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Biotechnology in Animal Agriculture: Status and Current Issues

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Tadlock Cowan
Analyst in Agricultural Policy
Resources, Science, and Industry Division

Geoffrey S. Becker
Specialist in Agricultural Policy
Resources, Science, and Industry Division

Biotechnology in Animal Agriculture: Status and Current Issues

Summary

Animal agriculture is being transformed by rapid advances in biotechnology — a term often used as a synonym for a variety of technologies that includes genetic engineering, genetic modification, transgenics, recombinant DNA techniques, and cloning, among others. Producers are interested in the application of biotechnology to improve productivity, consistency, and quality; to introduce new food, fiber, and medical products; and to protect the environment. Potential human health applications of transgenic animals include producing biopharmaceuticals and generating organs, tissues, and cells for xenotransplantation. Criticisms of such applications range from food safety and social resistance to potential negative impacts on animal welfare and on ecosystems. Questions also have arisen about the adequacy of the current regulatory structure to manage the complex interaction among environmental issues, public health, and food safety that developments in animal biotechnology may create.

The tools for introducing specific new genetic material into livestock have been available since the mid-1980s. However, few transgenic animal projects to date have focused on actual agricultural issues such as animal health and production. More recently, however, cloned cattle capable of resisting mastitis are touted as a first example of genetic engineering to improve animal well-being. Pigs have been engineered for increased sow milk production, which has resulted in faster growing piglets. Transgenic fish with enhanced growth characteristics are nearing the final stages of commercialization.

In 2003, the U.S. Food and Drug Administration (FDA) released a draft risk assessment stating that food products derived from cloned animals and their offspring likely are as safe to eat as food from their non-cloned counterparts. With that statement, the FDA also continued its voluntary moratorium request to companies on sales of such food products. It is anticipated that the FDA will issue its final risk assessment report in 2006. Since the cloning of the sheep, Dolly, in 1997, Congressional concern with these advances has largely been confined to their implications for human cloning. However, Congress may be asked to play a larger role in weighing the benefits and costs of these evolving technologies, and to refine existing government oversight.

This report will be updated as significant developments in agricultural biotechnology occur and as Congress develops legislation addressing emerging agricultural biotechnology issues.

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Introduction

Biotechnology is a broadly defined term of relatively recent origin describing the range of modern knowledge, applications, and techniques underlying advances in many fields, notably health care and agriculture. Animal biotechnology has been defined as "that set of techniques by which living creatures are modified for the benefit of humans and other animals."[1] By its very nature, agricultural development is the history of humans modifying plants and animals to maximize desirable traits. For example, domestication and selective breeding of animals date back many thousands of years. Artificial insemination of livestock, notably dairy cattle, is another, more recent, biological technology, first finding wide commercial acceptance in the 1950s.

Discovery of the genetic code in the 1950s gave birth to modern techniques of biotechnology. One of the first commercial products of this new biotechnology in animal agriculture was bovine somatotropin (bST). BST is a naturally occurring metabolic modifier that is now being manufactured in larger quantities through the use of recombinant DNA technology. Manufactured bST came onto the market in 1994 and is now administered to as many as half of all U.S. dairy cattle to increase per-cow milk output. Although bST is being used commercially in approximately 20 countries, it is banned in the European Union (EU).

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[1] National Research Council (NRC), *Animal Biotechnology: Science-Based Concerns*, (Washington, D.C., National Academy Press, 2002). Unless noted, this CRS report is based on material in that document and the following additional sources: Institute of Medicine (IOM) and NRC, *Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects*, (Washington, D.C., National Academy Press, 2004); Council for Agricultural Science and Technology (CAST), *Biotechnology in Animal Agriculture: An Overview* (Issue Paper 23), (Washington, D.C. February, 2003); Pew Initiative on Food and Biotechnology, *Issues in the Regulation of Genetically Engineered Plants and Animals*, (Washington, D.C., Pew Initiative April 2004. [http://pewagbiotech.org/research/regulation/]); Pew Initiative on Food and Biotechnology, *Post-Market Oversight of Biotech Foods*, (Washington, D.C., Pew Initiative April 2003; (and other Pew materials); information accessed through the websites of the Biotechnology Industry Organization at [http://www.bio.org/]; the Center for Food Safety: [http://www.centerforfoodsafety.org/]; the Union of Concerned Scientists [http://www.ucsusa.org/]; and the Consumer Federation of America [http://www.consumerfed.org/]. Some material is adapted from CRS Report RL32809, *Agricultural Biotechnology: Background and Recent Issues*, by Geoffrey S. Becker.

