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Testimony on House Bill 664
Labeling of Food Containing a Product of Cloned Animals
Health and Government Operations Committee
Maryland House of Delegates
Annapolis, Maryland
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By Jaydee Hanson, Policy Analyst

We commend Delegates Boteler, Ali, Aumann, Eckardt, Elmore, Frank, George, Glenn, Haddaway, Howard, McComas, Myers, Olszewski, Robinson, Schuler, Shewell, Smigiel, Stein, Stocksdale, Stull, Walkup, and Weir for introducing House Bill 664 to require the labeling of any product of a cloned animal or its offspring.

While we believe that the United States Food and Drug Administration inadequately assessed the safety of meat and milk from cloned animals, we also believe that if products from cloned animals are allowed on the market, they must be labeled. The US people do not want to eat meat or milk products from cloned animals or their progeny.

It is urgent that the State of Maryland enact a labeling bill, as there are now an increasing number of cloned animals and the owners of these animals are advertising to sell the gametes of these animals on the internet, in defiance of the voluntary moratorium requested by the United States Department of Agriculture. My staff found that six producers were advertising as of last summer. While the industry insisted that cloned animals are too valuable to send to the slaughterhouse, the high rate of illness among cloned animals and rapid aging of some of these animals may mean that some of the cloned animals have already made their way to the market. A number of cattle breeding associations now require that the cloned status of animal be included in their pedigree so that the buyer of the animal knows the cloned status. If the beef and dairy breeders can track the clones and their progeny, it is time for the public to be able to do likewise.

In poll after poll, (See attachment A for a summary of the polls) the public has said that it does not want to consume the products ofcloned animals or their progeny. Even people who have said that they would eat cloned meat or milk products want to have the products labeled. Even industry-sponsored polls find that majorities of consumers do not want to purchase cloned food products. In the fall of 2007, a the International Food Information Council poll found that 50% of Americans viewed animal cloning as "not very favorable" or "not at all favorable" compared to 6% viewing it as "very favorable." 53% of Americans are unlikely to buy meat, milk and eggs from cloned animals even though FDA determined such products to be safe. 51% are unlikely to buy milk, meat and eggs from offspring of cloned animals.

Without labeling, consumers of meat and milk cannot act on their preferences. Currently the only organic meat and milk is guaranteed to be clone free. Not all consumers have access to organic products, so another guarantee is needed. That guarantee is a label telling the purchaser that the product is not from a clone or its progeny

The FDA Risk Assessment is inadequate. Without labeling, we would not be able to track possible health effects of eating cloned animals. The FDA final risk assessment on meat and milk from cloned animals relied on the limited data available for cattle and swine, and approved goat clones with virtually no data. The assessment of food safety relies on this assumption and on the analysis of the composition of meat and milk from a small number of peer-reviewed studies. The largest study looked at milk from only 15 cows. Only one study used standard methods of toxicology, and that study looked at the effects of feeding 20 rats products from clones for 14 weeks.

The FDA insists there is no expectation that clones or their progeny would pose any new or additional risks compared with conventionally bred animals. However, the abundance of information on the unique problems with cloning presented in the papers cited by the FDA belies these assumptions.

Genetic defects in clones pass down to their offspring

The Executive Summary in the final FDA risk assessment notes, "If clones were to pose food consumption risks, the only mechanism by which those risks could arise would be from inappropriate epigenetic reprogramming."[1] Then it goes on to say, "anomalies present in clones do not appear to be transmitted to the next generation."

But a 2003 peer-reviewed study[2] cited by the FDA found that progeny of mammal clones can inherit certain epigenetic changes and a 2005 study[3] found that epigenetic changes in telomeres passed down to offspring[4] but the FDA dismissed these findings. Dr. Betts, the lead author of the 2005 study, recently criticized the FDA use of his study: "Based on my study, I wouldn't support that [FDA] statement [that genetic errors are probably reset in the offspring of clones]. My study would say the opposite, that they are not reset."[5] The US National Academy of Sciences in 2004 stated, "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." The inadequate understanding of the epigenetic

effects of cloning does not argue for the safety of the cloning process, but rather argues for more studies involving more animals. Tracking the progeny of clones through labeling is quite important and we commend your bill for requiring tracking of both clones and their progeny.

