On 28 December 2006, the Center for Veterinary Medicine (CVM) at the U.S. Food and Drug Administration (FDA) issued a draft risk assessment, a risk management plan, and guidance to industry on meat and milk from cloned animals. The documents address the risks associated with somatic cell nuclear transfer (SCNT), the most common method used to create cloned animals.

While animal cloning has been legal—and largely unregulated—in the United States since 2001, there has been a voluntary moratorium on the sale of milk or meat from cloned animals. But with no enforcement mechanism in place, there has been the possibility of products from cloned animals or their offspring entering the human food supply.

Industry officials estimate there are now about 500 or 600 cloned cows in the United States, out of tens of millions of beef and dairy cows. There are roughly 200 cloned pigs. The FDA's 2006 announcement could end the voluntary moratorium, making it easier to persuade farmers and breeders to pay $15,000 to $20,000 to copy a prized bull or dairy cow, thus benefiting companies that have invested in cloning technology.

While the FDA's draft risk assessment reviewed industry data and scientific studies of animal health effects and the safety of products from cloned animals, it did not address the economic, environmental, social, or ethical issues associated with this technology. This essay provides an analysis of the FDA's proposal and the cloning process so that readers can better understand the FDA's scientific assessment and the impacts of cloning on animal health and food safety. The essay also explores the possible environmental, ethical, and economic impacts of animal cloning and explains the status of cloned animals in organic agriculture.

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According to the notice, the FDA developed the draft risk assessment to evaluate the health risks to animals involved in the process of cloning and to identify the food consumption risks that may result from consumption of edible products derived from animal clones or their progeny. The FDA’s executive summary states that juvenile or adult cattle, pig, and goat clones, as well as milk from cloned dairy cows, “pose no additional food consumption risk(s) relative to corresponding products from contemporary conventional comparators.” The FDA concluded, however, that there was insufficient information to draw a final conclusion regarding food safety risks associated with consumption of meat from cloned sheep.

In the case of just-born bovine calves, the FDA recommended against human consumption, but concluded that rendering these animals for livestock feed or pet food would not pose risks in animal feed or to humans consuming animals fed material derived from the clones, and therefore should be allowed without restrictions. Cloned animals that are deformed were also found to be safe for rendering. For all species of animals, the FDA concluded that the meat and edible products from the progeny of clones “pose no additional food consumption risk(s) relative to corresponding products from other animals.”

Finally, the risk assessment addressed health risks to the surrogate mothers involved in the cloning process. The FDA concluded that surrogate mothers used to grow out clones are “at increased risk of adverse health outcomes relative to conventional animals.” The agency went on to say that “none of these adverse outcomes, however, are unique to cloning.”

**What the FDA has Proposed**

According to the draft risk assessment, the FDA’s role in performing the assessment was to determine whether SCNT poses any risk to animals involved in the cloning process and whether the consumption of food products from clones or their progeny poses any additional risk compared with food from conventionally produced animals. In its guidance to industry, the FDA states that its assessment “did not identify any unique risks for human food from cattle, swine, or goat clones. Therefore, there is no science-based reason to recommend any additional safeguards. As such, we do not have any recommendations for any additional measures related to the use of products from cattle, swine, or goat clones as human food.” In other words, the FDA proposed that the meat and milk from clones and from the progeny of clones be allowed for human and livestock consumption without further testing, tracking, or labeling.

Under the FDA’s proposal, clones that are “virtually indistinguishable” from
normal progeny may enter the food supply, even if they contain “subtle hazards.” Clones with gross abnormalities may be rendered and enter the food supply indirectly via animal feed, or may find their way into pet food.

The concept of cloned animals and their products being “virtually indistinguishable” from non-cloned animals is similar to the doctrine of “substantial equivalence,” used in the 1990s by the FDA to justify approval of genetically engineered plants. Neither “substantial equivalence” nor “virtually indistinguishable” are scientific standards, since they are based on physical appearance alone. The FDA appears to acknowledge this fact by recognizing that cloned animals that are “virtually indistinguishable” to the human eye might contain subtle hazards at the genetic level, due to “inappropriate” epigenetic reprogramming, that can affect food safety or nutritional quality. The next section discusses the science of epigenetic programming.