Other agricultural biotechnology developments include pigs that have been engineered for increased sow milk output to produce faster growing piglets. Cloned cattle also have been developed to resist mastitis, and transgenic salmon with enhanced growth characteristics are under regulatory consideration for possible commercialization. Output traits such as producing drugs recovered from animal milk ("pharming"), making milk that lacks allergenic proteins, and producing animal organs for human transplant that resist rejection (xenotransplantation) are other contemporary objectives of animal biotechnology research. In March 2006, researchers at the University of Missouri announced the creation of transgenic pigs whose tissue contains omega-3 fatty acids.[2] The consumption of omega-3 fatty acids, found primarily in fish, has been linked to lowered incidence of heart disease in humans. Similar research is also under way to produce omega-3 fatty acids in cow's milk and in chicken eggs.

This report describes several scientifically emerging animal biotechnologies that, while not yet commercialized, are raising a variety of questions concerning risks to humans and animals, the environment, and ethical issues pertaining to animal welfare. The report describes applications of the technologies and discusses major issues that may arise. Consumers, agricultural producers, the biotechnology industry, and federal regulatory bodies are debating the relative costs and benefits of these technologies. As these technologies reach commercialization, Congress may be asked to play an increasing role in weighing their costs and benefits and in refining the current federal regulatory structure governing these technologies and their agricultural products.

Animal Biotechnologies

Given the breadth of the term "animal biotechnology," one might reasonably include thousands of years of humans selectively breeding animals as a biotechnology: Observing desirable animal traits and attempting to breed those traits into successive lines of animals. Artificial insemination (AI) in the 1950s was a technological advance in traditional selective breeding and an important adjunct to the development of modern industrial animal production, especially in dairy and poultry. AI was adopted by producers and accepted by the public with virtually no controversy. Estrus synchronization, a related technology that improved the efficiency of AI by more accurately controlling when a female was in heat, is also an important animal biotechnology. With the development in the 1970s and patenting in the 1980s of recombinant DNA techniques, and the subsequent analysis of genes, their resulting proteins, and the role played by the proteins in animal biochemical processes (functional genomics), modern biotechnology is increasingly equipped with a set of sophisticated tools holding the promise of transforming the selective breeding of animals. The range of new techniques and technologies is only now beginning to transform animal biotechnology in ways that plant biotechnology was transformed in the 1980s and 1990s.

Modern animal biotechnology is developing against the background of public experience with plant biotechnology, and controversy over the technologies may be

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[2] New York Times, March 27,2006.

a continuing feature of animal biotechnology development, not least because of the closer connection between humans and some animals and the belief that techniques developed for animals are only a step away from application to humans. Some of the better known animal biotechnologies include:

Embryo Transfer. After AI and estrus synchronization, embryo transfer (ET) is the third most commonly used biotechnology. In ET, a donor cow of superior breeding is chemically induced to superovulate. The eggs are then fertilized within the donor, the embryo develops and is then removed and implanted in a recipient cow. Between removal and implantation, embryos may be frozen for safekeeping. Because of the relatively high costs, ET is used mostly within registered cowherds.

In Vitro Fertilization. With in vitro fertilization (IVF), a technician removes unfertilized eggs (oocytes) from the donor cow's ovaries, usually recovering 6-8 useable oocytes. The oocytes mature in an incubator and are fertilized with sperm. The resulting zygotes incubate and develop in the laboratory before being placed into the recipient cow. While IVF can produce many fertilized embryos, the added expense of ET makes the procedure prohibitive in most cases.

Sexing Embryos. The dairy industry prefers heifers and the beef industry prefers bulls. Embryo sexing methods in cattle have been developed using a bovine Y-chromosome probe. Technicians remove a few cells from the embryo and assess the DNA in these cells for the presence of a Y-chromosome. Presence of a Y-chromosome determines the embryo is male. Research is also developing in sperm sexing technology.

