
MEMORANDUM

TO: UNITED STATES SENATE COMMITTEE ON AGRICULTURE, NUTRITION
& FORESTRY
DEBBIE STABENOW, CHAIRWOMAN
PAT ROBERTS, RANKING MEMBER

FROM: STANLEY ELLICOTT

DATE: FEBRUARY 19, 2010

RE: REASSESSING THE SAFETY OF MEAT AND MILK FROM CLONED
ANIMALS AND THE NECESSITY OF "CLONED" FOOD LABELS

Summary

The United States Senate should consider options to commission new research into the safety of meat, milk or animal byproducts from cloned animals and inquire if existing food labeling regulations should be expanded to label these products as "cloned." The forthcoming 2012 Farm Bill presents an opportunity to respond to conflicting rulings issued in 2008 by the FDA, which reported cloned food was safe for human consumption, and the USDA, which indefinitely extended its voluntary moratorium on using first-generation clones¹ for food.² Congress should act with the intent of resolving two key questions: is cloned food safe for human consumption; and secondly, if scientific evidence points to safety, are labels necessary?

To better understand the implications of introducing clones into the food supply, and its impact on consumer choice, I recommend the following steps:

1: Require the FDA to conduct a mandatory pre-market review of food from clones based on the "New Animal Drug" process under the Federal Food, Drug and Cosmetic Act. Concurrently, the USDA should consider establishing a mandatory moratorium on the sale of cloned meat or their offspring.

2: If the FDA report finds that cloned animals pose no threats to human health and safety, and are biologically indistinguishable from sexually reproduced animals, Congress should act to incorporate "clone free" into existing organic labeling standards and/or allow for voluntary labeling measures.

¹ A first-generation clone is the resulting animal from the duplication process, whereas as a second-generation clone is the sexually reproduced offspring of the first-generation clone.

² The Washington Post. "USDA Recommends That Food From Clones Stay Off the Market." January 16, 2008. Retrieved 2/18/2011, from <http://www.washingtonpost.com/wp-dyn/content/story/2008/01/16/ST2008011600975.html>

Background

Cloning is a recent innovation in biotechnology that allows engineers to render a genetic twin from a selected animal. The process of cloning is not cost-effective to produce first-generation cloned animals for consumption, as each clone can cost up to \$15,000-\$20,000.³ Instead, cloned animals are introduced into the breeding stock to produce offspring with desirable attributes, such as a higher capacity to produce milk or quality meat. In this sense, cloning is an evolved method of selecting top-producing animals from a herd to breed for offspring with their parents' desirable traits. ViaGen and Trans Ova Genetics, two leading producers of cloned cows, argue that selecting for healthier animals producing higher quality and quantities of meat, milk and byproducts will lower consumer costs, reduce the administration of antibiotics and improve long-term food security.⁴

Not all meat and milk industry groups endorse cloning. The dairy industry has rejected cloning practices as they may tarnish the wholesome image of milk.⁵ For small farms, the investment costs to begin cloning a program may be too high, which could impact their ability to compete with larger suppliers. Additionally, the USDA currently purchases surplus dairy and meat products from farmers. If productive capacity is further increased, payments to farmers or purchases of surplus food would increase as prices fall, resulting in higher levels of government subsidization of these industries.

Responding to the development of cloning technologies, the Federal Drug Administration (FDA) issued an extensive report on the safety and health implications of consuming milk and meat from cloned animals, the Risk and Safety Assessment report (RSA) in 2008. In the report, the FDA determined that, "Extensive evaluation of the available data has not identified any subtle hazards that might indicate food-consumption risks in healthy clones of cattle, swine, or goats."⁶ At the same time the United States Department of Agriculture indefinitely extended its voluntary moratorium on the sale or distribution of first-generation clones as food products.⁷ However, the moratorium does not apply to sexually reproduced offspring of clones. Producers and owners of cloned animals have agreed to this moratorium, although no binding guarantee to prevent contamination into the food supply is in effect. These decisions, taken together, have clouded the future of cloned food production. They have also failed to definitively resolve questions of long-term food safety and health consequences of cloned food products.

³ Reuters. "Welcome to the Clone Farm." November 13, 2009. Retrieved 2/19/2011, from <http://www.reuters.com/article/2009/11/13/food-cloning-idUSN127887120091113>

⁴ ViaGen. "Benefits of Bovine Cloning." 2011. Retrieved 2/18/2011, from <http://www.viagen.com/en/benefits/bovine/>.

