

Animal Cloning: Transitioning from the Lab to the Market

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Good morning. I'm here to talk with you this morning about something that **ISN'T** under your purview—but many people may think it is. And that's cloning. Since you may get questions—or have questions of your own, we wanted to brief you on what's happening and how USDA is involved.

While cloning isn't biotechnology, it **IS** advanced technology. Animal cloning does not involve genetic modification like biotechnology. It produces twins, not altered animals. Animal clones begin life in a laboratory, their embryos are implanted, and they are born in the usual way.

Cloning is not really new, as I'm sure you know. We've been cloning plants for decades, except that the process is referred to as "vegetative propagation." Most bananas, potatoes, apples, grapes, pears and peaches come from clones.

Researchers have been cloning livestock since 1996. Cloning is just one more step forward in assisted reproductive technology. This technology moves beyond artificial insemination, embryo transfer and *in vitro* fertilization.

Recent developments in cloning have occurred largely in the private sector—with three companies. USDA has not been heavily involved in the scientific oversight of cloning.

However, once the science was settled, the marketing oversight issue landed on the MRP doorstep in January. We are now seeking to help with a seamless transition as animal clones—or more likely their offspring—move into the market.

FDA Approval

Let me give you some background. In June 2001, the Food and Drug Administration posted on its website a request that animal clones and their offspring be kept out of the food supply until the agency had a chance to evaluate whether cloning posed any risks to consumers.

Technology providers acceded to this request and established a voluntary moratorium. They later developed a supply chain management program to identify animals produced through cloning so these animals could be tracked throughout their lifetimes. The tech providers made clear to all the producers who purchased animal clones that the neither the clones nor their offspring could go into the food supply until FDA made its determination on the safety of the food.

In December 2006, FDA issued a preliminary finding that meat and milk from animal clones posed no food safety concerns, following review of more than 100 scientific studies conducted over several generations of animals. The National Academy of Sciences also issued two earlier reports concluding that animal clones were safe to eat.

On January 11, 2008, the European Food Safety Authority released its own draft scientific opinion, which came to similar conclusions. Further, animals are being cloned for agricultural and research purposes in many countries, including Argentina, Australia, Brazil, Canada, Chile, China, France, Germany, Japan, New Zealand, South Korea and the UK.

Then on January 15 this year, FDA announced its final assessment on animal clones concluding that meat and milk from clones of cattle, swine and goats and the offspring of clones from any species traditionally consumed as food are as safe to eat as food from conventionally bred animals. There wasn't enough information to make a decision on the safety of sheep clones. But the meat from all offspring cannot be distinguished from the meat of conventionally bred animals. Therefore, all products of offspring were determined to be safe.

USDA Response

In mid-January, I attended the FDA news briefing on its risk assessment as USDA's representative and spokesperson. At that time, we stated our support for the FDA finding. We also announced that USDA would work with stakeholders to

ensure a smooth and seamless transition into the marketplace for products of clones.

We encouraged technology providers to maintain the voluntary moratorium on sending milk and meat from animal clones into the food supply during the transition time. Further, we promised to implement the report language in the 2008 omnibus appropriations bill suggesting that USDA study domestic agricultural and international trade economic implications of commercialization of milk and meat from animal clones.

Marketing Animal Clones

I want to share with you where things stand, and then talk about our transition plans. Today there are about 600 animal clones—mostly beef cattle. And it's unlikely that they will be headed to market soon—or possibly ever. They're too expensive to produce. Instead, they are being used for breeding stock—to transmit their exceptional qualities to their offspring. However, as I mentioned, the voluntary moratorium for clones in the food supply is continuing.

The sexually reproduced offspring of the clones are the animals that will wind up in the meat case or producing the milk in the dairy counter. The moratorium has been lifted for these animals.

USDA's role will be to facilitate a smooth and orderly transition so that technology providers, producers, processors, retailers and domestic and international customers can work together as meat and milk from animal clones and their offspring becomes available for the market.

National Organic Program

Before going into our plans for transition, I want to just briefly mention the National Organic Program. Last year, on January 31, 2007, NOP issued on its website a statement that cloning was incompatible with the Organic Foods Production Act and prohibited under NOP regulations.

