F.D.A. Says Food From Cloned Animals Is Safe

By ANDREW POLLACK and ANDREW MARTIN

Bob Schauf, with two of his cloned cows in Barron, Wis. Mr. Schauf said his family has been drinking the milk from cloned animals.

After years of delay, the Food and Drug Administration tentatively concluded yesterday that milk and meat from some cloned farm animals are safe to eat. That finding could make the United States the first country to allow products from cloned livestock to be sold in grocery stores.

Even if the agency’s assessment is formally approved next year, consumers will not see many steaks or pork chops from cloned animals because the technology is still too expensive to be used widely.

But the F.D.A.’s draft policy triggered immediate storm of criticism from consumer groups, as well as some concerns from meat and dairy companies worried about consumer reaction.

“At the end of the day, F.D.A. is looking out for a few cloning companies and not for consumers or the dairy industry,” said Joseph Mendelson, legal director for the Center for Food Safety, an advocacy group.

Mr. Mendelson and other consumer representatives argue that the science backing the F.D.A.’s decision is shaky and that consumer surveys show that most people are opposed
to cloning animals, let alone eating them. Some also said that cloning causes harm to the animals involved and could pave the way for human cloning.

Opponents hope to bring Congressional pressure to bear to derail the policy before it becomes final or at least to require that such foods be labeled so consumers can choose to avoid them. F.D.A. officials said that it was unlikely that labeling would be required because food from cloned animals is indistinguishable from other food, although a final decision about labeling has not been made.

Senator Patrick J. Leahy, Democrat of Vermont, yesterday called for a “careful, deliberative and open process” before cloned animals are approved for food.

The F.D.A.’s finding comes more than six years after the agency first decided to study the matter, after recognizing that the advent of cloned farm animals raised a food safety issue. After that study, the agency in 2003 gave a tentative approval to cloned animals for food. But the F.D.A. retreated after its own advisory panel found there was insufficient scientific backing for that conclusion.

This time, F.D.A. officials said they had substantial new data, which they presented yesterday in a nearly 700-page “draft risk assessment.”

The officials denied the contention from some critics that the policy was announced during a holiday week in order to reduce publicity, saying it had taken until now to analyze the data and obtain comment from other government agencies.

The assessment concluded that milk and meat from cloned cows, pigs and goats, and from their offspring, were “as safe to eat as the food we eat every day,” Stephen F. Sundlof, the F.D.A.’s chief of veterinary medicine, said in a telephone call with reporters.

Mr. Sundlof said that by law the agency could consider only the scientific issues, not consumer demand or the ethics of cloning.

While animal cloning has always been legal, since 2001 there has been a voluntary moratorium on the sales of milk or meat from such animals to give the F.D.A. time to study the matter. Some experts say that some products from clones or their offspring have probably nonetheless made their way into the food supply.

The moratorium will stay in place until the new policy is completed, after a 90-day period for public comment and additional time for the F.D.A. to review the comments. Mr. Sundlof said he could not say when the final policy would be ready, though it might be by the end of 2007.

Even then, the moratorium would remain for products from sheep, the F.D.A. said, because there was not enough evidence of their safety. No one has yet succeeded in cloning chickens or other poultry.
The finding was hailed by cloning companies, which have been struggling to build a business. It also drew praise from some farmers and breeders who have already made clones of their prized livestock but have had to pour milk down the drain and keep their meat off the market.

They say that cloning is just another breeding technique, like artificial insemination or in-vitro fertilization.

“This just sort of lifts the stigma of the clones,” said Bob Schauf, a Holstein breeder and dairy farmer in Barron, Wis., who had two of his prized cows cloned. He said his family and the families of his employees have been drinking the milk from those clones rather than see it go to waste. But dairy marketers have expressed concern.

A survey conducted last summer by the International Dairy Foods Association, an industry trade group, found that 14 percent of women would turn away from all dairy products if milk from clones were introduced into the food supply. The association surveyed women because its research has found them to be the main household decision makers on dairy products.

The American Meat Institute, while saying yesterday that cloning was safe, also urged the F.D.A. to be cautious about approval “if most consumers are unwilling to accept the technology.”

A poll this month from the nonprofit Pew Initiative on Food and Biotechnology found that while most consumers knew little about animal cloning, 64 percent said they were uncomfortable with it, with 46 percent saying they were “strongly uncomfortable.”

F.D.A. officials said no other country had yet approved food from cloned livestock, although some are considering it. That raised the prospect that American exports of milk or meat could be blocked by certain countries if they contain products from cloned animals. An official in the Washington delegation of the European Union said politicians and consumers in Europe would no doubt debate the issue.

Carol Tucker Foreman, director for food policy at the Consumer Federation of America, said consumer groups would ask food companies, retailers and restaurant chains to shun products from cloned livestock.

That raises the possibility that some food companies will label their products “clone free,” just as some now label milk as not coming from cows injected with growth hormone.

Cloning involves putting an animal’s DNA into an egg that’s own DNA has been removed. The resulting embryo, after being implanted into a surrogate mother, makes 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. And 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 the surrogate mother. 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.

But the F.D.A. said that obviously sick and deformed animals were already barred from the food supply. It added that clones that survived past the first few days “appear to grow and develop normally” and that healthy adult clones were “virtually indistinguishable” from noncloned livestock, making their meat or milk safe.

The draft assessment based its conclusions on an extensive review of scientific literature on cloning as well as on studies, some done by cloning companies, comparing the composition of the milk, meat and blood of cloned animals and conventional animals.

Mr. Sundlof said the agency also found that cloning “poses no unique risks to the health of animals” beyond those seen with other forms of assisted reproduction such as in-vitro fertilization. The frequency of problems is higher with cloning, however, perhaps because it is a newer technology. The first cloned mammal, Dolly the sheep, was born in 1996.

The F.D.A.’s announcement, by paving the way for the end of the moratorium, could make it easier to persuade farmers and breeders to pay $15,000 to copy a prized bull or dairy cow.

“I think that this draft is going to provide the industry the comfort it needs,” said Mark Walton, president of ViaGen, a cloning company based in Austin, Tex., that has yet to turn a profit after five years.

Industry officials estimate there are now only 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.

Experts say that cloning is too expensive to be used to make animals only to then grind them into hamburger or even to milk them. Rather, farmers and breeders are cloning prized livestock so they can then be used for breeding using more conventional means of reproduction.

That means that most food from cloning would come from the sexually produced offspring of the cloned animals. The F.D.A. said milk and meat from such offspring were safe, because any abnormalities in clones do not carry into the next generation.
The agency’s assessment did not include genetically modified animals, in which a foreign gene is introduced. The agency is still deciding whether to allow the first of those, a fast-growing fish, into the food supply.