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FDA to Back Food From Cloned Animals

Move Would Defy Congress's Wish for Delay

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Having completed a years-long scientific review, the [Food and Drug Administration](#) is set to announce as early as next week that meat and milk from cloned farm animals and their offspring can start making their way toward supermarket shelves, sources in contact with the agency said yesterday.

The decision would be a notable act of defiance against Congress, which last month passed appropriations legislation recommending that any such approval be delayed pending further studies. Moreover, the Senate version of the Farm bill, yet to be reconciled with the House version, contains stronger, binding language that would block FDA action on cloned food, probably for years.

With a conference committee poised to finalize the farm bill in the next few weeks, that left the FDA a potentially narrow time frame within which to act if it wanted to settle the issue in sync with America's major meat-trading partners.

[New Zealand](#) and [Australia](#) have released reports concluding that meat and milk from clones are safe. [Canada](#) and [Argentina](#) are reportedly close to doing the same.

And although European consumers are generally uncomfortable with agricultural biotechnology, the [European Union](#)'s food safety agency is expected to endorse the safety of meat and milk from clones in a draft statement that could be released within the next week.

"The science seems to be leading them and us to the same conclusion," said a U.S. trade official, speaking on the condition of anonymity because U.S. policy is technically still under review.

The FDA has hinted strongly in the past year that it is ready to lift its "voluntary moratorium" on the marketing of milk and meat from clones and

their offspring, saying that the science led them to that decision. Multiple studies compiled by the agency have shown that the chemical composition of those products is virtually identical to that of milk and meat from conventionally bred animals. And studies in which rodents were fed food from clones have found no evidence of health effects.

But public opinion has been negative on the issue, with some saying that not enough safety studies have been conducted and others concerned about the health of the clones, which are far more likely than ordinary farm animals to die early in life.

As of yesterday, the FDA would neither confirm nor deny that it is close to releasing its so-called final risk assessment. Spokeswoman Julie Zawisza said the agency had received a lot of feedback -- about 30,500 comments -- on its draft risk assessment, released in December 2006. That document found no "food consumption risks or subtle hazards" associated with meat or milk from clones or their offspring.

The agency has not revealed how many comments were in favor or opposed.

Clones are genetic replicas, typically made from a single skin cell of a desirable animal. A handful of U.S. companies have pushed for marketing approval, saying the technology will make products from the tastiest beef cattle, leanest pigs and most generous milk producers more widely available to consumers.

"Thousands of data points, hundreds of peer-reviewed journal articles and two reviews by the National Academies have all said the same thing," said Mark Walton, president of ViaGen, an [Austin](#)-based cattle cloning company that provided many of the animals that independent researchers studied for the FDA. "There is nothing left to review."

Walton emphasized that for now, because clones are so expensive to make, they will be used almost entirely as breeding stock to produce conventional offspring for market. Scientists largely agree that although some clones harbor genetic peculiarities of uncertain relevance, their sexually produced offspring are healthy and normal.

But even Walton concedes that eventually both clones and their offspring will find their way to market. And as word spread through back channels in recent days that the FDA was poised to give a green light, opponents expressed

surprise and anger.

"The FDA has been on the Hill on bended knee asking for more money, yet they are willing to turn around and thumb their nose at the appropriators," said Carol Tucker Foreman, of the [Consumer Federation of America](#), referring to the omnibus spending bill that called for a delay. "The president signed that bill and it is in effect, and they are acting like it doesn't exist."

Margaret Mellon of the [Union of Concerned Scientists](#), an advocacy group, said she had read the entire 678-page draft risk assessment and found it to be "long on assumptions and short on data, and especially short on the data that are directly relevant to food consumption safety."

Of particular concern, she said, was that even though the vast majority of clones die either before birth or soon after, those that survive are deemed normal. She said the FDA should withhold approval at least until it has a regulatory plan in place that will give it an ability to track food from clones and watch for human health impacts.

Others have called for mandatory labeling so consumers can avoid products from clones.

The FDA has said that lacking any safety concerns, it will not demand such labels. But last month, the two largest U.S. farm animal cloners, ViaGen and Trans Ova Genetics of Sioux Center, [Iowa](#), announced a voluntary plan under which cloned animals would be registered and segregated from the conventional meat processing streams. If accepted by regulators, it could allow some food distributors to label their products as "clone free."

The [Agriculture Department](#) has also declared that meat from clones cannot be deemed organic.

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