Transgenics. A prominent area of contemporary animal biotechnology research is the development of *transgenic animals* through genetic engineering (GE) technology.[3] Transgenic animals are produced by introducing an isolated DNA fragment into an embryo so that the resulting animal will express a desired trait.[4] The only current routine use of transgenic animals, primarily mice, is in the area of human disease research. Potential agricultural applications for such genetic engineering, however, include improved feed use and faster growth; more resistance to disease; meat that is leaner or that has more of some other desirable quality; and possibly even animal waste that is more environmentally benign. **Table 1** provides examples of various objectives of animal biotechnology involving genetic modification.

Cloning. Cloning is a biotechnology developing rapidly and with significant public controversy. Most people think of cloning as the creation of an organism that is genetically identical to another one. However, scientists use the term more broadly, to refer to production not only of such organisms but also genetically

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[3] *Genetic engineering* (GE) here refers to the use of molecular biology to alter cells by inserting or removing genes. GE is a form of *genetic modification*, which refers more broadly to the practices of altering an organism's genetic composition by both GE and non-GE methods.

[4] Transgenic animals may be generated by the introduction of foreign DNA obtained through animals of the same species, animals of different species, microbes, humans, cells, and *in vitro* nucleic acid synthesis.

identical cells, and to replication of DNA and other molecules. It also refers to a form of reproduction found naturally in many single-celled organisms, as well as plants and animals. Those differences in meaning and usage have caused some confusion in public debate about cloning, where the main area of genuine controversy relates to artificial cloning involving higher organisms, including humans.[5]

Table 1. Agricultural Applications of Animal Genetic Modification

Purpose	Animal Model	Transgenic Source
Faster growth/leaner meat	Cattle, swine, rabbits, sheep	Growth hormones/factors: *Human, Bovine, Porcine, Rat, Chicken*
Altered milk composition (higher protein)	Cattle	Extra copies of casein genes; disruption of lactoglobulin gene: *Cow*
"Biosteel" production in milk[a]	Goat	Spider
Reduced phosphorus in swine feces	Swine	Phytase gene; *Bacteria*
Increased wool production	Sheep	Cysteine synthesis gene: *Bacteria* Growth factor: *Sheep*
Disease resistance	Swine, sheep, rabbit	Monoclonal antibodies: *Mouse* Viral envelope genes: *Sheep*
Xenotransplantation: Developing animal organs for human transplantation	Swine	CD55 (DAF-decay activating factor: *Human* CD59: *Human*

Source: GeneWatch UK, April 2002

a. "Biosteel" is the trade name for spider web material intended to be produced in the milk of a transgenic goat. Said to be twenty times stronger than steel, "Biosteel" has an envisioned breaking strength of about 300,000 pounds per square inch and could produce microscopically fine, super strong fibers for industrial use.

In 1997, scientists at the Roslyn Institute in Scotland used nuclei from the mammary cells of an adult sheep to clone "Dolly." Such nuclear transfer (NT) techniques were first developed in amphibians in the 1950s. They were first used in sheep in 1986, with the production of clones using nuclei taken from sheep embryos. The significance of "Dolly" was that she was cloned from differentiated cell types

[5] See CRS Report RL31358, *Human Cloning*, by Judith A. Johnson and Erin D. Williams.

obtained from an adult (called "somatic cell NT"), rather than undifferentiated cells from an embryo ("embryonic NT").

Although the success of animal cloning has raised the provocative issue of human cloning, cloning in animal agriculture is generally not applied in isolation from other biotechnologies such as genetic engineering. The production of an NT clone is a multi-step process that generates an entire organism from the DNA of a single donor cell using NT. Currently, NT is not a notably efficient technique that would lead to widespread commercial adoption. For example, only about 6% of the embryos transferred to recipient cows result in healthy, long-term surviving clones.[6] A more efficient cloning technology, one that can overcome the range of cloning abnormalities that result from NT, however, may provide new opportunities in human medicine, agriculture, and animal welfare. This is the focus of much of the current international animal biotechnology research.

Regulation and Oversight

The basic federal guidance for regulating the products of agricultural biotechnology is the Coordinated Framework for Regulation of Biotechnology (51 *Fed. Reg.* 23302), published in 1986 by the White House Office of Science and Technology Policy (OSTP). A key principle has been that GE products should continue to be regulated according to their characteristics and unique features, not methods of production, that is, whether or not they were created through biotechnology. The framework provides a regulatory approach intended to ensure the safety of biotechnology research and products, using existing statutory authority and previous policy experience.

