BIO BIOTECHNOLOGY INDUSTRY ORGANIZATION

Fact Sheet
Animal Cloning

Livestock cloning is the most recent evolution of selective assisted breeding in animal husbandry, a practice dating back to the dawn of time. Arab sheikhs first used artificial insemination (AI) in horses as early as the 14th century. In the last 50 years, techniques such as *in vitro* fertilization[1], embryo transfer[2], embryo splitting[3], and blastomere nuclear transfer[4] have become commonplace — providing farmers, ranchers and pet enthusiasts with powerful tools for breeding the best animals.

Cloning is a new breeding method that does not manipulate the animal's genetic make-up nor change an animal's DNA; it is simply another form of sophisticated assisted reproduction. Cloning allows livestock breeders to create a genetic copy of an existing animal — essentially an identical twin. Animal clones are not "biotech" or "genetically engineered" animals; and their offspring are considered "conventional" animals.

Cloning animals is a reliable way of maintaining high quality and healthy livestock to supply our nutritional needs and consumer demand. Identifying and reproducing superior livestock genetics ensures herds are maintained at the highest quality possible. Animal clones will primarily be used as breeding stock to improve the health and quality of animals used for food production. So, most consumers will likely never eat an animal clone; rather, meat and milk products in the marketplace will come from the offspring of animal clones. These offspring would be bred through other conventional breeding techniques, and not be clones themselves.

In January 2008, the U.S. Food and Drug Administration published a final risk assessment on meat and milk products from animal clones and their offspring which concluded that these products are as safe as conventionally produced food products.

Currently, there are no meat and milk products from cloned animals and their offspring in the marketplace. With FDA's safety conclusion now in place, cloned animals produced to date are unlikely to enter the food supply for another three to five years.

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[1] *In vitro* fertilization (IVF) involves extracting eggs from a female specimen's ovaries and fertilizing them with sperm in a laboratory dish or test tube. The fertilized eggs are implanted into the female's uterus.

[2] After an embryo is produced in vitro, either by nuclear transfer or IVF, it is inserted in the uterus of a recipient female animal *via* an embryo transfer procedure.

[3] The splitting of embryos can occur naturally when an early embryo spontaneously divides in half, producing identical twins, or thirds or quarters early in development. Each piece can then develop as an independent embryo. For more than two decades, scientists have mimicked this process by dividing early embryos from other animals in the laboratory and then implanting them in females, where they develop normally.

[4] The first reports of animal cloning were in the late 1980s and were the result of the transfer to enucleated oocytes of nuclei from blastomeres (cells from early, and presumably undifferentiated, cleavage-stage embryos) a technique that is referred to as blastomere nuclear transfer or BNT. A decade later, cloning was successfully conducted using somatic cell nuclear transfer (SCNT) technology.

Livestock Cloning Benefits

Animal cloning offers great benefits to consumers, farmers, and endangered species:

- Cloning enhances the availability of the best possible stock by allowing farmers to be certain of the genetic make-up of a particular animal, thus allowing them to produce high-quality, safe, and healthy food.
    - Cloning can offer a tremendous advantage for farmers whose livelihoods depend on selling high-quality meat and dairy products. The breeding technique allows a greater number of farmers the ability to preserve and extend proven, superior genetics.
    - Through cloning, ranchers will be able to select and propagate the best animals — for example, beef cattle that have lean but tender meat.
    - Through cloning, ranchers will be able to breed animals that are more resistant to diseases, thereby improving the health of the herd and reduce the need for medical intervention.

- For superior animals that can no longer reproduce, for example gelded horses, or have passed away, cloning offers the capability to produce a genetic twin. This new assisted reproductive technology can allow for the continuation of a genetic line that might otherwise not be possible.

- Cloning reproduces the strongest, healthiest animals, thus optimizing animal well-being and may minimize the need for veterinary interventions.

- Cloning can be used to protect endangered species. For example, in Southeast Asia, both the banteng and the guar, which are meat-type bovines, have been cloned in conservation efforts that are focused on increasing populations of species threatened by extinction. In China, researchers are preserving giant panda cells in the event that their numbers are threatened by extinction.

Safety of Milk and Meat Products from Animal Clones and Their Offspring

Many scientific organizations, as well as over 300 independent scientists worldwide, have concluded that foods from animal clones and their offspring are safe. Most consumers will never eat a cloned animal because clones are very costly, and will be few in number compared to their offspring. Instead, meat and milk products from the offspring of animal clones will eventually be on the market, and these offspring are no different than any other conventionally produced animals.

The U.S. Food and Drug Administration, in its final risk assessment released in January 2008, concluded that "edible products from normal, healthy clones or their progeny do not appear to pose increased food consumption risks relative to comparable products from conventional animals."

The National Academy of Science, in two separate reports, had the same conclusions:

- "At present there is no supportive evidence for increased risk to consumers of animal products from cloned animals" (*Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects,* 2004).
- "There is no current evidence that food products derived from adult somatic cell clones or their progeny present a food safety concern" (*Animal Biotechnology: Science-Based Concerns,* 2002).

In addition, in April 2005, the Kagoshima Prefectural Cattle Breeding Development Institute (Japan) and the University of Connecticut published the following findings in the *Proceedings of the National Academy of Science*:

"The composition of the meat and milk from somatic animal clones were not significantly different from those of their genetically matched comparators or industry breed comparators, and that all parameters examined in this study were within the normal range of beef and dairy products approved for human consumption."

Several studies have been conducted which demonstrate the safety of consuming food products from cloned animals. The most recent, published in October 2006, show that rats fed a fourteen-week diet of meat and milk from cloned cattle exhibited no physiological effects and were healthy.

Milk and Meat Products from Animal Clones and Their Offspring in the Marketplace

Currently, there are no known meat and milk products from animal clones and their offspring in the marketplace. In 2001, at the request of FDA, the biotech industry agreed to a voluntary moratorium on placing food products from animal clones and their offspring in the market. However, in January 2008, FDA concluded that food products from animal clones and their offspring are safe. BIO will work with the U.S. Department of Agriculture (USDA) and the food value chain to ensure an orderly transition of these products to the marketplace. Since most consumers will purchase food products from the offspring of animal clones, with FDA's safety conclusion now in place, cloned animals produced to date are unlikely to enter the food supply for another three to five years.

Under current FDA labeling guidelines, meat and milk products from animal clones and their offspring will not require additional labeling as they have been determined to be equivalent to products from conventionally bred animals. FDA's labeling guidelines only require labels if there are nutritional or compositional changes to the food, or if any allergens are introduced.

To address consumer, livestock producer, and meat and milk processor requests for "clone-free" products, in December 2007, the major animal cloning technology providers introduced an animal clone tracking system that identifies animal clones. This clone registry will help ensure "clone-free" marketing claims, which are based on consumer choice, not safety or nutritional concerns.