Update on Cloning of Animals for Food Production

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the campaign on
GM food, crops and patents

This briefing provides details and background on the presence of the offspring of cloned cattle in the UK and the implications of these highly controversial developments for health, animal welfare and consumer choice. GM Freeze is calling for an EU-wide ban on cloning, imports of clones and their offspring, as well as products derived from them. For further information see our previous briefing *Clones in the food chain: They are there, but we don't know where* (December 2008, see www.gmfreeze.org/uploads/F27_clones_final.pdf).

Background

Reports that offspring of cloned cattle had been imported into the UK first emerged in January 2007 with stories that a daughter of a cloned Holstein Friesian dairy cow had been born in the Midlands.[i] This calf, known as Dundee Paradise, was produced from an imported frozen cloned cow embryo from the US company Cyagra Clone and went on to produce calves at a farm in Gwent.

In August 2010 meat from a bull clone offspring (Dundee Paratrooper, born in December 2006 and reared on a farm near Nairn, Scotland) was reported to have entered the food chain.[ii] Meat from a second bull (Dundee Perfect, born in March 2007) had been prevented from entering food supply.[iii]

It was also reported that these two bulls had produced 96 pedigree calves on a the same farm, which is home to Newmeadow Holsteins owned by farmer Callum Innes, who uses cloned offspring in breeding to enhance milk yields. These calves are believed to be poised to enter the Newmeadow (or other) herd and begin to produce milk for commercial sale.

Novel Food Regulations

There has been considerable confusion in the UK as to whether products from the offspring of clones (as this milk and meat would be) require approval under the Novel Food Regulations EC258/97. In 2007 the FSA made it clear that they believed such products did require approval:

> *"The FSA's view is that products from the offspring of cloned animals, like those from cloned animals themselves, should be considered as novel foods...The Agency expressed this view at an EC discussion group meeting that took place in Brussels on 12 January 2007. The Agency's view was also shared by a significant number of other Member States."* [iv]

In August 2010 FSA officials repeated this position to a meeting of consumer organisations (including GM Freeze):

> *"Cloned animals are not specifically mentioned as part of the regulation as they apply to a wide range of novel foods. The interpretation of the regulation in respect of cloned animals varies across the EU, specifically regarding the number of generations of offspring classified as novel foods. Clarification is currently being sought from other EU Member States regarding their positions on the issue of meat and products from cloned animals and their descendants.*
>
> *"Since 2007 the Agency's view has been that, in relation to animal cloning,* ***the definition of non-traditional breeding practices applies to cloned animals and all subsequent generations of offspring.*** *The group unanimously supported this position."*

Yet by the FSA Board Meeting in December 2010 their view had changed:

> *"The FSA was minded to adopt the position taken by the European Commission and others, that food obtained from the descendants of clones of cattle and pigs does not require authorisation under the novel foods regulation*." [v]

This about turn by the FSA was apparently due to *"current and new evidence from ACNFP, [that] there are now no food safety grounds for regulating foods from the descendants of cloned cattle and pigs".*[vi]

The FSA say that no food from the offspring of cloned cattle has entered the food chain since August 2010, and no application under the Novel Food Regulations has been made for either milk or meat from the current batch of cloned offspring in the UK. However, the problem has not gone away and may come to a head as the cloned animals become capable of producing milk or if farmers decide to bring their milk or meat to the market – the Government (with backing from the FSA) have stated clear opposition to these foods being labelled as the products of cloning, so consumers won't be able to choose to avoid them.

What is cloning?

Cloning is a process to produce offspring which are close to being genetically identical to an ancestor. It does not involve normal sexual reproduction. An unfertilised ovum cell is removed from a selected adult female and the nucleus is removed and replaced with the nucleus of a body cell from the another animal (normally one which has a characteristic which is desirable, such as high milk yield). This cell is then subjected to an electric stimulation to re-programme the genes so they can produce the full range of cells needed for the development of an embryo (eg, liver, brain and skin cells). Once re-set in this way the cell is implanted into a surrogate mother to grow the embryo and eventually give birth as with a normal pregnancy. In pigs the process of implantation involves surgical procedures, but not in cattle.[vii] The process of cloning in this way is known as the somatic cell nucleus transfer (SCNT) technique.