Some newer applications of biotechnology did not exist when the current regulatory framework was enunciated. The NRC animal biotechnology report concluded that this regulatory regime "might not be adequate to address unique problems and characteristics associated with animal biotechnologies" and that federal agency responsibilities are not clear.[7]

Food and Drug Administration (FDA). Within the Department of Health and Human Services (HHS), the FDA regulates food, animal feed ingredients, and human and animal drugs, primarily under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. §301 *et seq.*). The FDA has stated that most — although probably not all — gene-based modifications of animals for production or therapeutic claims fall within the purview of the agency's Center for Veterinary Medicine (CVM), which regulates them under the FFDCA as new animal drugs. A new animal drug (NAD) must be approved by the agency after it is demonstrated to be safe to man and animals, as well as being effective. Regulation of transgenic animals as NADs, however, suggests to some observers (e.g., the Center for Food Safety, Union of Concerned Scientists) the inherent weakness of existing regulatory structures to

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[6] D.N. Wells, "Animal cloning: problems and prospects." *Review of Science and Technology*, 24(1):251-264, 2005.

[7] NRC, *Animal Biotechnology*, p. 14.

respond adequately to the complexities that arise with animal biotechnology innovations.[8]

Primarily under the FFDCA, FDA's Center for Food Safety and Applied Nutrition (CFSAN) is responsible for assuring that domestic and imported foods are safe and properly labeled. Generally, FDA does not review new foods themselves for safety before they enter commerce but does have enforcement authority to act if it finds foods that are adulterated under the act. Also, all food *additives*, whether or not introduced through biotechnology, must receive FDA safety approval before they can be sold; the exception to pre-market approval are those on a list the FDA has determined to be "generally recognized as safe" (GRAS).[9]

Sections of the FFDCA and of the Public Health Service Act (42 U.S.C. §262 *et seq*.) provide the authorities for FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to regulate the safety and effectiveness of human drugs and other medical products, including those produced by GM animals. Under these laws, the FDA requires pre-market review and licensing of such products, and requires that their production conditions ensure purity and potency.[10]

U.S. Department of Agriculture (USDA). Several USDA agencies, operating under a number of statutory authorities, also have at least potential roles in the regulation of transgenic and cloned animals and their products. However, as several critical reviews have indicated, USDA does not appear to have a clearly spelled out policy in this area, including whether it intends to exercise these authorities to regulate GE animals.[11] The USDA's Animal and Plant Health Inspection Service (APHIS) has broad authority, under the Animal Health Protection Act (AHPA; 7 U.S.C. §8301 *et seq.*) to regulate animals and their movement to control the spread of diseases and pests to farm-raised animals. APHIS also administers the Viruses, Serums, Toxins, Antitoxins, and Analogous Products Act (21 U.S.C. §151-159), aimed at assuring the safety and effectiveness of animal vaccines and other biological products, including those of GM origin, and the Animal Welfare Act (7 U.S.C. §2131 *et seq.*), portions of which govern the humane treatment of several kinds of warm-blooded animals used in research (but generally not agricultural animals). Elsewhere at USDA, the Food Safety and Inspection Service (FSIS) is responsible for ensuring the safety to humans of most food animals and

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[8] See Center for Food Safety Website [http://www.centerforfoodsafety.org/geneticall7.cfm] and the Union of Concerned Scientists [http://www.ucsusa.org/food_and_environment/genetic_engineering/genetically-engineered-salmon.html].

[9] The FDA, as of March 2006, has not granted approval for any human foods from transgenic (or cloned) animals, although a "very limited number have been approved for rendering into animal feed components." The only FDA-approved product of biotechnology in wide commercial use is bST, and an application is pending for a GE salmon. *(Questions and Answers about Transgenic Fish* at [http://www.fda.gov/cvm/transgen.htm]).

[10] NRC: *Animal Biotechnology*, p.163.

[11] See, for example, Pew, *Issues in Regulation*. Beginning on p. 139, the report contains an extensive discussion on how these and several other USDA authorities might be utilized for oversight of animal biotechnology.

meat and related products derived from them under the Federal Meat Inspection Act (21 U.S.C. §601 *et seq.*) and Poultry Products Inspection Act (21 U.S.C. §451 *et seq.*).

