The Comments of Food Animal Concerns Trust
to

U.S. Food and Drug Administration
Center for Veterinary Medicine

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Comments submitted by:

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Re: Docket No. 2003N-0573 (Draft Animal Cloning Risk Assessment; Proposed Risk Management Plan; Draft Guidance)

## Introduction

Food Animal Concerns Trust (FACT) is a non-profit organization founded in 1982 which advocates for humane and sustainable farming practices that: improve the safety of milk, meat and eggs; promote the humane husbandry of food animals; reduce environmental pollution, and broaden economic opportunities for family farmers.

FACT is pleased to have this opportunity to provide comments to U.S. Food and Drug Administration (FDA) on the agency's Draft Animal Cloning Risk Assessment and related documents.

## Comments

In December 2006, the FDA released its Draft Animal Cloning Risk Assessment which concluded that "cloning poses no unique risks to animal health when compared to other assisted reproductive technologies currently in use in U.S. agriculture."[1] The agency also found that "meat and milk from clones of adult cattle, pigs and goats, and their offspring, are as safe to eat as food from conventionally bred animals."[2] In addition, FDA stated that it will not be necessary to label cloned meat and milk as such, making cloned products virtually indistinguishable from conventional products.

FACT is concerned with this decision because it fails to protect animal health due to the documented negative impacts of cloning on animal welfare. Furthermore, FACT believes that FDA's draft assessment does not adequately consider the risks of allowing

[1] FDA News Release, "FDA Issues Draft Documents on the Safety of Animal Clones," December 28, 2006, online at http://www.fda.gov/bbs/topics/NEWS/2006/NEW01541.html

[2] Ibid.

cloned animals and their progeny into the food supply. Therefore we urge the agency to issue a mandatory moratorium on food from cloned animals until:

(1) Cloning can meet the highest standards for animal health and welfare; and

(2) The FDA has established a mandatory pre-market review process, regulating cloning as a new animal drug and requiring generational studies including investigations into potential food safety threats created by the cloning process.

Moreover, if food from cloned food animals or their progeny is allowed in the food supply, FACT believes that it is essential these products be clearly labeled. This is consistent with the advice issued by the National Academies of Science on the need for monitoring and tracking food from cloned animals if it is to be released into the market.[3]

*Animal Health and Welfare*

Many of the animals involved in the cloning process are exposed to increased risk of adverse health outcomes relative to conventional animals, including a range of problems with both the birthing process and the cloned animal itself.

*Pre-Natal Failures:*

FDA reports that cloning, which employs 'nuclear transfer' technology, is a biologically imprecise and inefficient process resulting in few live births, and that some animals are born with obvious defects or subtle anomalies. For example, a meta-analysis by Panarace et al. found that only 9% of transferred embryos resulted in calves.[4]

*Surrogate Suffering:*

Cloning also threatens the welfare of surrogate mothers. Of the cloned fetuses that do survive, most exhibit placental abnormalities that pose serious health risks not only to themselves and their offspring, but also to the surrogate mothers carrying the pregnancies, resulting in the deaths of both the fetuses and the surrogate mothers.[5] In addition, the birth weight of cloned cattle calves may be 25 percent heavier than normal.[6]

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[3] National Academy of Sciences (2004). Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. Sub-report: Methods and Mechanisms of Genetic Manipulation and Cloning of Animals, p. 232. Available at: http://www.nap.edu/openbook.php?chapselect=yo&page=232&record_id=10977 (accessed 04.16.07)

[4] Panarace,M., et al., 2007. "How healthy are clones and their progeny: 5 years of field experience." Theriogenology. 67:142-151. Abstract available at: http://www.sciencedirect.com/science?_ob=ArticleURL&_udi=B6TCM-4M69JC5-1&_user=10&_coverDate=01%2F01%2F2007&_rdoc=20&_fmt=summary&_orig=browse&_srch=doc-info(%23toc%235174%232007%23999329998%23638868%23FLA%23display%23Volume)&_cdi=5174&_sort=d&_docanchor=&view=c&_ct=27&_acct=C000050221&_version=1&_urlVersion=0&_userid=10&md5=c0215c934f19db5786da8bb3b56bd946 (accessed 04.18.07)

[5] Westhusin M. 2001. Issues raised by human cloning research. Hearing before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce. 107th Congress, 1st Sess. 41.

