropin to the development of genetically engineered vaccines, biotechnology is changing the livestock industry. As research continues, more applications of biotechnology will affect the production of livestock.

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Lesson 4:
The Impact of Biotechnology in Animal Agriculture

With more than twenty companies dedicated to the development of animal biotechnology products and many other large companies that conduct research in this field, new animal biotechnology products will likely be on the market soon. A variety of career opportunities exist in this new but rapidly growing field. A number of economic and social impacts accompany this growth in animal biotechnology. The industry will have to address these issues.

Careers in Animal Biotechnology

Careers in animal biotechnology include jobs that use the products of animal biotechnology (such as a livestock producer) and positions in the companies that develop and market these products. Biotechnology companies have a variety of job positions. Large companies usually have more specialized positions, while smaller companies have positions that include a broad range of responsibilities. However, most companies have one or more employees working in eight major areas. These major areas are research and development, quality control, clinical research, manufacturing and production, regulatory affairs, information systems, marketing and sales, and administration. The jobs in the different areas vary in the amount of education they require, ranging from a high school diploma to a doctorate in a specific scientific field.

Research and development - The area of research and development (R&D) involves the actual laboratory research needed to develop potentially useful products. Positions in this area include glass washer, laboratory assistant, research assistant, postdoctoral fellow (a term for a new scientist), and research director/principle investigator (experienced scientists).

Quality control - This area includes positions such as quality control analyst, environmental health and safety specialist, equipment validation engineer, and validation technician.

Clinical research - After some products are developed, they must be tested on live animals in a clinical research setting. Positions in this area include clinical coordinator, clinical data specialist, clinical research associate, and animal handler/technician.

Manufacturing and production - The manufacturing and production area offers a variety of positions, including product development engineer, manufacturing engineer or technician, instrument calibration technician, and packaging operator.

Regulatory affairs - Regulatory affairs offers positions for specialists who work with regulatory agencies to obtain approval for products. Examples of positions available in this area include regulatory affairs specialist and documentation specialist.

Information systems - Positions in information systems include scientific programmer analyst and literature research assistant.

Marketing and sales - Biotechnology products must be marketed, which is the responsibility of those involved in the marketing and sales area. Positions in this area include market research analyst, sales representative, and customer service representative.

Administration - In administration, positions such as human resources representative, supply buyer, and patent administrator are available.

Economic Factors Affecting Producers

One of the most important questions livestock producers face when a new technology is put on the market is whether to use it. To answer this question, producers must consider the benefit-to-cost ratio. The ratio is a comparison of the economic benefits of using the product to the costs of using the product. For example, if a new genetically engineered feed additive costs $6 per feeder calf to use but increases feed efficiency by 20 percent, which saves $18 in feed costs, then the benefit-to-cost ratio would be 3 (18 ÷ 6). If the ratio has a value of two or greater, the product is considered cost effective.

A second economic consideration that producers must take into account is the cost of not using a biotechnology product, which is not a simple task. Producers must be able to provide a competitive product. If most producers begin to adopt a new technology, the price of livestock may drop, making the use of the product necessary.

The reliability of a biotechnology product is also important. Producers must evaluate the actual effects of using the product. If a product does not perform as well as expected or is not reliable in its performance, the value of the product is not as high.

Finally, livestock producers must consider not just the cost in actual dollars but the time required for the additional management and training that is often associated with the use of new products. This economic consideration is frequently overlooked when a new product is introduced.

Consumer Health and Safety Concerns

The public, those who buy meat, dairy, and egg products, are consumers of animal biotechnology. Many people are concerned or fearful about animal biotechnology because they do not understand the technology. This lack of understanding lends itself to the acceptance of rumors as fact. Consumers have also become skeptical about research findings due in part to research reports like those about substances “shown” to cause cancer, since the quality of some cancer research studies has come into question.