Strictly speaking clones can never be a perfect copy of their ancestor because factors other than genes impact on the final genetic make-up of the offspring. These include:

- Mitochondrial DNA comes from the egg donor and not the cell of the donor of the nucleus.
- Gene expression is not just controlled by the DNA but also by DNA modifications, chromatin structure and the presence of small RNAs (these changes are the basis of epigenetic mechanisms).[1]
- The eventual animal is the product of millions of cell divisions from the single ovum that are subject to DNA mutations and phenotypical differences.
- Development of some organs, such as the brain and immune system, continues after birth and therefore difference will occur compared with the donor nucleus.

Cloning is another step up in the intensive breeding of farm animals that crosses carefully selected males and females in order to produce high-yielding or high-performance offspring. The use of artificial insemination has meant that individual prize bulls have been able to father thousands of offspring on many farms. Beef and dairy cows, chicken and pigs have all been subjected to such highly selective breeding programmes, often with serious implications for the welfare of the animals.

Cloning could also lead to a smaller gene pool than is a already used in selective breeding programmes, leading to increased susceptability to disease or other undesirable results. Many dairy cow breeders have recognised that selective breeding has already begun to have an deleterious impact on the animals without cloning. Life expectancy, reproductive, skeletal and general health problems have all occurred. Some cattle breeders are now introducing different breeds to address these problems brought about by highly selective breeding.

[1] Epigenetics is the study of changes in phenotype (appearance) or gene expression caused by mechanisms other than changes in the underlying DNA sequence.

Why clone?

Cloning is said to enable animal breeders to keep the very best genetic characteristics of an animal without the need to fertilise an egg with sperm and mix two sets of chromosomes, which may mean some desired characters are lost from the offspring. Thus characteristics, like very high milk yield, can almost be guaranteed in the clone (if it survives to adulthood, see below). The economic pressure to produce food at the lowest possible cost encourages farmers and breeders to try cloning, although the vast expense of cloning itself may not make this achievable (see more below).

Who is cloning?

Although the first ever cloned animal, Dolly the sheep, was cloned and born in Scotland, most commercial cloning is mainly taking place in cattle and pigs in the US. Cloning has also taken place in Japan, China and Argentina. Pet cloning is also permitted in the US, and the first commercially cloned kitten was born in 2004.[viii]

Some experimental cloning is taking place in the EU, but commercial cloning has not been given the go ahead. Embryos and semen from clones and their offspring are imported from the US without full traceability. The EU is currently considering whether commercial cloning should be permitted in Europe, but the European Parliament voted in July 2010 for the Commission to ban the sale of products from clones and their offspring and introduce an immediate moratorium until that ban can be put in place.[ix]

Problems with cloning

Food safety

The food safety of products from cloned animals and their offspring is not fully resolved because of the lack of data and subsequent analysis. The European Food Safety Agency (EFSA) has published a scientific opinion on the food safety, animal health, animal welfare and environmental implications of animal clones. The ethical issues involved in cloning were dealt with by the European Group on Ethics in Science and New Technologies (see below).

