CAST® Issue Paper
Number 46
June 2010

Ethical Implications of Animal Biotechnology: Considerations for Animal Welfare Decision Making

Animal Agriculture's Future through Biotechnology, Part 9

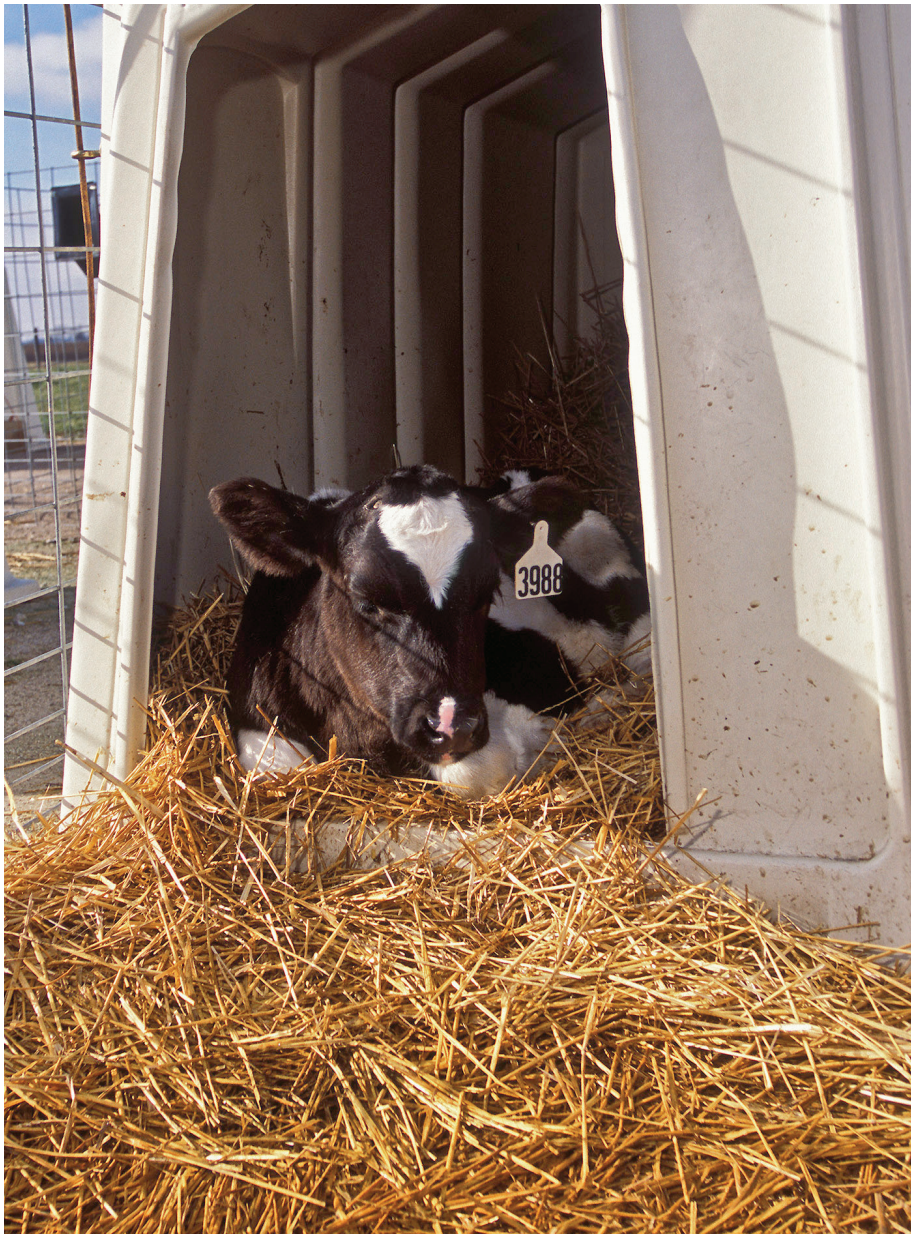
Abstract

Animal biotechnology—which includes both genetic engineering and mammalian cloning—has expanded rapidly in recent decades. These technologies already have been applied in biomedical research and now are nearing application within the food system. Both the U.S. Food and Drug Administration (FDA) and the European Food Safety Authority recently have concluded that meat and milk from cloned animals are safe, but public perceptions will continue to have a significant impact on the development and commercialization of animal biotechnology applications.

Public opinion studies regarding animal biotechnology reveal that people are concerned about the purpose of the applications, the methods of research, and the objects of manipulation. Additional public concerns include the moral status of animals, the boundary between what is considered "natural" and "unnatural," and the consequences of genetic modification, particularly the long-term impacts on human health and the environment.

Three broad categories of ethical issues are associated with animal biotechnology: (1) the technology's impact on the animals themselves, (2) the institutions and procedures that govern the research and applications within the agrifood system, and (3) the relationships between humans and other animals.

Among the world's largest religions, there are very few clear-cut taboos prohibiting animal biotechnology, although ethical implications can be drawn from the general role



Animal behavior scientists are working to identify and reduce excessive animal stress on the farm to improve health and productivity. (Photo courtesy of the USDA Agricultural Research Service.)

This material is based upon work supported by the U.S. Department of Agriculture's (USDA) National Institute for Food and Agriculture (NIFA) (formerly Cooperative State Research, Education, and Extension Service) Grants No. 2009-38902-20041, No. 2008-38902-19327, and No. 2007-31100-06019/Iowa State University (ISU) Project No. 413-40-02, and USDA's Agricultural Research Service (ARS) Agreement No. 59-0202-7-144. Any opinions, findings, conclusions, or recommendations expressed in this publication are those of the author(s) and do not necessarily reflect the views of USDA, NIFA, ISU, or ARS.

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of animals within the religious tradition and from beliefs and practices that address animal care and use, animal breeding, and human diet.

In the United States, animal biotechnology is regulated primarily by the FDA and the U.S. Department of Agriculture. Because U.S. regulators do not view biotechnology as being inherently "risky," regulations generally apply only to the products of biotechnology. But this regulatory strategy has ethical ramifications. The scope of the issues, impacts, and practices deemed relevant to decision making reflect a norm or evaluative judgment about what will and what will not be addressed in the regulatory process. The U.S. regulatory discussion does not focus on whether cloning, genetic engineering, or other biotechnologies are appropriate methods—or even whether the resulting products are socially or economically valuable or ethically appropriate—but rather on whether the products are safe for use.

In contrast, European regulators view biotechnology as a novel process that requires novel regulatory provisions. This "process-versus-product" method means that the technology does not go forward and/or importation is delayed while the general approach to regulatory evaluation is being debated. Even if regulators ultimately make decisions similar to those made in the United States, the European approach provides a forum in which open debate can cover the range of issues, impacts, and practices that ultimately will be decisive. The European method still provides opportunities for product-specific ethical debate when a product is about to be commercialized. In contrast, the political tradition of the United States emphasizes ethical debate within the legislative process. Congress has not seen fit to provide a clear place for it in regulatory decision making.

Two main international protocols affect animal biotechnology: The Codex Alimentarius Commission sets international safety standards for foods; the Cartagena Protocol on Biosafety to the Convention on Biological Diversity—primarily an environmental treaty—protects biological diversity from risks posed by living modified organisms, taking into account potential risks to human health.

There have been relatively few formal efforts to bring science, ethics, religious tradition, public opinion, and legal practice into dialogue regarding animal biotechnology. Decisions about the future development and use of animal biotechnology may be more effective and widely accepted if parties from various disciplines increase their commitment to frequent and sustained cooperative efforts to analyze the multitude of complex facets of this issue, including knowledge of the science of animal biotechnology, philosophical reflections on the moral significance of animals, religious traditions of animal use, and research on public attitudes to animal biotechnology.