Reports and studies have cited a number of other authorities and federal agencies that are or could be relevant. The National Environmental Policy Act (42 U.S.C. §4321 *et seq.*) requires federal agencies to consider the environmental impacts of their actions. The Environmental Protection Agency derives its authority from, among other laws, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA; 21 U.S.C. §301 *et seq.*); pesticides derived from living organisms, including those of biotechnology, are within its purview. The Interior Department's Fish and Wildlife Service, and the Commerce Department's National Marine Fisheries Service have also been cited.

Policy Concerns

Environmental Issues. Environmental concerns arising from emerging animal biotechnologies are largely speculative at this time because few products have been commercialized. Industrial developers of agricultural biotechnology might argue that more efficient production of animal-based feeds could reduce the resources necessary to produce food and, thereby, reduce the environmental burden of animal production. Should the development and widespread adoption of the "EnviroPig" (tm), which produces less phosphorus in its waste, occur, it might be considered by some to be a positive environmental benefit of agricultural biotechnology.

The 2002 NRC animal biotechnology report noted potential negative environmental impacts of genetically altered animals. Escape, survival, and gene flow into wild populations were identified as major concerns. Of most concern to the NRC committee was the escape into the environment of "super" salmon that have been genetically modified for rapid growth, and the likelihood that they could then breed with wild populations in the environment.[12] Other genetically altered animals such as fish, insects, and shellfish could also potentially escape into natural environments and become feral, disrupt ecosystems, or introduce novel genes in a natural population.

Food Safety. Unexpected and unintended compositional changes arise with all forms of plant and animal genetic modification, including GE, concluded the IOM-NRC report on genetically engineered foods.[13] The report added that, so far, no GE-related adverse human health effects have been documented. However, the report's authors cited "sizeable gaps" in the ability to identify compositional changes caused by all forms of genetic modification — whether GE or conventional — and their relevance for human health, and they recommended new approaches for assessing the safety of new foods both before and after they enter the market.

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[12] NRC, *Animal Biotechnology,* p. 73.

[13] IOM-NRC, *Safety of Genetically Engineered Food,* p. 1.

Previous research and experience with commercializing transgenic plants suggest that negative effects on human health are virtually nonexistent. While not asserting that genetically modified organisms necessarily generate health problems, more recently reported research in peer-reviewed scientific journals has suggested that GMOs may raise food safety concerns:

- Australian researchers have published an article explaining that the transfer from a bean to a pea gene that expresses an insecticide protein has resulted in antibody production in mice fed the transgenic pea. The antibody reaction is a marker of allergic reaction.[14]

- Italian researchers at the University of Urbino had previously shown that absorption of transgenic soy by mice induced modifications in the nuclei of their liver cells. Recent research showed that a return to non-transgenic soy made the observed differences disappear.[15]

- Norwegian scientists at the University of Tromso demonstrated that the catalyst 35S CaMV, an element of the genetic structures used to modify a plant, can provoke gene expression in cultured human cells. This catalyst was previously believed to operate in this way only in plants.[16]

In the NRC animal biotechnology report, experts observed that the scientific principles for assessing the safety of GE animals are "qualitatively the same" as for non-GE animals.[17] However, because GE can introduce new proteins into foods, the potential for allergenicity, bioactivity, and/or toxicity responses should be considered, they said. Others have remarked that animals genetically engineered for nonfood products like pharmaceuticals or replacement organs might be of concern if such animals entered *or* affected the food supply.[18]

Cloning. The biotechnology industry so far has agreed not to market milk and meat from cloned animals while it awaits FDA's final risk assessment on the safety of such products. In an October 2003 draft risk assessment, the FDA had concluded that "the current weight of evidence suggests that there are no biological reasons...to indicate that consumption of edible products from clones of cattle, pigs, sheep or

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[14] V.E. Prescott, P.M. Campbell, *et al*. "Transgenic Expression of Bean-Amylase Inhibitor in Peas Results in Altered Structure and Immunogenicity." *Journal of Agriculture and Food Chemistry*, 53(23); 9023-9030, November, 2005.

[15] M. Malatesta, C. Tiberi, *et al*. "Reversibility of hepatocyte nuclear modifications in mice fed on genetically modified soybean." *European Journal of Histochemistry*, 49(2):237-242, July-September, 2005.