EFSA's opinion highlighted the lack of scientific data on cloning:

> *"Cloning by SCNT has been applied to several animal species. Based on current knowledge and given the data available* ***it was only possible to make a risk assessment on clones of cattle and pigs and their progeny…Uncertainties in the risk assessment arise from the limited number of studies available****, the small sample sizes investigated and the absence of a uniform approach to allow all the issues relevant to this opinion to be addressed."*

Despite the acknowledged lack scientific data, the EFSA opinion[x] stated:

> *"Based on current knowledge, and considering the fact that the primary DNA sequence is unchanged in clones, there is no indication that differences exist in terms of food safety between food products from healthy cattle and pig clones and their progeny, compared with those from healthy conventionally-bred animals."*

And

> *"…none of the studies mentioned has identified differences outside the normal variability in the composition of meat (cattle and swine) and milk (cattle) between clones or clone progeny, and their comparators. In addition no novel constituents have been detected in products from clones or their progeny. However, it should be acknowledged that the data base is limited."*

The opinion is actually based on three studies: a comparison of 37 cloned cows and 38 normal cows over three years; five pig clones and 15 comparator animals; and 242 cloned offspring of four cloned boars compared to 162 control pigs.

EFSA acknowledge that in the cattle study "slight changes" in the composition of milk and muscles (fatty acid composition and a slight increase of stearoyl-CoA desaturase[2]), but these were within normal variations expected in livestock. EFSA report that the smaller pig study showed, *"No biologically relevant differences in fatty acid, amino acid, cholesterol, mineral and vitamin values."*

The larger pig offspring study found, "*Three individual values of the offspring were outside the control range."* In all the studies findings were, "*No novel constituents have been detected in products from clones or their progeny."*

These results leave some room for doubt about the comparability of food from cloned and conventional sources.

Scientific uncertainty also exists over toxicity, allergenicity and genotoxicity of products from cloned cattle and pigs. The model of feeding milk and meat to laboratory rats is not the ideal comparator for human health effects because the rodents do not naturally ingest milk in large quantities.

EFSA also say that there is no evidence that cloning can activate "silent genetic pathways" in domestic animals, which could lead to the generation of novel products in cloned meat or milk. Metabolic disorders in adults due to changes in the number and function of mitochondria in cloned cells or the transmissions of mitochondrial dysfunction were not ruled out by EFSA.

The conclusions on food safety in EFSA opinion failed to adopt a precautionary approach justified by the scientific uncertainty and shortage of data on cloned products and those from cloned offspring. Their conclusions on food safety were:

- *"There are unlikely to be significant differences between healthy clones in the physiological parameters measured from their healthy conventional counterparts (see Chapter 4).*
- *"Differences outside the normal variability are unlikely as regards the composition and nutritional value of meat (cattle and swine) and milk (cattle) between healthy clones or clone progeny and their healthy conventional counterparts.*
- *"Toxicological and allergenic effects related to the consumption of food products from clones and their progeny are unlikely."*

The UK's Advisory Committee on Novel Foods and Processes gave similar advice, although they did add, "*Further evidence is required on how the rearing of animals in different environments may affect the meat and milk."* [xi] This refers to possible epigenetic effects of the environment on the function of genes in clones and their offspring. These were noted by EFSA.

Following these sets advice, the FSA Board advised UK Ministers[xii] in December 2010 that:

- the marketing of products obtained from cloned animals should be subject to authorisation as novel foods.
- based on the current evidence, there are no food safety grounds for regulating foods from the descendants of cloned cattle and pigs.
- the FSA is minded to adopt the position taken by the European Commission and others, that food obtained from the descendants of clones of cattle and pigs does not require authorisation under the novel foods regulation.
- the Board will seek the views of interested parties in relation to this change of position and will return to this matter in the future if new information makes this necessary.

[2] stearoyl-CoA desaturase –is a key enzyme in fatty acid metabolism

However none of these decisions reflects the findings of the ethics committee (see below).

Animal welfare
EFSA's scientific opinion confirmed many problems for the health and welfare of clones and their surrogate mothers:

> "*The health and welfare of a significant proportion of clones … have been found to be adversely affected, often severely and with a fatal outcome…The occurrence of late gestational losses, dystocia and large offspring in SCNT is likely to affect the welfare of the surrogate dams carrying calf clones."*

EFSA list the following as causing health and welfare problems:

- High mortality of clones in the early stages of life due to cardiovascular failure, respiratory difficulties and immune system deficiencies.
- Increased pregnancy failure.
- Increased size of cloned offspring, making Caesarean sections more frequent in cattle carrying a clone than with conventional pregnancies.