Introduction

The last two decades have seen the development of new genetic technologies for nonhuman animals (hereafter, simply "animals") that already have been applied widely in biomedical research and now are nearing application within the food system. Genetic engineering—the manipulation of animal genomes using techniques derived from deoxyribonucleic acid (DNA) to produce recombinant DNA (rDNA) (artificial DNA engineered through insertion, rearrangement, or deletion of one or more DNA strands)—has the potential to introduce new traits into familiar animal products. The technologies also are envisioned to create nonfood uses for traditional livestock species that may present challenges for the animal products industry and consumers. Mammalian cloning almost certainly will be used in connection with genetic engineering and may have additional uses for livestock breeders who desire a means to improve the genetics within their herds. These two techniques encompass what is here referred to as "animal biotechnology."

The focus of this paper is to survey some key ethical, religious, and legal issues associated with animal biotechnology in traditional livestock species. Issues relating to biomedical research animals are not discussed, although some technologies using traditional farm animals (i.e., pigs, cows, and sheep) are included. On the one hand, the word "ethics" is associated with highly personal and subjective feelings or judgments. For many, ethical principles are grounded in religion or cultural tradition and depend on belief systems that are viewed as distinct from, or even at odds with, those of modern science. On the other hand, many specific ethical principles are common to almost all human cultures and traditions. Philosophical methods of analysis and

debate articulate the bases for cross-cultural agreement on many key ethical commitments understood to underlie a well-ordered society, and all of the world's major religions have endorsed the view that ethical dialog can be conducted both within and across theological traditions (Thompson 2007).

This paper begins with a review of animal biotechnology techniques, including some examples of how these techniques currently are being used. As of this writing, no animal biotechnologies are in widespread or general use for agricultural purposes, although experimental animals have been produced and reports note a few instances in which engineered or cloned animals may have been released, sometimes inadvertently, into the food chain. Following that discussion, key ethical issues raised in connection with animal biotechnology will be outlined, followed by an evaluation of the ways some religious traditions have viewed animals and speculative comments on how these views relate to animal biotechnology. This paper also summarizes public opinion research on the ethical issues associated with animal biotechnology as well as the current legal and regulatory framework for animal biotechnology. The concluding section evaluates how these multiple threads present both challenges and opportunities for the ethical development of agricultural animal biotechnology.

Animal Biotechnology Science

General Overview

During the twentieth century, scientists developed a number of techniques for manipulating DNA in cells. These techniques originated in research intended to understand better the role and function of genes in heredity, in the control of biological functions, and in disease. When combined with methods for regenerating organisms from single embryonic or other cells, these techniques can be used to create living plants and animals that have a specific genetic constitution. Genetic engineering is the alteration of an animal's traits through addition or subtraction of genetic constructs that control specific biological functions through the use of these new techniques for manipulating DNA. Cloning uses these techniques to create a cell that is a genetic copy of another cell.

For vertebrate animals used conventionally as food sources (e.g., cows, pigs, chickens, and fish), the ability to engineer embryonic cells genetically dates back to the 1980s, but difficulties in regenerating live animals from these cells have limited the usefulness of this process beyond pure research applications. In theory, however, this process could confer an ability to develop breeds or varieties of livestock with many novel traits. In fact, the theoretical applications of genetic engineering seemingly are bound only by the imagination. They include applications intended to limit both disease and clinical signs, to create animals that produce novel products in their milk or blood, to mitigate environmental impacts, and to lower the costs of livestock production.

Cloning of livestock embryos through a process not unlike that of "twinning" that occurs naturally also has been possible for several decades. But only in 1997 did it become clear that cloning might be used to regenerate animals from the DNA in cells from adult individuals of livestock species. As will be discussed, there still are challenges to accomplishing cloning of livestock species, but techniques have been developed that have practical applications. One key application is in conjunction with genetic engineering, where cloning is used to make the regeneration of genetically transformed animals less costly in time and money (Wilmut, Young, and Campbell 1998). Another application might be for livestock owners who wish to generate a clone of a particularly valuable individual animal.

The next section begins with a discussion of how genetics are used traditionally in animal breeding. It is followed by a considerably more detailed discussion of the DNA-based techniques that have been developed during the last 40 years, including a discussion of both known risks and possible beneficial applications of these techniques within the context of food animal production. Although this scientific discussion is critical for an adequately informed understanding of regulatory issues, readers interested primarily in ethical issues may choose to skim through discussions of the more complex technical issues.

Genetics in Conventional Animal Breeding Programs

The value of animal agriculture enterprises (poultry, livestock, and fish) in the United States was estimated at $173 billion in 2007 (USDA 2008), with the value expected to increase together with increases in both world population and standard of living (Pinstrup-Andersen and Pandya-Lorch 1999). Although techniques for cloning and producing transgenic animals are becoming more efficient, only commercial production of transgenic fish is poised to affect availability of animal protein in the near future.

Modern breeds of livestock have achieved high production efficiencies as a result of traditional animal breeding programs. Between 1945 and 1995, for example, milk production increased threefold; the number of eggs produced by laying hens increased from 134 to 254 per hen per year; production time of broiler chickens to 3 pounds (lb), 15.4 ounces (1.8 kilograms [kg]) body weight decreased from 84 to 43 days on one-half the feed; and growth of pigs, sheep, goats, and cattle was faster and resulted in leaner meat (NRC 2002, 2004).

These increases can be attributed to various factors depending on species and production systems, including

- the use of statistical models to predict breeding values of bulls coupled with sire testing and selection;
- cross-breeding and artificial insemination (AI) to capture the best genetics from males;
- synchronization of estrus and ovulation to enhance use of AI;
- superovulation, AI, and embryo transfer to take advantage of desired genetics from females;
- artificial incubation of eggs of poultry species to increase hatching rates;
- improved nutrition;
- effective disease control through improved animal health;
- control of seasonality or photoperiod to enhance production effi-

ciencies in specific species such as poultry;

- improved housing to avoid stress resulting from adverse effects of weather; and
- sex reversal in fish to either all female or all male to achieve desired production efficiencies in farm-raised fish.

Since the 1960s more advanced biotechnologies have been used to a limited extent. These biotechnologies include assisted reproductive technologies (in vitro maturation of *oöcytes*[1] and in vitro fertilization), embryo splitting to achieve identical twins (clones), sexing sperm, and *blastomere nuclear transfer cloning* (Norman et al. 2004).

Cloning

Cloning, a term originally used in horticulture to describe asexually produced progeny, is the process of making a copy of an individual or, in cellular and molecular terms, groups of identical cells and replicas of DNA and other molecules. Monozygotic twins are clones. Animal cloning in the late 1980s resulted from the transfer of nuclei from blastomeres of early cleavage-stage embryos to enucleated oöcytes, but it also can be achieved by transferring a nucleus from a *somatic cell* into an oöcyte from which the nucleus has been removed (Wilmut, Young, and Campbell 1998). Although there has been controversy over the validation of experimental results, *somatic cell nuclear transfer* has been used in experiments claimed to produce embryonic stem cells (i.e., undifferentiated stem cells genetically matched to the recipient for research and therapies for recovery of function that do not require reproductive cloning of animals).

The progeny from cloning using nuclei from either blastomeres or somatic cells are not exact replicas of an individual animal because of cytoplasmic inheritance of mitochondrial DNA from the recipient egg and other factors in the cytoplasm of oöcytes that may influence "reprogramming" of the genome of the transferred nucleus and subsequent development of the cloned organism (Cummins 2001; Jaenisch and Wilmut 2001). Cloning from blastomeres and somatic cells may result in large calves and lambs, the so-called "large offspring syndrome" (Sinclair et al. 2000; Young, Sinclair, and Wilmut 1998), as well as more serious abnormalities (Sinclair et al. 1999).