[16] M.R. Myhre, K. Fenton, *et al*. "The 35S CaMV plant virus promoter is active in human enterocyte-like cells." *European Food Research and Technology*, 222(1-2):185-193, January, 2006.

[17] NRC, *Animal Biotechnology*, p. 65.

[18] See CRS Report RS20507, *Labeling of Genetically Modified Food*, by Donna U. Vogt.

goats poses a greater risk than consumption of those products from their non-clone counterparts."[19] However, shortly after its publication, many members of the FDA's Veterinary Medicine Advisory Committee stated that there were not enough data to fully understand any potential risks from this relatively new techonology.[20] Industry officials assert that cloning will be used for breeding and that consumers will eat food from the offspring of cloned individuals, rather than the cloned animals themselves.[21] It is unknown whether this approach would eliminate risks, if any, associated with ingestion of cloned animals.

The NRC animal biotechnology report stated that embryonic splitting and nuclear transfer using embryonic (not adult) cells were used with some dairy cows to successfully produce genetically valuable offspring that were milked commercially and whose milk and meat entered the food supply. Few concerns were raised by NRC authors about using these types of cloned animals for food, and they are believed to pose a low level of food safety concern. However, evaluating cloned-animal food composition "would be prudent to minimize any food safety concerns. The products of offspring of cloned animals were regarded as posing no food safety concern because they are the result of natural matings."[22] Other issues, notably consumer acceptance, social values, and animal welfare could eventually overshadow any lingering questions about human health.

Consumer and Social Acceptance. Criteria for selecting desirable traits to be produced through transgenic animals will likely be based on the demand for specific commercial characteristics. Even if scientific evidence is convincing that GE and cloned animal products are safe and beneficial for human consumption or economically valuable to producers, other concerns may limit marketplace and consumer acceptance. Polls in recent years in the United States indicate that public knowledge about food and biotechnology generally remains limited. In two 2005 surveys, approximately half of those surveyed expressed opposition to the use of biotechnology in the food supply.[23] More than half of those in the Pew-sponsored poll said they opposed research into genetically modified animals, although opposition declined with increased knowledge. Many Americans have heard about animal cloning; two-thirds expressed discomfort with it — more of them out of religious or ethical concerns than food safety concerns. A majority of respondents to the Pew survey believe that regulators should take into account ethical and moral considerations.

Consumers may be less willing to accept the practice of genetically modifying animals than plants, some have argued, observing that people relate differently to

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[19] Accessed March 20, 2006, at [http://www.fda.gov/cvm/Documents/CLRAES.pdf].

[20] "Panel calls for more data on animal cloning risks," *Food Chemical News*, November 10, 2003.

[21] See [http://www.clonesafety.org/cloning/facts/faq].

[22] NRC, *Animal Agriculture*, p. 8.

[23] Gallup poll on biotechnology and food safety, July 2005; Mellman Group/Public Opinion Strategies poll conducted for the Pew Initiative on Food and Biotechnology, October 2005. See [http://www.pewagbiotech.org] (Accessed March 20, 2006).

animals, which many recognize as sentient beings. Some observers have expressed the concern that cloning farm animals might lead more quickly to human and pet cloning, which those observers oppose. Others believe that modifying animals, for example, to save human lives through xenotransplantation or the production of some important drug, might be more acceptable than doing so simply to produce more or cheaper food. Further, science alone cannot resolve ethical views which appear to vary widely:

> Some people, irrespective of the application of technology, consider genetic engineering of animals fundamentally unethical. Others, however, hold that the ethical significance of animal biotechnologies must derive from the risk and benefits to people, the animals, and/or the environment. Yet another view focuses on the right of humans to know what they are eating or how their food or pharmaceuticals are being produced and therefore labeling becomes an issue to be addressed.[24]

Such observations led some skeptics of animal biotechnology to propose that the FDA not only consider the science and safety issues, but also these broader concerns. In the area of human reproductive health, for example, the FDA and other federal agencies have invoked particular moral arguments either to reinforce scientific arguments or to counterbalance scientific evidence. Others believe that the FDA should base its decisions only on scientific evidence, and perhaps some other body should be established to consider the ethical and cultural questions. As the NRC animal biotechnology report observed, regulatory decisions and enforcement involving animal biotechnology "are difficult in the absence of an ethical framework."[25]

