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HEADLINE: **FDA Says Cloned Animals Are Safe as Food**

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BODY:

Cloned farm animals and their offspring pose little scientific risk to the food supply, the Food and Drug Administration has concluded in a new report that could pave the way for allowing products derived from clones or their offspring onto the nation's grocery shelves.

The draft report, to be released in summary form this morning and discussed at an FDA advisory committee meeting next week, is likely to kick off a fresh national debate about just how far to go in manipulating nature to achieve human ends. Nearly a year behind schedule, the report moves the agency closer to a formal declaration that cloning, the technology that produced Dolly the sheep, is permissible as a routine tool of American agricultural production.

If clones survive into adolescence, "the animals themselves appear to be healthy. And it's hard to imagine that healthy animals would somehow be capable of producing unsafe food," said Stephen F. Sundlof, director of the FDA's Center for Veterinary Medicine, which prepared the report. "No scientist I've talked to can come up with any rational theory of how that could possibly occur."

Some farmers and a handful of companies have been eager to exploit the potential of cloning, and some cloned animals -- most estimates put the number at 200 to 300 -- are already living on American farms. No federal rule prohibits sale of food products derived from clones or their offspring, but the FDA has informally asked producers to hold off, which they say they have done. A few farmers are even pouring out milk from cloned Holstein dairy cows. That voluntary moratorium will stay in effect for at least the next several months, the FDA said.

Despite repeated scientific assurances, food manufacturers and consumer groups are nervous about the technique, believing the public just isn't ready for cloned milk in the refrigerator or cloned hamburgers on the grill. This "yuck factor," as one consumer advocate calls it, could pose political problems for the Bush administration, since it looks increasingly likely that the FDA will give a green light to cloned food as the 2004 election enters full swing.

"What a perfect time for the FDA to put out a report on cloning, on Halloween," declared Carol Tucker Foreman, director of food policy at the Consumer Federation of America, in Washington. "Most Americans find it pretty scary."

Organic food advocates and animal welfare groups say animals will suffer unnecessarily if commercial interests push cloning technology into routine food production. And some people are starting to worry that a large commercial market in cloned animals could spur development of more sophisticated cloning techniques, hastening the day when human reproductive cloning can no longer be ruled unethical on safety grounds, as it has been so far.

As of yet, these forces have not converged into a strong movement against animal cloning. The FDA, hoping to spur public discussion, made its new report available early to a handful of news organizations. The report said that emerging research, though thinner than the FDA would like, suggests that while there may be genetic differences between healthy looking adult clones and ordinary animals, these are likely to be trivial.

"Edible products from normal, healthy clones or their progeny do not appear to pose increased food-consumption risks relative to comparable products from conventional animals," the report said.

Clones still cost about \$20,000 apiece to produce, so it's highly unlikely any of them would be eaten directly as food, at least in the next few years. Instead, farmers want to clone elite animals and use them as breeding stock to upgrade the genetics of entire herds. Milk from cloned cows and meat from the first- or second-generation offspring of cloned cows and pigs are the likeliest products to enter the food supply in the near term.

The FDA report said animal cloning does pose increased risks to the animals themselves, and to the surrogate mothers who give birth to them. The technology is plagued by high failure rates, spontaneous abortions and severe health problems in many clones and their mothers. But the report said these problems are no different in kind from the animal welfare problems caused by other reproductive technologies, such as artificial insemination or test-tube fertilization, that have been in use on American farms for decades.

Cloning problems are worse in some species than others -- they are notably severe in cows, the prime targets for firms working on commercial cloning -- but the difficulties are gradually lessening in all species as the technology improves, the FDA said. And the report said once cloned animals survive the critical first weeks after birth, their health seems to stabilize and it is hard to tell them from normal animals. Though most clones have yet to reach prime reproductive age, several have produced healthy offspring.

Concern about cloning is not confined to the most assertive animal rights groups. The technique has drawn sharp opposition from such organizations as the Humane Society of the United States. A panel of the National Academy of Sciences, the nation's premier scientific body, said last year that animal welfare was a serious concern, while also declaring that the cloned food was almost certainly safe to eat.

No federal law or policy appears to give government power to stop cloning on grounds of animal welfare, much less because the public might have aesthetic or ethical problems with it. Taking such concerns into account might require new legislation, and the biotechnology industry, with which the Bush administration is closely allied, has vigorously fought expanded oversight by the FDA or other agencies.

"We look forward to an expedient decision from FDA that allows livestock producers and biotechnology companies to begin marketing their products," the Biotechnology Industry Organization, a Washington trade group, said in a statement last night.

Foreman, the consumer food policy expert, called on the Bush administration to submit the ethical questions for broad public discussion, perhaps in hearings before a presidential commission already studying related issues. She and other consumer advocates largely accept the scientific view that cloned food would be safe but

say that shouldn't be the end of the discussion.

"I think many people think it's the first step down a slippery slope," Foreman said. "I won't defend that position, but when Dolly was cloned, immediately the discussion went straight to issues of human cloning. I suspect that will happen again."

The FDA plans to publish a more detailed version of its report this spring, then seek public comment before finalizing any national policy. But, barring some dramatic new scientific finding, the agency appears likely to conclude that cloning is safe and it therefore has no power to regulate.

Even as the discussion has unfolded in Washington, American entrepreneurs have been pushing the technology forward. The nascent cloning industry has been roiled by uncertainty about the FDA's position and by the stock market downturn, with some small companies going under, but a handful of labs are still offering cloning services. Cyagra Inc. of Worcester, Mass., is the biggest, charging \$19,000 apiece to clone 50 to 60 animals a year. The firm has returned more than 100 clones to American farmsteads, said Steve Mower, director of marketing.

Most farmers haven't embraced cloning yet, but quite a few that own champion farm animals are hedging their bets. Cyagra offers to store cells from prized animals so clones can be produced any time, and farmers have already put more than 500 animals into deep freeze.

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