Cloning can be accomplished by (1) embryo splitting to achieve genetically identical individuals, (2) embryonic cell nuclear transfer, or (3) somatic cell nuclear transfer. With embryo splitting, the genome is established and the success rate for producing twins with identical genomic DNA is high. Embryonic cell nuclear transfer involves transfer of a nucleus from a cell in which the genome may be *totipotent* and requires little reprogramming for development of a new individual. Somatic cell nuclear transfer is problematic because the genome of cells of an adult animal requires that *cytoplasmic factors* from the recipient oöcyte reprogram the genome for development of a new individual(s).

Epigenetics is defined as influences on a cell that do not alter the genome, such as cytoplasmic factors of the oöcyte. Epigenetic reprogramming of the genome in nuclei of adult cells often is abnormal such that cells of the embryo and placenta express some proteins incorrectly. This incorrect expression often leads to high rates of embryonic, fetal, and neonatal deaths, as well as abnormal development of the placenta. The fetus and newborn also may suffer from an enlarged liver, hemorrhaging, and abnormalities of the respiratory, immune, nervous, and digestive systems (Young and Fairburn 2000).

Nuclear transfers resulting in calves whose meat and milk have entered the food chain have been from transfer of nuclei from cells of embryos. Through 2001, the number of registered Holstein clones that resulted from embryo splitting was 2,226 (754 males and 1,472 females), and 187 were from nuclear transfers (61 males and 126 females). On the basis of measures of total milk yield, fat content, protein content, somatic cell score, and productive life span, cows selected for cloning were superior genetically for milk yield, but the values for clones resulting from embryonic nuclear transfer and embryo splitting were similar to and slightly less than values for noncloned *full sibs*, respectively (Norman et al. 2004). Calves also have resulted from fetal fibroblasts (cells from fetuses), skin biopsies (cells from adults), and cumulus and granulosa cells (cells from adult ovaries and cells surrounding embryos, but not embryonic themselves). In fact, several companies specialize in producing nuclear-transfer-derived calves from skin biopsies sent in by their customers.

Cloning Animals for Animal Agriculture

Cloning livestock species for use in animal agriculture is for genotype replication; that is, to increase the number of males or females with a desired genotype and phenotype such as milk production. Cloning also may be used for genetic conservation of a unique animal that may, for example, be highly resistant to disease or parasites. Conservation of genetics of early ancestors of a species such as the Texas Longhorn or Criolla cattle from South America may be used to obtain animals for studies to understand the genetic basis for desirable traits.

Gene Targeting and Cloning for Expression of Proteins by Mammary Gland

Genetic engineering may be used to create animals such as goats and cows whose milk can produce valuable pharmaceuticals. The animal is genetically engineered to express a gene for a protein with pharmaceutical value only in milk, including enzymes and clotting factors (Colman 1996; Murray and Maga 1999). But this technology also can be used to produce many bioactive proteins or commercial products such as silk, using genes from spiders. Transgenic animals used as *bioreactors* to produce pharmaceuticals in milk likely would be cloned to replicate the desired genotype.

Somatic Cell Nuclear Cloning and Gene Targeting

Pigs are being genetically engineered so that their organs can be used successfully for organ-replacement therapies in human medicine (i.e., xenotransplantation) (CAST 2004).

[1] Italicized terms (except genus and species names) are defined in the Glossary.

Humans produce antibodies directed against *sugar moieties* present on the surface of pig cells (Sandrin et al. 1993), resulting in acute rejection of organs from pigs. Therefore, pigs are being engineered to silence appropriate functional genes for the sugar moieties (Lai et al. 2002) so that their organs can be used successfully for xenotransplantation. Pigs or other species used for xenotransplantation could be cloned to replicate the desired genotype, although they also could be reproduced by conventional breeding.

Cloning for Biomedical and Medical Research

Cloning has great value to researchers who study animals that have essentially the same genotype regarding their response to such issues as growth and development, aging, cancer, and various diets and nutrients. Animal models for biomedical research also include those with specific *gene knockouts* that mimic human disease (e.g., sheep carrying a mutated collagen gene can serve as a model for studies of human connective tissue diseases) (McCreath et al. 2000).

Position of Regulatory Agencies on Cloned Animals

In January 2008, both the U.S. Food and Drug Administration (FDA) (cattle, swine, and goats) and the European Food Safety Authority (EFSA) (cattle and swine) concluded that meat and milk from clones were safe. The FDA indicated that clones of cattle, swine, and goats and the offspring of clones from any species traditionally consumed as food are as safe to eat as food from conventionally bred animals. But they contended that they had insufficient information to reach a conclusion on the safety of food from clones of other animal species, such as sheep.

Ectopic DNA to Alter Phenotype

Biotechnology can provide methods for modifying the endocrinology of domestic animals to affect reproduction, lactation, and growth. Ectopic DNA, for example, refers to DNA introduced into muscle cells that will increase circulating levels of hormones such as growth hormone (GH) and insulin (Khan et al. 2002). This technology has been used in pigs and rats to increase circulation levels of GH and insulin-like growth factor 1 (IGF-1) in the mothers, which results in offspring that are heavier at birth and at weaning (Draghia-Akli et al. 2002). This is one example of the use of biotechnology to affect reproductive and endocrine systems during critical development periods, thereby enhancing growth and development of the fetus during gestation to ensure its survival and well-being as a newborn, and to enhance the mother's milk production.

Sperm-Mediated Gene Transfer for Production of Transgenic Animals

Sperm-mediated gene transfer is based on biotechnologies that allow DNA to be taken up by sperm and used in breeding programs to produce transgenic pigs (Lavitrano et al. 2006). This biotechnology is inefficient, as uptake of DNA and its expression ranges from 0 to 88%; it is attractive, however, because it is inexpensive and the transgene that is integrated is stable. The major disadvantages include random insertion sites of the transgene, the uncontrolled number of copies integrated into the genome, the effects of the transgene on other genes may lead to undesired effects, and the expression vector may have lethal effects on sperm or early embryos.

Biotechnology for Identifying Desirable Genotypes

Sequencing and mapping genomes of livestock allow scientists to identify genes and understand their regulation in the context of improving production characteristics and health of animals. One outcome is the establishment of linkages between inheritance of a desirable trait (e.g., milk yield) and segregation of specific genetic markers coupled to that trait. *Single nucleotide polymorphisms* (SNPs) are specific differences in DNA that can be used as gene markers to assist in selection of *quantitative trait loci* (QTL) responsible for the desired trait.

There are examples of QTL for production traits in cattle and swine. A QTL related to actions of growth hormone is expected to increase annual milk production by about 441 lb. (200 kg) per lactation and decrease milk fat from 4.4 to 3.4% (Pitman 2003). A QTL in pigs is associated with increased litter size and increased survival of piglets (King et al. 2003), and an SNP in beef cows is associated with growth traits and production of twin calves (Allan et al. 2007). Additional QTL and SNPs will have a large impact on the livestock industry. This technology can be coupled with biopsy and genetic analyses of embryos to allow selection of embryos with the desired genotype to enhance genetic progress in breeding programs. In addition, embryos can be sexed to benefit the animal production enterprise (e.g., all females for dairy farms), or semen can be sorted as X chromosome and Y chromosome sperm to achieve desired sex of offspring.

Ethical Issues Overview

The ethical issues associated with transgenic animals and mammalian cloning (as these techniques are applied to traditional food animals) fit into three broad categories. First are issues that pertain to the impact of this technology on the animals themselves. Second are issues that relate to the institutions and procedures that govern the research and applications context within the agrifood system. Finally, there are issues that relate to the relationship between humans and other animals; the way that humans think of or act in regard to nonhumans, irrespective of the effect that human conduct has on the animals. The underlying ethical principles within each of these three domains are distinct, and the following discussion will treat them as such. Yet arguably, the very diversity of these issues contributes to the sense that animal biotechnology challenges the moral order of society. It is therefore important to recognize that introducing this analytic framework may itself seem to impose a rational ordering on the discussion of animal biotechnology, undercutting concerns that are difficult to express

clearly but still may be the basis of negative reactions.

