An HSUS Report: Welfare Issues with Genetic Engineering and Cloning of Farm Animals

Abstract

Developments in biotechnology have raised new concerns about animal welfare, as farm animals now have their genomes modified (genetically engineered) or copied (cloned) to propagate certain traits useful to agribusiness, such as meat yield or feed conversion. These animals have been found to suffer from unusually high rates of birth defects, disabilities, and premature death. In the United States, there is significant public opposition to the introduction of meat and milk from cloned animals and their progeny into the food supply and currently no regulations exist to protect the welfare of farm animals during cloning or genetic engineering agricultural research.

Background

Both the genetic engineering and cloning of animals involve the artificial manipulation of deoxyribonucleic acid (DNA).

Genetic engineering involves the alteration of an animal's genetic information, including the addition (or "knock-in") and the removal or inactivation ("knock-out") of genes or their control sequences.[1] For example, the process of adding a growth hormone gene to increase growth rates starts with isolating the gene, cloning it in bacteria to produce large quantities, and then injecting the gene under a microscope into a pronucleus of an embryo flushed from his or her mother's oviduct. This embryo is then implanted into a surrogate mother who will give birth to offspring, some of whom will be transgenic—that is, containing the exogenous growth hormone gene in all of their cells.[2]

Clones are nearly exact genetic copies of an individual animal.[*] A recipient cell, usually an egg, is enucleated (nearly all of its genetic information is removed), and the nucleus of a cell from the animal to be cloned (the donor animal) is inserted or fused inside the cell. Embryos produced by this nuclear transfer are then cultured *in vitro* for several cell divisions before being implanted into a surrogate mother.[3] The first mammal successfully cloned from an adult cell, a sheep called Dolly, was born in 1996.[4]

Researchers are genetically engineering and cloning farm animals for the food supply for a number of reasons, such as more profitable muscling and disease resistance. However, many applications of these technologies have been shown to be detrimental to animal welfare.

Genetic Engineering and Animal Welfare

While genetically engineering farm animals to increase bone strength or reduce reception to pain, for example, may improve animal well-being, the broad use of such technology would be unlikely to result in a reduction of suffering. Gene insertion techniques have limited success, as inserted genes may fail to properly reach target cells and may finish in cells of unintended organs. Many embryos develop abnormally and die *in utero*, while

[*] A cloned animal is not genetically identical to the animal from whom nuclear material was taken because of the very minor contribution of mitochondrial DNA from the egg.

others may be infertile or born with developmental defects, some of which are attributable to these so-called insertional problems.[5]

Still other health issues may not become apparent until later in life. Transgenic animals often exhibit variable or uncontrolled expression of the inserted gene, resulting in illness and death.[5] In one study, ten transgenic piglets were followed from birth through puberty. Half of the animals died or had to be euthanized due to severe health problems during the investigation, indicating a high mortality rate among genetically engineered piglets. In addition, three of the surviving piglets showed decreased cardiac output.[6]

The genetic modification of sheep containing an extra copy of a growth hormone gene resulted in animals who reportedly grew faster, leaner, and larger than those conventionally bred; produced more wool; or produced milk for prolonged periods. Developing more economically profitable sheep reportedly resulted in negative welfare side effects from the excess growth hormone, including increased incidences of diabetes and susceptibility to parasites.[7]

The transgenic "Beltsville pigs" had human growth hormone genes inserted in their genomes with the goal of increasing the animals' productivity. While that was partially achieved, the genetically modified animals reportedly suffered from numerous problems that severely compromised their welfare, including arthritis, diarrhea, lameness, mammary development in males, disruption of estrous cycles, skin and eye problems, loss of libido, lethargy, pneumonia, pericarditis (inflammation of the sac surrounding the heart), and peptic ulcers. Of the 19 pigs expressing the transgene, 17 reportedly died within the first year.[5]

Similarly, a research effort led by U.S. Department of Agriculture (USDA) scientists modified the genes of dairy cows so the animals would be more resistant to mastitis, an inflammation of the udder. Of 330 attempts, only 8 calves were born alive, and of those 8 animals, only 5 survived to adulthood.[8]

