# ARE THE PROGENY OF CLONED ANIMALS SAFE TO EAT?

Alison Van Eenennaam, PhD Cooperative Extension Specialist University of California Department of Animal Science One Shields Avenue Ph:(530) 752-7942 Davis, CA 95616 Fax:(530) 752-0175 Email: <u>alvaneenennaam@ucdavis.edu</u> Website: <u>http://animalscience.ucdavis.edu/animalbiotech</u>

## Background

In 2001, the Center for Veterinary Medicine at the U.S. Food and Drug Administration (FDA) determined that it should undertake a comprehensive risk assessment to identify hazards and characterize food consumption risks associated with somatic cell nuclear transfer (SCNT) animal clones<sup>1</sup>. As there was no fundamental reason to suspect that clones would produce novel toxins or allergens, the main underlying food safety concern was whether epigenetic (DNA programming) anomalies that can result from the SCNT cloning process could produce subtle changes in the composition of animal food products<sup>2</sup>. They asked companies and producers to adhere to a voluntary moratorium not to introduce SCNT cloned animals, their progeny, or their products into the human or animal food supply during the multiyear duration of the risk assessment. On January 15<sup>th</sup>, 2008 the FDA published its final 968-page risk assessment on animal cloning. That document, which summarizes worldwide data on the health of clones, their progeny and food safety studies of their products, concludes that meat and milk from cloned cattle, swine and goats, and the offspring of any species traditionally consumed as food, are as safe to eat as food from conventionally bred animals.<sup>i</sup>

## Are the progeny of clones safe to eat?

The FDA's assessment that the progeny of SCNT clones are not likely to pose food safety concerns is shared by the National Academy of Sciences<sup>3</sup>, and international food safety authorities including the European Food Safety Authority which recently released a report stating that "*it is very unlikely that any difference exists in terms of food safety between food products originating from clones and their progeny compared with those derived from conventionally bred animals,*" <sup>ii</sup> and Food Standards Australia New Zealand (FSANZ) which concluded that "*there are well founded scientific reasons, supported by a mounting body of experimental evidence, to confidently expect that the health profile of any offspring, produced by natural mating, would be entirely normal.*" <sup>iii</sup> The FDA is not recommending any additional measures related to the use of the progeny of clones for the production of food for humans, or feed for animals, based on the fact that these are progeny of clones. In a stakeholder teleconference on January 15<sup>th</sup>, 2008, the USDA stated that "based on the findings that the FDA has shown, it would not be necessary to continue with the moratorium on the progeny." This effectively opens the way for milk and meat from the progeny of clones to enter the food supply.

# Why will the progeny of clones be used for food?

Vastly more edible products (both meat and dairy) will be derived from the progeny of clones, than will be produced from the relatively small number of livestock clones themselves. Cloned animals in agriculture will be used in the same way as other elite breeding animals are - to be the sires or dams of sexually-reproduced animals, and it will therefore mostly be their progeny that will be used to produce animal food products.

iii http://www.foodstandards.gov.au/ srcfiles/Cloning Review Final June%202003.pdf

<sup>&</sup>lt;sup>i</sup> http://www.fda.gov/cvm/CloneRiskAssessment\_Final.htm

<sup>&</sup>lt;sup>ii</sup> http://www.efsa.europa.eu/EFSA/DocumentSet/sc\_opinion\_clon\_public\_consultation.pdf

## Is it true there have been no peer-reviewed studies on the offspring of clones?

There have been a limited number of peer-reviewed studies on the offspring of clones, three in pigs<sup>4-6</sup>, and three in cattle<sup>7-9</sup>. This is perhaps not surprising given that it is estimated that at the current time there are only 500-600 SCNT livestock clones in the United States (Barbara Glenn, Biotechnology Industry Organization, personal communication). The largest study of the progeny of clones compared the quality and composition of meat derived from the progeny of cloned swine and non-cloned swine. That study was carried out by ViaGen (www.viagen.com), a company that provides animal cloning services, and reported data on 404 swine: 242 clone progeny and 162 comparators. The composition of meat samples from these two groups was indistinguishable. After reviewing this very large data set, the FDA concluded that all of the blood values, overall health records, and meat composition profiles of the progeny of clones were in the same range as for very closely related conventionally bred swine.

## So why are regulatory authorities confident that the progeny of animal clones are safe to eat?

Although the amount of data describing the health of the progeny of clones is more limited than the amount describing the health of animal clones themselves, there is an underlying biological assumption behind the predicted health and resultant food safety of the sexually-produced progeny of clones. The genetic remodeling process that occurs during gametogenesis (i.e. the production of eggs and sperm), is thought to naturally reset any epigenetic anomalies that might result from the cloning process. In other words, sexual reproduction effectively corrects any programming errors that may have been introduced into the cloned parent's DNA, thereby resulting in the production of normal gametes and offspring. This assumption is supported by peer-reviewed studies in mice where it has been observed that abnormalities present in cloned mice are not passed on to their sexually-derived progeny<sup>10</sup>. In addition, empirical observations on the relatively small number of progeny of bovine and swine clones that have been born support the premise of normal development. Sexually-produced progeny of clones show no evidence of the developmental abnormalities that are sometimes observed in cloned animals themselves.

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