[6] Wells, DN. 2005. Animal cloning: problems and prospects. Revue Scientifique et Technique (International Office of Epizootics) 24(1):251-64. Abstract available at: http://www.oie.int/eng/publicat/RT/2401/A_R240122.htm (accessed 04.18.07)

Large Offspring Syndrome, common to sheep and cattle clones, generally necessitates delivery by caesarian section, an invasive and stressful surgery.

*Post-Natal Animal Health:*
Recent cloning research shows the low survival rates for the cloned fetus, suffering of the surrogate mother, and severe abnormalities in the cloned animal after birth, problems widely acknowledged as being indicative of poor animal welfare. Those cloned animals that manage to survive the prenatal and birthing process are likely to suffer from a wide range of health defects and deformities including: enlarged tongues; malformed faces; intestinal blockages; diabetes; shortened tendons; deformed feet; weakened immune systems; dysfunctional hearts, brains, livers, and kidneys; respiratory distress; and circulatory problems.[7, 8, 9]

Although the complications described above are not unique to cloning technology, cloning is known to increase the frequency at which such serious health problems occur. For example, studies have found that Large Offspring Syndrome occurs in up to 50 percent of clones, but is relatively rare in other reproductive techniques such as Embryo Transfer and *in vitro* fertilization. As described by the FDA, clinical signs associated with calves displaying Large Offspring Syndrome include: slowness to stand, inability to thermoregulate, weak or absent suckle reflex, large umbilicus with patent blood vessels, deformities of limbs (tendon contracture) and /or head, disproportionate or immature organ development, increased susceptibility to infection, insufficient lung surfactant, failure of lungs to inflate, enlarged heart.[10]

The rate of hydrops, an abnormality that can lead to stillborn animals, early death, and/or death of the surrogate cow due to abnormal fluid accumulation in one or more compartments of the placenta and/or the fetus itself, ranges between 13 and 42 percent in cloning. In the general population of cattle, the condition is extremely rare, with estimates as low as 1 in 7500.[11]

In light of this evidence demonstrating that animals in cloning research can and do suffer, FACT opposes the FDA's proposed plan to introduce food from cloned animals into the U.S. food supply. FACT does not support a technology that is detrimental to animal welfare, such as the well-documented increase in the incidence of reproductive complications found with cloning.

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[7] Rideout WM, Eggan K, and Jaenisch R. 2001. Nuclear cloning and epigenetic reprogramming of the genome. Science 293(5532):1093-8.
[8] Schatten G, Prather R, and Wilmut I. 2003. Letters: cloning claim is science fiction, not science. Science 299(5605):344.
[9] Jaenisch R and Wilmut I. 2001. Developmental biology: don't clone humans! Science 291(5513):2552.
[10] Food and Drug Administration (2006). "Animal Cloning: A Draft Risk Assessment." December 28, 2006, p. 115.
[11] Food and Drug Administration (2006). "Animal Cloning: A Draft Risk Assessment." December 28, 2006, p. 111-114.

*Food Safety*

The primary concern for milk and meat from animal clones is that inappropriate reprogramming of the nucleus of donor cells may result in epigenetic changes creating subtle hazards that may pose food consumption risks—hazards that may not be detectable on the surface. FDA states that problems in clones will not be found in progeny because sexual reproduction will "reset even those residual epigenetic reprogramming errors that could persist in healthy, reproducing clones."[12]

However, this may not necessarily be the case. For instance, a 2004 study conducted by Lawrence and Murphy stated that mutations from the less obvious defects in clones could be passed on to their progeny. The authors concluded that "…such problems could lead to inheritable anomalies among clones and their offspring."[13] A 2003 peer-reviewed study not cited by FDA in its Draft Risk Assessment found that progeny of mammal clones can inherit certain epigenetic changes.[14] The National Academies of Science has also stated that "little evidence is available in the scientific literature to assess whether the progeny of cloned animals are at increased risk for inherited or developmental defects."[15]

