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FDA News

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FDA Issues Draft Executive Summary of its Assessment of Safety of Animal Cloning; Current Voluntary Moratorium on Releasing Animal Clones Remains in Effect

As part of its ongoing review of the scientific evidence regarding the safety of food products derived from animal clones, the Food and Drug Administration (FDA) today released a draft Executive Summary of a risk assessment that will be discussed publicly at a meeting of FDA's Veterinary Medicine Advisory Committee (VMAC) November 4th. The risk assessment also evaluates the risks to animals involved in the cloning process.

The draft risk assessment builds on the findings of the National Academy of Sciences (NAS) and indicates that food products derived from animal clones and their offspring are likely to be as safe to eat as food from their non-clone counterparts, based on all the evidence available. These scientific findings also showed that healthy adult clones are virtually indistinguishable from their conventional counterparts. Most of the data available address cattle, pig, and goat clones. FDA made the assessment using data that it will later release publicly as part of the draft risk assessment. Some of these data will also be presented at the VMAC meeting November 4th.

The animal cloning risk assessment is part of an orderly and open process FDA has undertaken to assess the safety of food products derived from cloned animals and the risks to animals involved in the cloning process. The process began two years ago, when FDA commissioned the NAS to consider scientific information on animal biotechnology. The NAS concluded that although food from animal clones posed only a low level of food safety concern, it would be prudent to have more data in order to minimize further safety concerns. FDA decided that before it could address any policy issues on animal cloning, it needed to conduct a risk assessment, followed by development of commensurate risk management options, in an open and transparent process.

Through numerous public meetings on animal cloning, FDA has stated up front that the risk assessment methodology and all of the information used in performing the risk assessment would be publicly available.

As part of this process, FDA is committed to providing the public the information about animal cloning as it becomes available. To that end, FDA is holding the November 4 public VMAC meeting to preview the draft risk assessment, even though some ancillary portions of the document such as the glossary and several appendices are not complete. The preliminary review and discussion with the Advisory Committee is another step in the Agency's effort to ensure that the complex issues facing the Agency regarding animal cloning are evaluated using a process that affords the greatest degree of transparency and scientific rigor.

FDA intends to present at the VMAC, in some detail, the risk assessment methodology, summary data from the risk assessment, and conclusions for food safety and animal safety. The agency believes these presentations will be of sufficient depth for the advisory

committee to answer the questions of food safety and animal safety at issue.

The Advisory Committee meeting represents an important step in the process, but the Agency will take additional steps prior to finalizing the risk assessment or reaching any subsequent decisions about the safety of food products derived from animal clones. These steps include providing the public with the opportunity to comment on the draft risk assessment and thoroughly reviewing and responding to those comments prior to finalizing the assessment.

Although the document being released today does not specifically address ethical issues, that fact does not mean FDA is overlooking those issues. The draft risk assessment is intended only to address the safety of food from animal clones and the risks to animal clones, and the assessment is only one part of an orderly and public process to address the many facets of the cloning issue.

While this open public process is underway, FDA's position with respect to releasing animal clones or their progeny into the food supply has not changed: these products should not be released into the food supply. FDA has made no policy decision that these products may be sold. A risk management options paper dealing with such questions will follow the assessment currently underway.

Until such time as FDA makes any final decisions on cloned animals, the agency will continue to request that producers withhold these products from the market, with the full expectation that firms will comply with this request as they have willingly done in the past.

This draft assessment was developed by scientists at FDA's Center for Veterinary Medicine (CVM), after the NAS published its report on animal biotechnology. The Academy concluded that although food from animal clones posed a "low level of food safety concern" that it would be prudent to have more data with which to minimize any further safety concerns. With respect to progeny of clones, NAS concluded that "no food safety concerns" would be posed because progeny arose as the result of natural matings. In FDA's analysis of the available data on animal clones, no differences were detected in overall behavior and health of juvenile and adult animal clones and conventional animals, even at the level of blood chemistry.

Cloning is a process that allows livestock breeders and others to replicate their best animals that are then used for breeding stock. The specific cloning technique CVM is focusing on is known scientifically as somatic cell nuclear transfer (SCNT). Dolly the sheep, born on July 6, 1996, was produced using this technology. SCNT lends itself to commercial use because it allows the generation of large numbers of animals from a single donor. Often, donor animals are adults whose genetic superiority has already been demonstrated. Cloning can also be used to expand populations of endangered species.

SCNT involves transferring the genetic information from one animal and inserting it into an oocyte, or egg, that has had its nucleus removed. The resulting embryo is implanted into a surrogate mother, which carries the fetus to birth. Although cloning is relatively new, because of its promise, breeders have expressed strong interest in using this technology to improve the quality of their breeding stock. To date, FDA believes that no animal clones have entered the food supply.

The conclusions of the review apply only to animal clones. The researchers did not consider animals that had been altered through genetic engineering, so-called "transgenic" animals. Cloning involves copying an existing animal only, while transgenics allows scientists to alter the gene structure of an animal, thus changing its attributes.

The draft assessment also looked at the risks to animal health from cloning, and concluded that, although there were risks to animals involved in the cloning process, cloning technology does not present any type of risk that is not present with other forms of reproduction. However, the adverse outcomes may occur at a higher frequency with cloning than with other assisted reproductive technologies now in common use, such as in vitro fertilization or embryo transfer.

Problems associated with animal cloning are likely to be detected at birth or early in life. A small number of these animals do not survive, or may be culled from the herd, just as conventional animals are. By the time clones reach adolescence, however, anomalies that may have been noted at birth are generally resolved and the clones are as normal and healthy as their conventional counterparts.

The report is limited to an assessment of the risks, and offers no recommendations about the potential need for rules about marketing food from animal clones. That subject will be addressed after the draft risk assessment has been posted for public comment. Following the close of the public comment period on the risk assessment (60 days after posting), the agency will review the public comments in preparing the final risk assessment and the draft risk management options.

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[Draft Summary of Cloning Risk Assessment \(pdf\)](#)

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