The effect of these factors on biotechnology is that when research is published that suggests that new biotechnology products are safe, many consumers are not convinced. Consumers of fresh vegetables have recently turned to higher-priced “natural” or “organic” foods because they see them as healthier than nonorganic foods. This consumer perspective may be transferred to animal products, producing a new market for “natural” meat, milk, and eggs.

Is there a justification for these consumer concerns? The answer to this question is both yes and no. Yes, because consumers should always be concerned about the safety and wholesomeness of the foods they buy. They should also be informed about the methods used to produce those foods. No, because animal biotechnology products must be shown to be safe before regulatory agencies approve them.

Global Social Impacts of Animal Biotechnology

Agriculture has historically had a worldwide social impact. As the world population grows, the need for animal products will increase as well. Biotechnology has the potential to increase the global supply of meat, dairy products, and eggs. The real question, which cannot be conclusively answered, is whether animal biotechnology can increase the production of animal products without an equal increase in production inputs. BST, for example, causes cows to produce more milk, but these cows require more feed. Unless those extra inputs are available, production cannot increase.

The mid-1990s has also seen a considerable amount of debate take place in Europe over the use of biotechnology by the developed world. For example, Europeans have debated the development of transgenic animals, such as genetically modified species of fish. Scientists have developed thirteen genetically modified species of fish that grow 20 to 100 percent faster than unmodified fish. If these modified fish are accidentally or intentionally released into some of the world’s oceans, will the unmodified fish be able to compete for food?

Will the fish spawn differently? What would be the result of a cross between a modified and an unmodified fish? Could one country release modified fish without the approval of other countries? These types of international concerns must be addressed. The international political environment will determine the extent of the use of animal biotechnology.

A third impact of animal biotechnology is that it may change the number of livestock producers needed in the United States and the world. If animal products can be produced more quickly and with fewer losses due to disease, will fewer producers be able to supply the meat, milk, and egg demands of the national and worldwide markets? The answer to this question is unclear. On one hand, if population growth causes demand to increase faster than production, the need for producers will grow. On the other hand, if the production of animal products increases faster than the demand, fewer producers will be needed.

Summary

Livestock producers demand biotechnology products that make economic sense. Consumers demand food products that are safe and healthy. The world needs answers concerning the social impact of animal biotechnology. The field of animal biotechnology faces several challenges but promises many rewards. As animal biotechnology continues to advance, the number of career positions available in this field will increase.

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Lesson 1:
Traditional Plant Breeding

Traditional plant breeding technologies are described in this lesson. Basic breeding practices include natural crossbreeding, selective breeding, and hybridization. Modern plant biotechnology is founded in plant breeding practices that are thousands of years old.

Natural Crossbreeding

Natural crossbreeding is the name for the reproductive process in which two plant varieties, which have different genotypes, sexually reproduce without human intervention. Natural crossbreeding allows the random mixing of genes to occur within a species. Desirable and undesirable traits are combined within the plant species. Plants that receive more vigorous genes generally grow and reproduce better than plants that do not. Weaker plants will therefore very gradually diminish in number as stronger plants dominate. This gradual improvement of the species can be accelerated through selective breeding practices.

Selective Breeding

Selective breeding is the process of identifying plants with desirable traits and causing them to reproduce. Plants are selectively bred mainly for two reasons: to increase the production of the useful parts of the plant or to increase the ability of a plant to withstand harsh environments, disease, or plant pests. Selective breeding can be done asexually or sexually. Many horticulture crops are reproduced asexually. Most field crops have traditionally been reproduced by sexual breeding methods, but more recently the asexual method of plant tissue culture has been used. Sexual breeding methods include inbreeding and hybridization. Inbreeding is the crossing of closely related plants to cause their offspring's traits to become more homozygous. Hybridization occurs when two inbred plants that are genetically different are crossed to produce plants that are superior to both the parent plants.

Advantages and Disadvantages of Selective Breeding

Selective breeding has two advantages. It allows the plant breeder to increase the occurrence of desired plant traits; typically, the most important trait is crop yield. Selective breeding also helps to make the performance of a crop more predictable since the selected plants are multiplied by controlling their pollination to produce a more uniform crop of seeds. This seed crop is sold to farmers who produce the final product.

