I'll have the cloneburger and fries;
Who wouldn't want cloned meat and milk if it was guaranteed to be the best you ever tasted? Sharon Oosthoek finds plenty of opposition

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LIVESTOCK auctions are not normally the stuff of headlines, but then it's not every day that cows as unusual as Dundee Paradise and Dundee Paratrooper are going under the hammer. The dairy cows were due to be sold at Easter Compton cattle market near Bristol, UK, last month, but at the last minute their owner withdrew them, reportedly unsettled by negative media coverage and local opposition.

The problem? The cows' mother was a clone, conceived in a laboratory from a cell taken from the ear of a prize-winning Holstein in Wisconsin. "A cow created in Frankenstein's lab," as one local newspaper put it.

This episode was one of the opening skirmishes in what is shaping up to be a battle on par with that over genetically modified food. This time the issue is the production of meat and milk from cloned animals.

On one side are the livestock producers, who stand to gain or lose significant amounts of money depending on the outcome. On the other are consumer groups and animal welfare organisations who say that food from cloned animals is unwanted, unnecessary, possibly dangerous and a catastrophe for animal welfare.

The battle began in earnest in January, when food safety authorities in the US and Europe released reports that effectively opened the door to the sale of meat and milk from cloned animals and their offspring.

In the US, the Food and Drug Administration (FDA) published a 968-page report detailing the results of a six-year investigation. The document stated in no uncertain terms that milk and meat from cloned cattle, pigs, goats and their offspring are just as safe as food from conventionally bred animals. That conclusion was echoed in a draft opinion from the European Food Safety Authority (EFSA).

"It is beyond our imagination to even find a theory that would cause the food [derived from clones] to be unsafe," Stephen Sundlof, the FDA's chief food safety expert, told reporters. In fact, so confident is the FDA about its decision that it says there is no need even to label food from clones or their offspring.

The controversy over meat and milk from cloned animals can be traced back to the birth of Dolly the sheep in 1996. Livestock breeders immediately saw the possibilities: unlimited copies of their prize animals. Imagine a bull that consistently sires offspring with top-quality meat or milk. That bull has a limited reproductive lifetime and there's no guarantee that any of its offspring will inherit its qualities. But clone the bull and you have an exact copy with the same reproductive capabilities.

"Cloning is the only artificial reproductive technology to take an animal with proven performance and replicate it," says Mark Walton, president of one of the world's largest livestock cloning companies, ViaGen of Austin, Texas.
It's unlikely that anyone will clone animals simply for meat, because they are expensive to buy - between $13,000 and $17,500 for a cloned cow, compared to between $1500 and $3000 for a standard cow. Prices, however, are expected to drop as the technology improves, says Barbara Glenn of the Biotechnology Industry Organization in Washington DC.

For now, clones will be used as breeding animals to produce high-quality offspring for meat or milk. Still, meat from clones is likely to find its way into the food supply eventually when the clones come to the end of their reproductive lives, says Walton, while milk from clones could be produced as soon as the animals reach sexual maturity.

Proponents of the technique say cloning has many advantages for consumers. "There's a whole laundry list of benefits," says Kenneth White of Utah State University in Logan, whose lab produces clones for research. This includes reduced cholesterol in meat and milk, plus higher levels of good fatty acids and antioxidants.

Cloning has other advantages, too. For instance, it would allow relatively easy reproduction of cattle genetically engineered to lack the prion protein that makes them susceptible to mad cow disease (Nature Biotechnology, vol 25, p 132). Cloning would also make it possible to replicate animals engineered to resist illnesses or with a smaller ecological footprint, such as the Enviropig, whose waste contains less phosphorus - a problematic pollutant from pig farming.

Yet those on the other side of the debate are not licking their lips at the prospect of cloned meat and milk, citing their own laundry list of concerns.

One of these is the issue of food safety, which critics say is beset with niggling scientific uncertainties. "There are very few peer-reviewed studies addressed to [clones and] food safety," says Margaret Mellon, a senior scientist at the Union of Concerned Scientists in Washington DC. She points out that most of the studies that exist were done by livestock companies themselves, who have a vested interest in a positive outcome. "While it's good to do that, it's not enough," she says.

