

Cloning Q&A for Editors

What is the current status of food from cloned animals being allowed on the US market?

- Livestock cloning (and the sale of these animals) is and always has been legal in the United States.
- On January 15, 2008, the U.S. Food and Drug Administration (FDA) released the Final Risk Assessment that confirms food from clones and their offspring is safe for humans to consume.
- The FDA reviewed more than 400 scientific studies for this Final Risk Assessment.
- The FDA concluded that the meat and milk from cloned animals is no different from food derived from other, conventionally-bred livestock.
- Following the FDA's announcement, the USDA has requested that technology providers assist with an orderly transition for clone animals that may one-day enter the food supply. But, it has agreed that the offspring of these animals can freely enter the marketplace.

What have experts other than FDA said about food from cloned animals?

- The FDA's Risk Assessment was reviewed by a group of independent scientific experts in cloning and animal health, who serve on the FDA's veterinary medicine Advisory Committee. They agreed with the FDA's conclusions.
- The National Academy of Sciences (NAS) has conducted in-depth reviews of many of the studies and published its findings in 2002 and 2004.
 - Animal Biotechnology: Science Based Concerns, 2002.
http://www.nap.edu/catalog.php?record_id=10418
 - Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects, 2004.
http://books.nap.edu/catalog.php?record_id=10977-toc
- The NAS concluded that "there is no scientific evidence that cloning is associated with any unintended compositional change that results in an unintended health consequence in humans."
- The NAS also pointed out that consumers would get better food because clones have "increased genetic merit for increased food production, disease resistance and reproductive efficiency".
- France, New Zealand and Australia have published risk assessments with similar findings. Japan has conducted its own risk assessments that came to similar conclusions. Japan is waiting for the U.S. to release its document before finalizing. The European Food Safety Authority released a draft risk assessment in January 2008 that also found no safety problems with meat and milk from clones and their offspring.



Has the FDA heard from the public on this issue?

- Before issuing the Final Risk Assessment, the FDA received more than 35,000 comments from the public. (Duplicate submissions were counted as one comment.)
- The comments also included a strong statement of support (<http://www.fass.org/pr050207.asp>) signed by more than 200 scientists including leading scientists in the field, Dr. Terry Etherton who was on the NAS panel that evaluated the science, and Dr. Ian Wilmut, one of the “fathers” of Dolly the Sheep.
 - The Federation of Animal Science Societies (FASS) collected the signatures.
 - Jerome Baker, chief executive officer of FASS, said, "This is one of the most rigorous food safety reviews ever conducted. The American people should be absolutely confident in the FDA's good work."

How long has the FDA been looking at the issue of food from cloned animals?

- In 1999, the FDA asked the industry to voluntarily withhold cloned animals from the food supply. The Agency formalized this request in 2001.
- In 2001, the FDA asked for a report from the National Academy of Sciences.
- In 2002, the first NAS report was published.
- In August 2002, the FDA started its review and analysis.
- In November 2003, the FDA Veterinary Medicine Advisory Committee reviewed the data compiled to date and advised the FDA to review more studies.
- In December 2006, the FDA published the Draft Risk Assessment.
- The FDA's risk assessment has undergone extensive review, including a complete review of global science as well as original research conducted jointly by the USDA and the FDA. The risk assessment supports the two NAS reviews from 2002 and 2004.
- In addition, the risk assessment was reviewed by the FDA Veterinary Medical Advisory Committee, independent peer expert reviews, and underwent a year of public comment, including significant comment from foreign governments and major trading partners.

Will the public accept cloning?

- New technology is often met with skepticism and resistance.
 - When milk pasteurization was introduced in the 19th Century, it was met with great skepticism – even hysteria.
- Data from the International Food Information Council (IFIC) shows a five-point increase in favorable opinions about eating food from cloned animals and their offspring.
 - The data also shows that as the public becomes educated about cloning technology, it also becomes more comfortable.
 - IFIC also noted “this data suggests that assurances and safety determinations from the FDA would yield significantly increased consumer confidence in the area of food produced through animal cloning in particular.”
- This is consistent with public opinion research conducted by Dr. William Hallman, Director of the Food Policy Institute at Rutgers University, showing that as consumers learn more about the topic they become more accepting.
 - Dr. Hallman noted that consumers are influenced strongly on this topic by authoritative bodies such as the FDA and the NAS.
 - Reference: Public Opinion and Media Coverage of Animal Cloning and the Food Supply, November 21, 2006.
[http://www.foodpolicyinstitute.org/docs/summary/Animal Cloning Summary.pdf](http://www.foodpolicyinstitute.org/docs/summary/Animal%20Cloning%20Summary.pdf)

What is a clone?