Cloning and Animal Welfare

Cloning research also reveals abnormalities and high failure rates, problems widely acknowledged by scientists in the field and potentially indicative of poor animal welfare.[5,9] Seemingly healthy bioengineered animals are at risk for a variety of defects. "All cloned babies have some sort of errors," cloning pioneer Ryuzo Yanagimachi reportedly claimed. "I'm surprised they can survive it."[10] The list of problems from which clones have suffered is extensive, including diabetes, enlarged tongues, malformed faces, intestinal blockages, shortened tendons, deformed feet, weakened immune systems, respiratory distress, circulatory problems, and dysfunctional hearts, brains, livers, and kidneys.[10-14]

A 2003 review of cloning procedures found that while hundreds of calves have been cloned worldwide, less than 5% of all cloned embryos transferred into recipient cows have survived, and the majority of the 95% who did not survive died at various stages of development from a predictable pattern of placental and fetal abnormalities. "The low efficiency seriously limits commercial applicability and ethical acceptance of somatic cloning," wrote the scientists, "and enforces the development of improved cloning methods."[15]

Two years later, a review further identifying the challenges of cloning farm animals continued to note a high failure rate:

> "[A]t present it is an inefficient process: in cattle, only around 6% of the embryos transferred to the reproductive tracts of recipient cows result in healthy, long-term surviving clones. Of concern are the high losses throughout gestation, during birth and in the post-natal period through to adulthood. Many of the pregnancy losses relate to failure of the placenta to develop and function correctly. Placental dysfunction may also have an adverse influence on postnatal health."[16]

Upon review of the world's cloned animals, Ian Wilmut, who led the team to clone Dolly the sheep, also reportedly found low success rates and a host of problems such as fetal overgrowth, or large offspring

syndrome, in cattle and sheep; heart defects in pigs; developmental difficulties, lung problems, and malfunctioning immune systems in cows, sheep, and pigs; and individual problems, including a lamb barely able to breathe due to grossly thickened muscles surrounding the lungs. He is quoted as saying: "The widespread problems associated with clones has [*sic*] led to questions as to whether any clone was entirely normal….There is abundant evidence that cloning can and does go wrong…."[17]

The U.S. National Academy of Sciences acknowledged many of these problems in its 2002 report, "Animal Biotechnology: Science-Based Concerns,"[5] and the U.S. Food and Drug Administration (FDA) also identified these issues during an earlier hearing on cloning. Kathryn Zoon, Director of the FDA Center for Biologics Evaluation and Research, testified before Congress that the failure rate remains extremely high for cloned animals. Furthermore, Zoon testified that "when live births occurred there have been deaths and major abnormalities such as defective hearts, lungs and immune systems in the newborns and older animals. In addition, significant maternal safety risks including deaths have been observed."[18]

Despite the high level of inefficiency and recognized animal welfare concerns, the FDA's draft executive summary, "Animal Cloning: A Risk Assessment," claimed that "the proportion of live, normal births appears to be increasing."[19] Members of the FDA's own Veterinary Medicine Advisory Committee, however, reportedly felt that the FDA had not properly characterized the risk to animals and were uneasy about the level of animal suffering a large cloning industry might cause.[20] In 2005, an FDA representative reportedly acknowledged that cloned animals were indeed more likely to suffer birth defects and health problems when very young.[21] Likewise, an article published in 2007 by FDA researchers noted "that perinatal calf and lamb clones have an increased risk of death and birth defects," demonstrating these problems had not been resolved.[22]

A large-scale study of cloned sheep was published in 2006. Out of 93 initial attempts, only 12 clones reached full-term development. Of these 12, 3 lambs were delivered stillborn, 5 died of liver and kidney abnormalities within 24 hours of delivery by caesarian section, 2 died one day after birth from respiratory distress syndrome, and the remaining 2 lambs died at approximately four weeks due to a bacterial complication.[23]

Cloning also threatens the welfare of surrogate mothers. According to the 2001 congressional testimony of Mark Westhusin, Director of the Reproductive Sciences Laboratory at Texas A&M University's College of Veterinary Medicine, of the cloned calves who survived after 35 days of gestation, most exhibited placental abnormalities that pose serious health risks not only to the developing fetus and offspring, but also to the surrogate mothers carrying the pregnancies, and have resulted in the deaths of both the fetuses and the surrogate mothers.[24] In addition, the birth weight of cloned calves may be 25% heavier than normal.[16] Fetal overgrowth, common to sheep and cattle clones, generally necessitates a caesarian section for the surrogates, an invasive surgery which, along with other intrusive reproductive procedures, may be performed repeatedly on the same animal.

