# ANIMAL BIOTECHNOLOGY & IT'S SIGNIFICANCE

Animal biotechnology is the use of science and engineering to modify living organisms. The goal is to make products, to improve animals and to develop microorganisms for specific agricultural uses.

Examples of animal biotechnology include creating transgenic animals (animals with one or more genes introduced by human intervention), using gene knock out technology to make animals with a specific inactivated gene and producing nearly identical animals by somatic cell nuclear transfer (or cloning).

## HISTORY

The animal biotechnology in use today is built on a long history. Some of the first biotechnology in use includes traditional breeding techniques that date back to 5000 B.C.E. Such techniques include crossing diverse strains of animals (known as hybridizing) to produce greater genetic variety. The offspring from these crosses then are bred selectively to produce the greatest number of desirable traits. For example, female horses have been bred with male donkeys to produce mules, and male horses have been bred with female donkeys to produce hinnies, for use as work animals, for the past 3,000 years. This method continues to be used today.

The modern era of biotechnology began in 1953, when American biochemist James Watson and British biophysicist Francis Crick presented their double-helix model of DNA. That was followed by Swiss microbiologist Werner Arber's discovery in the 1960s of special enzymes, called restriction enzymes, in bacteria. These enzymes cut the DNA strands of any organism at precise points. In 1973, American geneticist Stanley Cohen and American biochemist Herbert Boyer removed a specific gene from one bacterium and inserted it into another using restriction enzymes. That event marked the beginning of recombinant DNA technology, or genetic engineering. In 1977, genes from other organisms were transferred to bacteria, an achievement that led eventually to the first transfer of a human gene.

## THE TECHNOLOGY INVOLVED

Animal biotechnology in use today is based on the science of genetic engineering. Under the umbrella of genetic engineering exist other technologies, such as transgenics and cloning, that also are used in animal biotechnology.

## Transgenics

Transgenics (also known as recombinant DNA) is the transferal of a specific gene from one organism to another. Gene splicing is used to introduce one or more genes of an organism into a second organism. A transgenic animal is created once the second organism incorporates the new DNA into its own genetic material.

In gene splicing, DNA cannot be transferred directly from its original organism, the donor, to the recipient organism, or the host. Instead, the donor DNA must be cut and pasted, or recombined, into a compatible fragment of DNA from a vector — an organism that can carry the donor DNA into the host. The host organism often is a rapidly multiplying microorganism such as a harmless bacterium, which serves as a factory where the recombined DNA can be duplicated in large quantities. The subsequently produced protein then can be removed from the host and used as a genetically engineered product in humans, other animals, plants, bacteria or viruses. The donor DNA can be introduced directly into an organism by techniques such as injection through the cell walls of plants or into the fertilized egg of an animal.

This transferring of genes alters the characteristics of the organism by changing its protein makeup. Proteins, including enzymes and hormones, perform many vital functions in organisms. Individual genes direct an animal's characteristics through the production of proteins.

## Cloning

Scientists use reproductive cloning techniques to produce multiple copies of mammals that are nearly identical copies of other animals, including transgenic animals, genetically superior animals and animals that produce high quantities of milk or have some other desirable trait. To date, cattle, sheep, pigs, goats, horses, mules, cats, rats and mice have been cloned, beginning with the first cloned animal, a sheep named Dolly, in 1996.

Reproductive cloning begins with somatic cell nuclear transfer (SCNT). In SCNT, scientists remove the nucleus from an egg cell (oocyte) and replace it with a nucleus from a donor adult somatic cell, which is any cell in the body except for an oocyte or sperm. For reproductive cloning, the embryo is implanted into a uterus of a surrogate female, where it can develop into a live being.

## Other Technologies

In addition to the use of transgenics and cloning, scientists can use gene knock out technology to inactivate, or "knock out," a specific gene. It is this technology that creates a possible source of replacement organs for humans. The process of transplanting cells, tissues or organs from one species to another is referred to as xenotransplantation. Currently, the pig is the major animal being considered as a viable organ donor to humans.

Unfortunately, pig cells and human cells are not immunologically compatible. Pigs, like almost all mammals, have markers on their cells that enable the human immune system to recognize them as foreign and reject them. Genetic engineering is used to knock out the pig gene responsible for the protein that forms the marker to the pig cells.