⁵ The Washington Post. "'Clone-Free' Milk Could Get Label." December 19, 2007. Retrieved 2/18/2011, from http://www.washingtonpost.com/wp-dyn/content/article/2007/12/18/AR2007121802235_2.html.

⁶ Food and Drug Administration. "Animal Cloning: A Risk Assessment." January 1, 2008. Retrieved 2/17/2011, from <http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AnimalCloning/UCM124756.pdf>.

⁷ Knight, Bruce. March 5, 2008. "Animal Cloning: Transitioning from the Lab to the Market." Retrieved 2/17/2011, from http://www.aphis.usda.gov/newsroom/speeches/content/2008/03/Biotech_Comm_final_3-5-08.pdf.

ISSUE 1: Consumers believe cloned food is unsafe, but know little about the cloning process or its purpose.

Consumers have responded to cloned food products with apprehension. A 2006 study by the Pew Charitable Trusts on Food and Biotechnology found that 64% of those surveyed were “uncomfortable with animal cloning” and that “attention to animal cloning is higher than to genetically modified foods, though consumers acknowledged knowing very little [about cloning].”⁸ The survey also found that consumers were principally concerned with the “impact on you and your family” as the most important determining factor for support of biotechnology.⁹ Aversion to cloned food is partially explained by the widespread myth that first-generation clones are intended for human consumption. The Pew survey demonstrated higher levels of education or awareness of biotechnology was strongly correlated with a more favorable opinion of cloned foods.

A closer analysis of the methods used by the FDA in its RSA imply government regulators also know little about the risks of consuming cloned meat or its long-term impact. In its 900-page RSA, the FDA acknowledged it was unable to find a single peer-reviewed study on the meat of cloned cows, pigs, goats, or their offspring, and only three studies on milk from cloned cows. Instead, the FDA based its ruling on indirect research focused on basic cloning technology.¹⁰ These studies were not designed to evaluate the safety of food clones and their offspring. Further, the studies were primarily focused on the early-life stages of development, before sexual maturity, when cloned animals are least likely to participate in food production. The FDA reported that, “little information is available on animals during this phase, and much of that information comes in the form of single sentences or short mentions in journal articles that address some other issue.”¹¹ Given the substantial impact this technology may have on the security of our food supply and health of consumers, the FDA’s research is simply inadequate. Congress must act in the interests of both consumers and farmers to require further review.

RECOMMENDATION: Require the FDA to conduct a mandatory pre-market review of food from clones based on the “New Animal Drug” process under the Federal Food, Drug and Cosmetic Act. Concurrently, the USDA should consider establishing a mandatory moratorium on the sale of cloned meat or their offspring.

Congress should call on the FDA to revisit the oversights in its research and conduct clinical work where no peer-reviewed journal articles can shed light on safety risks. One method of accomplishing this is to provide funding in the 2012 Farm Bill to conduct trials in cooperation with cloning firms and farmers, or to classify cloned-food as a “new drug” which would require a more rigorous safety testing than the risk

⁸ The Pew Charitable Trusts. “Review of Public Opinion Research” November 16, 2006. Retrieved 2/18/2011, from http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Public_Opinion/Food_and_Biotechnology/2006summary.pdf.

⁹ IBID.

¹⁰ Center for Food Safety. “FDA’s Flawed Approach to Assessing the Safety of Food from Clones.” March, 2007. Retrieved 2/18/2011, from http://www.centerforfoodsafety.org/pubs/FINAL_FORMATTEDprime%20time.pdf

¹¹ IBID.

assessment process conducted in its 2008 report. This work must carefully analyze the later-life outcomes of cloned animals, variation amongst future generations, long-term environmental impacts, and the risks stemming from genetic monoculture.

The USDA should similarly consider a mandatory moratorium on the sale of cloned meat or offspring. However, a mandatory moratorium could further deteriorate consumer confidence in the FDA,¹² create widespread panic of food contamination, and affect aggregate demand for meat and animal byproducts. Public confidence in the FDA's ability to protect the food supply has been rattled following recent major recalls; 2010 Eggs (Salmonella), 2009 (Peanut butter, pistachio nuts, raw cookie dough, ground beef).¹³ Perceived losses in reputation would be offset by actual health problems resulting from the legal sale of food and byproducts from second-generation clones.