**Epigenetic Reprogramming—A Fundamental Flaw**

SCNT, commonly referred to as “cloning,” is the sole subject of the FDA’s draft risk assessment. It is a relatively new technology that is complex, technically demanding, and inefficient—in cattle, only around 6 percent of the cloned embryos transferred to the reproductive tracts of recipient cows result in healthy, long-term surviving clones.

In SCNT, the nucleus from a non-reproductive cell of an existing animal is inserted into an oöcyte (immature egg) that has had its nucleus (and thus its genome) removed. Then, following some manipulations, it is induced to start replicating, usually by a mild electric shock. If all goes well, the dividing cell reprograms and forms a zygote, and then an embryo, which is implanted into a female animal (surrogate dam), where it continues to develop into a fetus.

Despite the fact that every cell carries the full genome of an animal, the donor cells used in the cloning process, generally taken from the ear or skin of an animal, have developed to be specialists. As the cells developed, their genomes were “reconfigured” to carry out the particular function for which they were destined by their particular developmental fate. For example, skin cells do not transcribe the milk-producing instructions of the mammary gland, even though they carry those genes.

In order for cloning to be successful, donor cells must be reprogrammed from being specialized cells into being generalized cells through a process called epigenetic reprogramming. Epigenetic reprogramming allows a cell to express the full set of instructions contained in its genome, so that “normal” development of an embryo can occur.

In the process of cloning, the donor nucleus must be coaxed to direct embryonic development. In SCNT, most of the time this is not successful. Biologists are just beginning to understand the highly complex processes that must occur to choreograph the
millions of molecular interactions that signal the expression or silencing of genes in a particular cell at any point in its life cycle. Even if two animals have identical genes, they can turn out differently if those genes are turned on or off at different times. Studies have shown that patterns of gene activity are different in embryos created by cloning compared with embryos created by the fusing of sperm and egg. These differences are presumed to account in large measure for the low success rate of cloning. Fetuses can grow unusually large, posing a risk to surrogate mothers. Many clones die during gestation or shortly after birth. Some are born with deformed heads or limbs or problems with their hearts, lungs, or other organs.

Although some clones may develop into healthy animals, the low success rate of SCNT is linked to the fact that donor cells are often reprogrammed incorrectly. In fact, gene expression analyses and extensive phenotypic characterization of cloned animals suggest that most, if not all, clones suffer from at least subtle abnormalities. Several studies present research data implying that even apparently normal cloned animals may have subtle abnormalities in gene expression. The most severe errors in reprogramming result in death, obvious malformations, or metabolic derangements. They are reflected in the low success rate of cloning, the prenatal difficulties observed in some newborn clones, and occasional examples of altered metabolic pathways in very young animals.

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.” The report acknowledges that animal clones can develop with apparently normal functions, but with subtle sub-clinical physiological anomalies, which can “include alterations in key proteins affecting the nutritional content of food and leading to dietary imbalances.” It also states that many cloned animals die during gestation or develop abnormally due to a misarranged genetic code.

Given its current high costs and relatively low success rates (4 to 7 percent), the FDA poses that SCNT will likely be used primarily to improve and propagate breeding animals, not directly for production animals. Thus, the FDA has concluded that the progeny of cloned animals are safe. This conclusion is based on the assumption that sexual reproduction effectively “clears” or “resets” the genome of livestock progeny and eliminates incomplete or inappropriate genetic and epigenetic signals produced in parent clones.

Research indicates that this assumption is not correct: progeny of cloned livestock have been shown to inherit and exhibit physiological and genetic differences from cloned parents. In order words, the progeny of clones can carry traits and subtle genetic hazards from the cloned parent, even when the progeny are produced through sexual reproduction.
**Potential Impacts of Cloning on Food Quality and Safety**

The primary concern for milk and meat from cloned animals is that inappropriate re-programming may result in subtle hazards that pose food consumption risks. As stated by the FDA, there is no a priori reason to expect that SCNT will introduce any new, potentially toxic substances into the milk or meat of otherwise healthy animals. The remaining food safety concerns addressed by FDA centered on whether subtle changes would alter the presence of important nutrients. The most likely dietary risk would be the absence or significant decrease in levels of vitamins and minerals for persons whose daily requirements are in large part met by milk or meat.

Based on the available data, FDA concluded that milk from cow clones does not appear to differ significantly in composition from milk from non-clones. Small differences have been noted in milk from clones and non-clones, but given the different diets and husbandry conditions of the animals, it is difficult to determine with certainty whether the changes resulted from their diet, handling, or cloning.