Selective breeding also has some disadvantages. While the occurrence of desired traits increases, the occurrence of undesirable traits may also increase. As the selected plants are bred, the plants become more homozygous for both desired and undesired traits. A second disadvantage is that the genetic diversity of a crop species decreases as more similar plants are selected. Some native varieties of crops have been lost due to the extensive use of fast-growing high-yield varieties that crowd out the plants that grow more slowly. Another disadvantage of selective breeding is that the uniformity of the crop plants can increase insect problems. Insects that like a certain crop can multiply quickly when the crop is more uniform and cause a greater amount of crop damage.

Hybrids

Hybrids are plants produced by crossing two inbred lines of plants that are greatly different genetically. Before a hybrid is produced, inbreeding is used to develop a consistent plant phenotype. Breeders force a plant to self-pollinate and then force its offspring to do the same. They repeat this process five to seven times so that the plants will consistently express the same phenotype.

Breeders use three common methods to produce a hybrid seed. The first method is called a single cross. When inbred plant Z is crossed with inbred plant Y, the result is a single cross hybrid, ZY. The second method

of hybridization is called a three-way cross. A three-way cross is made by taking a single cross ZY and crossing it with another unrelated inbred plant X to produce a three-way cross hybrid, ZYX. The third type of hybridization is the double cross. In a double cross, breeders make two single crosses, and then they cross the two single cross hybrids.

A hybrid generally displays more vigorous growth than both of its parents. This extra vigor in its growth is called hybrid vigor, or heterosis. However, hybrid plants usually either are sterile or

produce offspring that do not perform well and are inferior to the hybrid. Extensive work must continually be done to supply hybrid seed to producers.

Summary

Breeders have replaced natural crossbreeding of plants with selective breeding and hybridization to produce superior plants. These crop development methods have laid the foundation for the modern methods of plant development--plant tissue culture and genetic manipulation.

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Lesson 2:
Plant Tissue Culture

The horticulture industry regularly uses a biotechnology technique called plant tissue culture as an effective method of propagating horticultural crops such as ferns and orchids. Plant tissue culture is also being used to grow whole plants from genetically modified plant cells. This lesson will introduce and explain the process of plant tissue culture. The steps in tissue culturing and the stages of tissue culture growth will also be examined.

Plant Tissue Culture

Plant tissue culture is an asexual method of reproduction. The plants produced will be exact clones of a single parent plant. Plant tissue culture involves selecting a piece of a parent plant and placing it in a sterile artificial media where it grows into a new plant.

Advantages and Disadvantages of Plant Tissue Culture

One of the main reasons that plant tissue culture was developed was that some plants are very difficult to propagate commercially. Tissue culturing allows plant growers to mass propagate clones of a highly desirable plant. They can produce thousands of plants from a few pieces of one plant. Another advantage of plant tissue culture is that pathogen-free plants can be produced since certain portions of a plant do not contain viruses that are found in the rest of the plant. A third advantage is the conservation of time, because plants can be propagated from tissue culture at any time during the year. A fourth advantage is the conservation of growing space. Tissue culture plants are divided multiple times and begin as very small plants that grow slightly more slowly than normal. The number of plants traditionally grown on one acre can therefore be grown on shelves in 50 to 60 square feet of space.

With the advantages come some disadvantages. Plant tissue culture is an expensive method of plant propagation requiring an extensive amount of sophisticated equipment and facilities. In addition, plant tissue cultures are susceptible to contamination by microorganisms. Tissue cultures are destroyed if contamination occurs. A third disadvantage is that commercial tissue culture requires skilled workers, which adds to the total cost of producing the plants.