Some believe that segregating and labeling the products of biotechnology in agriculture, including meat and milk, would enable the consumer to choose whether or not to buy such products. Both failing to segregate and label biotechnology products as well as doing so can contribute to public suspicion that these products are flawed or different in some negative way, which may lead to contradictory policy decisions.[26] Others counter that such products essentially are the same — and subjected to the same rigorous safety standards — as more conventional products, and therefore should be treated no differently in the marketplace. Interestingly, a study by USDA's Economic Research Service reported that consumers' willingness

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[24] NRC, *Animal Biotechnology,* p. 13.

[25] NRC, *Animal Biotechnology,* p. 13

[26] C.T. Foreman. *Can U.S. Support for Food Biotechnology Be Salvaged?* Paper prepared for the American Enterprise Institute for Public Policy Research Conference on Biotechnology, the Media and Public Policy, June 12, 2003.

to pay for a food item declines when the food label indicates that it was produced with the aid of biotechnology.[27]

Animal Welfare. Some aspects of gene transfer have the potential to create infectious disease hazards or impaired reproduction. Looming large in the ethical debate are questions about whether genetic modifications, cloning, and other technologies, stress animals unnecessarily, subject them to higher rates of disease and injury, and hasten death.[28] The NRC animal agriculture report noted, for example, that ruminants produced by *in vitro* culture or nuclear cell transfer methods tend to have higher birth weights and longer gestation periods than those produced by artificial insemination, creating potential calving problems. Nuclear transfer techniques to propagate genetic modifications may increase risks to the reproductive health and welfare of both the surrogate female animals and their transgenic offspring. The report cited other evidence of problems such as anatomical, physiological, or behavioral abnormalities in many transgenic animals.[29] Some scientists have countered that animal welfare problems have been exaggerated, particularly as the technologies have advanced. Most appear to agree, however, that animals originating from some forms of genetic modification may require closer observation and care.

International Trade Issues

Any exports of the products of animal biotechnology would presumably encounter a wide spectrum of foreign regulatory regimes, some more restrictive than the U.S. system. For example, the current European Union restriction on new biotechnology products is likely to encompass various restrictions on animal biotechnology as it does on plant biotechnology. International standards pertaining to exports of animal products derived from biotechnology would have to be developed. The Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology held its first meeting in September 2005 in Chiba, Japan, to determine the new work projects for the four-year life of the task force. Almost every country, except for the United States, proposed an animal biotechnology project. The task force agreed to move forward with a recombinant DNA (r-DNA) animal project, specifically to develop a guideline for how countries would assess the safety of foods derived from r-DNA animals.[30]

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[27] A. Tegene, W. Huffman, *et al*. *The Effects of Information on Consumer Demand for Biotech Foods: Evidence from Experimental Auctions*, USDA, Economic Research Service, Technical Bulletin 1903, March 2003.

[28] Some animal biotechnology researchers also have pointed to the potential importance of preserving unaltered germlines in domestic animals because they could prove to be an invaluable "gene bank" in the event that novel infectious diseases or heritable genetic defects were inadvertently introduced into modified sub-populations as a consequence of genetic modification. See H.P.S. Kochhar, G. Adlakha-Hutcheon, and B.R. Evans. "Regulatory considerations for biotechnology-derived animals in Canada." *Review of Science and Technology*, 24(1):117-125, 2005.

[29] NRC, *Animal Biotechnology*, p. 11.

[30] Codex is recognized by the World Trade Organization (WTO) as the body that sets food
(continued...)

Congressional Activity

While Members of Congress have proposed various bills prohibiting human cloning, no legislation is pending to address animal biotechnology issues directly. With a forthcoming FDA risk assessment on the safety of the offspring of cloned animals in the food supply, consumer and production issues may move to a more prominent public position. As with human cloning, ethical issues concerning animal clones and other animal biotechnologies may also become more visible public issues. Congress may be asked to play a larger role in weighing the benefits and costs of these evolving technologies, and to refine existing government oversight.

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[30] (...continued)
safety standards for facilitating international trade of food products. The WTO cites Codex texts as a benchmark in the Agreement on Sanitary and Phytosanitary Measures (SPS).