Impacts on Animals

Most cultural traditions have accepted the view that at least certain kinds of harm to nonhuman animals are morally significant. Traditionally, these views have stressed prohibitions of cruelty. Within recent decades, there have been attempts to articulate more carefully the basis for these views, and, in some instances, to introduce dramatic reforms in the way that ethical duties to animals are conceived. In particular, philosophers and animal advocates have inveighed against a view associated with Rene Descartes, who saw animals as "machines" without ability to register sensory impressions or feel pain. Although this view may have been quite influential in the biomedical sciences, Bernard Rollin, a professor of both philosophy and animal science, has argued that those who manage livestock for a living have never doubted that animals have subjectively felt needs and are capable of feeling pain. Effective husbandry always has recognized an implicit ethic that regards animals as moral subjects, but the terms in which duties to animals are specified remain largely unspoken within that ethic (Rollin 1989).

Three philosophical strategies have been proposed as a way to articulate the basis of ethical duties to animals. The animal welfare strategy usually is associated with the work of Peter Singer, a professor of bioethics. Singer argues that people should attempt a rough estimate of the pain or suffering in dealings with animals, then weigh this against the benefit derived. Practices in which benefits are offset by the suffering of animals are viewed as ethically unacceptable (Singer 1993). This approach generally is understood as a version of ethical utilitarianism.

The animal rights strategy associated with philosopher Tom Regan is intended to block this kind of trade-off reasoning by proposing that animals are wronged when they are treated simply as a means to an end, as a practice that justifies animal suffering in light of benefits derived presumably would do. Regan argues that animals possess a form of individual identity, coherence in their subjective experience that deserves ethical respect (Regan 2003). This view would prohibit any use of animals that is contrary to the interest of the individual animal, including many common agricultural practices such as the slaughter of animals for food.

Rollin also uses the term "rights" to convey the fact that people do regard themselves as having duties to individual animals, but he regards the basis for these duties as residing in a social consensus on moral duty, noting that whereas this consensus forbids certain exploitative practices without regard to the benefits derived, it nonetheless continues to find the use of animals for food to be morally acceptable (Rollin 1993). This third strategy can be called the new social ethic for animals.

Of these three philosophers, only Rollin has written extensively on animal biotechnology. He has argued that transgenic and cloning technologies would be ethically unacceptable if they resulted in greater animal suffering or frustration than would be experienced by animals of the same species and breed under similar husbandry (Rollin 1996). If there are no adverse impacts on individual animals, however, there is no basis for an ethical objection to animal biotechnology. It seems likely that Singer's animal welfare approach would reach a similar conclusion. Although an animal rights view might provide a basis for opposing experimental work on animals intended for human benefit, it is difficult to see how even this view could articulate an objection to successfully accomplished transgenic or cloning work, provided the resulting animals led functional and cognitively satisfying lives. Of course, an animal rights advocate might object to the research phase of animal biotechnology, and the objections would be supported by animal welfarists if the path to a successful transgenic or cloned animal involved its suffering.

Institutions and Procedures

As discussed more fully in the section on "Regulation of Animal Biotechnology," animal research in the United States is subject to the provisions of the Animal Welfare Act (AWA) of 1966. Although agricultural animals technically are exempt from the Act, the majority of both for-profit and nonprofit research organizations use the provisions of the Institutional Animal Care and Use Committee (IACUC) to oversee research. The IACUC committees are regarded widely as having an ethical as well as legal function. Applying a rough test commensurate at least with Rollin's new social ethic to projects involving animal biotechnology would be among these functions.

One of the key ethical questions associated with an IACUC is: Has the committee been constituted so that animal interests will be taken into account when experimental protocols are reviewed? Although U.S. Department of Agriculture (USDA) procedures for IACUC oversight require membership of nonscientists and unaffiliated parties (i.e., people who are not employed by the organization conducting the research), some organizations have recruited committee members who have a declared interest in ensuring that research goes forward (such as members of groups that advocate for specific disease cures), whereas others have appointed members from humane societies or other "pro-animal" groups. Arguably, the latter choice represents a more ethically appropriate way to discharge institutional responsibilities associated with IACUC procedures.

Currently, no comparable institutional approach governs the care and treatment of agricultural animals in production environments. But several trade organizations (such as the National Pork Board and the United Egg Producers), as well as large retail interests who buy animal products (such as the National Council of Chain Restaurants), currently are developing new entities and practices to address ethical issues associated with commercial animal production. These entities include advisory councils and the incorporation of ethical recommendations into husbandry guidelines that long have been promulgated by such groups. Because transgenic and cloned animals are, at present, rare within the context of commercial animal agriculture, these nascent institutional approaches have yet to consider the ethical issues that

are the subject of this Issue Paper. If and when transgenic and cloning applications become more common, it will be important that these emerging entities for animal ethics adjust their procedures to address issues relevant to biotechnology.

A final category of institutional issues addresses the need for consumers to retain the ability to lead lives consistent with the diverse values that exist throughout society. As other sections indicate, it is reasonable to expect that some individuals will resist animal products from genetic engineering or cloning, perhaps for religious or even arbitrary reasons. Is a food system ethically justifiable if it makes it impossible for people who have a strong preference for avoiding these products to do so? Here, the safety or animal health implications of biotechnology may be irrelevant to a given individual.

Yet, as discussed in the section on "Regulation of Animal Biotechnology," current regulatory approaches are unrelated to an individual's ability to make dietary choices based on personal values. The USDA Organic Standard may be the only recourse for such individuals, even though other aspects of organic food may be of little interest to them. As such, there are critical ethical questions about the institutional structure of animal products markets as they relate to an individual's ability to express values in animal product consumption decisions.

Relationships between Humans and Animals

Some of the most strident ethically based opposition to animal biotechnology focuses on the ways modern technologies have caused the traditional relationship between humans and farm animals to change. The willingness to deploy techniques such as genetic engineering and cloning in research programs that change, in some views dramatically, both the nature of animals and the way they are used can be seen as ethically problematic in this light. Researchers' attitudes then are viewed as a form of domination, pride, and manipulation, even when no individual animals are harmed. Here, the ethical focus is on the moral character of the people or the society that undertakes these projects rather than on the ethical acceptability of what is done to the individual animal. Thus, whereas an animal rights view would object to any practice that sees the animal merely as the means to an end, the objection here is focused more on the venality or corruption of character either within the scientific and animal production community, or perhaps within society at large.

Sheila Jasanoff, professor of science and technology studies, has characterized this type of ethical issue as a challenge to society's moral order. She sees religiously based objections that characterize genetic engineering as a form of "playing God" in similar terms. The point is not that this science violates specific religious precepts. Rather, the point is that human beings have set themselves and their interests so far above those of the creatures in their care as to have violated implicit expectations that frame our understandings of civility, humility, grace, and charity. The specific scientific interventions may be less characteristic of this ethical failing than is an overall attitude or manner of conduct regarding the development and governance of the technology. The fact that regulatory agencies are unable to intervene against specific technologies deemed to meet standards of animal, human, and environmental health can be interpreted, in this regard, as part of a general societal failure to regulate human conduct in light of moral expectations (Jasanoff 2007).