The European Group on Ethics in Science and New Technologies raised serious ethical concerns about the impact on animal welfare (see below).

The UK Government view is, "Existing EU legislation is considered sufficient to deal with welfare issues." In fact legislation covering clones once they leave the experimental stage and are used for farming purposes is very limited.

The only relevant provision is paragraph 20 of the Annex to EU Directive 98/58 Concerning the protection of animals kept for farming purposes, which states, *"Natural or artificial breeding or breeding procedures which cause or are likely to cause suffering or injury to any of the animals concerned must not be practised."*

This would hardly be adequate to deal with the complex health problems arising from cloning to the clone and surrogate mother.

Further down the wrong road
Selective breeding of cattle, pigs and poultry has been practiced for centuries. However in recent times technological developments and economic pressure to produce higher-yielding or faster-growing animals or birds has pushed many breeds beyond their metabolic and physical limits. In very high-yielding dairy cows life expectancy is falling, reproductive, lameness and disease problems are all increasing.[xiii] In pigs highly selective breeding brings skeletal and reproductive problems and lower disease resistance.[xiv] In broiler chickens heart failure, brittle bones and lameness are common problems.[xv]

Cloned animals will be selected from the same small groups of high-yielding animals. A move away from intensive breeding in dairy cattle has been called for already, for example:

> *"The economic future of the dairy industry is related directly to public acceptance of its breeding and production practices. It is important to the dairy industry that welfare problems should be addressed before there is widespread condemnation of breeding and management practices. A new breeding goal aimed at improving fitness and tolerance of metabolic stress is necessary to prevent the decrease in the quality of life of dairy cows and instead, perhaps, enhance it."* [xvi]

Cloning takes us in the opposite direction. It is another step in selective breeding that could lead to a reduction in genetic diversity within animals used in intensive production systems at a time when

many are calling for more cross breeding and diversity of breeds to combat metabolic disorders and disease.

Ethical blackspot

The debate about cloning raises many ethical issues. These have been examined by The European Group on Ethics (EGE) in Science and New Technologies to the European Commission. Their 2008 report[xvii] concluded:

> *"Considering the current level of suffering and health problems of surrogate dams and animal clones, the Group has doubts as to whether cloning for food is justified…At present, the EGE does not see convincing arguments to justify the production of food from clones and their offspring*."

The EGE listed many issues raising ethical concerns about cloning techniques:

- The health and welfare of cloned animals (and for their offspring).
- Human health and wellbeing (including food safety and food security).
- The environmental impacts.
- Using the animals for humans' purposes.
- Animal "integrity" ("animal rights"?).
- Industrialisation of agriculture.
- Public perception.
- Social desirability.
- Social acceptance.
- Consumers' rights.

Cloning is expensive, so it is highly unlikely that clones themselves will find their way into the food chain. Clones will be used to produce sperm and embryos to be sold on for breeding high performing offspring. Semen and embryos will be sold at a premium price that reflects the expense of developing them.

Many supermarkets have already signalled they will not stock milk from clones or their offspring, so farmers run the risk of market rejection. Labelling of such products, given the deep public opposition (see below), would make it even more risky to invest in cloning. The long-term health of cloned offspring is not certain, and this only adds to the financial uncertainty.

Genetically modification and cloning

Although none of the embryos imported in the UK so far have been genetically modified, its commercial use in the future cannot be ruled out. Cloning has already produced a transgenic lamb[xviii] genetically engineered to produce human coagulation factor IX[3] in its milk.