Plant Tissue Culture Equipment

The equipment and supply needs for plant tissue culture can be broken down into three separate areas--preparation, transfer, and growth. Several types of equipment and supplies are needed when preparing to do a tissue culture. A refrigerator is needed to store the chemicals for the growing media. The pH of the growing media must be checked with a pH meter. A scale or balance is required to measure the quantities of the media ingredients. The ingredients are warmed on a heating plate. Finally, an autoclave is required to sterilize the media and the equipment used in transferring the plants. When transfer is carried out, a fume or air flow hood is used to reduce the movement of air (which may contain microorganisms) in the work area. The technician holds the plant tissue with a sterile forceps and uses a scalpel to divide the plant for culturing. Test tubes or petri dishes hold the growing media and the plant tissue after transfer. For some types of tissue culture, a dissecting microscope is used to help in the selection of the tissue for culturing. When the process is completed, the tissue cultures are put in a growth chamber, a room that controls exposure to heat and light.

Steps in Plant Tissue Culture

The first step in plant tissue culture is media preparation. The initial growing media varies slightly in composition depending on the plant species. However, it generally contains plant nutrients, mineral salts with vitamins, plant hormones that regulate growth, pure water, sugar, and agar (if a semi-solid media is needed).

The second step in the process is the selection and collection of the explant. The explant is the portion of the parent plant that will be used to grow new plants. Depending on the plant being propagated, a shoot tip, bud, section of a leaf with veins, node, or bud scale may be chosen. Different plants grow better from different types of explants. The explant is nearly always selected from rapidly growing tissue since this tissue is best able to produce the new plant. It is also important that healthy and disease-free parent tissue be used.

After the explant has been chosen, the next step is cleaning the explant. It must be disinfected. If the explant is woody tissue, alcohol is used as a disinfectant; for most other plant tissues, a 10 percent bleach solution is used. The explant is soaked in the bleach solution for only ten minutes. If it is soaked longer than ten minutes, damage to the plant tissue can occur. Often a drop or two of detergent is added to the bleach solution as a wetting agent to help the disinfectant apply to surfaces more effectively. After it is soaked in the disinfectant, the explant is rinsed at least three times in pure water to remove any remaining bleach solution.

The fourth step involves transferring the explant to the growing media. The collected plant tissues are trimmed, and some types of tissues can be divided for growing more plants. A dissecting microscope is sometimes needed if the explant is very small. The explant is then transferred to the growing media. This procedure must take place in a sterile environment.

Stages of Tissue Culture Growth

The first stage of tissue culture growth is called the initiation and establishment stage. This stage lasts about four to six weeks. A callus composed of rapidly dividing cells forms and grows in response to the wounding or cutting of the plant tissue. A shoot or immature stem begins to grow during this first stage.

The second stage of tissue culture growth is the proliferation or multiplication stage. It lasts one to three months. During this stage, the shoot multiplies into many shoots. These new shoots can be divided to increase the number of plants produced. A slightly different growing media is used in this stage.

The third stage is the pretransplant stage. It lasts about three weeks. Roots begin to grow. A slightly different growing media is used. The plants begin to photosynthesize and require more light. Near the end of this stage, the young plants are stressed slightly in a process called hardening off, which involves exposing the young plants to conditions outside the sterile container in which they grow.

The fourth stage of plant tissue culture growth is called the transplanting stage. The growing plants are put into pots and moved to a shady, humid greenhouse. After a several weeks, the plants are again hardened off and then moved to a regular greenhouse where they will receive full sun and less humidity.

The Use of Tissue Culture in Genetic Engineering

When a single plant cell or group of cells is genetically modified, tissue culture is often used to rapidly grow a set of plants. These plants are genetically identical to the plant cell or cells used to create them. A second use of plant tissue culture is for the screening of a large number of plants for certain characteristics. If a more drought-tolerant plant is desired, then hundreds of tissue cultures can be taken from a wide range of plant varieties and mutations to find this characteristic. The tissue cultures from the plants are grown and exposed to drought conditions. Those plants that show promise are grown to full size. This screening allows researchers to focus on plant varieties that might contain desirable genetic traits.

