FDA Is Set To Approve Milk, Meat From Clones

By Rick Weiss
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Three years after the Food and Drug Administration first hinted that it might permit the sale of milk and meat from cloned animals, prompting public reactions that ranged from curiosity to disgust, the agency is poised to endorse marketing of the mass-produced animals for public consumption.

The decision, expected by the end of this year, is based largely on new data indicating that milk and meat from cloned livestock and their offspring pose no unique risks to consumers.

"Our evaluation is that the food from cloned animals is as safe as the food we eat every day," said Stephen F. Sundlof, the FDA's chief of veterinary medicine, who has overseen the long-stalled risk assessment.

Farmers and companies that have been growing cloned barnyard animals from single cells in anticipation of a lucrative market say cloning will bring consumers a level of consistency and quality impossible to attain with conventional breeding, making perfectly marbled beef and reliably lean and tasty pork the norm on grocery shelves.

But groups opposed to the new technology, including a coalition of powerful food companies concerned that the public will reject Dolly-the-Lamb chops and clonal cream in their coffee, have not given up.

On Thursday, advocacy groups filed a petition asking the FDA to regulate cloned farm animals one type at a time, much as it regulates new drugs, a change that would drastically slow marketing approval. Some are also questioning the ethics of a technology that, while more efficient than it used to be, still poses risks for pregnant animals and their newborns.

"The government talks about being science-based, and that's great, but I think there is another pillar here: the question of whether we really want to do this," said Carol Tucker Foreman, director of food policy at the Consumer Federation of America.

That there is a debate at all about integrating clones into the food supply is evidence of the remarkable progress made since the 1996 birth of Dolly, the world's first mammalian clone, created from an udder cell of an anonymous ewe.

Scientists have now applied the technique successfully to cattle, horses, pigs, goats and other mammals. Each clone is a genetic replica of the animal that donated the cell from which it was grown.

Cloning could solve a number of long-standing farm problems. Many prize males are not recognized as such until long after they have been tamed by castration. With cloning, that lack of semen would not matter. Cloning also allows farmers to make many copies of exceptional milk producers; with natural breeding, cows have only one offspring per year, and half are males.

In the eyes of many in agriculture, cloning is simply the latest in a string of advances such as artificial insemination and in vitro fertilization that have given farmers better control over animal reproduction.

"Clones are just clones. They are not genetically engineered animals," said Barbara Glenn, chief of animal biotechnology at the Biotechnology Industry Organization.

The FDA agrees with that distinction, Sundlof said. The agency has already said it will regulate transgenic animals -- those that have been engineered by adding specific, valuable genes -- in much the way it regulates pharmaceuticals, under a new category called "New Animal Drugs." No such animals are currently on the market.

By contrast, proponents say, clones are simply twins, albeit born a generation apart.

It was October 2003 when the FDA released its first draft document concluding that clones and their offspring are safe to eat, prompting several cloning companies to scale up their operations.

But an agency advisory panel and the National Academies, while generally supportive, raised flags, citing a paucity of safety data.

That, and opposition led largely by the International Dairy Foods Association, which represents such large, brand-sensitive companies as Kraft Foods, Dannon, General Mills and Nestlé USA, put FDA approval on hold. For years the agency has asked producers to keep clones off the market voluntarily while the issues got sorted out, a delay that bankrupted one major company and has left others increasingly frustrated.

But now a large collection of new data submitted to the FDA has revitalized the effort, according to government officials and others.

The biggest new study is a detailed comparison of meat from the offspring of cloned and conventional boars created by Austin-based ViaGen Inc., a major producer of cloned farm animals. Company scientists agreed to share key results with a reporter but withheld details as required by the journal Theriogenology, which will publish the full report in its January issue.

Semen from four clones and three conventional boars was used to inseminate 89 females. A total of 404 progeny (242 from clones) were raised identically by government scientists at the U.S. Department of Agriculture's Meat Animal Research Center in Clay, Neb., and slaughtered when they reached market size.

(Because clones are so valuable, companies for now anticipate sending only their offspring to market.) Of the 14,036 measures of protein composition, fatty acid profiles and other meat components done on the offspring of clones by an independent lab, all but three were within the same range as those of the conventional animals, and only one was outside what the Agriculture Department considers normal.

The other large research report came from Cyagra, a cloning company in Elizabethtown, Pa.

In that study, 80 blood and urine measures, including various hormone levels, were taken in 10 newborn, 46 weanling and 18 adult clones. Results were indistinguishable from those obtained from conventional animals. Then 79 biochemical measurements from three cuts of meat taken from five male and six female adult clones were compared with those from matched cuts from conventional animals. Again, no differences were found, said Cyagra's director of marketing, Steve A. Mower. The results have been submitted to the FDA and are being reviewed by a scientific journal.

"The data are very clear," said ViaGen President Mark Walton. "You really can't tell them apart."

In light of the new findings, and the FDA's near completion of a complicated, interagency review demanded by the White House Office of Management and Budget, Sundlof anticipates releasing a formal draft risk assessment by the end of the year, along with a proposed "risk management" plan. Those documents would allow the marketing of clones and their offspring for food and milk after a final period of public comment.

Unless, that is, the opponents manage to stop the process, which they are trying to do on two fronts.

One is the petition filed Thursday by the Washington-based Center for Food Safety. It asks the FDA to regulate clones, not just transgenics, as New Animal Drugs. It also calls for environmental impact statements to evaluate the environmental and health effects of each new proposed line of clones.

"The available science shows that cloning presents serious food safety risks, animal welfare concerns and unresolved ethical issues that require strict oversight," the petition states.

Industry scientists derided the petition's safety concerns, built largely on a theoretical possibility that subtle genetic changes seen in some clones may alter the nutritional nature of meat. If those genetic changes were significant, Mower said, they would cause biochemical changes in milk or meat, none of which have been found.

But issues of ethics and public acceptance are not easily dismissed, several experts said.

Surveys show that more than 60 percent of the U.S. population is uncomfortable with the idea of animal cloning for food and milk. The single biggest reason people give is "religious and ethical," with concerns about food safety coming in second, said Michael Fernandez, executive director of the Pew Initiative on Food and Biotechnology, a nonpartisan research and education project.

Those sentiments are a big concern to dairy companies, which fear that any association with cloning could harm milk's carefully honed image of wholesomeness.
Confidential documents from the International Dairy Foods Association, obtained by The Washington Post, indicate the group has played a key role in slowing FDA action and propose a strategy for blocking any future FDA approval.

Association spokeswoman Susan Ruland said the group opted not to adopt the lobbying strategy described in those documents, which included using friends in Congress and "continued outreach to the White House."

In any case, Sundlof said, the FDA has no authority to make decisions based on ethics concerns. Nor is it inclined to call for labeling of products from clones, as some have demanded. For one thing, clonal meat or milk would be impossible to authenticate, since there is no way to distinguish them from conventional products.
The FDA may already be too late. Several owners of clones have been selling semen to farm clubs and others vying to grow prize-winning cattle. Most of those animals end up being slaughtered, sold and eaten, experts said.

"That you can go online today to any number of different Web sites and purchase semen from cloned bulls tells you there are cloned sires out there fathering calves in the food supply," Walton said.

Like it or not, Walton and others said, the clones are out of the barn.