Public opinion

Opinion surveys on cloning show strong opposition among the public in the UK. The FSA's own opinion research[xix] showed a wide range of concerns amongst participants including:

- *"Most participants felt animal cloning represents a quantum leap from 'giving mother nature a helping hand' to 'interfering with mother nature'.*
- *"Participants struggled to identify any convincing benefits of the technique.*
- *"As participants learned about the current low efficiency rates of the cloning method they became increasingly concerned about the implications for animal welfare. This became a*

[3] A protein in blood plasma that participates in and is essential for the blood-clotting process. A deficiency of this factor is the cause of Christmas disease.

significant factor behind their reluctance to accept food derived from clones and their offspring.

- *"There was a call for all food derived from cloned animals and their offspring to be clearly labelled - not just from a food safety perspective but to enable consumers to make an informed choice."*

A poll carried for *Which?* in 2008 found 80% of respondents would prefer to avoid products from clones.[xx]

Clear need for labelling

Given that decisions to ban food from clones and their offspring appear to be lagging behind the arrival of such products on the market, there is a clear and urgent need to address labelling.

Many bodies, including The European Group on Ethics[xxi] and the Advisory Committee on Novel Food and Processes[xxii], express the opinion that products from cloned animals and their offspring should be labelled, saying, "*Consumers may want to see effective labelling of products from clones and their offspring*." (ACNFP)

The FSA's own opinion research supported full labelling (see above).

This would clearly require that clones, their offspring, products from both and cloned embryos and semen would have to be fully traceable.

However the UK Government has taken an opposite view. Defra Minister Jim Paice told the Environment, Food and Rural Affairs Committee, saying, *"It would be very difficult to apply,"* and saying he would, "*Find it very difficult to conceive a value to it.*" [xxiii] The FSA position is that they do not see a need for the products from cloned offspring to be labelled on food safety grounds.[xxiv]

People who have ethical and moral reasons to avoid products from the offspring of cloned animals will only be able to do so if a full traceability and labelling scheme is in place. Offspring of clones can only exist if the cloning has taken place in the first place, so food from them is the direct product of the process so many have clear difficulty justifying.

In the absence of an EU-wide ban on cloning, offspring and food products from them, people would only have their ability to boycott such products as a means of registering their concern – and that means labelling.

Write to your MP and MEPs

You can find who your MP and MEPs are at www.theyworkforyou.com/.

Please ask your MP to press the Government to support an EU-wide ban on:

- cloning and the import of clones.
- the use of cloned animals and their offspring on-farm.
- the import of the offspring, semen and embryos of clones.
- the sale of meat and milk from both clones and their offspring.

Feel free to express your concern on grounds of animal welfare of clones and surrogate mothers, ethics and potential risk to health of consumers.

Please ask your MEPs to support all moves to press the Commission to come forward with the ban voted for by the Parliament in July 2010, and for the requested immediate moratorium on all products from clones and their offspring until that ban can be enacted.

Please send copies of any responses you get to eve@gmfreeze.org.

[i] Poulter, S. “Clone farming has arrived”. *Daily Mail.* 10 January 2007. See www.dailymail.co.uk/news/article-427714/Clone-farming-arrived.html

[ii] Poulter, S. “100 clone cows on UK farms: Shocking evidence of how 'super calves' have secretly spread into our food system”. *Daily Mail*. 3 August 2010. See www.dailymail.co.uk/news/article-1299773/100-clone-cows-UK-farms-How-Super-calves-spread-food-system.html#ixzz1B1pm8rPW,

[iii] Poulter, S. “Clone beef's been on sale: After clone milk, now food watchdogs launch an investigation into illegal meat sold in British shops”. *Daily Mail*. 4 August 2010. See www.dailymail.co.uk/news/article-1300097/Clone-beefs-sale-After-clone-milk-investigation-launched-illegal-meat.html

[iv] Food Standards Agency, 2007. “Cloned offspring novel food, says Agency”. See www.food.gov.uk/news/newsarchive/2007/jan/clonedoffspring

[v] Food Standards Agency, 2010. Draft minutes of FSA open Board meeting held on 7 December 2010.