Summary

Tissue culture has become an important tool for plant breeders and researchers. It allows breeders to quickly produce large numbers of mature clones of a parent plant. Researchers are able to genetically modify a plant cell or group of cells and then grow these modified cells into a mature plant. However, plant tissue culture is an expensive process and can fail if the cultures become contaminated. Tissue culturing involves four major steps: media preparation, choosing the explant, cleaning the explant, and transferring the explant to the growth media. Growth also occurs in four stages: initiation and establishment, proliferation, pretransplant, and transplant.

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Lesson 3:
Genetically Modified Plants

The era of genetic engineering in plant agriculture began with the approval of the first genetically modified food crop in 1994. Since then several genetically modified plants have been developed and approved for use. This lesson will examine how these modified plants were developed and how they function.

Developing Genetically Modified Plants

The first step in the development of a genetically modified plant is to find, isolate, and clone the gene or genes that cause the expression of the desired trait in an organism. Often the gene expressing a desired trait has not been identified or located in the DNA of that organism. The process of finding the needed gene can be very difficult. It is easier, however, if researchers have made a genome map of the particular organism, since they will have identified markers that will narrow the search considerably.

The second step involves the selection of a means of genetic transfer. A bacterium or virus can be used as a vector, the vehicle for moving the desired gene into the plant cells. The desired gene and a marker gene are inserted into the bacterium or virus, and the microorganism is placed in contact with the plant cells to be modified. The bacteria or virus infects the cells and transfers the desired gene to the plant cells.

A gene gun can also be used to transfer a desired gene into a plant cell. The desired gene and a marker gene are inserted into plasmid; the plasmid is then placed on the surface of very small (1 mm in diameter), heavy metal pellets. These pellets, usually made of gold, are shot into the plant cells with the use of a small high-pressure gun. High pressure is needed to penetrate the plant's cell wall.

A third method of gene transfer involves the use of chemicals to weaken or dissolve the cell wall. The desired gene could then physically be placed in the cell. After the gene is incorporated, the plant cell is stimulated to repair the cell wall.

The third step in developing genetically modified plants is the selection of the plant cells that incorporate the desired gene into their DNA. The plant cells that contain the desired gene will also contain the marker gene, which is designed to be easily identifiable. These cells will be grown into mature plants through tissue culturing.

How Herbicide-Tolerant Plants Function

Many herbicides kill plants by chemically blocking a metabolic pathway. A metabolic pathway is a series of chemical reactions that are necessary for the survival of a plant. Herbicide-tolerant plants can bypass the blocked portion of the metabolic pathway. This ability comes from genes that produce certain enzymes that provide a different chemical route around the blocked portion. An example of a herbicide-tolerant crop is Roundup Ready™ soybeans from Monsanto. These plants can tolerate glyphosate, the active ingredient in the herbicide. Glyphosate blocks a section of the metabolic pathway, which kills most types of plants. Researchers discovered that a common bacteria found in soil contains a gene that resists glyphosate. They inserted this gene into soybean plants. It produces an enzyme that provides a chemical path around the blocked portion. With this new gene, the soybean plants are not noticeably affected by Roundup™ or any glyphosate herbicide.

How Insect-Resistant Plants Function

A common soil bacterium called *Bacillus thuringiensis (Bt)* was first identified in 1911. Different strains of the bacteria produce a protein that kills some types of insects. When ingested it dissolves the wall of the insect's gut, which causes the insect to be unable to eat and eventually to die. *Bt* was registered as a biopesticide in 1961. However, the pesticide produced from the bacteria had several drawbacks; it was expensive, had to be

eaten by insects to work, broke down in sunlight, and was easily washed away by rain. These factors have limited the use of *Bt*-derived pesticides.

Each *Bt* strain kills a specific type of insect. The genes that cause the production of the protein in specific *Bt* strains have been isolated and transferred to several crop plants. For example, Monsanto has developed potatoes, corn, and cotton plants that incorporate *Bt* to protect them against particular insects.