The FDA report discusses two possible pathways that might pose an increased allergenic risk from the edible products of animal clones. One is an increase in the relative amount of an individual protein component of milk or meat that may only be present in very low or trace amounts. The other possible pathway is through the processing of the proteins during their generation in the mammary gland, which may alter their antigenic presentation. Similar risks are not likely to occur for meats, as meat allergies are less prevalent in the population, and individuals who suffer from meat-related allergies are likely to avoid those meats entirely.

**Impacts on the Organic Food Sector**

Animal cloning is not allowed for organic production under the USDA National Organic Program (NOP) regulation. According to the USDA, “cloning as a production method is incompatible with the Organic Foods Production Act (OFPA) and is prohibited under the NOP regulations.” Cell fusion, the initial technical step in animal cloning, is prohibited by definition as an “excluded method” under the NOP regulation. In addition, cloning is dependent on the use of artificial hormones to induce labor of surrogate dams, another practice that is prohibited in organic agriculture.

The NOP regulation requires organic livestock producers to establish and maintain animal husbandry systems that allow natural behaviors, including those involved in reproduction. Organic livestock producers are required to promote the health and well-being of the animals. Breeding practices like cloning that result in deformities, pain, suffering, and death do not meet the NOP’s proactive health care requirements.
There are inherent uncertainties associated with the release of cloned animals into the agricultural environment. While sheep and cattle might be unlikely to interbreed with a local wild population, goats and swine are more likely to escape and interbreed with wild populations. This issue is not addressed in the FDA’s assessment, nor is protection from an escape or remedial actions for those who suffer adverse consequences from such a release.

One specific environmental risk of primary concern is the potential for cloned animals to have compromised immune systems, due to the numerous health complications discussed above. Animals with compromised immune systems can serve as hosts or vectors for pathogens, for both animals and humans. The impact of such a scenario could cause irreversible damage in the ecosystem.

Another environmental concern is the indirect entry of the products of cloned animals into the food supply via the application of animal by-products as fertilizers and feed additives. The use of cloned animals raises unprecedented livestock health and food safety concerns, since animals with compromised immune systems may become reservoirs for food- and manure-borne pathogens. Those pathogens are likely to be released into the environment when manure from cloned animals is applied as a fertilizer or when slaughter by-products from rendered cloned animals are used as fertilizers or feed additives.

The narrowing of genetic diversity of animals threatens to increase the susceptibility of animals to opportunistic diseases, parasites, and changing environmental conditions. Biologically speaking, the survival of a species 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. It is well known that a population with a narrow gene pool can collapse when animals encounter unanticipated diseases or environmental changes.

In addition to narrowing the gene pool, the animals selected to be cloned are likely to be high-producing animals bred to survive in high-input industrial confinement systems, rather than animals that are well adapted to more environmentally sound production systems. As such, cloning is another industrial tool that facilitates the growth of concentrated animal feeding operations (CAFOs). As reported by the Congressional Research Service, “some agricultural activities, especially large livestock facilities, are concentrated sources of nutrients, which can leach into ground and surface waters.” Facilities such as CAFOs are known to contribute to the contamination of ground and surface water and the development of diseases and environmental toxins, such as pathogenic E. coli and pfisteria.
ECONOMIC IMPACTS OF UNREGULATED AND UNLABELED CLONES

The U.S. livestock sector is heavily dependent on the export of meat and dairy products. According to the USDA Foreign Agriculture Service (FAS), exports of dairy, livestock, and poultry products for 2007 were forecast to reach $14.8 billion. The presence in the marketplace of unregulated and unlabeled meat and milk from cloned animals is likely to have a significant economic impact on the U.S. livestock sector, especially on exports. No other country has approved the sale of food or feed from cloned animals, and no country has indicated that it is considering approval in the short term. This fact raises the likelihood that trading partners will reject meat and dairy products from the United States, especially if the products from cloned animals are undifferentiated from products derived from non-cloned animals.