A Texas A&M University study of cloned transgenic calves resulted in four surrogate cows dying. Of the 13 fetuses studied, 4 were stillborn and 2 died after birth. One calf was diagnosed with neonatal respiratory distress at birth, only to die four days later. A necropsy revealed that the calf suffered from severe abnormalities: The animal's lungs had never properly developed, the heart was enlarged, and the liver was grossly abnormal.[25] Michael Bishop, past president of former biotechnology company Infigen, is reported as saying such deaths still happen despite improvements in cloning. "We sacrifice the cow and the clone," he stated in a 2001 interview with *New Scientist*. "[A]ll the heroics in the world can't rescue those animals."[10]

Long-Term Welfare Problems

Biotechnology has produced animals with a range of gross deformities. So-called "legless mice," resulted from foreign DNA being inserted into the mice's chromosomes in a manner that altered an endogenous gene, resulting in a mutation. The first generation of mice produced by this procedure, known as insertional mutagenesis, appeared normal. However, when the transgenic mice were interbred, their progeny suffered severe abnormalities, including the loss of limbs, craniofacial malformations such as a cleft lip or cleft palate,

and brain anomalies, including highly aberrant or missing olfactory lobes. None of the mice survived for more than 24 hours after birth.[26]

Some abnormalities may not show up until later in life. Rudolph Jaenisch, a Founding Member of the Massachusetts Institute of Technology Whitehead Institute for Biomedical Research, was quoted as stating that "[c]loned animals that reach birth or beyond may appear normal, but our research shows they're not."[27] "From what we know, I would argue that cloned animals cannot be normal," Jaenisch reportedly concluded. "They can be closer to normal, but not normal."[28]

According to leading[29] cloning scientist David Norman Wells, the development of musculoskeletal problems, such as chronic lameness and severely contracted flexor tendons, in these high-production animals "emphasises the point that any underlying frailties in cloned animals may not be fully revealed until the animals are stressed in some manner."[16] Wells *et al*. found that the most common cause of death of cattle they cloned were late-developing musculoskeletal problems so severe that the cows needed to be euthanized.[30]

Immune deficiency may be another defect challenging cloned animals. Researchers with the USDA and the University of Missouri found the immune systems of cloned pigs produced lower levels of cytokines, which are necessary to fight infections.[31] This impaired immune function may contribute to cloned animals' susceptibility to illness and early death. Combined with the decrease in genetic diversity that would necessarily follow from the large-scale adoption of cloning, this technology may have the potential to exacerbate the already serious problem of transboundary epizootics.[32]

Mounting evidence shows that the death and deformities found among many cloned and genetically engineered species appear to be the norm rather than the exception, resulting in needless animal suffering.

Lack of Oversight

The federal Animal Welfare Act does not cover farm animals used in food and fiber research. The lack of regulatory or legal constraints on what can be done to animals in pursuit of increasing agricultural output, coupled with the historical willingness of industrialized agriculture to sacrifice animal welfare for productivity and profit, reveal many of the problems with much biotechnological animal research.[33]

While the FDA is charged with regulating genetically engineered farm animals destined for the food supply under the New Animal Drug Application (NADA) process, it has not yet developed regulations or public guidance that provide a clear determination of how the NADA process will apply to these animals. As NADAs are confidential by law, there may be no opportunity for prior public review of applications. The regulation of cloned animals is also under the FDA's jurisdiction.[34]

On September 19, 2005, four days before his resignation, former FDA Commissioner Lester Crawford explained its position:

> "With respect to use of cloned animals for human food, FDA has stated upfront that the risk assessment methodology and all the information used in performing the risk assessment would be publicly available….Until the risk assessment is complete and publicly available, the voluntary moratorium on release of these products into the food supply remains in effect; and secondly, while our risk assessment only addresses the safety of food from animal clones and the risks to the cloned animals, we are well aware that there are many social and ethical issues related to the cloning of animals."[35]

The agency denied a petition filed by a number of organizations, including Center for Food Safety, Consumer Federation of America, and the Humane Society of the United States in October 2006, seeking regulation of cloned animals.[36] Responding to one of the requests in the petition, which asked that an advisory committee be created to address ethical issues, the FDA's deputy commissioner for policy wrote: "We do not believe we are

required…to establish an advisory committee to consider animal welfare….We note that we have considered the animal health impacts of animal cloning."[37]

