

# With FDA's approval, cloning could benefit both producers and consumers

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## Summary

Soon, the U.S. Food and Drug Administration (FDA) is expected to release a final risk assessment affirming that the meat and milk from the offspring of cloned animals, including beef cattle, are safe to eat. Once the FDA decision is final, beef producers will be able to raise cloned cattle for market, and add one more reproductive technology to their production toolbox.

While some industry observers worry that U.S. consumers won't accept meat from cloned animals and their offspring, a new survey suggests that the majority would consider buying such foods. Several studies confirm the safety of meat and milk produced from cloned animals. However, FDA asked in 2001 for livestock producers to voluntarily refrain from selling clones and offspring into the food supply.

## Background

Similar to embryo transfer (ET) and artificial insemination (AI), cloning is an assisted reproductive technology that breeders can use to improve herd quality. Cloning essentially creates identical twins of the chosen animals without altering the genetic makeup of the animals. The most common procedure today, somatic cell nuclear transfer (SCNT), makes it possible to produce many animals from a single donor. SCNT transfers the genetic information from one animal into an empty egg. The resulting embryo is implanted into a surrogate cow that carries the pregnancy to term. The newborn calf, the clone, is genetically identical to the chosen donor animal.

### *Beef producers see benefits*

Currently, a few hundred cloned cattle exist among the 100 million cattle in the United States. Producers are finding that cloning is a highly reliable way to produce top-performing cattle because cloning accelerates reproduction and removes the guesswork from breeding. Identifying and reproducing the most superior genetics available can help producers raise the level of quality in their herds and produce a desirable end product for consumers. Cloning can also be used to reproduce the healthiest animals in the herd, which can reduce the added costs of veterinary care.

Cody Gillispie, a beef producer from Decatur, Texas, had his Beefmaster cow, Cathy Lee, cloned two years ago. "We have always been able to keep bulls around after they die by keeping their semen. Until cloning, we have not been able to do the same with top females," he says. "A few years ago, some producers thought embryo transfer was a crazy concept. Cloning could someday take the place of ET, help us improve our herd more quickly and provide a good return on the money we invest in the technology."

Many producers are familiar with Forever Lady, one of the most productive Angus females in history. Her clone sold at auction for \$170,000, notes Sara Davis, co-founder and Senior Vice President of ViaGen, Inc, the leading cloning company in the country. Davis recently started a Red Angus ranch in Texas. "With cloning, producers can get the best genetics more reliably at a more affordable price than buying the cow. Cloning costs about \$15,000 for the first copy and less for each additional clone," Davis says. "Purebred producers can use cloning as another advanced reproductive technology in their herds. Commercial producers can buy a cloned bull and get consistency more quickly than they would if they bought the brother of a bull that has been a successful sire for them."

Similarly, Elvis, a cloned Angus-Simmental cross bull, was produced with cells from a U.S. Department of Agriculture (USDA) prime yield grade No. 1 carcass. This quality of carcass is so rare, USDA estimates only one in 3,500 grade similarly. So clearly, Elvis carries some of the best carcass genetics available. While Elvis is an experimental animal, he will be bred and tested and his clones made available in a few years for commercial producers to benefit from his superior genetics.

Donald Brown, who runs the cattle breeding program at his family's Throckmorton ranch in Texas explains cloning this way, "It's like duplicating Michael Jordan until you have five Michael Jordans on a team" (*Fort Worth Star Telegram*).

### *Consumer opinion is promising*

Public opinion on animal cloning is considered "soft" or changeable. Nearly all Americans have heard the word cloning and many have strong impressions. But few have thought about cloning as a reproductive technology for breeding cattle for food.

In October 2005, KRC Research conducted a survey on behalf of ViaGen, Inc., that focused exclusively on animal cloning. The survey found that one-third of respondents were willing to buy meat and milk from the offspring of cloned animals, one-third were willing to consider it once they learned more and one-third said they would never buy it.

But after asking consumers about their likely purchase behavior, a large majority also said that animal cloning would be acceptable to improve animal health, improve the nutrition of meat and milk, to breed animals immune to diseases and to save rare animal breeds. Respondents were most comfortable learning that animal cloning is regulated by three federal agencies, and that clones are like those bred using in vitro fertilization.