[vi] Food Standards Agency, 2010. Draft minutes of FSA open Board meeting held on 7 December 2010.

[vii] The European Group on Ethics in Science and New Technologies to the European Commission, 2008. *Ethical aspects of animal cloning for food supply - Opinion No 23.* See http://ec.europa.eu/european_group_ethics/publications/docs/opinion23_en.pdf.

[viii] American Anti vivisection Society, undated. *Pet cloning: Background.*

[ix] European Parliamant, 2010. “MEPs reiterate opposition to food from cloned animals”. See www.europarl.europa.eu/en/pressroom/content/20101019IPR88128/html/MEPs-reiterate-opposition-to-food-from-cloned-animals

[x] European Food Safety Agency, 2008. *Scientific Opinion of the Scientific Committee Food Safety, Animal Health and Welfare and Environmental Impact of Animals1 derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals*. (Question No EFSA-Q-2007-092) EFSA Journal 767; 1-49. See www.efsa.europa.eu/en/efsajournal/doc/767.pdf.

[xi] Food Standards Agency. *Animal cloning for food production*. Paper to Board 7 December 2010.

[xii] Food Standards Agency, 2010. Draft minutes of an FSA open Board meeting held on 7 December 2010.

[xiii] Euro Group for Animals. *Areas of Concern 2010*. See www.eurogroupforanimals.org/pdf/EurogroupForAnimals-AreasOfConcern2010.pdf.

[xiv] CIWF, 2006. *Animal Welfare Aspects of Good Agricultural Practice*. Section 3, Chapter 10, “Selective breeding”. See www.ciwf.org.uk/includes/documents/cm_docs/2008/g/gap_chapter_10.pdf.

[xv] Euro Group for Animals. *Areas of Concern 2010*. See www.eurogroupforanimals.org/pdf/EurogroupForAnimals-AreasOfConcern2010.pdf

[xvi] Oltenacu, PA and Algers, B. 2005. “Selection for increased production and the welfare of dairy cows: are new breeding goals needed?” *Ambio*, 34: 311-315.

[xvii] The European Group on Ethics in Science and New Technologies to the European Commission, 2008. *Ethical aspects of animal cloning for food supply - Opinion No 23.* See http://ec.europa.eu/european_group_ethics/publications/docs/opinion23_en.pdf.

[xviii] Schnieke, AE, Kind, AJ, Ritchie, WA, Mycock K, Scott, AR, Ritchie, M, Wilmut, I, Colman, A and Campbell, KHS, 1997. “Human Factor IX Transgenic Sheep Produced by Transfer of Nuclei from Transfected Fetal Fibroblasts”. *Science* 19: Vol. 278 no. 5346 pp. 2130-2133.

[xix] Creative Research, 2008. *Animal Cloning and Implications for the Food Chain Findings of Research Among the General Public*. See www.food.gov.uk/multimedia/pdfs/clonereport.pdf.

[xx] *Which?*, 2008. “Which? food cloning statement”. See www.which.co.uk/about-which/press/press-releases/campaign-press-releases/food-and-health/2008/07/which-food-cloning-statement/.

[xxi] The European Group on Ethics in Science and New Technologies to the European Commission, 2008. *Ethical aspects of animal cloning for food supply - Opinion No 23.* See http://ec.europa.eu/european_group_ethics/publications/docs/opinion23_en.pdf.

[xxii] Food Standards Agency. *Animal cloning for food production*. Paper to Board 7 December 2010.

[xxiii] EFRA Committee, 2010, Uncorrected evidence the use of cloned animals and their offspring in agriculture. Wednesday, 15 December 2010. Mr James Paice MP, Lord Rooker and Mr Tim Smith. See www.publications.parliament.uk/pa/cm201011/cmselect/cmenvfru/uc692-i/uc69201.htm.

[xxiv] Food Standards Agency, 2010. Draft minutes of an FSA open Board meeting held on 7 December 2010.