Here, too, the large scale and automation of husbandry associated with concentrated animal feeding operations (CAFOs) is undoubtedly a component of the concern. Although CAFOs currently in use do not in any way use biotechnology, they are the end result of scientifically based studies on animal nutrition, reproduction, and husbandry, combined with principles of agricultural engineering. As such, it is not unreasonable for someone not personally involved in science or animal agriculture to perceive a pattern of change in livestock production and to interpret developments in animal biotechnology as elements in this broader pattern. Thus, without regard to whether biotechnology will improve or materially affect the welfare of animals within a CAFO system, it is possible, particularly given no reason or evidence to draw a contrary conclusion, for a member of the public to associate ethical concerns with the general drift of science-based animal husbandry, and to see animal biotechnology as a particularly cogent example of this drift.

Religious Views on Animal Biotechnology

Among the world's largest religions, there are actually very few clear-cut religious taboos prohibiting transgenic and other animal technologies. Religions typically draw on traditions involving several centuries of religious teachings. Because biotechnology is a creation of recent decades, it is not surprising that traditional religious sources do not address it directly. Ethical implications of religious traditions, however, can be drawn from the general role and status of animals within the religious tradition, as well as from traditions that address animal care and use, animal breeding, and human diet. On a few occasions individuals or groups representing religious traditions have issued opinions on the ethics of animal biotechnology, although even these opinions are understood as advice to religious authorities rather than as definitive pronouncements.

Western Religions

The traditional approach of many Western religions—those based on Christianity, Judaism, and Islam—permits animal biotechnology because humans are the instruments through which God works toward bringing creation to final perfection. Whereas animals are God's creatures and have their own moral value, they are at the service of men and women, so that humans also can achieve their overall development through them. Humans cannot use animals indiscriminately, but if animals are used to provide a significant human benefit, that use is permissible. Thus, creating and using animals through biotechnology is permissible as long as the need is sufficient and animal welfare is respected. But this view is balanced by

other considerations. Some religious leaders in all three major Western religions have opposed animal biotechnology as an impermissible usurpation of God's role as Creator. Other leaders have opposed some aspects of biotechnology because of its potential threat to biodiversity or "the integrity and ecological balance of creation" (UMC 1992).

The result is that there is no consensus about general permissibility of animal biotechnology within Western religions and even within denominations. For example, Jewish theological reaction to cloning animals has been mixed, although cloning generally raises fewer issues than transgenics because cloning does not involve mixing species. In Islam, Shiite leaders generally have been more open to animal biotechnology than Sunni leaders, but even within sects there has been considerable division. The Church of Scotland, which has studied aspects of animal cloning extensively, supports the use of animal biotechnology for therapeutic purposes, but rejects uses of animal cloning for meat and milk production as an inappropriate commodification of animals (Church 2002).

Although there has been little specific religious discussion about the implications of animal biotechnology and even less joint discussion, American religious leaders acted with one voice opposing the patenting of genetically engineered animals. In May 1995, a group of religious leaders representing more than 80 faiths and denominations joined Jeremy Rifkin, an economist who has attacked expansion of biotechnology through patent law, in a press conference denouncing the patenting of genetically engineered animals, and human genes, cells, and organs. Their statement said: "We believe that humans and animals are creations of God, not humans, and as such should not be patented as human inventions" (Crawford 1987). The statement did not take a stand on the permissibility of genetic engineering itself, nor did the overall group oppose patents on techniques involving genetic manipulation. Although the statement garnered considerable media attention, it did not have any impact on American patenting law.

Eastern Religions

Eastern religions such as Buddhism, Hinduism, and Confucianism do not use the concept of animals in the service of humans. Instead, these religions give animals a moral status that often is almost equal to that of humans. Humans have a higher status only to the extent that they are more capable of achieving the philosophical ideals of spiritual wisdom and liberation. For Hindus, incarnations of the Gods include animal forms (Crawford 2003). Both Buddhism and Hinduism have a belief in cross-species reincarnation. Most Eastern religions embrace the idea of continuing evolution of humans, animals, and plants as an ideal, and the fact that such evolution is man-made is not a barrier.

There also is a pervasive notion, however, that there must be a balance of nature in human, plant, animal, and environmental interactions (Epstein 1998). This interpretation means that animal suffering would be balanced equally against human benefit (Crawford 2003). But there is no consensus among scholars of Eastern religions about the religious permissibility of animal biotechnology. Some religious scholars believe technology can be used on an animal only to benefit that animal, and most biotechnology is a violation of that principle (Epstein 1998). Other scholars believe that animal biotechnology may be used if it is necessary for life but not to enhance pleasure (Crawford 2003).

Asian religious traditions notably are distinct from Western traditions in the breadth and variety with which ethical teachings are interpreted by practitioners of the faith tradition. Thus the key ethical questions about animal biotechnology from the Asian perspective may have less to do with the ultimate permissibility of genetic engineering or cloning than with whether practitioners of a particular variety or sect within a faith tradition have had ample opportunity to discern how and whether the technology is relevant to the often-complex dietary and household practices believed to affect fate and fortune. As such, information about animal biotechnology and the opportunity to study the implications of transgenic or cloned animals may be deeply important to these traditions, even when no specific prohibitions are made.

Views on Food Use

There are specific religious concerns involving food use of animal biotechnology. For example, most Hindus attempt to be strict vegetarians, and there could be concerns about the extent that animal DNA is mixed in with genetically modified (GM) plants. Because Hindu bioethics is concerned with sentient life rather than DNA, however, this concern seems diminished. Both Jewish law and Islamic law have food restrictions that may be affected by biotechnology. Although the U.S. Islamic Jurisprudence Council has ruled that GM plants currently on the market that may contain animal genes are permissible, or halal, the permissibility of foods using genes derived from swine or more significant species mixing has not been determined (Mirza 2004).

Jewish kosher rules also are unclear when it comes to transgenic animals; the use of transgenic animals with some genetic mixing, even swine, has been found acceptable for food use as long as the genetic change is not visible to the naked eye (Reisner 2000). Jewish law also includes the prohibition kilayim, which forbids the mixing of different species of animals and plants. Kilayim forbids the act of mixing species, but does not forbid receiving the benefits of that mixing. Moreover, Jewish law has been interpreted to mean that the act must be a sexual act, which would exclude in vitro laboratory genetic manipulation.

Public Perceptions of Animal Biotechnology

Animal biotechnology has been expanding rapidly in the last three decades. Public perceptions have played, and will continue to play, a significant role in the development and commercialization of its applications. Technologies do not develop in a vacuum; rather, their trajectories take place within a cultural context. This context includes public opinions that, like other social factors, can play a role in the pace and direction of technology development.

Public Opinion Studies

Two key questions can be gleaned from public opinion studies on agricultural biotechnology generally, and on animal biotechnology particularly. These questions underlie the views of many publics: What is the purpose for the specific application? How is the work carried out? Many public opinion studies reveal a fairly consistent hierarchy of purpose: Applications intended to generate health and medical benefits are viewed most positively, followed by applications with environmental benefits. European surveys have found a consistent ordering, in decreasing favorability, for "genetic testing for heritable diseases; drug production using bacteria modified to contain human genes; bioremediation using GM bacteria; medicinal human cell or tissue cloning; use of plant genes in GM crops; animal cloning to produce drugs in their milk; and for producing foods to make them higher in protein, keep longer, or change the taste" (Gaskell 2000). The percentage of survey respondents seeing usefulness ranged from 83% to 54%, and moral acceptability from 74% to 36%.

The way research is carried out—including the object of manipulation—also influences public perceptions. In this regard, public acceptability also exhibits a hierarchy. Work on microorganisms generates the least concern, followed by work on plants. More objections are registered for genetic modification of animals (Frewer and Shepherd 1995; Frewer, Howard, and Shepherd 1996; Hoban 2004). Whereas approximately one in five persons in the United States thinks that creating hybrid plants through genetic modification is "morally wrong," more than half feel that way about GM animals (Hallman et al. 2002). This disapproval of GM animals seems to cut across gender, age, and educational categories among Americans, although more women than men have expressed disapproval (Table 1). Although health and medical benefits provided by genetic modification are supported most frequently, that support sometimes is modulated by how the benefits are obtained. For example, U.S. and Canadian respondents view drugs and vaccines produced through animals less favorably than drugs and vaccines produced through plants (Decima 2004).