Welfare of progeny

The FDA assumes that most of the meat and milk from clones will come from the progeny of clones, but finds few studies on progeny of clones and none on the welfare of the progeny. The data provided to the FDA by Viagen, the largest cloning company,[6] raises a number of troubling findings: smaller and more variable litter size for progeny of pig clones, 25% of progeny dying compared to 17% of comparators; progeny of clones had an abnormality rate of 2.5% versus 1% in comparators; the total number of disposed pigs was 21 percent for the progeny of clones, compared to 14 % for the comparators; four percent of the progeny were destroyed for weakness; the percentage of animals reaching slaughter age was lower for progeny than comparators and the progeny took 5.6 extra days to reach slaughter weight.

No standards for "normal" in meat and milk

The FDA Final Risk Assessment notes that none of the studies mentioned are outside the normal variability in the composition of meat (cattle and swine) and milk (cattle) between clones or clone progeny and their comparators.[7] There exists no agreed upon standard for what constitutes the protein, lipid, and hormone mix of meat or milk in the US. The source of the implied standards for "normal variability" are not identified in the FDA document and the studies themselves do not make clear how they determined "normal" for the choice of comparators. The small sample sizes for both the clones/clone progeny and the comparators make it difficult to draw meaningful conclusions.

The FDA looked at only one study on the toxicology of meat and milk from clones[8].That study fed 10 male and 10 female rats cloned meat and milk products for 14 weeks. Unfortunately, this small study, with a number of design problems, is the most robust study the FDA used to assess the safety of cloned meat and milk.

The other studies cited in the Risk Assessment for the proposition that milk from cattle clones does not pose a food safety concern, reported significant differences between the milk of cloned and non-cloned cattle. The FDA did not do its own studies, but relied on 10 small studies, mostly from the cloning companies themselves. Half of the studies of cow meat found differences in the composition of food from clones and ordinary animals; both studies of pork meat relied on the Viagen data and they both found significant differences in meat from clones and ordinary pork.

The largest study of the safety of milk from cloned cattle[9] looked at only 15 animals. Testing of 15 dairy cow clones from five donor cell lines of three breeds of cattle revealed: 1) significant differences in the amount of palmitic acid and linolenic acid;

2) different fatty acid profiles for the cloned milk; and 3) the greatest variability observed in the mineral content of the cloned milk--differing significantly in potassium, zinc, strontium, and phosphorous levels. Though the researchers speculated that the differences could be attributed to diet, lactation cycle differences and seasonality, no additional studies showing whether differences in milk and meat composition are likely attributable to these dietary and other differences or to the cloned status of the animals were cited by the FDA. The largest published study cited[10]used data from three other studies to get 37 clones to assess. The coauthor of that paper, Dr. Chavette-Palmer says, "There is not enough data to indicate there will be no problem. We feel there is a rush to accept those clones."[11]

The significant differences in cloned milk composition revealed by these studies raise serious concerns about whether milk from clones is safe for human consumption. Without more data, and standards for which "normal variations" in protein and fatty acid compositions of meat and milk are safe, any conclusions regarding the safety of food products derived from clones and their progeny are premature.

Impact on the Environment and Genetic Diversity

The US National Academy of Sciences (NAS) 2002 report identifies reduction in genetic diversity as a direct, indisputable result of animal cloning and identifies specific risks associated with it. The NAS report warned that in cloned livestock: "disease could spread through susceptible populations more rapidly than through more genetically diverse populations. This…concern is well documented and several studies illustrate the susceptibility of species with low genetic diversity to infectious disease." [12]The FDA Risk Assessment barely discusses this risk to animal health and does not cite any studies specific to how cloning would decrease genetic diversity or increase susceptibility to disease. The FDA ignored the possible environmental effects of cloning and dismissed the threat to genetic diversity by saying that it does not regulate animal breeding.[13]

Conclusion/Overall Assessment

The admittedly sparse and obviously inconclusive studies reviewed by the FDA do not provide an adequate basis for concluding that cloning livestock is even relatively safe. The studies cited in the Final Risk Assessment observed significant differences between cloned and conventionally bred animals and in the products derived from them. Dismissing these important differences as a function of small sample sizes and dietary differences and then determining that livestock cloning is safe enough to be used in the livestock industry without mandating further study is clearly arbitrary, capricious, and irresponsible.