## IT'S APPLICATIONS

Animal biotechnology has many potential uses. Since the early 1980s, transgenic animals have been created with increased growth rates, enhanced lean muscle mass, enhanced resistance to disease or improved use of dietary phosphorous to lessen the environmental impacts of animal manure. Transgenic poultry, swine, goats and cattle that generate large quantities of human proteins in eggs, milk, blood or urine also have been produced, with the goal of using these products as human pharmaceuticals. Human pharmaceutical proteins include enzymes, clotting factors, albumin and antibodies. The major factor limiting the widespread use of transgenic animals in agricultural production systems is their relatively inefficient production rate (a success rate of less than 10 percent).

A specific example of these particular applications of animal biotechnology is the transfer of the growth hormone gene of rainbow trout directly into carp eggs. The resulting transgenic carp produce both carp and rainbow trout growth hormones and grow to be one-third larger than normal carp. Another example is the use of transgenic animals to clone large quantities of the gene responsible for a cattle growth hormone. The hormone is extracted from the bacterium, is purified and is injected into dairy cows, increasing their milk production by 10 to 15 percent. That growth hormone is called bovine somatotropin or BST.

Another major application of animal biotechnology is the use of animal organs in humans. Pigs currently are used to supply heart valves for insertion into humans, but they also are being considered as a potential solution to the severe shortage in human organs available for transplant procedures.

# THE FUTURE OF ANIMAL BIOTECHNOLOGY

While predicting the future is inherently risky, some things can be said with certainty about the future of animal biotechnology. The government agencies involved in the regulation of animal biotechnology, mainly the Food and Drug Administration (FDA), likely will rule on pending policies and establish processes for the commercial uses of products created through the technology. In January 2008, the U.S. Food and Drug Administration (FDA) approved the sale of cloned animals and their offspring for food, despite fierce opposition from animal welfare and consumer advocacy groups, environmental organizations, some members of Congress, and many consumers. It also is expected that technologies will continue to be developed in the field, with much hope for advances in the use of animal organs in human transplant operations.

## RELATED ISSUES

The potential benefits of animal biotechnology are numerous and include enhanced nutritional content of food for human consumption; a more abundant, cheaper and varied food supply; agricultural land-use savings; a decrease in the number of animals needed for the food supply; improved health of animals and humans; development of new, low-cost disease treatments for humans; and increased understanding of human disease.

Yet despite these potential benefits, several areas of concern exist around the use of biotechnology in animals. To date, a majority of the American public is uncomfortable with genetic modifications to animals.

According to a survey conducted by the Pew Initiative on Food and Biotechnology, 58 percent of those polled said they opposed scientific research on the genetic engineering of animals. According to a survey conducted by the Pew Initiative on Food and Biotechnology, 58 percent of those polled said they opposed scientific research on the genetic engineering of animals. And in a Gallup poll conducted in May 2004, 64 percent of Americans polled said they thought it was morally wrong to clone animals

Concerns surrounding the use of animal biotechnology include the unknown potential health effects to humans from food products created by transgenic or cloned animals, the potential effects on the environment and the effects on animal welfare.

Before animal biotechnology will be used widely by animal agriculture production systems, additional research will be needed to determine if the benefits of animal biotechnology outweigh these potential risks.

## FOOD SAFETY

The main question posed about the safety of food produced through animal biotechnology for human consumption is, “Is it safe to eat?” But answering that question isn’t simple. Other questions must be answered first, such as, “What substances expressed as a result of the genetic modification are likely to remain in food?” Despite these questions, the National Academies of Science (NAS) released a report titled *Animal Biotechnology: Science-Based Concerns* stating that the overall concern level for food safety was determined to be low. Specifically, the report listed three specific food concerns: allergens, bioactivity and the toxicity of unintended expression products.

The potential for new allergens to be expressed in the process of creating foods from genetically modified animals is a real and valid concern, because the process introduces new proteins. While food allergens are not a new issue, the difficulty comes in how to anticipate these adequately, because they only can be detected once a person is exposed and experiences a reaction.

