



Animal Cloning and Food Safety

By Linda Bren

Researchers have been cloning livestock since 1996. It is estimated that a few hundred cloned cattle, pigs, and goats exist in the United States. When it became apparent in 2001 that cloning technology was poised for commercial use to help improve the quality of herds, the FDA's Center for Veterinary Medicine (CVM) asked livestock producers to voluntarily keep food from clones and their offspring out of the food supply. The agency, ensuring the safety of the nation's food supply and safeguards animal health, began an intensive evaluation to determine whether cloning posed any risks to the animals or food from the animals that differed from risks presented by other assisted reproductive technologies currently used in U.S. agriculture.

The Food and Drug Administration is inviting public comments on three draft documents discussing the safety of animal cloning and food products derived from animal clones. The documents—a draft risk assessment, proposed risk management plan, and draft guidance for industry—issued on Dec. 28, 2006, are available for public comment until April 2, 2007.

Cloned dairy cows Cyagra, left, and Genesis, right, share a meal at the farm of Greg Wiles in Williamsport, Md.

Associated Press

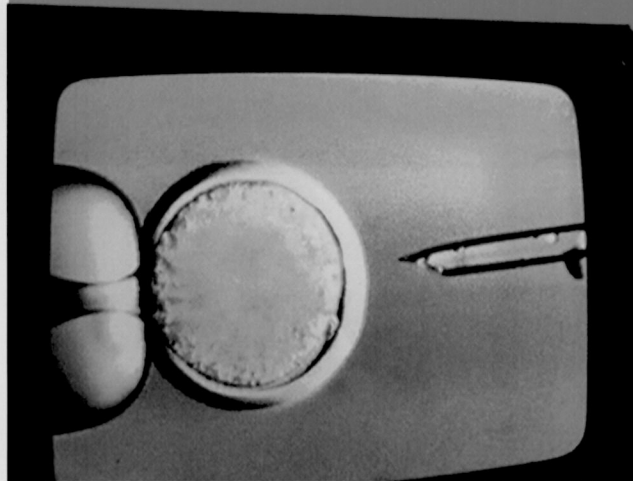
"The issuance of these three documents does not lift the voluntary moratorium on introducing food from clones or their offspring into the food supply," says CVM Director Stephen F. Sundlof, D.V.M., Ph.D. "Because the release of these documents marks the beginning of our interaction with the public on these issues, we are continuing to ask producers of clones and livestock breeders to abide by the voluntary moratorium until we have had the opportunity to consider the public's comments and to issue any final documents."

What Is a Clone?

Despite their portrayal in science fiction books and movies, "animal clones don't spring forth fully formed, and they aren't even grown in test tubes," says Larisa Rudenko, Ph.D., a molecular biologist and senior adviser for biotechnology in the CVM. "They are born just like any other animal."

"Clones are biological copies of animals," Rudenko says. "They're similar to identical twins, but born

A scientist uses an inverted microscope fitted with micromanipulators to begin the animal cloning process.



Roslin Institute

at different times." The FDA's draft documents do not address genetically engineered animals, in which DNA may be added or altered.

In the most traditional forms of animal reproduction, animals mate through natural means, physically getting together to reproduce. "But this doesn't happen as often as you might think in agricultural production," says Rudenko. "Livestock breeders use artificial insemination, embryo transfer, and even in vitro fertilization to produce high-quality offspring." All of these methods are assisted reproductive technologies, and are in widespread use in commercial agriculture. For example, most dairy cows are bred using artificial insemination, and the most elite livestock are bred using embryo transfer. According to the International Embryo Transfer Society, more than 600,000 embryo transfers took place around the world in 2005, and about a quarter million in vitro-produced embryos were implanted that same year.

"So after a long period of evaluating a lot of data, the scientists at CVM concluded that cloning is just another form of an assisted reproductive tech-

nology," says Rudenko.

Most cloning uses somatic cell nuclear transfer (SCNT), a process whereby scientists take an egg from a female animal, often from ovaries obtained at the slaughterhouse, and instead of combining the egg with sperm, they remove the gene-containing nucleus. They then introduce the genetic material from an animal with known desirable traits (the "donor"), and coax the resulting embryo to fuse and start dividing. The donor nucleus frequently comes from a skin cell taken from a live or recently deceased animal. The embryo is implanted in the uterus of a surrogate dam, which carries it to term and delivers it like her own offspring.

Draft Risk Assessment

The draft risk assessment, conducted by CVM scientists, was based on a four-year analysis of hundreds of peer-reviewed publications and other studies on the health and food composition of clones and their offspring. The draft risk assessment found that cloning poses no unique risks to animal health compared to those observed with other assisted reproductive technologies or

even natural mating.