The failure to consider important risks to both animal health and food safety specifically identified by the US National Academy of Sciences raises serious doubts about the legitimacy of the Final Risk Assessment scope and hence its utility in assessing the risk posed by livestock cloning. The French Food Safety Agency[14] in its assessment of the safety of animal cloning recommended assessments of at least two generations and more

in depth tests with a larger number of animals and comparative studies with conventional animals.

Because the FDA did not meaningfully assess the safety of animal cloning, and relied on a small set of peer reviewed published studies and data provided by cloning companies with a financial conflict of interest in the outcome of the FDA opinion, substantial doubts as to the safety of cloning persist.

While some SCNT animal clones appear healthy and reach reproductive maturity, there are limited data on effects that may be more subtle and less easily detected, including aberrant expression of imprinted-genes; effect of in vitro culturing conditions on cloned embryos, chromosomal abnormalities, altered epigenetic control of gene expression and possible expression of retroviruses. The reliance on only a single study that meets standards for toxicity testing, a single study of allergenicity, and no cited study for the microbiological effects of the cloning process is a major problem, requiring more study. The assumption that sick cloned animals will be removed from the food system is not borne out by the recent experience of the slaughterhouse—Hallmark/Westland in California. The public will expect even greater ability on the part of both importing and exporting countries to prevent ill cloned animals from entering the food chain. Research studies presented in the FDA document the presence of infectious disease in cloned livestock, but are ignored under the assumption that they cause early death. For example, Park et al. (2005) [15]reported that 22 of 35 live born SCNT cloned pigs died within one week of various infectious diseases in including cerebromeningitis and possibly E.coli, Salmonella, Streptococcus and other bacteria.15 FDA did not assess the food safety risk presented by the presence of these bacterial agents or other infectious diseases. Instead, the Risk Assessment relies on the assumption that diseased animals will not enter the food supply, although the FDA gives no plan for how such animals will be identified and culled. The FDA failed to address whether potentially hazardous infectious disease agents could go undetected or could enter the food supply by other means (i.e. from contact with fecal matter) and if they can, whether the use of SCNT technology could increase the risk of food contamination.

The failure on the part of the FDA to identify potential harms associated with livestock cloning, including those already identified in the NAS report on animal biotechnology, and the French Food Safety Agency assessment on animal cloning constitutes a clear failure to assess the potential risks of livestock cloning.

RECOMMENDATIONS

In light of the clear deficiencies in the FDA's risk assessment on animal cloning, Center for Food Safety urges the state of Maryland to require labeling of the products of cloned animals and their progeny and urges the committee to pass HR 664 to authorize this labeling.

The cloning process, at present, is one of the most brutal methods of breeding animals and consumers interested in the welfare of animals will want to know whether the animal products they consume contributed to the frequent deformities and health problems of animal clones. The high likelihood that cloned animals will be sicker than their non-cloned counterparts and may require additional drugs to keep them well, raises food safety concerns, too. Labeling will help consumers make ethical choices about the meat and milk they eat and the welfare of the animals used to produce it.

Finally, the passage of labeling legislation by the state of Maryland will help encourage the US Congress to pass labeling legislation such as that introduced by Maryland's Senior Senator, Barbara Mikulski.

ENDNOTES

[1] Executive Summary, FDA Final Risk Assessment of Animal Cloning, http://www.fda.gov/cvm/CloningRA_ExecSummary_Final.htm p.4

[2] Archer, et al. (2003) "Hierarchical Phenotypic and Epigenetic Variation in Cloned Swine." BiolReprod,69, 430–436

[3] Betts, et al (2005) "Telomere length analysis in goat clones and their offspring," Mol Reprod Dev 72: 461-470.

[4] Alan Roslin, (2008) "Clone, clone on the Range," Straight.com See: http://straight.com/node/132924

[5] National Academy of Sciences (2004). Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects. Subreport: Methods and Mechanisms of Genetic Manipulation and Cloning of Animals, p. 222

[6] The Viagen Dataset. http://www.fda.gov/cvm/CloningRA_AppendixF.htm

[7] Executive Summary of Final Risk Assessment, p. 7-8.