Another food safety issue, bioactivity, asks, “Will putting a functional protein like a growth hormone in an animal affect the person who consumes food from that animal?” The FDA approves these drugs only after information and/or studies have shown that the food from the treated animals is safe for people to eat, and that the drugs do not harm the treated animal or the environment. The drugs also have to be effective, meaning that they work as intended. The labeling for each product provides all instructions for safe and effective use and is approved by FDA. For each approved product, the FDA also makes available to the public via its website a Freedom of Information Summary that summarizes the information that FDA used to determine that the drug is safe for the treated animals, the animal products (edible tissues such as meat) are safe for humans to eat, and that the product is effective.

Finally, concern exists about the toxicity of unintended expression products in the animal biotechnology process. While the risk is considered low, there is no data available. The NAS report stated it still needs be proven that the nutritional profile does not change in these foods and that no unintended and potentially harmful expression products appear.

## ENVIRONMENTAL CONCERNS

Another major concern surrounding the use of animal biotechnology is the potential for negative impact to the environment. These potential harms include the alteration of the ecologic balance regarding feed sources and predators, the introduction of transgenic animals that alter the health of existing animal populations and the disruption of reproduction patterns and their success.

To assess the risk of these environmental harms, many more questions must be answered, such as: What is the possibility the altered animal will enter the environment? Will the animal’s introduction change the ecological system? Will the animal become established in the environment? and Will it interact with and affect the success of other animals in the new community? Because of the many uncertainties involved, it is challenging to make an assessment.

To illustrate a potential environmental harm, consider that if transgenic salmon with genes engineered to accelerate growth were released into the natural environment, they could compete more successfully for food and mates than wild salmon. Thus, there also is concern that genetically engineered organisms will escape and reproduce in the natural environment. It is feared existing species could be eliminated, thus upsetting the natural balance of organisms.

# LEGAL IMPLICATIONS

## Regulations

The regulation of animal biotechnology currently is performed under existing government agencies. To date, no new regulations or laws have been enacted to deal with animal biotechnology and related issues. The main governing body for animal biotechnology and their products is the FDA. Specifically, these products fall under the new animal drug provisions of the Food, Drug, and Cosmetic Act (FDCA). In this use, the introduced genetic construct is considered the “drug.” This lack of concrete regulatory guidance has produced many questions, especially because the process for bringing genetically engineered animals to market remains unknown.

In 2015, the FDA determined that Aqua Advantage Salmon meets the statutory requirements for safety and effectiveness under the Federal Food, Drug, and Cosmetic Act.

Many people question the use of an agency that was designed specifically for drugs to regulate live animals. The agency’s strict confidentiality provisions and lack of an environmental mandate in the FDCA also are concerns. It still is unclear how the agency’s provisions will be interpreted for animals and how multiple agencies will work together in the regulatory system.

When animals are genetically engineered for biomedical research purposes (as pigs are, for example, in organ transplantation studies), their care and use is carefully regulated by the Department of Agriculture. In addition, if federal funds are used to support the research, the work further is regulated by the *Public Health Service Policy on Humane Care and Use of Laboratory Animals*.

### Labelling

Whether products generated from genetically engineered animals should be labelled is yet another controversy surrounding animal biotechnology. Those opposed to mandatory labelling say it violates the government’s traditional focus on regulating products, not processes. If a product of animal biotechnology has been proven scientifically by the FDA to be safe for human consumption and the environment and not materially different from similar products produced via conventional means, these individuals say it is unfair and without scientific rationale to single out that product for labelling solely because of the process by which it was made.

On the other hand, those in favour of mandatory labelling argue labelling is a consumer “right-to-know” issue. They say consumers need full information about products in the marketplace — including the processes used to make those products — not for food safety or scientific reasons, but so they can make choices in line with their personal ethics.

### Intellectual Property

On average, it takes seven to nine years and an investment of about $55 million to develop, test and market a new genetically engineered product. Consequently, nearly all researchers involved in animal biotechnology are protecting their investments and intellectual property through the patent system. In 1988, the first patent was issued on a transgenic animal, a strain of laboratory mice whose cells were engineered to contain a cancer-predisposing gene. Some people, however, are opposed ethically to the patenting of life forms, because it makes organisms the property of companies. Other people are concerned about its impact on small farmers. Those opposed to using the patent system for animal biotechnology have suggested using breed registries to protect intellectual property.