The uses of the *Bt* gene are limited because not all insects are affected by one of the strains of *Bt*. In addition, some people are concerned that insects will become tolerant of the protein produced by the *Bt* gene. If this happens, crops incorporating *Bt* will lose their advantage.

How Disease-Resistant Plants Function

Researchers have developed virus-resistant plants by inserting a small portion of DNA from the virus into the DNA of the plant. This modification gives the plant an immunity to the disease. The Freedom II™ yellow crookneck squash developed by Asgrow is an example of a virus-resistant plant. It resists two types of the mosaic virus.

The development of bacteria- and fungus-resistant plants has not been as easy or as fast as the development of virus-resistant plants. Current research in this area centers on trying to enhance the plant's natural immune response to attacks by bacteria and fungi. Some plants seem able to withstand them better than others. Scientists are trying to find out how these plants work so that they can genetically modify crop plants to have this ability. Bacteria- and fungus-resistant plants are not currently available, nor are they expected to be for several years.

The Effect of Biotechnology on Food Quality and Processing

Biotechnology has been used to enhance food quality and food processing. One of the first genetically engineered plants was the FlavrSavr™ tomato. The tomato was developed by Calgene, a subsidiary of Monsanto, to have a vine-ripened taste and a longer shelf life. Genes were inserted into the tomato plant to delay the softening of the tomato by causing the production of an enzyme that slows the breakdown of pectin in the tomato. Pectin prevents the tomato from getting soft and rotting. Four other companies have gained approval for similar genetically modified tomatoes.

Genetically modified canola and corn plants have also been developed. Both corn and canola plants have been genetically modified to produce grains that are higher in oil content and have a modified oil composition. This means that the levels of saturated and unsaturated oil from these plants have been changed to meet different uses. An example of this type of product is a canola plant from Calgene named Laurical® that produces seeds high in lauric acid. The oil they produce can be used in processing many food products.

Monsanto is working on high-starch potatoes. These potatoes are higher in starch and lower in water content than unmodified potatoes. When the new potatoes are sliced into chips or french fries and deep fried, they will absorb less oil. They will therefore have a lower fat content.

Summary

The genetic engineering of plants has yielded better quality foods and plants that are herbicide tolerant, insect resistant, and disease resistant. The development of these plants involves the location, isolation, cloning, and transferral of the desired genes.

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Lesson 4:
Emerging Applications of Plant Biotechnology

The field of plant biotechnology is one of the most rapidly developing areas of biotechnology. The pace of growth is due to several factors, but the most important reasons are the potential for high profits and the relative simplicity of plant manipulation through recombinant DNA technology. As plant biotechnology continues to advance, the list of products developed through its application will grow. Some of these products are examined in this lesson. Biofuels and biopolymers, for example, are two of the most promising products currently under development. The needs of the plant products industry will influence the future of plant biotechnology.

Biofuels

Biofuels are combustible substances derived from organic sources. Nearly all biofuels are plant-derived. Several types of biofuels exist. Alcohol-based fuels are made by fermenting plant materials. Gasohol is one example; it is a fuel composed of 10 percent alcohol and 90 percent gasoline. Gasohol with a 10 percent ethanol (a type of alcohol) blend is available to motorists in many gas stations across the country. Normally, the ethanol blend is slightly higher in price than the regular petroleum fuel. Researchers are searching for plants that can be modified to produce ethanol more economically.

Plant oil-based fuels, or biodiesels, are made from seeds with a high oil content. Most of these fuels are the result of the addition of methanol (wood alcohol) to the plant oil and the removal of a sticky substance called glycerine. Soybean and rapeseed oils are most commonly used in the production of biodiesel. Biodiesel can be used as a fuel by itself, or it can be blended with petroleum diesel fuel. It is a cleaner-burning fuel that produces less wear on an engine than petroleum diesel. The challenge facing those seeking to increase the use of biodiesel is its cost, which is currently nearly four times the cost of petroleum diesel. Scientists are looking for ways to engineer plants to produce larger quantities of oil and to require less extensive processing to produce biodiesel.