Additional research will benefit all stakeholders. Not only will it lead to improved assessment of health and environmental risks, it may yield convincing evidence in support of cloned food. If such is the case, producers and animal growers should be free to use these technologies to reap the economies of scale and improved production capacities exhibited by these animals.

ISSUE 2: If cloned food is biologically indistinguishable from sexually reproduced animals, labels are not required under current FDA policy.

Following additional FDA research, if no substantive difference between cloned and sexually reproduced animals exists and cloned food products are approved for human consumption, the FDA will not require labeling standards for these products. Political, social or religious forces demanding labeling policies are not factors considered by the FDA's science-based approach in setting mandatory labeling policies.

RECCOMENDATION: If the FDA report finds that cloned animals pose no threats to human health and safety, and are biologically indistinguishable from sexually reproduced animals, Congress should act to incorporate "clone free" into existing organic labeling standards.

Federal regulation should continue to target real, and not perceived risks. As such, the FDA's science-based approach to assessing the risks of food safety should not be fundamentally changed or circumvented to appease political, social or religious forces. Instead, Congress should act to protect these interests by incorporating the "clone free" label into existing organic labeling standards.

Consumers have a right to know the processes and methods underlying food production. Labeling products as "cloned" or allowing a "clone-free" label could reinforce consumer autonomy and the ability to vote with one's dollar. However, the introduction

¹² Responsibilities for the safety of food and its production are divided haphazardly between the USDA and FDA, creating tension between the two agencies and paralyzing policy change. See: Nestle, Marion. (2007). *Food Politics: How the Good Industry Influences Nutrition and Health*. California: UC Press.

¹³ Nestle, Marion. (2010). *Safe Food: The Politics of Food Safety* (pp. 286-295). California: UC Press.

of genetically modified foods (GMO) has demonstrated it is impossible to claim one's food product has not intermingled with the genetically modified species. This has prevented food producers from labeling their products as "GMO" free, in compliance with current FDA labeling policy.¹⁴ Since second-generation cloned animals can be legally sold as food in the United States, and distribution into the food supply may have already occurred undetected, a mandatory or voluntary "clone free" labeling policy would suffer from the same challenges as the "GMO free" label.

Consumers may have negative opinions toward cloned meat, but research suggests additional regulation would not encourage consumers to eat more of it.¹⁵ Other research suggests that if cloned meat yielded a less expensive grocery store product, opinions *would* change. In the Pew Charitable Trusts on Food and Biotechnology survey, those who identified themselves as having some knowledge of GM/cloned food, were asked if they would consume more of it if the FDA was required to regulate those products more carefully; less than half of respondents were "willing to eat more."¹⁶ New consumer research suggests consumers are much more likely to reject the idea of cloned or GM food in a survey, but be unwilling to pay more for a sexually reproduced, or "natural," product sold grocery stores.¹⁷ If cloned animals offer a more abundant supply of milk or meat, and reduce the cost of these products, more consumers are likely to embrace the practice of cloning. Mandatory labeling would interrupt this process of acceptance, and void the gains in efficiency cloning technology could provide.

The most efficient method of allowing consumer choice in the market is to expand the definition of "organic" to also be "clone-free." This option is a middle road between mandatory labeling and voluntary labeling.¹⁸ Organic farmers of meat and animal byproducts are already committed to traditional farming practices and many organic farmers have formally pledged not to use clones in their production process.¹⁹ Tax credits could offset any new administrative burden posed to these farmers or to offset the foregone efficiency. Expanding the organic label would also increase its market from the new demand for clone-free products and further sustain this important alternative food system.

¹⁴ IBID.

¹⁵ IBID.

¹⁶ IBID.

¹⁷ Weirich, Paul. (2007). *Labeling Genetically Modified Food: The Philosophical and Legal Debate* (pp. 106-128). USA: Oxford University Press.

¹⁸ David Vogel, Professor, Haas School of Business, agreed that some form of private, voluntary or organic label expansion should be sufficient to ensure consumer autonomy without impacting the continued investment and research done by the biotechnology industry. Personal communication, February 17, 2010.

¹⁹ IBID.