Following that announcement, last March the National Organic Standards Board recommended that NOP add “animal cloning technology” to the definition of “Excluded Methods” and update other sections of the rule to ensure that all generations of progeny of cloned animals would be excluded.

One of the issues that we've needed to address with cloning is whether products from cloned animals or their offspring should be labeled as such. I've suggested that one option for those who prefer to avoid clones and their offspring, is to purchase organic products.

In line with the March 2007 recommendation of the National Organic Standards Board Livestock Committee, the Agricultural Marketing Service is working on an Advance Notice of Proposed Rulemaking to resolve ambiguities and inconsistencies involved in the origin of livestock. One of the issues to be covered in this rulemaking is offspring of clones.

Completing the rulemaking will provide clarity as to whether both clones and their offspring are excluded from NOP. This could be helpful in offering a clear alternative for customers who seek one.

Transition Plan

Let me turn now to the USDA transition plan. Since the FDA announcement, we have pulled together a group of MRP staffers and others within USDA to develop a transition plan for moving products of clones into market channels.

I want to reiterate that we are taking these steps on the basis of the FDA finding that these products are safe, and in fact indistinguishable from products from conventionally bred livestock.

While our transition plan is not yet final, I'd like to share some of the broad concepts and general directions with you. As we move forward, we'd welcome your comments and suggestions in light of your experience addressing issues raised by new technologies.

Our overarching goal with the plan is to facilitate a smooth and seamless transition. To do that, we want to be sure that all stakeholder groups have access to all the available information on animal clones so that they understand the scientific evidence that demonstrates the safety of these products.

We are also seeking to draw a distinction between clones, which remain under a voluntary moratorium, and their offspring, bred in the conventional manner, which are no longer under the moratorium. Further, we want to assist the technology providers in implementing the supply chain management system using a third party verification system.

If we receive requests for voluntary labeling programs or marketing claims, we want to offer a coordinated, helpful response. And we intend to follow through on our commitment to report to Congress, as requested, on the domestic and international market implications of introducing products of clones into the food supply.

Strategies for Moving Forward

To accomplish these goals, we'll be meeting with stakeholders here and abroad and sharing information with them. We'll be in touch with ag attachés through the Foreign Agricultural Service to engage in dialogue with our trading partners on their views and regulations and requirements in their countries. We'll respond promptly to questions and concerns.

We'll take a pro-active approach with some of our major trading partners, such as Japan and Canada. We'll look for other opportunities to provide information on cloning. And, in our communications, we will continue to emphasize the FDA finding that meat and milk from clones is safe—and that other groups such as the National Academy of Sciences and the European Food Safety Authority have reached similar conclusions. Safety is first and foremost, and it is the basis for permitting clones into the food supply. We'll also stress that cloning is simply the next step in assisted reproductive technology.

As we speak with stakeholders or provide material on the USDA website, we want to be transparent and offer access to the full range of scientific information available. At the same time, we want to make a distinction between animal clones and their offspring.

Clones are produced with advanced technology—at considerable expense. Their offspring, however, are sexually reproduced following traditional breeding or the use of well-accepted technologies, like artificial insemination.

Another aspect of our transition effort will be working with the technology providers to facilitate the voluntary moratorium by developing a third party verification system for the supply chain management program currently in place at the two U.S. technology providers.

The other issue we'll need to address in our transition plan is labeling. FDA has made clear that there is no safety issue involved. Therefore, there's no legal requirement to label products of clones. Also, there's no scientific way to

determine whether meat or milk came from a clone or clone offspring or traditionally produced animals. However, should there be an interest in labeling, the organic and “naturally raised” claims that AMS oversees may be sufficient to meet the need.

Finally, we’ll be working with USDA’s Economic Research Service to analyze the impact of the movement of cloned animals into the food supply to report to Congress as requested.

Conclusion

In closing, we would welcome your input on our transition effort. In your work on biotechnology, you’ve assisted us in addressing similar issues.

This is a delicate matter. We want to be upfront and above board. At the same time, FDA has determined, after extensive scientific review, that there is no safety issue here. So we need to find a balance between providing the information our customers want and calling unnecessary attention to a non-issue.

We appreciate your taking time to take a look at this issue. We’ll look forward to your thoughts and guidance as we work with producers and technology providers to move from the laboratory to the market.