Table 1. Acceptance of plant-based and animal-based genetic modification, by gender, age, and education (adapted from Hallman et al. 2002)[1]

	Approve (percentage)		Disapprove (percentage)		Unsure (percentage)	
	Plant	Animal	Plant	Animal	Plant	Animal
Sex						
Male	65	36	32	59	4	5
Female	53	21	40	74	7	5
Age						
<35	63	31	34	65	3	4
35–54	56	27	38	67	6	6
55+	55	21	37	71	8	8
Education						
High school graduation or less	51	24	43	73	6	3
Some college	65	27	31	66	4	8
College graduation	64	36	29	59	7	5

[1]Note: "Approve" includes those who "strongly" and "somewhat approve"; "Disapprove" includes those who "somewhat" and "strongly disapprove." N=1203. Question: "In general, do you approve or disapprove of creating hybrid (plants) animals using genetic modification?"

These opinion patterns are similar internationally. Consumers in 10 countries were surveyed about different biotechnology uses. More than 80% supported using biotechnology to develop human medicines; 75% supported using biotechnology for environmental clean-up. Slightly more than 50%, however, indicated support for GM animal feed that resulted in healthier meat products, whereas 40% supported the use of cloned animals for medical research. It is noteworthy that almost 75% of consumers in these 10 countries opposed the genetic modification of animals to increase productivity (Hoban 2004).

There are additional nuances to public views on animal biotechnology that need to be considered, including the moral status of animals. The advocacy of animal rights and animal welfare groups and the incorporation of pets as part of the family circle have made the status of animals a mainstream concern (AEBC 2002). Investigations into public views on animal experimentation, for example, have shown that people are concerned with (1) knowing the purpose of the experiment, (2) avoiding potential unnecessary suffering of the animals, (3) ensuring that requirements for protecting animal welfare are met, and (4) determining whether alternatives are available (AEBC 2002; Knight 2007).

A second concern is the boundary between what is considered "natural" and "unnatural." Many people feel that the crossing of species' boundaries is unnatural, and this cross-species work becomes especially problematic when higher life forms are involved (AEBC 2002; Gaskell 2000; Hallman et al. 2002; Verhoog 2003). The process of genetic engineering also is associated with images of the "unnatural." A third concern relates to the consequences of genetic modification, particularly the long-term impacts of GM crops and animals on human health and the environment.

Public Awareness

In general, public awareness of plant and animal biotechnology is low, although more people are aware of biotechnology in plants than in animals (Table 2). The majority of Americans—at least two-thirds—are unaware that foods produced through biotechnology currently are in the supermarket

Table 2. Americans' awareness of plant and animal biotechnology (IFIC 2007)

	Plant Biotechnology (Percentage)	Animal Biotechnology (Percentage)
Heard or read about		
Some—A lot	37	22
Little or nothing	63	78
Overall impression		
Somewhat—Very favorable	33	24
Neither favorable nor unfavorable	30	26
Not very—Not at all favorable	18	23
Don't know	19	27

(Hallman et al. 2003; IFIC 2007). An International Food Information Council survey asked about three approaches to animal biotechnology: (1) genomics ("animal biotechnology that uses knowledge about the genetic make-up of animals to aid in conventional breeding and selection"); (2) genetic engineering ("animal biotechnology that allows us to move beneficial traits from one animal to another in a more precise way"); and (3) cloning ("animal biotechnology that retains desirable traits by producing an animal that is an identical twin"). The numbers of respondents who were at least somewhat favorable were 40, 35, and 22%, respectively (IFIC 2007), suggesting that cloning still may be associated with the negative side of biotechnology (Einsiedel 2000).

Influencing Factors

Certain factors help to explain perceptions and attitudes toward applications of agricultural biotechnology. The risk–benefit calculus is certainly one influencing factor. Some studies have found that it is the perception of benefits that acts as an important decision rule, leading individuals to determine whether perceived risks are more or less significant (Gaskell et al. 2004; Knight 2007). It also is important to note that quite often, publics do not always interpret risk and benefit in purely utilitarian terms. "In the public mind, risks go beyond issues of health to include moral hazards (is it right to do this?), democratic hazards (who is funding and controlling biotechnology?), and uncertainties (will there be as-yet-unknown adverse consequences?)" (Gaskell et al. 2003; Marris et al. 2001).

Another factor that has some influence on public views is knowledge or understanding (Allum et al. 2008). Significantly, the explanatory role of knowledge is not as simple as "information acquisition leads to acceptance." Depending on the application, more knowledge can indeed influence opinions—sometimes in the direction of more positive attitudes and sometimes in the direction of a negative or more precautionary stance (Hallman et al. 2003; Scholderer and Frewer 2003).

One of the more consistent predictors seems to be trust in the managers of a technology, including its regulators (Hornig Priest, Bonfadelli, and Rusanen 2003). A study of consumers in five European countries demonstrated that "proactive consumer protection" was related positively to consumers' evaluation of food risk management quality, whereas "opaque and reactive risk management" was related negatively to food risk management quality (Van Kleef et al. 2007).

Regulation of Animal Biotechnology

When the biotechnology industry became an economic reality in the early 1980s, the White House Office of Science and Technology undertook a study to determine how science and industry should be regulated. In the *Coordinated Framework for Regulation of Biotechnology*, it was determined that the new technology was not inherently risky and could be integrated into existing statutory and regulatory structures under the auspices of the FDA, the Environmental Protection Agency (EPA), and the USDA (Coordinated Framework 1986). These agencies derive their regulatory authority from an assortment of statutes,[2] none of which anticipated the specific issues of biotechnology. As a result, there are gaps in—and overlaps of—authority, as well as considerable ambiguity.

Regulatory Responsibility

Animal biotechnology primarily is regulated by the FDA and the USDA. The FDA is responsible for food safety issues for food animals created through biotechnology and for drug safety issues for transgenic and otherwise modified animals used for pharmaceutical production. The USDA, through the Animal and Plant Health Inspection Service (APHIS) and the Food Safety and Inspection Service, regulates food products created by animal biotechnology. Until recently, the FDA was the sole agency responding to issues regarding animal transgenics, but that responsibility now is being shared with APHIS, whose role may grow. Nonetheless, although the APHIS Biotechnology Regulatory Services considered new regulations for transgenic animals as part of an initiative dealing with all genetically engineered organisms (USDA–APHIS 2009), the FDA took the lead role with guidelines issued in January 2009 (USFDA–HHS 2009). The FDA also determined that meat and milk from cloned cattle, swine, and goats are as safe to eat as those from conventionally produced animals (USFDA–HHS 2008). Although animal biotechnology may raise environmental issues, the EPA currently

[2] Animal Health Protection Act of 2002, United States Code, vol. 7, sec. 8301-8320; Animal Quarantine Laws, United States Code, vol. 21, sec. 101-135; Animal Welfare Act, United States Code, vol. 7, sec. 2131-2159; Egg Products Inspection Act, United States Code, vol. 21, sec. 1031-1056; Federal Meat Inspection Act, United States Code, vol. 21, sec. 601-691; Food Drug and Cosmetic Act, United States Code, vol. 21, sec. 301-399; Health Research Extension Act, United States Code, vol. 42, sec. 201-300gg-92; Public Health Service Act, United States Code, vol. 42, sec. 262, 264; Poultry Products Inspection Act, United States Code, vol. 21, sec. 451-471; Virus, Serums and Toxins Act, United States Code, vol. 21, sec. 151-159.

does not regulate in that domain; environmental assessments of specific products are undertaken by the FDA.