This assessment also concluded that there were no additional risks to people eating food from clones or their offspring. "Meat and milk from clones and their offspring are as safe as food we eat every day," says Sundlof. These conclusions agree with those of the National Academy of Sciences, released in a 2002 report, "Animal Biotechnology: Science-Based Concerns."

The FDA experts reached these conclusions first by examining the health of the clones and their offspring. An extensive search of the peer-reviewed literature on clones produced around the world was combined with a review of the medical records and blood samples from clones and their offspring. The agency found that except for a short time right after birth, the clones and other animals used as controls—usually animals of the same breed and age, and raised on the same farm—were so similar that it could not tell them apart.

Then, the agency analyzed the composition of food products from clones and their offspring, examining

The FDA recognizes that cloning, like any newer complex technology, poses some risks.

the proteins, fats, amino acids, vitamins, minerals, and other chemical constituents. "We found that there were no material differences between the foods," says Sundlof. "We've looked very, very closely at any potential hazards that might be introduced and we cannot identify any that would be harmful to the public."

As required for influential government risk assessments, a group of independent scientific experts in animal cloning peer-reviewed the draft risk assessment. They agreed with the agency's methods to evaluate the data and the FDA's conclusions. Committed to transparency, the FDA has posted the unedited review comments of peer reviewers and its responses to those comments on its Web site.

Proposed Risk Management Plan

Some critics of animal cloning claim that it results in unhealthy animals and needless suffering. "American consumers are increasingly concerned about the treatment of animals raised and slaughtered for food," says Wayne Pacelle, president and chief executive officer of the Humane Society of the United States. The society cites studies finding animal clones to have premature deaths, internal organ abnormalities, and other health problems.

The FDA recognizes that cloning poses some risks, but none are unique to the technology. "The same kind of developmental abnormalities that are seen with clones are also seen with currently widely used reproductive technologies, like in vitro fertilizations, embryo splitting, or even natural mating," says Sundlof. "The actual incidence of abnormalities is greater with cloning at this point, but it was quite high with in vitro fertilization when it was first introduced as well." As scientists gain further experience with cloning, the risks are expected to decrease.

Nonetheless, because the agency is concerned about animal health, the proposed risk management plan outlines the approach that the FDA would take to address risks to the animals involved in cloning. This approach includes working with professional and scientific organizations with expertise in animal health and reproduction to develop a set of care standards for animals involved in cloning. In addition, the agency proposes to work with international scientific organizations to create a publicly accessible database on the health of animal clones and their offspring as well as the composition of meat or milk derived from animal clones.

Draft Guidance for Industry

This document is directed at clone producers, livestock breeders, and farmers and ranchers purchasing clones. It explains the FDA's draft recommendations on using cattle, swine, and goat clones and their offspring for human food and animal feed. Because of limited data on sheep clones, the FDA recommends that these clones not be used for human food.

Why Clone?

Cloning gives a farmer complete control over an offspring's inherited traits, overcoming the unpredictability of conventional forms of breeding. Through cloning, breeders can produce multiple genetic copies of the best animals in the herd—those with naturally occurring desirable traits, such as disease resistance or quality meat production, and introduce these traits into production herds more rapidly than with sexual reproduction.

The FDA neither supports nor opposes cloning food-producing animals. It evaluates the safety aspects of cloning, based on the best available science, and serves as a reliable source of information on the technology to

the public. To that end, the agency has posted additional documents on its Web site that describe the cloning process, explain why breeders might want to use animal cloning in their business, and dispel myths about cloning introduced by science fiction novels and movies.

The agency acknowledges that cloning may raise some ethical issues. "Although FDA does not have the legal authority to address ethics surrounding cloning, we will continue to provide scientific expertise to interested parties working on these issues so that those discussions can be based on facts," Sundlof says.

What's Next?

The FDA encourages public comments on the draft risk assessment, proposed risk management plan, and draft guidance for industry for a 90-day period ending April 2, 2007. Visit www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm?AGENCY=FDA, and search for docket number 2003N-0573 to submit comments online. Comments also may be sent to: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments should include the docket number 2003N-0573.

The agency will review comments and evaluate additional data that may be shared during the comment period. The FDA will then issue a final risk assessment, risk management plan, and guidance for industry. The FDA will continue to closely monitor any changes in cloning technology and the development of clones and their offspring as a source for food as further data become available. ■

For More Information

www.fda.gov/cvm/CloneRiskAssessment.htm