

Guidance for Industry
**Use of Edible Products from Animal Clones
or their Progeny for Human Food or Animal Feed**

DRAFT GUIDANCE

This guidance is being distributed for comment purposes only.

Comments and suggestions regarding this draft guidance should be sent to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Comments may also be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments>. All written comments should be identified with Docket No. 2003N-0573.

For questions regarding this draft guidance, contact Larisa Rudenko, Center for Veterinary Medicine (HFV- 100), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240 453-6842. E-mail: clones@cvm.fda.gov

Additional copies of this draft guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at <http://www.fda.gov/cvm/cloning.htm>

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine**

December 28, 2006

CONTAINS NON-BINDING RECOMMENDATIONS

Draft – Not for Implementation

179

Draft Guidance for Industry Use of Edible Products from Animal Clones or their Progeny for Human Food or Animal Feed

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

FDA's Center for Veterinary Medicine (CVM) recently completed a draft risk assessment entitled "*Animal Cloning: A Draft Risk Assessment*" on the potential risks presented by cloning food-producing animals. Among the goals of the risk assessment were the determination of whether somatic cell nuclear transfer (SCNT, the process used to produce the clones being considered in the risk assessment) poses any unique risks to animals involved in cloning relative to other assisted reproductive technologies (ARTs), and whether foods derived from animal clones or their progeny pose consumption risks greater than those posed by foods derived from their conventional counterparts. This draft guidance document describes FDA's recommendations regarding the introduction of edible products from animal clones and their progeny into the food and feed supply.

II. Background

In July 2001, FDA's Center for Veterinary Medicine (CVM) issued an Update on Livestock Cloning (available at http://www.fda.gov/cvm/CVM_Updates/clones.htm) and

CONTAINS NON-BINDING RECOMMENDATIONS

Draft – Not for Implementation

proceeded to work with stakeholders to assess potential risks presented by cloning food-producing animals. CVM also requested that companies voluntarily refrain from introducing meat or milk from animal clones or their progeny into the human or animal food supply pending completion of the risk assessment process.

The Draft Risk Assessment specifically addresses SCNT, which allows the copying of a specific animal without sexual reproduction, and focuses on those domestic livestock that have been cloned, i.e., cattle, swine, sheep, and goats. Among the goals of the Draft Risk Assessment were the determination of whether SCNT poses any unique risks to animals involved relative to other assisted reproductive technologies (ARTs), and whether foods derived from animal clones or their progeny pose consumption risks in addition to those posed by foods derived from their conventional counterparts.

All of the data evaluated in the Draft Risk Assessment are either available in peer-reviewed publications, or in the Draft Risk Assessment itself. In addition, the methodology used to evaluate the data, underlying assumptions used by the risk assessors; residual uncertainties, including sources of potential bias; and the basis for our conclusions are explicitly provided in the Draft Risk Assessment.

III. Animal feed derived from clones

No animal feed risks unique to clones were identified in the Draft Risk Assessment. FDA therefore does not have recommendations for any additional measures related to the use of clones of any age or species for the production of feed for animals that are based on the fact that the animals are derived from cloning. This conclusion applies to rendered products from any clones and the use of milk from clones for animal feed.

IV. Human food derived from clones

No unique risks for human food consumption were identified in cattle, swine, or goat clones. No anomalies have been observed in animals produced by cloning that are not also observed in animals produced by other assisted reproductive technologies (ARTs) and natural mating. The frequency of these outcomes, however, is increased over other ARTs and natural mating. As was the case with other ARTs, the success rate is improving over time.

Various systems are in place in the United States to assure the safety of human food. These food safety systems do not require that information be provided on the method by

CONTAINS NON-BINDING RECOMMENDATIONS

Draft – Not for Implementation

which the animals were produced, e.g., natural mating, assisted reproductive technologies, etc. Because no unique food consumption hazards have been identified for clones, food from animal clones would be subject to the same food safety systems as food from any other animal. Therefore, for example, clones that pass ante- and post-mortem inspections would be considered as safe as any other animals that pass those inspections. Similarly, milk from animal clones that is subject to the Pasteurized Milk Ordinance and/or other federal, state, or local requirements, and meets those requirements would be considered as safe as any other milk which is subject to and meets those requirements.

As stated earlier, the Draft Risk Assessment did not identify any unique risks for human food from cattle, swine, or goat clones. Therefore, there is no science based reason to recommend any additional safeguards. As such, we do not have any recommendations for any additional measures related to the use of products from cattle, swine, or goat clones as human food.

As stated in the Draft Risk Assessment, insufficient information was available on sheep clones to make a decision on food consumption risks. Therefore, at this time, the agency recommends that edible products from sheep clones not be introduced into the human food supply.

V. Animal feed and human food derived from clone progeny

FDA anticipates that most of the food products from SCNT technology will be derived from clone progeny, the sexually-reproduced offspring of clones. No human food or animal feed risks were identified for clone progeny in the Draft Risk Assessment. The agency believes that food products from clone progeny are suitable to enter the food and feed supply under the same controls as applied to any animal that is the product of sexual reproduction.

Therefore, FDA does not have recommendations for any additional measures related to the use of the progeny of clones for the production of food for humans or feed for animals that are based on the fact that these are progeny of clones.