Product-versus-Process

In determining the use of existing statutory and regulatory structures to regulate biotechnology, the Coordinated Framework also essentially determined the focus of the regulatory review. Because U.S. regulators do not view the process of biotechnology to be inherently risky, generally only the products of biotechnology are regulated. This product-versus-process distinction is based on the fact that a significant amount of American federal law regulating biotechnology draws its jurisdictional authority from the commerce clause. For example, under the Food, Drug and Cosmetic Act (FDCA), the FDA's authority to regulate the use of animals for food or pharmaceutical use may be limited to "articles" whose commercial distribution the FDA can regulate (FDCA 2006). The FDA's legal authority to regulate those articles is grounded in its power to regulate their distribution in interstate commerce. Hence, the process is implicated only to the extent it affects the final product.

"Animal Drug" Regulations

The FDA bases its authority to regulate genetically engineered animals under the FDA's "animal drug" regulations, because like a drug, the engineering is intended to "alter the structure or function" of the animals (Pew Initiative 2004). This involves stretching the statutory definition considerably because the FDCA implies that drugs work through chemical action, and unlike a typical drug, the engineering continues beyond the affected animal to its progeny (FDCA 2006; Pew Initiative 2004). Thus, at the very least, the FDA's authority under this rubric is questionable. The Supreme Court, however, has allowed fairly broad interpretations of FDCA drug definitions when the FDA has sought regulatory authority over some segments of the industry (*United States* 1969). Moreover, the FDA's assertion of authority is unlikely to be challenged, as the biotechnology industry has embraced the animal drug rubric because it is anxious to have regulations in place to ensure consumer acceptance and promote growth of the industry (Gottlieb and Wheeler 2008).

This regulatory focus on products rather than process has ethical ramifications. Other than in issues raised by the AWA, which is itself limited, much ethical review does not occur until a product is far along in the development process, and most of that ethical review tends to be about whether the article is safe for its intended purpose. Thus, the discussion does not focus on whether cloning, genetic engineering, or other biotechnologies are appropriate methods—or even whether the resulting products are socially or economically valuable or ethically appropriate—but rather on whether the products are safe for use, or "generally recognized as safe" (GRAS).

Postmarket and Labeling Regulations

Once a product created by animal biotechnology comes to market, it is subject to FDA and APHIS labeling requirements. These requirements, however, center on the function of the product rather than on the method whereby it was created. In food biotechnology, a product that is considered GRAS and substantially equivalent to food products already on the market is not required to be labeled. Thus, the FDA rejected labeling requirements for milk products derived from cows given *recombinant bovine somatotropin* (rBST), and the FDA Risk Assessment considering food products derived from cloned animals or their progeny also does not recommend labeling the products as such. The exception to this pattern may be irradiated foods, but the FDA's contention there is that the irradiation at least minimally modifies the food. Moreover, the FDA recently has recommended that labeling requirements for irradiated foods be relaxed (Irradiation 2007). Foods created through genetic engineering that changes the animals' genome, however, would not be substantially equivalent, and those products presumably would be subject to labeling requirements.

To date, attempts to have state laws label food created through biotechnology as such have failed. The U.S. Court of Appeals for the Second Circuit rejected an attempt by Vermont to require rBST milk products to be labeled (*International Dairy Foods* 1996). That decision, however, may be flawed, and new attempts through federal or state statute to label food derived through cloning methods may be successful. The ethical question implicated by such labeling is whether consumers have a right to know, apart from FDA safety assessments, the process by which food is manufactured. But supporting such a right to know causes other problems. On one hand, transparency is an ethical goal; on the other, labeling could needlessly frighten or confuse consumers. The FDCA currently does not give the FDA authority to consider that question; FDA's authority is limited to safety issues.

It is not clear what kind of postmarketing requirements the FDA can impose on biotechnologically derived animal production. The FDA has secured voluntary commitments from product sponsors to conduct postmarket research on rBST (Pew Initiative 2004), but it is uncertain whether the FDA has authority to require such research. In addition, it is not clear what kind of tracking systems the FDA or APHIS can impose on GM animals. Several companies engaged in livestock cloning have introduced a tracking system for cloned livestock and their progeny, but that program is voluntary (Pollack 2007). Under current law, neither agency has authority to regulate all animals that might be used under that technology; therefore, there are certainly potential gaps.

Animal Welfare and Institutional Animal Care and Use Committees

The AWA regulates the treatment of animals used in experimentation by research facilities that receive federal funds or transport live animals in interstate commerce. The word "animal" includes warm-blooded animals such as dogs, cats, nonhuman primates, guinea pigs, and rabbits; but excludes birds, rats, mice, and farm animals used for food or for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality

of food or fiber (AWA 2006). Thus, depending on how broadly that definition is interpreted, quite a few animals used in biotechnology may be excluded. The AWA is enforced by the USDA, a fact that has a certain irony, given that many of the animals that fall under the USDA's traditional scope are not included in the Act's definition.

The AWA requires research facilities to create IACUCs (AWA 2006) to inspect animal care facilities and to review experimentation and care of animals. The IACUCs must have at least three members, one of whom must be a veterinarian, and another who may not be associated with the institution. The legislative history of the AWA encourages the use of the ethical construct of the "three Rs": Reduction in the number, Refinement of techniques, and Replacement (*Congressional Record* 1991; Russell and Burch 1959). Institutions that receive federal funding for their research are subject to additional broader guidelines (PHS 2002), and many entities choose to seek accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC).

Importantly, although the AWA does set standards for the use of animals in experimentation, it does not regulate the purpose of experimentation (AWA 2006). Thus, under the AWA, an IACUC's ethical review is limited considerably. For example, because of the three Rs construct, IACUCs may determine that an experiment is impermissible because of redundancy (i.e., other similar or identical experimentation already has tested a hypothesis such that additional use of animals is not ethical). Similarly, IACUCs will make sure that animals born with considerable deformities are euthanized. IACUCs may not determine, however,—beyond the humane requirements of the AWA—that a cloning or genetic engineering technique is unethical. If that review occurs, it occurs outside the IACUC rubric, and usually only because the research facility has voluntarily elected to do so.

European Union

In contrast to the American approach to biotechnology, European regulators view biotechnology as "a novel process requiring novel regulatory provisions" (Gaskell et al. 1999). The European Medicines Agency is responsible for the approval of pharmaceuticals derived through animal biotechnology, and the EFSA is responsible for approval of food derived from animal biotechnology. The interaction of these agencies and member states is beyond the scope of this paper. Some directives are required to be passed into legislation by member states, and some issues, especially those with moral implications, are left to member states' discretion. In certain circumstances, member states also may require stricter regulation than required by the European directives.

Pharmaceutical or other biomedical use of biotechnology is much less controversial in Europe than food use, and the level of regulation reflects that attitude (Gaskell et al. 2006). There is also only a tiny industry involved in food biotechnology. For example, until recently, only Spain was truly involved in genetically modified organism (GMO) plant production. Therefore, many GMO regulations actually are directed at importation of GMO products, and this focus has had an important effect on the evolution of the regulation.

Regarding regulation of food biotechnology, the EFSA is responsible for scientific risk assessment; risk management policy is handled by the European Parliament and member states (Podger 2004). That division of labor insulates the scientific assessment from political meddling. Directive 2001/18/EC regulates the distribution of GMOs and GMO use in food products, but there are no specific European regulations for food products derived from biotechnology, such as cloning that does not involve genetic modification. No distinction is made between animal or plant products (Directive 2001).