## ETHICAL AND SOCIAL CONSIDERATIONS

Ethical and social considerations surrounding animal biotechnology are of significant importance. This especially is true because researchers and developers worry the future market success of any products derived from cloned or genetically engineered animals will depend partly on the public’s acceptance of those products.

Animal biotechnology clearly has its skeptics as well as its outright opponents. Strict opponents think there is something fundamentally immoral about the processes of transgenics and cloning. They liken it to “playing God.” Moreover, they often oppose animal biotechnology on the grounds that it is unnatural. Its processes, they say, go against nature and, in some cases, cross natural species boundaries.

Still others question the need to genetically engineer animals. Some wonder if it is done so companies can increase profits and agricultural production. They believe a compelling need should exist for the genetic modification of animals and that we should not use animals only for our own wants and needs. And yet others believe it is unethical to stifle technology with the potential to save human lives.

As of May 27, 2016, under the Federal Food, Drug, and Cosmetic Act, the FDA can only require additional labelling of foods derived from Genetically Engineered sources if there is a material difference – such as a different nutritional profile – between the GE product and its non-GE counterpart.

While the field of ethics presents more questions than it answers, it is clear animal biotechnology creates much discussion and debate among scientists, researchers and the American public. Two main areas of debate focus on the welfare of animals involved and the religious issues related to animal biotechnology.

## ANIMAL WELFARE

Perhaps the most controversy and debate regarding animal biotechnology surrounds the animals themselves. While it has been noted that animals might, in fact, benefit from the use of animal biotechnology — through improved health, for example — the majority of discussion is about the known and unknown potential negative impacts to animal welfare through the process.

For example, calves and lambs produced through in vitro fertilization or cloning tend to have higher birth weights and longer gestation periods, which leads to difficult births that often require caesarean sections. In addition, some of the biotechnology techniques in use today are extremely inefficient at producing foetuses that survive. Of the transgenic animals that do survive, many do not express the inserted gene properly, often resulting in anatomical, physiological or behavioural abnormalities. There also is a concern that proteins designed to produce a pharmaceutical product in the animal's milk might find their way to other parts of the animal's body, possibly causing adverse effects.

Animal "telos" is a concept derived from Aristotle and refers to an animal's fundamental nature. Disagreement exists as to whether it is ethical to change an animal's telos through transgenesis. For example, is it ethical to create genetically modified chickens that can tolerate living in small cages? Those opposed to the concept say it is a clear sign we have gone too far in changing that animal.

Those unopposed to changing an animal's telos, however, argue it could benefit animals by fitting them for living conditions for which they are not "naturally" suited. In this way, scientists could create animals that feel no pain.

## RELIGIOUS ISSUES

Religion plays a crucial part in the way some people view animal biotechnology. For some people, these technologies are considered blasphemous. In effect, God has created a perfect, natural order, they say, and it is sinful to try to improve that order by manipulating the basic ingredient of all life, DNA. Some religions place great importance on the "integrity" of species, and as a result, those religion's followers strongly oppose any effort to change animals through genetic modification.

Not all religious believers make these assertions, however, and different believers of the same religion might hold differing views on the subject. For example, Christians do not oppose animal biotechnology unanimously. In fact, some Christians support animal biotechnology, saying the Bible teaches humanity's dominion over nature. Some modern theologians even see biotechnology as a challenging, positive opportunity for us to work with God as "co-creators."

Transgenic animals can pose problems for some religious groups. For example, Muslims, Sikhs and Hindus are forbidden to eat certain foods. Such religious requirements raise basic questions about the identity of animals and their genetic makeup. If, for example, a small amount of genetic material from a fish is introduced into a melon (in order to allow it grow to in lower temperatures), does that melon become "fishy" in any meaningful sense? Some would argue all organisms share common genetic material, so the melon would not contain any of the fish's identity. Others, however, believe the transferred genes are exactly what make the animal distinctive; therefore the melon would be forbidden to be eaten as well.