Despite the apparent lack of extensive, long-term research on epigenetic and other subtle hazards, the FDA concluded in its Draft Risk Assessment that meat and milk from cloned animals and their progeny are "as safe to eat" as food from conventionally bred animals. This FDA assurance is countered by a report from the Center for Food Safety that claims the agency found only a limited number of scientific studies to support the commercial release of these foods:[16]

- FDA found no peer-reviewed studies on meat from cloned cows or on milk or meat from the offspring of cow clones.
- FDA found no peer-reviewed studies on meat from cloned pigs or their offspring.
- FDA found no peer-reviewed studies on meat or milk from cloned goats or their offspring.
- FDA found just three peer-reviewed studies on milk from cloned cows; all three studies showed differences in milk from clones that should prompt further research.

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[12] Food and Drug Administration (2006). "Animal Cloning: A Draft Risk Assessment." December 28, 2006, p. 8

[13] Smith, Lawrence and Bruce Murphy, (2004). "Genetic and epigenetic aspects of cloning and potential effects on offspring of cloned mammals." Cloning Stem Cells. 6(2):126-32. Abstract available at: http://www.liebertonline.com/doi/abs/10.1089/1536230041372319 (accessed 04.18.07)

[14] Rakyan, et. al. (2003) "Transgenerational inheritance of epigenetic states at the murine AxinFu allele occurs after maternal and paternal transmission." PNAS, vol. 100, no. 5, 2538-2543. Available at: http://www.pnas.org/cgi/content/full/100/5/2538 (accessed 04.18.07).

[15] National Academy of Sciences (2004). Safety of Genetically Engineered Foods: Approaches to AssessingUnintended Health Effects. Sub-report: Methods and Mechanisms of Genetic Manipulation and Cloning of Animals, p. 222. Available at: http://www.nap.edu/openbook.php?chapselect=yo&page=222&record_id=10977 (accessed 04.18.07)

[16] Center for Food Safety, 2007. *Not Ready for Prime Time: FDA's flawed approach to assessing the safety of food from animal clones.*

Until conclusive and replicable research is done that guarantees the safety of consumers, products from clone animals and their progeny must not be allowed on the market.

Recent public opinion polls also that show the majority of Americans do not want milk or meat from cloned animals in their food. For example, a December 2006 poll by the Pew Initiative on Food and Biotechnology found that 64 percent of U.S. consumers surveyed were uncomfortable with animal cloning.[17] Moreover, the food industry is opposed to cloning. In February 2007, Dean Foods, the largest milk producer in the U.S, announced that the company will not sell milk from cloned animals. In their announcement, Dean Foods stated, "Numerous surveys have shown that Americans are not interested in buying dairy products that contain milk from cloned cows and Dean Foods is responding to the needs of our consumers."[18]

Therefore, if cloned products are allowed in the food supply, FDA should, at minimum, require clear and consistent labeling to monitor for harmful effects (as advised by the National Academy of Sciences) and to protect consumers who wish to avoid cloned food. Consumers have the right to know whether or not the food they eat comes from cloned animals and/or their progeny.

Conclusion

FACT opposes cloning as a reproductive option for livestock both because of its negative impacts on animal welfare and its potential to compromise food safety. FACT therefore urges the agency to issue a mandatory moratorium on food from cloned animals and their progeny until:

(1) Cloning can meet the highest standards for animal health and welfare.

(2) The FDA has established a mandatory pre-market review process, regulating cloning as a new animal drug and requiring generational studies including investigations into potential food safety threats created by the cloning process;

If cloned products are allowed in the food supply, FACT believes it is essential that they be clearly labeled so that consumers can make informed purchasing decisions.

FACT thanks FDA for the opportunity to submit these comments.

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[17] Animal Cloning Causes Great Discomfort Among American Consumers, Dec. 2006. Public Sentiment About Genetically Modified Food**,** Pew Initiative on Food and Biotechnology. Available at: http://pewagbiotech.org/research/2006update/9.php (accessed 04.17.07).

[18] Dean Dairy Rejects Cloned Milk, Feb. 2007. http://www.meatprocess.com/news/ng.asp?n=74503-dean-foods-cloning-milk (accessed 04.25.07)