

Cloning and Food Safety

Genetically engineered crops have been widespread in the market in the United States for just a few years, yet despite growing consumer concerns about these untested, unlabeled foods, the biotech industry is rapidly moving into other areas of the food supply, including meat and dairy production. Monsanto, the world's leading producer of gene altered crops, recently predicted that cloning and genetic engineering will soon be routine practices for creating "designer cows" for food production.¹ Unfortunately, even though virtually no regulations exist to protect consumers, the environment, or farm animals from the risks of these untested techniques, it appears that the Food and Drug Administration (FDA) may soon allow industry to put unlabeled food from cloned animals on our grocery store shelves.²

Safety of Food from Cloned Animals

In animal cloning (also called "somatic cell nuclear transfer), the nucleus (which contains DNA) of an unfertilized egg is removed, and replaced with the nucleus from an adult (somatic) cell from a donor animal. In place of fertilization with a male animal's sperm, an electric current is used to kick-start cell division, and the embryo is then transferred to the uterus of a surrogate female animal. This technique first succeeded in producing a live birth with the famed sheep clone Dolly in 1997, and has since been used in many other animal species, including dairy cows and beef cattle, poultry, hogs, and other livestock.

Some livestock breeders hope to pursue cloning because they believe that the technology enables them to regenerate identical copies of prized animals with favorable characteristics, without the uncertainties of natural breeding or even other assisted reproduction techniques. Theoretically, since the cloned animal has exactly the same DNA as its donor, it will exhibit the same genetic tendencies. Dairy cows that produce exceptionally high quantities of milk, for example, have been cloned in hopes of producing an ongoing line of high-yielding milk cows. But the theories of cloning and its uses has met some harsh realities in practice. Dolly's birth was widely heralded, but less well known is that the clone's premature arthritis and lung disease forced her creators to euthanize her at age six (normal sheep live to age eleven or twelve).³

The safety of food from cloned animals is largely unknown, as there have been few studies and no long-term evidence of safe livestock production. In late October, 2003, the FDA released a draft assessment of the safety of food from clones, in which the agency claimed to find no reasons that the food would not be safe.⁴ Review of FDA's draft found the agency relied on a single study of milk from cloned animals, and no data at all on cloned meat.⁵ In 2004, the National Academy of Sciences also noted the paucity of data on the safety of food from cloned animals, saying "There are to date no published comparative analytical data assessing the composition of meat and milk products of somatic cell clones, their offspring, and conventionally bred individuals."⁶ A Biotechnology Industry Organization spokesperson pointed to the results of a 2005 study, heralded as "the first to examine specific proteins and nutrients in the milk and meat from somatic cloned animals," to claim that "the science is clear" on the safety of food from clones.⁷ The BIO representative (and most of the media) failed to note that the study looked at milk from just four cows and beef from only two cattle.⁸

Moreover, many scientists believe that cloning inherently produces unstable animals⁹, so even clones that appear healthy may suddenly become sick or have concealed illnesses that could affect food safety. For instance, the National Academy of Sciences had the following to say in their report, *Animal Biotechnology: Science Based Concerns*

A number of data sets suggest that the health and wellbeing of neonatal and young somatic cell clones often are impaired relative to those of normal individuals. Direct effects of any abnormalities in patterns of gene expression on food safety are unknown. However, because stress from these developmental problems might result in shedding of pathogens in fecal material, resulting in a higher load of undesirable microbes on the carcass, the food safety of products, especially such as veal, from young somatic cell cloned animals might indirectly present a food safety concern.¹⁰

It is difficult to assess the safety of food from cloned animals, since health problems in clones often arise suddenly and unexpectedly. The head of one cloning company said that the data his company has collected on surviving cloned cows “suggested to the vets that some of them should be dead.”¹¹ Dolly’s creator Ian Wilmut warned that even small imbalances in a clone’s hormone, protein or fat levels could compromise the safety of its milk or meat, stating “If companies start marketing this food and there are problems it will bring the whole technology into disrepute.”¹² Wilmut also pointed out that most studies of cloned livestock are of relatively young animals, while studies in mice have shown health problems at proportionally later ages.¹³

Cloning in commercial livestock production will also increase animal cruelty, as the process inherently involves needless suffering of surrogates and the deformed and sick offspring that often result. Cloning may cause problems other than unexpected effects on the animal’s health or its meat and milk products. Loss of genetic diversity among livestock, leading to disease-susceptible animals, is also a concern. One NAS scientist has warned that allowing cloning in livestock production could lead to “genetic bottlenecks” that dilute diversity and leave farms vulnerable to epidemic disease.¹⁴ Noting the unanswered animal welfare as well as food safety issues about cloning, another scientist remarked, “If a drug for headaches worked only 2 percent of the time, the FDA wouldn’t approve it. [But] that’s where we’re at [with cloning].”¹⁵

Indeed, in the approximately 98% of the cases in which cloning does not produce a normal animal there are many animal clones born with hideous deformities, often from difficult pregnancies that cause suffering to surrogate breeding animals as well. Cloning involves high rates of late abortion and early prenatal death, with failure rates of 95 percent to 97 percent in most mammal cloning attempts.¹⁶ Severe pregnancy complications and caesarian births in cloned cows are common, as are defects such as grossly oversized calves, enlarged tongues, squashed faces, intestinal blockages, immune deficiencies and diabetes.¹⁷ One scientific review stated that in clones