[8] Yamaguchi, M, et al (2007) "Fourteen week feeding test of meat and milk derived from cloned cattle in the rat." Theriogeneology 67: 152-165

[9] Walsh, MK, et al (2003) "Comparison of milk produced by cows cloned by nuclear transfer with milk from noncloned cows. Cloning Stem Cells 5: 213-219

[10] Heyman Y, Chavette-Palmer P, et al (2007), "Assessing the quality of products from cloned cattle: an intergrative approach." Theriogeneology 67: 134-141

[11] Alan Roslin, (2008), ibid

[12] National Academy of Sciences (2002), "Animal Biotechnology", Appendix B "Regulatory Framework for Animal Biotechnology", p. 45

[13] FDA's Response to Public Comment, p.9, see: http://www.fda.gov/cvm.CloningRA_FDAResponse.htm

[14] See: Thematic folder on cloning of breeding animals in www.afssa.fr

[15] Park, et al (2005), "A rare and often unrecognized cerebromenigitis and hemodynamic disorder: major cause of sudden death in somatic cell cloned piglets," Proteomics 5: 1928-1939

Attachment A:
COMPILATION AND ANALYSIS OF PUBLIC OPINION POLLS ON ANIMAL CLONING
(UPDATED FEBRUARY 2008)

1. 50% of Americans view animal cloning as 'not very favorable' or 'not at all Favorable' compared to 6% viewing it as 'very favorable' 53% of Americans unlikely to buy meat, milk and eggs from cloned animals even if FDA determines such products are safe. 51% unlikely to buy milk, meat and eggs from offspring of cloned animals even if FDA determines such products are safe. (International Food Information Council, Sept. 20, 2007).

2. 89% of consumers want meat and milk derived from cloned animals to be labeled. 69% of consumers were concerned about eating milk or meat from cloned animals. (Consumers Union, July 11, 2007).

3. 66% of adults disapprove of the cloning of animals for food and only 27% approve of it. 46% of adults have ethical or moral objections to cloning animals for food. 87% of adults think the government needs to have public discussion on the ethical issues of animal cloning before allowing animal clones to be sold as food. (Opinion Research Corporation for American Anti-Vivisection Society, December 22, 2006)

4. 66% of Americans are uncomfortable using cloning techniques to reproduce animals, including 78% among women. 35% would never buy meat products from cloned animals and their offspring even if FDA determined it was safe. 32% viewed animal cloning as morally wrong. (Center for Food, Nutrition, and Agricultural Policy, December 14, 2006).

5. 64% of Americans are uncomfortable with animal cloning and only 22% are comfortable with it. Even among Americans who say they are likely to eat genetically engineered foods only 34% with comfortable with animal cloning as a food source. (The Mellman Group, for Pew Initiative on Food and Biotechnology, November 16, 2006).

6. 59% would not buy food containing ingredients from cloned animals. Only 12% supportive of cloned animals for use in food and only 11% would buy foods that have ingredients from cloned animals. 44% oppose the idea of food containing ingredients from cloned animals on moral

grounds.(Synovate, for Kraft, November 2006).

7. 33% of Americans would never again buy milk derived from the offspring of clones even if the FDA determines it is safe. (KRC Research, forViaGen October 23, 2005).

8. 60% of milk consumers have an unfavorable opinion of cloning animals that produce food products.41% of milk consumers would not purchase products from cloned animals even if FDA says they are safe. 33% believe it is morally wrong to consume milk from cloned cows. 15% decrease in total household milk consumption will result from introduction of milk from cloned animals. (Data Development Worldwide, for MilkPEP, August 2005).

9. 64% view animal cloning as morally wrong (Gallup, June 22, 2004).

10. 68% view cloning of animals as morally wrong (Gallup, May 14, 2003).

11. 66% view cloning of animals as morally wrong (Gallup, May 16, 2002).

12. 59% of Americans believe that animal cloning should be illegal (ABC/BeliefNet, Aug 16, 2001).

13. 64% of Americans thought animal cloning should not be allowed (Gallup, May 2001).

14. 66% not morally acceptable to reproduce livestock by cloning (Fox News/Opinion Dynamics Apr. 18, 2001).