A clone is a genetic twin of the original animal that provides the tissue sample from which a cell line is made. Clones are not genetically modified. The clone has the exact same chromosomal DNA – genetic material – as the original animal.

Are clones genetically modified animals?

Clones are not genetically modified. They carry the exact copy of DNA as the original animals.

How long has Bovance been cloning dairy and beef cattle?

Through the parent companies of Trans Ova Genetics and ViaGen, Bovance has been working closely with cattle breeders on advanced reproductive technologies for more than twenty-seven years. For more than eight years, cloning has been a successful tool for those clients who have chosen to create genetic twins of their elite cattle.



Have any clone calves been produced for the international marketplace?

To date, Bovance has produced clone calves only for clients located in the United States. With the growing awareness that meat and milk produced from clones and their offspring is safe, Bovance anticipates – in time – that international interest and marketability for clone animals from superior U.S.-bred cattle will grow as well. Bovance is prepared to work closely with its clients to meet these future marketing opportunities.

How much does it cost for a cattle breeder to clone an animal?

The cost of cloning an animal can range from \$10,000 to \$20,000 depending on the goals of the breeder and the success of propagating a specific cell line.

How does Bovance advise clients as to the financial feasibility of cloning an individual animal?

Cloning allows breeders to copy or replace special individuals that may have been lost too early in their breeding careers, or to increase the genetic impact of existing superior individuals. As with the other technologies and services offered, Trans Ova Genetics' team of cattle reproductive consultants, who have exclusive marketing rights to the Bovance brand and technology, will help clients evaluate the potential and value that may be realized through the cloning of an elite animal. Only the most elite animals will be cloned for reproductive purposes, so as to extend their genetics.

Under what circumstances might cattle breeders want to clone their animals?

Through cloning, producers can duplicate the animals that contribute the most value in their herds and toward their goals to produce better quality food products. The influence of these animals, through breeding, can help create a more consistent supply of tender, flavorful beef, for example. Clone animals will be used for intensive breeding and genetic purposes, not specifically for meat or milk production. Another example of cloning application is in the case of an animal lost early in its breeding career, perhaps even before the value of its genetics is fully discovered. Cloning technology can help extend this animal's genetic influence to contribute to the improvement of food animal production.

Is there special care or steps Bovance provides to ensure greater client success with cloning?

Cloning is a part of a carefully planned and implemented genetic advancement program, uniquely defined to achieve individual client goals. For clients that have animals at the elite genetic level and marketing caliber for cloning, Trans Ova Genetics dedicates its trained, professional team specialists to ensure the best possible care throughout the entire cloning process - from DNA preservation to the birth of healthy cloned calves.



Does Bovance expect more producers to clone their animals?

With recent FDA assessments confirming the safety of clones and their offspring in the food system, Bovance does expect the interest in and application of cloning to increase. However, even now, cloning will remain a technology suited exclusively for the most elite tier of genetics, and cloned individuals will represent only a fraction of a percentage of tomorrow's cattle breeding foundation.

How does cloning affect the genetic diversity of cattle breeding populations?

Cloning and the use of cloned animals in an elite breeding program must be managed just like A.I. in order to ensure lack of genetic diversity doesn't become a limitation. Furthermore, cloning technology can allow for the preservation of all genetics, and in particular those of unique, diverse bloodlines that may otherwise be lost or missed in traditional genetic selection programs. Using cloning technology, outcross genetics can be preserved to help diversify the population. The production of a clone does not offer genetic gain from the previous generation of parents per se, but does greatly increase the opportunities for multiple mating selections that can, in turn, create significantly greater genetic gains.

Are there animal welfare concerns with cloning?

Bovance maintains the highest standards of care and comfort for all animals housed at its facilities. This same care and superior animal husbandry is critical to the success of all reproductive technologies. Dairy and beef cattle breeder clients trust Trans Ova Genetics (exclusive source of Bovance) to give their valuable animals the best care possible, which in turn helps ensure the best results for their breeding program goals.

Should food from cloned animals and their offspring be labeled as such?

Bovance supports the FDA's position on labeling. FDA has indicated that there is no difference in food produced from clone animals and their offspring, and therefore there is no reason to discern which products were from those animals. Mandatory labeling requirements for products from clone animals might falsely imply that there is a difference, when in fact there is not.

Understanding that many leading food processors may feel the need to reply to consumer concerns for certain products, the parent companies of Bovance (Trans Ova Genetics and ViaGen) recently introduced a Supply Chain Management Program. Debuted in December 2007, this program provides a national registry to track clone animals throughout their lives.