Another type of biofuel is biogas. Methane gas is a byproduct derived from the anaerobic (oxygen-free) digestion of plant materials and/or animal waste by microorganisms. Many people in India and China use small-scale methane production chambers to supply fuel for cooking and lighting. Although methane gas has some limitations as a fuel because it cannot be easily transported or compressed into a liquid, researchers are examining the possibility of developing plants that would produce crop residue that is more useful for methane production. Microorganisms are also being examined to see if they can be modified to better digest crop residues and produce more methane.

Biopolymers

Biopolymers are complex chemical compounds produced by living things. Biopolymers from genetically engineered plants may be useful in a variety of industries. Several different groups of biopolymers are used for a variety of applications.

Carbohydrates are one group of biopolymers. All plants produce carbohydrates, but not all plants are a good source of food-grade carbohydrates. Modified corn starch is one of the plant carbohydrates most widely used in foods because it is a cheap source of starch. However, it breaks down when heated in a microwave oven. Researchers are looking at ways that the corn plant can be modified to produce a starch that can be heated. Another important carbohydrate molecule is sugar. Scientists are researching the possibility of genetically altering potato plants so that their leaves will have a high sugar content. The plants could then be used as a source of sugar.

Fatty acids are a second type of biopolymer. Researchers are working on modifying corn and canola to produce oils with an altered level of fatty acids. They may contain a high level of either saturated or unsaturated fatty acids, depending on which is needed for a given application.

Another kind of biopolymer is high-value pharmaceutical proteins. Two examples of human health products that are proteins are insulin and blood plasma. Plants provide the potential for such proteins to be produced at a lower cost than currently available.

A fourth group of biopolymers is industrial enzymes. Enzymes are needed for brewing to aid in fermentation, in the paper industry to process and bleach paper, and in the livestock industry as a feed additive to aid in digestion in animals. These types of enzymes are needed in large quantities, and scientists are trying to modify plants to provide these enzymes at a low price.

Another type of biopolymer being researched is bioplastics. Plants naturally have a very small amount of the chemical components of plastic in their tissue. Scientists are attempting to develop plants with tissue that contains a much higher level of these components. Researchers have already engineered plants to increase these levels; the chemicals make up 4 percent of the modified plants. If this percentage can be increased, the world will have an expanded source of biodegradable plastics.

Plant Traits Desired by Producers

The ability to genetically engineer plants has caused plant breeders and researchers to stop asking what traits are available in a plant species and to start asking what traits are needed or desired by producers and which plant can best be modified to fulfill this need. As genes for more and more traits are discovered, the possible genetic combinations grow as well. Researchers are focusing on several major areas. One of these areas is that of environmentally tolerant plants, including the development of plants that are drought-tolerant, frost-tolerant, and salt-tolerant. The development of better forestry products is another area of plant research. Traits desired in this area include stronger wood, fire-resistant wood, and trees that grow more quickly. A third area of research involves the development of food products with an improved taste. Products being investigated include sweet corn and peas that stay sweet longer and naturally decaffeinated coffee. Research into fiber crops is being conducted as well. Scientists are trying to produce naturally colored and fade-resistant cotton. Naturally blue cotton that resists fading would create a revolution in the denim industry.

Summary

The rapidly expanding field of plant biotechnology is the focus of a great deal of interest. Biofuels and biopolymers are two examples of the emerging applications of plant biotechnology. Scientists are examining many plants, animals, and microorganisms as a part of their attempts to enhance the traits of crop plants and increase their usefulness.

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Lesson 5:
The Impact of Plant Biotechnology

Many biotechnology products recently released on the commercial agricultural market have been genetically modified plants. *Bt* corn, *Bt* cotton, Roundup Ready™ soybeans, and modified canola are a few examples. The effect of these products and of plant biotechnology is only beginning to be realized. This lesson will explore the impact that plant biotechnology is having on the creation of jobs, economics, human health, and society.

