

## **Can You Clone an Organic Cow?** **By Jim Riddle**

On December 28, 2006, the Center for Veterinary Medicine (CVM) at the US Food and Drug Administration (FDA) issued a Draft Risk Assessment on meat and milk from cloned animals.

The FDA concluded that animal cloning, or somatic cell nuclear transfer (SCNT), “results in an increased frequency of health risks to animals involved in the cloning process.” The CVM found that, “surrogate dams are at risk of complications from birth” and “the frequency of live normal births appears to be low, although the situation appears to be improving as the technology matures.”<sup>1</sup>

Despite the documented negative impacts on animal health, the CVM concluded that, “extensive evaluation of the available data has not identified any food consumption risks or subtle hazards in healthy clones of cattle, swine, or goats. Thus, edible products from healthy clones that meet existing requirements for meat and milk in commerce pose no increased food consumption risk(s) relative to comparable products from sexually-derived animals.”

In sum, the CVM concluded that meat and milk from healthy cloned animals are “virtually indistinguishable” from meat and milk from non-cloned animals with no “biologically significant” differences in composition.

### **Impacts on Organic Agriculture**

According to the FDA report, one of the initial technical steps in animal cloning is cell fusion. DNA is transferred from one cell to another. As such, the practice is prohibited in organic production under the National Organic Program (NOP) regulation as an “excluded method.”

Excluded methods, which are not allowed in organic production or processing, are defined as, “a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion...”<sup>2</sup>

Animal cloning is not allowed for organic production under the NOP for several reasons. Since cloning relies on cell fusion, it is explicitly prohibited in organic production. Clearly, it is not possible under natural conditions. It is not considered compatible with organic production, since cloning narrows the gene base, while organic production relies on maintenance of a broad and diverse gene pool.

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<sup>1</sup> Available at: <http://www.fda.gov/cvm/CloneRiskAssessment.htm>

<sup>2</sup> 7 CFR 205.2 Terms defined. USDA National Organic Program Final Rule, October, 2000.

In addition, cloning is dependent on the use of artificial hormones to induce labor of surrogate dams. The use of artificial hormones to induce labor is prohibited in organic agriculture.

### **Animal Husbandry Issues**

During cloning, an animal's DNA is inserted into an egg, where the DNA has been removed. The resulting embryo is implanted into a surrogate mother, where it forms a genetically identical copy of the original animal.

But even if two animals have identical genes, they can turn out differently if those genes are turned on or off at different times, or are sequenced differently from the original sequence. These unpredictable genetic variations are linked to the high failure rate of cloned animals. Many clones die during gestation or shortly after birth, while some are born with deformed heads or limbs or problems with their hearts, lungs or other organs.<sup>3</sup>

In its report, the FDA admits animal health problems, by stating that “some animals involved in the cloning process (*i.e.*, cattle and sheep surrogate dams, and some clones) are at increased risk of adverse health outcomes relative to conventional animals.” “Cows and ewes used as surrogate dams for SCNT-derived pregnancies appear to be at increased risk of late gestational complications.” “There is an increased risk of mortality and morbidity in perinatal calf and lamb clones.”<sup>4</sup>

The NOP regulation requires organic livestock producers to establish and maintain preventative livestock health care practices and accommodate the health and natural behavior of the animals. Breeding practices, such as cloning, that result in “adverse health outcomes,” “increased risks of late gestation complications,” and “increased risks of mortality and morbidity” do not meet the NOP's proactive health care requirements.

### **Unlabeled Clones and the Organic Market**

While the CVM report concludes that livestock products from healthy clones are likely to be safe for human consumption, the FDA has not ruled on whether or not cloned animals and their products will need to be tracked and labeled.

