



CENTER FOR
FOOD SAFETY

food&waterwatch

5 December 2006

Dr. Richard Raymond
Undersecretary for Food Safety
United States Department of Agriculture
Room 227-E Jamie L. Whitten Bldg.
12th Street and Jefferson Drive, S.W.
Washington, DC 20250

Via Fax (202) 690-0820

Dear Dr. Raymond:

We are writing to request that the Food Safety Inspection Service (FSIS) take immediate action to prevent the potential adulteration of the U.S. food supply with meat derived from cloned dairy animals and their progeny. It is our understanding that in a court case entitled Wiles v. Wiles (Docket No. 2006-1102-4995)(Md. Dist. Ct.) a judge may imminently order that certainly dairy animals be sold for slaughter to satisfy a financial judgment. A number of animals that may be subject to this ruling are cloned dairy animals and the first and/or second-generation offspring of cloned animals. We urge FSIS to take all necessary action to prevent the slaughter of these animals and the placement of meat from these cloned animals into the food supply.

There are a number of reasons that this situation demands immediate action. First, the slaughter of cloned animals and their progeny would be contrary to existing United States' policy governing these animals. As you know, in July 2001 the Food and Drug Administration (FDA) asked that companies not introduce cloned animals, their progeny, or their food products into the human or animal food supply.¹ Should FSIS stand idle while the Wiles' cloned animals and progeny are slaughtered, the agency would be abetting a violation of this current FDA policy.

Second, the slaughter of the clones without any FSIS approval process would be contrary to existing federal regulation. Under 9 C.F.R. § 309.17, livestock used in research involving an experimental biological product or drug are not eligible for slaughter unless, *inter alia*, the slaughter establishment provides data or a summary evaluation showing that the use of biological product or drug will not cause

¹ See e.g. FDA, Update on Livestock Cloning (Sept/Oct 2001) available at http://www.fda.gov/cvm/Sep_Oct01.htm#2380 (last visited Dec. 4, 2006)

such animal to be adulterated. To date, no such evaluation has been proffered and the FDA itself has not finalized its risk assessment on these animals. Given the current status of cloned animals and their progeny, these animals (such as the Wiles' herd) fall within this regulatory rubric.² The regulations also require that an agency employee approve such slaughter and that the Deputy Administrator, Meat and Poultry Inspection Operations provide written approval of the slaughter. Given the paucity of safety data on cloned animals, providing any such slaughter approval at this time would clearly be arbitrary and capricious.

Third, should the Wiles' cloned animals be slaughtered and disposed of in the food supply the USDA and FDA would be depriving themselves of important research information concerning the health and safety of milk and meat from cloned animals. It is our understanding that the clones and clone progeny in Wiles' herd have suffered several reproductive and growth problems that warrant further investigation. Given the FDA's current development of a risk assessment on meat and milk from such animals, the wanton destruction of these animal without serious investigation and study would be both an opportunity lost and a dereliction of the agency's scientific duty to investigate all aspects of this controversial new area of food production.

Fourth, consumers have overwhelming voiced concerns over the health and safety and the ethics of using cloned animals and their progeny as sources of milk and meat. Should FSIS fail to use its regulatory powers to prevent cloned animals from being slaughtered at official establishments, it will have failed to ensure the protection of the food supply, ignored consumer interests, and likely dealt a serious blow to the economic situations of the dairy and livestock markets.

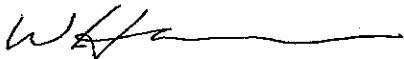
In sum, we urge FSIS to take the following steps: (1) enforce its regulation on livestock involved in experimental research and prevent the slaughter of the Wiles' clones and/or any other clones; (2) intervene in the case of Wiles v. Wiles to the extent necessary to prevent the selling of the cloned animals and/or their progeny; and (3) take the proactive step of affirmatively stating that at this time FSIS will not approve the slaughter of any animal clones or their progeny.

Sincerely,



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² Animal clones and their progeny are new animal drugs. See e.g. FDA Docket No. 2006P-0415/CP1 establishing that animal clones meet the definition of animal drug under the Federal Food Drug and Cosmetic Act.



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