Half also said they were more comfortable after learning about the extent of the research, that companies cloning animals oppose human cloning, that cloned animals are as healthy as other animals and that cloning does not involve genetic modification. Interestingly, one-third believes cloning is currently used in breeding while two-thirds expect it in the future.

“Most people’s understanding of cloning comes from science fiction, so people will want to know more about how it’s used in agriculture,” says Mark David Richards, Ph.D. and senior vice president, KRC Research, Washington, D.C. “People also say they feel more comfortable knowing that like in vitro fertilization, the animals begin in a laboratory, are born to their mothers in the usual way and grow up like other farm animals.”

Ultimately, the jury is out on whether cloning will affect consumer choices. Measuring consumer behavior has proven difficult. One example is rbST, the genetically engineered bovine growth hormone that increases milk production in cows. When rbST became available, polls reported widespread concern and experts predicted a 4 percent to 20 percent drop in milk consumption. However, those predictions proved to be wildly inaccurate according to a 1998 U.S. Department of Agriculture (USDA) Economic Research Service (ERS) report. Consumption did not drop as predicted.

A Pew poll released in mid-November underscored consumer concerns about cloning, but indicated that consumers found cloning acceptable for use to breed healthier, disease-resistant animals.

### ***Research proves cloning safety***

In its 2003 draft risk assessment, FDA stated that meat from the clones and offspring of clones is as safe as meat from traditionally bred animals. This was after a rigorous review of science, as well as two National Academy

of Sciences’ (NAS) research reviews. In the draft, the government referenced more than 10 public safety acts, including the Food, Drug and Cosmetic Act, federal meat and poultry inspection acts, Animal Health Protection Act, Animal Damage Control Act and National Environmental Protection Act. The laws are overseen by FDA, USDA and the U.S. Environmental Protection Agency.

In rendering its initial assessment, FDA analyzed more than 100 scientific studies on cloning encompassing years of safety data plus several generations and large families of livestock – all indicating that food products derived from animal clones and their offspring are likely to be as safe as food from non-clone counterparts. These findings also showed that healthy adult clones are virtually indistinguishable from their conventional counterparts.

NAS has also scrutinized numerous studies, publishing in-depth reviews in 2002 and 2004. NAS concluded, “There is no scientific evidence that cloning is associated with any unintended compositional change that results in unintended health consequence in humans,” and noted consumers get better food because clones have, “increased genetic merit for increased food production, disease resistance and reproductive efficiency.”

A recent study completed by a University of Connecticut and Kagoshima Prefectural Cattle Breeding Development Institute (CBDI in Japan) research team found the strongest evidence to date that beef from cloned cattle is safe for human consumption. The study is the first to examine specific proteins and nutrients in the meat, which fills an important gap in the scientific literature used for regulatory approval.

Dr. Xiangzhong (Jerry) Yang, animal science professor and director of the University of Connecticut’s Center for Regenerative Biology (CRB), says, “We found no significant differences between clones and their controls; and all parameters examined for the clones were within normal range of beef products approved for human consumption.”

The study compares the composition of beef derived from somatic cell cloning, versus those of genetic and breed-matched controls from conventional reproduction. More than 100 standard parameters were compared, and all parameters for the cloned beef fell within the Japanese beef industry standard ranges. Most were not different from the comparisons. In addition, the cloned beef had significantly higher marbling scores, as well as significantly higher mesentery fat and fatty acids contents.

**Key Points**

- Like ET and AI, cloning is an assisted reproductive technology that cattle breeders can use to improve herd quality. A clone is genetically identical to the chosen donor animal.
- FDA is expected to soon release a final risk assessment that affirms the offspring of cloned animals, including beef cattle, are safe to eat. Once the FDA decision is final, beef producers will be able to raise cloned cattle for breeding.
- Public opinion on animal cloning to date has been considered “soft.” Ultimately, the jury is out on whether cloning will affect consumer choice, but consumer surveys suggest that beef consumption probably will not be affected dramatically.
- In its 2003 draft risk assessment, FDA stated that meat from the offspring of clones is as safe as meat from traditionally bred animals. A recent study found strong evidence that beef products from cloned cattle are safe for human consumption.