Further, the introduction of cloning has the potential to seriously diminish consumer confidence in livestock products in the United States, depressing domestic markets for conventional meat and dairy products. A December 2006 poll by the Pew Initiative on Food and Biotechnology found that 64 percent of U.S. consumers said they were uncomfortable with animal cloning, with 46 percent saying they were “strongly uncomfortable.” Other polls have shown comparable levels of consumer reticence. As consumers learn more about the animal health impacts and environmental risks associated with animal cloning, it is hard to imagine a softening of consumer anxiety over cloning.

With unregulated approval of SCNT, biotech corporations who control cloning technology and own the proprietary strains of cloned animals are the economic sector that stands to profit, if farmers and ranchers are not concerned about the risk of market rejection. Farmers and ranchers will become dependent on biotech companies for their genetics, rather than maintaining breeding stock on their own operations.

The absence of tracking or labeling protects the biotechnology companies and producers of cloned animals from liability. Without traceability, it will be difficult, if not impossible, to link the marketing and consumption of cloned animal products to possible adverse impacts on human health or the environment. Companies who own and profit from the technology will be free from liability for damages, if “defective” cloned animals and animal products cannot be traced back to the source.

As domestic and export markets reject cloned meat and dairy products, sales of organic livestock products will almost certainly grow at an accelerated rate, as the organic sector will be the only market that prohibits, through regulation, the use of...
cloned animals, their progeny and their products.

Due to potential disruptions to foreign and domestic markets, documented consumer rejection, questions about ownership of the technology, and unresolved liability issues, a comprehensive economic impact analysis should be conducted to examine the impacts of cloning technology on existing markets for conventional and organic livestock products.

**ETHICAL CONSIDERATIONS**

The FDA documents a variety of animal health problems both with clones, especially in the first days and weeks of life, and the surrogate mothers required to bring them to term. According to the FDA report, cloning results in “adverse health outcomes,” “increased risks of late gestation complications,” and “increased risks of mortality and morbidity.” 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.\(^{15}\)

The FDA acknowledges that there are ethical, cultural, and religious issues raised by animal cloning, and the agency offers to participate in discussions of these issues “in other fora,” but it makes clear that such considerations are not germane to its conclusion that products from cloned animals should be de-regulated.

Cloning technology has created a brave new world, where animals (which are sentient beings) can be replicated in a laboratory. Due to the extremely high failure rate, the proportion of cloned animals that suffer negative health effects, and the documented negative effects on surrogate mothers, ethical issues about the humane treatment of animals cannot be ignored, or postponed for future discussion.

In reality, there is no shortage of meat or milk in the United States. There is no shortage of food-producing animals. Likewise, there is no shortage of good genetics for healthy, high-producing animals. The development and advancement of cloning technology revolves around control of genetic resources and profits for the corporations who own the technology and the proprietary genetics of the cloned animals. Ethical issues, such as control of genetic resources, patenting of life forms, sustainable food systems, and use of public research monies for private gain, must be addressed.

**CONCLUSION**

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 United States. In fact, meat and milk markets are often depressed due to over-production. In the short term, this experimental technology—with its high failure rate—introduces documented, inherent dangers to animal health and welfare;
raises unanswered ethical issues; and presents the potential for negative environmental, economic, and human health effects.

NOTES

3. Center for Veterinary Medicine, Animal Cloning: A Draft Risk Assessment.
5. The total genetic material of an organism is referred to as its “genome” and consists of long strands of DNA packaged in chromosomes.
6. Pollack and Martin, “F.D.A. Tentatively Declares Food From Cloned Animals to Be Safe.”
9. Center for Veterinary Medicine, Animal Cloning: A Draft Risk Assessment, 47.
10. Lawrence C. Smith and Bruce D. Murphy, “Genetic and epigenetic aspects of cloning and potential effects on offspring of cloned mammals,” Cloning and Stem Cells 6, no. 2 (2004):126−32.
11. On 31 January 2007, the USDA National Organic Program (NOP) posted a short series of questions and answers on its website, clearly stating that cloning technology is prohibited in organic production.
15. Pollack and Martin, “F.D.A. Tentatively Declares Food From Cloned Animals to Be Safe.”
Barry Carin, Richard Higgott, Jan Aart Scholte, Gordon Smith, and Diane Stone, editors

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Published in association with the Academic Council on the United Nations Systems (ACUNS) and the United Nations University (UNU).

- Volume 13, 2007 (4 issues) • ISSN 1075-2846
- Individuals: $54 • Students: $29
- Institutions: $123 (Base Rate)

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