“64% of cattle, 40% of sheep, and 93% of mice exhibit some form of abnormality. A large percentage of these animals die during gestation or shortly after birth...In cattle [abnormalities] include large offspring syndrome, diabetes, pulmonary hypertension, dilated cardiomyopathy, internal hemorrhaging umbilical artery, viral infection, dystocia, kidney problems, leg malformations, pneumonia, heart defects, liver fibrosis, osteoporosis, joint defects, anemia, and placental abnormalities. In sheep, abnormalities include large offspring syndrome, arthritis, and kidney, liver, and brain defects. Mice exhibit obesity, large offspring syndrome, enlarged placentas, umbilical hernias, respiratory failure, and failure to foster pups. Goats and pigs exhibit relatively few abnormalities, but they include bacterial infections of the lungs (goats) and abnormal teat numbers, cleft lips, and malformed limbs (pigs).”¹⁸

Finally, cloning is an essential technology for the genetic engineering industry. Biotech companies use cloning to replicate copies of their gene altered (transgenic) animals, since normal reproduction might not recreate the desired genetic alteration. As FDA notes, “Using a transgenic approach just makes it easier to get the desired genetic characteristics in the animal, which is then cloned to produce a core breeding herd.”¹⁹ Numerous companies are already producing cows, goats, chickens, pigs, poultry and other genetically engineered animals to produce foods or drugs. With such genetic engineering will come all of the health, safety and animal welfare issues of cloning, with the additional environmental concerns posed by the creation of engineered animals that may unexpectedly breed with natural populations.

The Center for Food Safety urges consumers to join us in rejecting food from cloned animals. Currently the FDA has no rules prohibiting the sale of these foods, and is relying on industry to keep cloned milk and meat out of the food supply voluntarily. CFS has urged FDA to impose a mandatory immediate moratorium on the sale of food products from cloned animals, and to take steps to insure that the food safety, consumer right-to-know, and animal welfare concerns have been addressed before these products come to market. For updates on this issue, sign up for e-alerts at <http://ga3.org/cfs/advocacy.html>, and see more information at <http://www.centerforfoodsafety.org/pubs/ClonedAnimalCommentFDANov2003.pdf>

¹ Teresa Halvorsen, “Holstein breeders prepare for future at national convention,” Ag Biotech Infonet, July 5, 2001 online at http://www.biotech-info.net/holstein_breeders.html

² Justin Gillis, “Clone-Generated Milk, Meat May Be Approved; Favorable FDA Ruling Seen as Imminent,” October 6, 2005, Washington Post.

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- ³ Will Knight, "Dolly the sheep dies young," *New Scientist*, February 14, 2003.
- ⁴ FDA, "FDA Issues Draft Executive Summary of its Assessment of Safety of Animal Cloning," press release, October 31, 2003.
- ⁵ Food and Drug Administration, "Animal Cloning: A Risk Assessment," October 21, 2003, p. 7
- ⁶ National Academy of Sciences, "Animal Biotechnology: Science Based Concerns," Board on Agriculture and Natural Resources, National Academies Press, Washington, D.C., 2002, pp. 8-9; 64-65. Online at <http://www.nap.edu/books/0309084393/html/R1.html>
- ⁷ Rick Weiss, "Cloned Cows' Milk, Beef Up to Standard," *Washington Post*, Tuesday, April 12, 2005; Page A03
- ⁸ X. Cindy Tian, et al., "Meat and milk compositions of bovine clones," *Proceedings of the National Academy of Sciences*, vol. 102, no. 18, pp. 6261-6266, May 3, 2005.
- ⁹ For example, see Merritt McKinney, "Flawed genetic 'marking' seen in cloned animals," *Reuters Health*, May 29, 2001; Kang, et. al., "Aberrant methylation of donor genome in cloned bovine embryos," *Nature Genetics* 2001;28:173-177; Helen Altonn, "Cloning Isn't Safe. UH Researchers warn," *Star Bulletin*, July 6, 2001; Rick Weiss, "Clone Study Casts Doubt on Stem Cells," *Washington Post*, July 6, 2001;
- ¹⁰ National Academy of Sciences, "Animal Biotechnology: Science Based Concerns," Board on Agriculture and Natural Resources, National Academies Press, Washington, D.C., 2002, p. 66. Online at <http://www.nap.edu/books/0309084393/html/R1.html>
- ¹¹ Duplicate Dinner, *New Scientist*, May 19, 2001.
- ¹² Duplicate Dinner, note 11.
- ¹³ James Meek, "Tears of a clone," *The Guardian* (London), April 29 2002
- ¹⁴ Antonio Regalado, "Cloned Livestock Mustn't Be Eaten Yet, FDA Warns," *Wall St Journal*, June 5, 2001
- ¹⁵ Sharon Cohen, "Cloning May Be Key in Animal Copies," *Associated Press*, July 13, 2001; for more on animal welfare issues, see *The Use of Transgenic Animals in the European Union, The Report and Recommendations of ECVAM Workshop 281,2*, at <http://altweb.jhsph.edu/science/pubs/ECVAM/ecvam28.htm>.
- ¹⁶ Rick Weiss, "Human Cloning Bid Stirs Experts Anger," *Washington Post*, March 7, 2001
- ¹⁷ Duplicate Dinner, note 11.
- ¹⁸ Jorge Piedrahita, et.al., "Somatic Cell Cloning: The Ultimate Form of Nuclear Reprogramming?," *J. Am. Soc. Nephrol* 15:1140-1144, 2004.
- ¹⁹ Carol Lewis, "A New Kind of Fish Story: The Coming of Biotech Animals," *FDA Consumer magazine*, January-February 2001