Brussels-based animal welfare group Eurogroup for Animals goes further, pointing out that the FDA report cites studies which suggest some differences in the meat of clones compared to non-clones.

For example, a team led by Xiangzhong Yang of the University of Connecticut in Storrs found that, though the composition of meat from cloned and non-cloned cows was "largely" the same, there were higher levels of fat and certain fatty acids in the meat from clones - though these were within in the normal range for human consumption (Proceedings of the National Academy of Sciences, vol 102, p 6261).

Other research has found differences in the fatty acid and mineral content of milk from clones. Marie Walsh of Utah State University examined the composition of milk from 15 cloned dairy cows and six non-clones, and found some variation in levels of two out of 14 fatty acids - palmitic acid and linolenic acid - as well as in levels of potassium, zinc, strontium and phosphorus. But her overall conclusion was that there were "no obvious differences" (Cloning and Stem Cells, vol 5, p 213).

Eurogroup for Animals doesn't claim that these findings mean meat or milk from clones or their offspring is unsafe or unfit for human consumption, but it says they suggest more research is needed. For its part, the FDA maintains that none of the differences in nutritional value are a cause for concern. It points out that there are plausible explanations for the differences that are unrelated to the cloning process. In the milk experiment, for example, the cloned cows were housed on different farms and fed different rations.

The FDA position reflects the scientific consensus. The majority of studies find no differences at all between meat and milk from cloned and non-cloned animals, (for example, Cloning and Stem Cells, vol 6, p 157, p 165 and p 172). What's more, in a recent review paper Yang concludes that "studies on the biochemical properties of food products from cloned and non-cloned animals have thus far not detected any differences" (Nature Biotechnology, vol 25, p 77).

There is also the inconvenient fact that food from cloned animals has been going into the human food chain for many years with no ill effects. In the 1980s and 1990s around 1500 cows and bulls were produced in North America by embryo cell nuclear transfer (ECNT - ), almost all of which were eventually slaughtered for meat. According to Yang around 300,000 kilograms of meat and more than 2 million litres of milk from cloned cattle entered the food supply this way.

Despite this, consumer groups including the Center for Food Safety and the Consumers Union, both in the US, are pushing for mandatory labelling of food from cloned animals. The problem is that there is no test capable of identifying meat or milk from cloned animals, nor from their offspring. Retailers would have to rely on voluntary agreements with suppliers, who in turn could only identify clones through a registry.
As it happens, two of the largest livestock cloning companies, ViaGen and Trans Ova Genetics of Sioux Center, Iowa, created a voluntary registry in December, which will allow slaughterhouses to identify clones by scanning the animal's ear tag.

Consumers certainly seem in favour of labelling. According to a 2007 poll carried out by the Consumers Union, 89 per cent of Americans want milk and meat from cloned animals labelled. Another poll by the International Food Information Council found that the majority of US consumers were unlikely to buy food derived from cloned animals.

Labelling, however, doesn't address the most heartfelt criticism of cloned meat and milk - the greater incidence of serious health problems afflicting cloned animals and their surrogate mothers. "We believe the cloning process has the potential to cause unnecessary pain, suffering and distress," says Nikki Osborne, a developmental biologist with Eurogroup for Animals.

That view is shared by the European Group on Ethics in Science and New Technologies (EGE), an advisory body to the European Commission. In January it issued a report about the grave implications of cloning for animal welfare. "Considering the current level of suffering and health problems of surrogate dams and animal clones, the EGE has doubts as to whether cloning animals for food supply is ethically justified," the authors wrote.

It's hard to say for sure how much more common health problems are among clones and surrogates, says Pere Puigdomenech of the Institute of Molecular Biology in Barcelona, Spain, a member of the EGE. "These kinds of numbers are not well known. It depends very much on breeds." Even so, everyone involved in the debate freely admits that health issues are more common in clones and their surrogate mothers than in animals that aren't cloned.

**Malformed and dysfunctional**

According to the EGE report, fewer than 5 per cent of cloned fetuses live long enough to be born; roughly 20 per cent of newborn clones don't survive the first 24 hours, and an additional 15 per cent die before weaning.