Directive 2001/18/EC requires notification before a GMO is placed on the market. The Directive also provides for a period of public comment; an assessment report, including an environmental risk assessment; and a "step-by-step" introduction into the market. Each step requires additional assessment and evaluation. The Directive also requires that each GMO product be labeled with the words "This product contains genetically modified organisms." Postmarket monitoring also is required, including complete traceability and immediate adverse event reporting.

Directive 2001/18/EC resulted in a European Union (EU) moratorium banning importation of all GM products. The Directive adopted a precautionary approach allowing for such a ban if there was a potential risk to human health or the environment. Because the trigger for a moratorium required only a potential risk rather than a proven risk, such a moratorium was an almost certain consequence of the language of the directive. In response, the United States and Argentina filed a complaint with the World Trade Organization (WTO), and the WTO ruled against the European ban. The EU has chosen not to appeal the WTO ruling, and there are some indications that EU citizens are poised to embrace biotechnology more fully (Gaskell et al. 2006; Zika et al. 2007). Whether that new enthusiasm will extend to food use of animal biotechnology remains to be seen.

Interestingly, the process taken by the EU does not mean a broader ethical review of biotechnology. Instead, at least so far, the process approach combined with the precautionary principle simply means that the technology does not go forward or importation is refused. The specific ethical debate still becomes kindled only when a product is about to be commercialized.

China

China currently is the sixth largest producer of GM crops, and its government has made a strong commitment to both plant and animal biotechnology. Animal biotechnology in China is governed primarily by three agencies: the Ministry of Health, the Ministry of Science and Technology, and the Ministry of Agriculture. A review of regulation in China is particularly difficult because there is relatively little formal legislation in the Western sense. But the government will affect patterns of practice significantly through funding initiatives as well as through informal means such as the cultivation of expectations and a cultural climate

(Döring 2004).

Although there are regulations regarding human cloning (Leggett 2003), there are no specific regulations regarding animal cloning. The human cloning regulations specifically ban research for human procreation, but they leave open virtually all other research. Generally, research endeavors are controlled much more lightly than clinical or commercial applications. An attempt to formally regulate animal welfare was abandoned in 2004 (Li 2004). New efforts to do so recently have begun, but no regulations have been proposed yet.

The most extensive regulation is centered on biosafety issues. Animal biotechnology that involves genetic modification is governed by six instruments that apply equally to plants and animals: A State Council of China general regulation on biosafety of GMOs, four Ministry of Agriculture decrees, and complementary customs regulations (Connor, Boucher, and Li 2006). These regulations require a full risk assessment of food safety and environmental impact for both importation and production of GMOs (Wang 2007). Labeling requirements reflect an approach that is at least partly process based. Although all these regulations formally apply to animals, there are few indications of enforcement; almost all enforcement involves plant importation and production.

Despite apparently conservative ethical thinking regarding human reproductive cloning (Döring 2004), it probably is fair to say that the Chinese government takes a very liberal stance regarding biotechnology ethics. There is little regulation of research, but there is considerable funding support and positive media reporting on technical achievements. The public shows little opposition (Yang 2004).

International Protocols

There are two main international protocols that affect animal biotechnology. The Codex Alimentarius Commission (Codex) and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The Codex, jointly administered by two United Nations agencies—the World Health Organization and the Food and Agriculture Organization—sets international safety standards for foods. Before a food produced by biotechnology can be marketed, it is subjected to a pre-market assessment that evaluates both the direct and unintended effects on food safety and nutritional aspects that might arise because of the use of technology (Codex 2003, 2007). Although it is a thorough risk assessment of the food safety issues, the Codex does not address the environmental, ethical, moral, or socioeconomic impacts of the technology.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity primarily is an environmental treaty (Cartagena 2000). Its main purpose is to protect biological diversity from risks posed by "living modified organisms" (LMOs), taking into account potential risks to human health. Although the Cartagena Protocol thus far primarily has focused on plant biotechnology, its definition of LMOs equally encompasses animals. The protocol adopts a precautionary approach; if a potential but not yet scientifically proven risk might exist, that potential risk may be used as a reason to limit the importation or use of an LMO. There are 157 parties to the Cartagena Protocol, including most European countries and China.[3] The United States and Australia are not parties.

Conclusions

Decisions about the development and use of animal biotechnology can be based on multiple factors. Knowledge of the science of animal biotechnology is needed to understand exactly what animal biotechnology involves and to appreciate its possible areas of applicability. Philosophical reflections on the moral significance of animals can inform the way applications of genetic engineering are evaluated, with respect both to their impact on animals and to the way that attempts to modify and control animals are viewed from an ethical perspective. A review of religious traditions of animal use highlights specific applications of biotechnology that may arouse sensitivities among adherents of those traditions. Social science research on the public's attitudes toward animal biotechnology illuminates the way that philosophical or religious attitudes toward animals and biotechnology may be reflected broadly throughout the public. This kind of research can be used in making inferences about those applications of biotechnology that are most likely to spark opposition or consumer resistance.

When science, ethics, religion, and social science are viewed concurrently in light of previous attempts to regulate animal biotechnology, it becomes apparent that society is struggling to develop public policies that appropriately reflect the diverse set of considerations that bear on applications of animal biotechnology in agriculture and the food system.

This review paper does not prescribe rules or principles that should be applied in making decisions about animal biotechnology. Its purpose has been to highlight some of the considerations that might be taken into account when decisions are made about genetic engineering or cloning of agricultural or food animals. No precise method for drawing simultaneously on science, ethics, religious tradition, public opinion, and legal practice has been specified. There have been relatively few formal efforts to bring these domains of human practice into dialogue for animal biotechnology. It is the authors' belief that decision making will be improved if more frequent and sustained efforts to consider and reflect the full range of ideas represented in this paper are undertaken in the future.

Glossary

Bioreactors. Animals used to produce pharmaceuticals or commercial products such as silk, usually by the mammary gland.

Blastomere nuclear transfer cloning. A cloning method using the nucleus from a cell from embryos at the blastocyst or earlier stage of development.

[3] For a list of the status of the ratifying Parties, see The Convention on Biological Diversity, Parties to the Convention on Biological Diversity, Cartagena Protocol on Biosafety, http://www.cbd.int/information/parties.shtml.

Cytoplasmic factors. Factors in that portion of a cell outside the nucleus.

Full sibs. Offspring from mating between the same sire and dam.

Gene knockouts. Individuals in which a gene has been rendered nonfunctional.

Oöcytes. Unfertilized eggs ovulated from ovarian follicles.

Quantitative trait loci. Regions of a chromosome with a genetic marker associated with a desired production trait (e.g., milk yield).

Recombinant bovine somatotropin. A hormone produced by microorganisms such as bacteria or yeast into which the gene for bovine somatotropin or growth hormone has been introduced.

Single nucleotide polymorphism. Variation in one or more nucleotides at a specific region of DNA; these may be associated with genes for differences in appearance or performance characteristics of an individual.

Somatic cell. A cell of an organ or tissue of the body that is not a gamete, i.e., sperm or oöcyte, or precursor cell of a gamete.

Somatic cell nuclear transfer. Cloning by using the nucleus taken from a fetus or an animal post-birth.

Sugar moieties. Sugars such as glucose and galactose attached to a protein that in some instances are required for biological activity.

Totipotent. A nucleus with genes capable of encoding for a fully developed offspring when transferred into an enucleated oöcyte.

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ISSN 1070-0021

Additional copies of this issue paper are available from CAST. Linda M. Chimenti, Director of Council Operations. World WideWeb: http://www.cast-science.org.

Citation: Council for Agricultural Science and Technology (CAST). 2010. *Ethical Implications of Animal Biotechnology: Considerations for Animal Welfare Decision Making*. Issue Paper No. 46. CAST, Ames, Iowa.

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