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FDA News

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FDA Issues Documents on the Safety of Food from Animal Clones

*Agency Concludes that Meat and Milk from Clones of Cattle, Swine, and Goats,
and the Offspring of All Clones, are as Safe to Eat as Food from Conventionally
Bred Animals*

After years of detailed study and analysis, the Food and Drug Administration has concluded 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 was insufficient information for the agency to reach a conclusion on the safety of food from clones of other animal species, such as sheep.

FDA today issued three documents on animal cloning outlining the agency's regulatory approach – a risk assessment; a risk management plan; and guidance for industry.

The documents were originally released in draft form in December 2006. Since that time, the risk assessment has been updated to include new scientific information. That new information reinforces the food safety conclusions of the drafts.

In 2001, U.S. producers agreed to refrain from introducing meat or milk from clones or their progeny into the food supply until FDA could further evaluate the issue. The U.S. Department of Agriculture will convene stakeholders to discuss efforts to provide a smooth and orderly market transition, as industry determines next steps with respect to the existing voluntary moratorium.

The agency is not requiring labeling or any other additional measures for food from cattle, swine, and goat clones, or their offspring because food derived from these sources is no different from food derived from

conventionally bred animals. Should a producer express a desire for voluntary labeling (e.g., "this product is clone-free"), it will be considered on a case-by-case basis to ensure compliance with statutory requirements that labeling be truthful and not misleading.

Because clones would be used for breeding, they would not be expected to enter the food supply in any significant number. Instead, their sexually reproduced offspring would be used for producing meat and milk for the marketplace. At this time, the agency continues to recommend that food from clones of species other than cattle, swine and goat (e.g., sheep) not be introduced into the food supply.

An animal clone is a genetic copy of a donor animal, similar to an identical twin, but born at a different time. Cloning is not the same as genetic engineering, which involves altering, adding or deleting DNA; cloning does not change the gene sequence. Due to their cost and rarity, clones are intended to be used as elite breeding animals to introduce desirable traits into herds more rapidly than would be possible using conventional breeding.

Risk assessment

The risk assessment finds that meat and milk from clones of cattle, swine, and goats, and food from the sexually reproduced offspring of clones, are as safe to eat as food from conventionally bred animals. The science-based conclusions agree with those of the National Academy of Sciences, released in a 2002 report. The assessment was peer-reviewed by a group of independent scientific experts in cloning and animal health. They found the methods FDA used to evaluate the data were adequate and agreed with the conclusions set out in the document.

The risk assessment presents an overview of assisted reproductive technologies widely used in animal agriculture, the extensive scientific information available on the health of animal clones and their sexually reproduced offspring, and an assessment of whether food from clones or their sexually reproduced offspring could pose food consumption risks different from the risks posed by food from conventionally bred animals. These conclusions were first presented in draft documents over a year ago. Since then, the agency has updated the risk assessment with data that became available, as well as taking into account comments from the public comment period.

"After reviewing additional data and the public comments in the intervening year since the release of our draft documents on cloning, we conclude that meat and milk from cattle, swine, and goat clones are as safe as food we eat every day," said Stephen F. Sundlof, D.V.M., Ph.D., director of FDA's Center for Food Safety and Applied Nutrition. "Our additional review strengthens our conclusions on food safety."

Risk management plan

The risk management plan outlines measures that FDA has taken to address the risks that cloning poses to animals involved in the cloning process. These risks all have been observed in other assisted reproductive technologies currently used in common agricultural practices in the United States.

FDA is currently working with scientific and professional societies with expertise in animal health and reproduction to develop standards of care for animals involved in the cloning process. Although the agency is not charged with addressing ethical issues related to animal cloning for agricultural purposes, FDA plans to continue to provide scientific expertise to interested parties working on these issues.

Guidance for industry

The guidance for industry addresses the use of food and feed products derived from clones and their offspring. It is directed at clone producers, livestock breeders, and farmers and ranchers purchasing clones, and provides the agency's current thinking on use of clones and their offspring in human food or animal feed.

In the guidance, FDA does not recommend any special measures relating to the use of products from cattle, swine, or goat clones as human food or animal feed. Because insufficient information was available on clones from other species, e.g., sheep clones, to make a decision on the food consumption risks, the guidance recommends that food products from clones of other species continue to be excluded from the human food supply. The guidance states that food products from the offspring of clones from any species traditionally consumed for food are suitable to enter the food and feed supply.

For more information, visit <http://www.fda.gov/cvm/cloning.htm>.

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