One of the main problems among cloned cows and sheep is "large offspring syndrome", a potentially fatal condition characterised by malformed limbs, livers, brains, urinary and genital tracts, and dysfunctional immune systems. The problem is thought to be caused by complications in resetting the genetic instructions during the cloning process.

The EFSA, for example, cites a study which found that the incidence of large offspring syndrome was 13.3 per cent for cloned calves compared to 9.5 per cent for non-cloned calves (Biology of Reproduction, vol 66, p 6). It also points to another study which found that up to 47 per cent of cloned calves derived from skin, ear or liver cells suffer from the syndrome (Journal of Reproduction and Fertility, vol 120, p 231).

Large offspring syndrome is also a problem for surrogate mothers. Cows and ewes carrying cloned offspring are known to have significantly more late miscarriages and difficult births due to large offspring.

Despite this, there appears to be little appetite for regulating cloning on animal welfare grounds. The FDA report describes clones' health problems as "of concern" but goes on to point out that once the clones mature, they are as healthy as non-clones. Both the EFSA and the FDA note that conventionally produced offspring suffer from the same problems as clones, albeit at a lower rate.

Currently, there aren't enough clones around to create an uproar about animal welfare. EFSA estimates the total number of clones worldwide in 2007 was fewer than 4000 cattle and 1500 pigs. The US is home to just over 600, including 570 cattle, 20 goats and eight pigs. The EU has roughly 120 cattle clones - 80 in France, 30 in Germany and 10 in Italy - and a smattering of pigs. Japan, China, Argentina, Australia and New Zealand also have cloned animals.

But those numbers could increase substantially if consumers accept meat and milk from clones, or have it foisted on them. If and when that happens, expect a backlash. "There's no outcry on the part of the consumer for this," says Mellon. "The question of why we're doing this is really important. It's almost because we can."

**Cloning basics**

**Sharon Oosthoek**

Scientists have been cloning animals since the 1970s using blastomere separation, in which embryos are split into several cells that are implanted into surrogate dams. But there is a limit to the number of clones that can be made from an embryo, and their characteristics are impossible to predict in advance.

In the 1980s blastomere separation was superseded by ECNT (embryo cell nuclear transfer), which involves implanting the
nuclei of embryonic cells into unfertilised eggs that have had their nucleus removed.

The birth of Dolly the sheep in 1996 ushered in a new and more efficient technique - somatic cell nuclear transfer (SCNT), which enables an unlimited number of copies of an adult animal with known characteristics to be made. Scientists first remove the nucleus from an unfertilised egg and replace it with the nucleus from an adult cell. They then stimulate the egg with a mild electrical pulse. If this is successful, the resulting cell divides and turns into an embryo.

Cloned meat and the law

Sharon Oosthoek

The position of the Food and Drug Administration (FDA) is that meat and milk from cloned pigs, cattle and goats and their offspring are safe to eat and do not need to be labelled. The FDA has not reached a conclusion for sheep, citing a lack of evidence. The Department of Agriculture has given the go-ahead for the offspring of clones to enter the food chain but is asking farmers not to sell food derived from clones until it has developed a regulatory scheme.

The European Commission has asked two advisory bodies for opinions. The European Food Safety Authority is due to report in May, but its draft position is that food from cloned cattle and pigs and their offspring is safe. The European Group on Ethics in Science and New Technologies issued an opinion in January warning of cloning's grave animal welfare implications.

The commission has indicated that it will not rush a final decision. It has the option of making its decision binding on all member states or simply offering guidelines.

There are no regulations in either country to prevent the sale of food from cloned livestock and their progeny. The New Zealand Food Safety Authority says there is no need for specific regulation; Australia's Department of Health says it is still looking into whether to regulate. The independent agency Food Standards Australia New Zealand says that researchers in both countries have voluntarily agreed to prevent clones from entering the food chain.

The Food Standards Agency, which is responsible for assessing food from cloned animals and their offspring, says it has received no applications to market such foods.

No food from cloned animals or their offspring is approved for sale. Health Canada has asked those who want to produce such food not to submit applications until it has a policy in place.

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The FDA report can be downloaded at http://www.fda.gov/cvm/CloneRiskAssessment_Final.htm

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