At a minimum, there should be mandatory tracking and labeling of cloned animals and animal products as:

- The best way to prevent entry of cloned animals and their products into the organic food system;
- The only way to conduct long-term epidemiological studies;
- The only way determine with any level of certainty the effects on human health;
- The best way to protect consumer confidence in the food system;

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<sup>3</sup> New York Times, December 29, 2006, “F.D.A. Tentatively Declares Food From Cloned Animals to Be Safe” By Andrew Pollack and Andrew Martin.

<sup>4</sup> <http://www.fda.gov/cvm/CloneRiskAssessment.htm>

- The only way to protect consumers' rights to know about the foods they consume; and
- The best way to protect the interests of conventional livestock producers, who are likely to suffer negative economic impacts from un-segregated products, similar to what has happened with losses related to un-segregated GMO rice.

### **Introduction of Experimental Technology**

While cloning may prove to be a benign technology in the long run, there is no shortage of highly productive breeds and lines of livestock. There is no shortage of meat or milk in the U.S. In fact, meat and milk markets are often depressed due to over-production.

This experimental technology introduces an inherent, and often overlooked, danger – narrowing of the gene base. Biologically speaking, a species' survival is directly linked to genetic diversity. With a broad and deep gene pool, a species, whether wild or domesticated, is better positioned to adapt to new disease threats and environmental changes. For instance, a species with a narrow gene pool can collapse when animals encounter unanticipated diseases.

The FDA report states, “The Center assumes that if clones were to pose food consumption risks, the only mechanism by which those risks could arise would be from inappropriate epigenetic reprogramming...”<sup>5</sup> Despite the fact that many cloned animals die during gestation or develop abnormally due to a misarranged genetic code, the FDA assumes that only those animals which appear to be healthy and normal would enter the human food chain, since they are “virtually indistinguishable.”

The report goes on to state that animal clones can develop with apparently normal functions, but with *subtle* sub-clinical physiological anomalies. “These could include alterations in key proteins affecting the nutritional content of food and leading to dietary imbalances.”<sup>6</sup> Because these animals appear to be normal, their products would find their way into the human food supply. Tracking of cloned animals is imperative for products from animals with sub-clinical anomalies to be identified and studied.

The concept of cloned animals and their products being “virtually indistinguishable,” is similar the doctrine of “substantial equivalence,” used earlier by the FDA to justify the untracked and unlabeled introduction of genetically modified organisms (GMOs). It is not a scientific standard. It is not even a rational standard, since the products of these technologies are proprietary for the profit of their developers. It is an economic and political conclusion weighted to the benefit of the technology companies and based on a favorable, but flawed assumption – the similarity of appearance.

### **Who Gains from Unregulated Cloning?**

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<sup>5</sup> <http://www.fda.gov/cvm/CloneRiskAssessment.htm>

<sup>6</sup> <http://www.fda.gov/cvm/CloneRiskAssessment.htm>

In the short-term, the presence of unregulated and unlabeled meat and milk from cloned animals will help further differentiate organic products from un-segregated conventional livestock products. This will likely result in more consumers purchasing organic products.

Corporations who control the technology and proprietary strains of cloned animals will profit through increased dependence of farmers on proprietary sources of genetic material.

The absence of tracking or labeling protects technology companies and users of cloned animals from liability. Without traceability, the determination of harm, should harm occur, is virtually impossible.

The Draft Risk Assessment does not address the potential economic effects of allowing the unregulated use of animal cloning without traceability or labeling. No other country has approved food from cloned animals. Unlabeled introduction of cloning has the potential to seriously diminish consumer confidence, further depressing domestic and export markets for conventional livestock products.

A December 2006 poll by the Pew Initiative on Food and Biotechnology found that 64 percent of consumers said they were uncomfortable with animal cloning, with 46 percent saying they were “strongly uncomfortable.” Likewise, an online poll conducted by the Minneapolis Star Tribune immediately after FDA’s announcement found that 60% of respondents said that they would not eat food products from cloned animals.

Prior to full approval, a comprehensive economic impact analysis must be conducted to examine the technology’s impacts on existing markets for conventional and organic livestock products.