FDA's Approval of Cloning

A 2005 Pew Initiative on Food and Biotechnology poll found that two-thirds of U.S. consumers indicated that they are uncomfortable with animal cloning in general.[38] An earlier Gallup poll reportedly found that two-thirds considered animal cloning "morally wrong."[39]

On December 28, 2006, the FDA released three documents for public comment: "Animal Cloning: A Draft Risk Assessment," "Animal Cloning: Proposed Risk Management Plan for Clones and Their Progeny," and "Guidance for Industry Use of Edible Products from Animal Clones or Their Progeny for Human Food or Animal Feed."[40] The FDA received approximately 30,500 comments.[41] Just over one year later, the agency released its final report, announcing its conclusion that meat and milk from cloned cattle, pigs, and goats, as well as sexually reproduced offspring of any cloned animal are as safe to eat as conventionally bred animals.[42] In considering animal health, the agency found "that animals involved in the cloning process (*i.e.*, cattle and sheep surrogate dams, and clones) are at increased risk of adverse health outcomes….Although none of the adverse outcomes is unique to cloning, the incidence of these abnormalities observed in animals produced by SCNT [somatic cell nuclear transfer] is increased compared to animals produced by other ARTs [assisted reproductive technologies]."[43]

Some companies have announced that they will not use meat or milk from cloned animals in their products regardless of what the FDA determines. The nation's largest processor and distributor of dairy products, Dean Foods,[44] stated: "Numerous surveys have shown that Americans are not interested in buying dairy products that contain milk from cloned cows and Dean Foods is responding to the needs of our consumers."[45] Smithfield Foods, the nation's and world's largest pig producer and previous funder of a pig cloning subsidiary of ViaGen, the leading farm animal cloning company,[46] reportedly announced that its decision was based on the fact that "[t]he science involved in cloning animals is relatively new."[47]

A few days before the FDA announced its decision, the European Food Safety Authority (EFSA) released its "Draft Scientific Opinion on Food Safety, Animal Health and Welfare and Environmental Impact of Animals Derived from Cloning by Somatic Cell Nuclear Transfer (SCNT) and Their Offspring and Products Obtained from Those Animals." EFSA found, in part, that "[r]educed welfare of clones is assumed to occur as a consequence of adverse health outcomes" and that the "occurrence of late gestational losses, dystocia and large offspring in SCNT is likely to affect the welfare of the surrogate dams carrying calf clones," noting that the "frequency of those adverse health outcomes is higher in SCNT than *in vitro* or *in vivo* reproduction."[48]

While the FDA failed to consider ethical issues, the European Commission's European Group on Ethics (EGE) in Science and New Technologies evaluated the ethical aspects of farm animal cloning and concluded: "Considering the current level of suffering and health problems of surrogate dams and animal clones…the EGE does not see convincing arguments to justify the production of food from clones and their offspring."[49] On May 22, 2008, the European Parliament passed a resolution stating it "[s]trongly believes that the cloning of animals for economic purposes should be banned…."[50]

Congress Advised FDA to Proceed with Caution

The U.S. legislature has similarly asked for a precautionary approach. In December 2007, both the House and Senate passed legislation responding to consumer concerns about the FDA's impending approval of these products.[51] The House and Senate approved language in the fiscal year 2008 omnibus package that strongly encouraged the FDA to delay its decision until a study with the USDA could be completed.[52]

The Senate-passed Farm Bill (HR 2419) includes a provision introduced by Senators Barbara A. Mikulski (D-MD) and Arlen Specter (R-PA) requiring additional studies by both the USDA and National Academy of

Sciences before the FDA can issue a final decision.[53] In a letter to FDA Commissioner Dr. Andrew von Eschenbach, Senator Mikulski wrote: "There is no urgency to issue a final decision, but there is a potential for unintended consequences if the FDA acts too quickly."[52]

Conclusion

High failure rates, defects, disabilities, and the premature deaths of both surrogate mothers and offspring have plagued the application of biotechnology to farm animals. There are currently no regulations to protect farm animals during cloning or genetic engineering in agricultural research and the welfare of these animals may suffer greatly.

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