Career Opportunities in Plant Biotechnology

Plant biotechnology offers many of the same career opportunities as those listed in Unit 5 for animal biotechnology. General career areas in biotechnology are research and development, quality control, clinical research, manufacturing and production, regulatory affairs, information systems, marketing and sales, and administration. However, some career positions are unique to the field of plant biotechnology. Plant scientists, greenhouse managers, and tissue culture technicians are a few examples. A bachelor of science degree in agronomy or biochemistry provides a good starting point for a career in plant biotechnology.

Economic Factors Affecting Producers

The true test of any technology is its feasibility and profitability. Developments in plant biotechnology must be financially beneficial for producers if the products are to succeed. Whether it is insect-resistant corn or herbicide-tolerant soybeans, the plant crop developed must be able to increase producer profits. The producer needs to be confident that the price charged for these genetically modified seeds will be recovered, along with a greater profit than that obtained with traditional plant crops.

Modified crops present both benefits and drawbacks for producers. Most of the genetically altered crops currently in use have been modified to resist insects, disease, or herbicides. These crops lower input costs by reducing the amount of chemicals needed to grow them. However, the seed for genetically modified crops is generally higher in price. In addition, several modified crops that producers are beginning to use yield a seed with a modified composition that must be kept separate from unmodified crops when they are harvested, transported, stored, and processed to avoid using them for the wrong application. Crops with a modified composition also must be sold to specific processors. The advantage to these specialized crops is that they are often sold at a premium price, which should offset the costs of handling them and the limited market. These additional risks to the producer require that the modified crop have a higher profit potential. If the profit potential is great enough, producers will readily accept these new crops.

Consumer Health and Safety Concerns

The public has shown much more confidence in the safety of plant biotechnology than in animal biotechnology. Consumers have some health concerns about genetically modified foods. Questions about the healthiness of modified foods arise with foods in which the composition of the edible portion of the plant has changed. The FDA has helped to ease some of these concerns by requiring that foods in which the composition of the food has changed be labeled. Some consumers also worry that a plant altered for an industrial purpose will wind up in the food supply; for example, corn genetically modified for ethanol production could be mixed with other corn for corn meal without anyone knowing. Such safety and health concerns held by consumers must be responsibly addressed if plant biotechnology products are to succeed.

The Global Social Impacts of Plant Biotechnology

Both positive and negative global impacts are associated with the introduction of plant biotechnologies. Some transgenic plants can greatly benefit developing countries, such as the sweet potato resistant to the feathery mottle virus (FMV) developed with support from Monsanto and the U.S. Agency for International Development

(USAID). This FMV-resistant sweet potato could nearly double the potato harvest in Africa, where sweet potatoes are grown as a staple crop, and farmers could provide more food for their families. The development of environmentally tolerant plants could help reduce the risk of famine caused by drought or flooding in some countries. Even more exciting is the possibility of developing edible plant vaccines, which would allow millions of poor people to receive vaccines.

However, the development of some genetically modified crops can destroy the profitability of agricultural cash crops that may be vital to a country's economy. For example, the new genetically modified canola seed has the same fatty acid content as many of the tropical oils, such as palm and coconut oils. Producers in the United States and Canada could raise a crop of canola cheaper than these oils could be imported. Many countries have depended on tropical oils for most of their national income, and their economies could be severely hurt if the modified canola is grown. Also, if potatoes, tobacco, and other plants are genetically modified to produce a high amount of sugar in their leaves, the price for sugar from sugar cane will drop, causing problems for growers worldwide. These changes have both an economic and social impact on the countries affected. Will the net effect of plant biotechnology be positive for most countries? Only time will reveal the answer to this question.

Summary

The field of plant biotechnology is growing quickly. Many different types of career opportunities exist in this field. As more genetically modified plants are developed and offered to producers, the ability of producers to measure the economic risks and profit potential of these crops will be vitally important. Consumer concerns about the safety and healthiness of foods made from modified plants must be addressed. The global social impact of each modified plant must also be examined to help minimize negative results.

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