

Guidance for Industry

Use of Animal Clones and Clone Progeny for Human Food and Animal Feed

Comments and suggestions regarding this 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.regulations.gov>. All written comments should be identified with Docket No. 2003N-0573.

For questions regarding this guidance, contact Larisa Rudenko, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, 240-276-8245, e-mail: larisa.rudenko@fda.hhs.gov.

Additional copies of this 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/AnimalVeterinary/SafetyHealth/AnimalCloning/default.htm>.

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

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CONTAINS NON-BINDING RECOMMENDATIONS

Use of Animal Clones and Clone Progeny for Human Food and Animal Feed

This guidance represents 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 risk assessment entitled "*Animal Cloning: A 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 guidance document describes FDA's recommendations regarding the introduction of edible products from animal clones and their progeny into the food and feed supply. To the extent any parts of SCNT or animal clones, based on being derived from SCNT, meet the requirements for regulation as new animal drugs under the Federal Food, Drug, and Cosmetic Act (Act), this guidance also sets out FDA's enforcement policy that FDA intends to exercise its enforcement discretion

II. Background

In July 2001, FDA's Center for Veterinary Medicine (CVM) issued an Update on Livestock Cloning (available at <http://www.fda.gov/AnimalVeterinary/NewsEvents/FDAVeterinarianNewsletter/ucm130770.htm>) and 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.

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The 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 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 Risk Assessment are either available in peer-reviewed publications, or in the 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 Risk Assessment.

III. Animal feed derived from clones

No animal feed risks unique to clones were identified in the 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 derived via SCNT. 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 those anomalies, however, is increased over other ARTs and natural mating. As was the case with other ARTs, the success rate is improving over time. Further, the results of the Risk Assessment have clearly indicated that cloning falls on the continuum of assisted reproductive technologies (ARTs).

Following extensive review, the Risk Assessment did not identify any unique risks for human food from cattle, swine, or goat clones, and concluded that there is sufficient information to determine that food from cattle, swine, and goat clones is as safe to eat as that from their more conventionally-bred counterparts. Because of these reasons, and because food from clones would be subject to the same requirements as food from their conventionally bred counterparts, we do not believe that meat or milk from cattle, swine, and goat clones would require any additional controls compared with meat or milk from cattle, swine, or goats currently entering the food supply today.

As stated in the Risk Assessment, insufficient information was available on sheep clones to make a decision on food consumption risks and assessments were not conducted for animals other than cattle, swine, goat, and sheep. Therefore, at this time, the agency continues to

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recommend that edible products from clones from animals other than cattle, swine, or goat (e.g., sheep) not be introduced into the human food supply.

V. Animal feed and human food derived from clone progeny of any species traditionally consumed as food or feed

FDA anticipates that most of the food products from SCNT technology will be derived from clone progeny, the sexually-reproduced offspring of clones, rather than from the clones themselves. Based on our evaluation, which included empirical evaluations, a careful assessment of the literature, and congruence with biological assumptions, we agree with the findings of the National Academies of Science (NAS 2002) that there are no human food or animal feed risks associated with the progeny of any clone of a species traditionally consumed for food that are not present in other sexually-reproduced animals of the same species. Therefore, the agency believes that food products from progeny of a clone from any species currently consumed as food 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. 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 based on the fact that these are progeny of clones.

VI. Enforcement discretion for new animal drug requirements applicable to SCNT or animal clones based on being derived from SCNT

Assuming, without here deciding, that any part of SCNT or animal clones, based on being derived from SCNT, meet the statutory definition of new animal drug under the Act, at this time, FDA does not intend to regulate any such new animal drugs. This intent not to regulate (i.e., the intent to exercise enforcement discretion) applies to both non-food and food-producing species.

REFERENCE:

NAS 2002. Animal Biotechnology: Science-Based Concerns. The National Academies Press. Washington , DC.