



Send in the Clones

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On July 5, 1996, scientists at Scotland's Roslin Institute succeeded in cloning the first livestock mammal using a somatic cell obtained from an adult animal. To produce Dolly the sheep, researchers replaced the nucleus of an egg with a nucleus isolated from the udder of a six-year old sheep. Roslin Institute announced Dolly's birth in early 1997. The news incited visions of herds of cloned animals. The point might have been missed that researchers had tried over 270 times to produce one cloned sheep.

Dolly's arrival raised questions about food products made from cloned livestock. Would the food be safe for human consumption? In January, US and European agencies offered their views. The opinions are so similar, they're almost clones.

Agencies Make Themselves Heard about Clones

In 2001, US Food and Drug Administration officials decided that cloning may become a standard method for improving livestock. The FDA's Center for Veterinary Medicine (CVM) asked livestock producers to keep food products derived from animal clones or their offspring out of the human food supply until the FDA could evaluate food safety. For five years, CVM researchers analyzed hundreds of peer-reviewed publications and data from unpublished studies on the health of clones and their offspring, and on the composition of food produced from the animals.

In December 2006, the FDA released three documents on animal cloning: a draft risk assessment, a proposed risk management plan, and a draft guidance for industry. The draft risk assessment revealed that the FDA deemed meat and milk from clones of adult cattle, swine, and goats, as well as their offspring, to be as safe to eat as food from conventionally-bred animals. The FDA also considered the effects of cloning technology on animals. "Cloning poses no unique risks to animal health," said CVM director Stephen F. Sundlof in a press release, "when compared to other assisted reproductive technologies currently in use in US agriculture."

The FDA sought comments from the public on its three draft documents. The agency received over 30,000 remarks.

On January 15, 2008, the FDA issued final versions of the three draft documents. The agency reiterated its assessment that the cloning process poses no unique risks to animal health, compared to the risks of other reproduction methods; that the composition of food products derived from cattle, swine, and goat clones, or their progeny, does not differ from food products of conventionally-bred animals; and that food derived from cattle, swine, and goat clones, or their offspring, does not pose unique risks to consumers. Due to a lack of information, the FDA did not include assessments of other cloned livestock animals, such as cloned sheep.

Under current law, the FDA may require food labeling if the agency has safety concerns, or if the agency finds a material difference in the composition of food. In the FDA's view, neither condition applies to food derived from clones or their offspring. Accordingly, the FDA will not compel labels to alert consumers that a product contains ingredients from cloned livestock or progeny.

The FDA underscores that their conclusions for the three livestock species have varying degrees of uncertainty. One source of uncertainty arises from the present understanding of the epigenetic processes involved in early embryonic development. Clones are genetically identical, but they differ in the epigenetic state of their genomes. For example, the genomes of clones differ in DNA methylation. Another source of uncertainty arises from ongoing developments in cloning technology. New techniques may introduce hazards not found in current cloning methods. The FDA has stated that it will continue to monitor the developing state of knowledge about animal cloning and new cloning technology.

The agency also addresses the manufacture of animal feed from clones. In its Guidance for Industry, the FDA takes the position that clones of any species could be used in the production of feed for animals without additional restriction. "Animal Cloning: A Risk Assessment" and other related documents are available from the FDA website (<http://www.fda.gov/cvm/cloning.htm>).

Animal cloning techniques have been associated with an increased risk of unfavorable health outcomes in surrogate dams carrying late-term clone fetuses and in very young clones, particularly in cattle and sheep. To minimize the impact of animal health risks, the FDA has been collaborating with the International Embryo Transfer Society to prepare a manual on animal care standards for animals involved in the cloning process. The two organizations plan to release a copy of the manual on the Society's website early this year.

On the day that the FDA announced the release of its animal cloning documents, Bruce Knight, the USDA's Under Secretary for Marketing and Regulatory Programs, stated that his organization agrees with the FDA's opinions about food safety. "Now that FDA has evaluated the scientific data and public comments and issued its final risk assessment," he said, "USDA will join with technology providers, producers, processors, retailers and domestic and international customers to facilitate the marketing of meat and milk from clones. We'll be working closely with stakeholders to ensure a smooth and seamless transition into the marketplace for these products." In the meantime, the USDA encourages the industry to maintain



the voluntary moratorium on sending milk and meat from animal clones into the food supply.

On January 11, the European Food Safety Authority issued its draft document on a review of food safety concerns. "The currently available data indicate," says EFSA, "that food products from clones of cattle and pigs and their progeny are as safe as food products of livestock derived by conventional breeding." EFSA also concluded that "there is no expectation that clones or their progeny would pose any new or additional environmental risks compared with conventionally bred animals." After reviewing comments from the public, EFSA plans to finalize its opinion by May 2008. A copy of the draft opinion is available on the EFSA website (<http://www.efsa.europa.eu>).

The European Group on Ethics in Science and New Technologies released its opinion on ethical aspects of animal cloning on January 16 (http://ec.europa.eu/european_group_ethics/index_en.htm). It is not a resounding endorsement of the technology. "Considering the current level of suffering and health problems of surrogate dams and animal clones," the group said, "the EGE has doubts as to whether cloning animals for food supply is ethically justified." The organization decided that further research is required to determine whether this applies to the progeny of clones. "At present, the EGE does not see convincing arguments to justify the production of food from clones and their offspring." EFSA's scientific conclusions and the report on ethical aspects of animal cloning will help to inform decisions about animal cloning by the European Community and the European Parliament.

Fears of a Clone

The FDA's long-awaited final opinion on food safety did not please everyone. "The FDA has acted recklessly and I am profoundly disappointed in their rush to approve cloned foods," declared Senator Barbara A. Mikulski (D-Md.) in a January 15, 2008, press release. "[T]he FDA has rushed into a decision that could have dangerous consequences. The long term effects of these products are still unknown and could be harmful to consumers." Last year, Senator Mikulski sponsored a bill to amend the Federal Food, Drug, and Cosmetic Act and the Federal Meat Inspection Act to require that food that contains products from a cloned animal or its progeny be labeled accordingly.

The flipside of labeling the presence of cloned animal ingredients is to label food as free from such ingredients. Since the FDA issued its draft documents in 2006, consumers have been pushing for clone-free labels on food products derived from conventional livestock. The FDA has said that, should a manufacturer want to voluntarily label a product as "clone-free," the request will be reviewed to ensure compliance with requirements that labeling be truthful and not misleading.

For now, stud farms and breeders constitute the target market for animal cloning technology. A clone, which can represent an investment of \$20,000, is too valuable to milk or to slaughter for meat, especially when the milk and meat are not worth more than that from a conventional animal. It may be years before food products from clone progeny flock onto grocery store shelves.

Selected Sources

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