Animal cloning

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Since 1997, when the first mammal was cloned from an adult cell at the Roslin Institute in Edinburgh, a number of commentators have raised concerns about the implications of animal cloning for food safety, food supply and animal welfare. Others stress that animal cloning has the potential to improve animal welfare and farming productivity. It may even be used in the conservation of endangered species.

The current preferred method of cloning, somatic cell nuclear transfer (SCNT), has a number of drawbacks. Cloned animals often suffer significant health problems compared to conventionally bred animals. The technology therefore has implications for animal welfare. There do not appear to be food safety issues with this technology.

EU Regulations mean that foods derived from cloned animals need to be scientifically assessed and specifically licensed. There is a debate about whether regulations apply to the offspring of clones. In the UK, the Food Standards Agency (FSA) stated that products from the offspring of cloned animals are also novel foods and therefore they needed to be specifically assessed and licensed. The FSA is reviewing this position.

European Commission proposals may ban the use of animal clones in food, although controls would not apply to the offspring of clones. European legislation is likely to come forward in 2011. The Government does not believe that a ban is justified.

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1 What is cloning?

The term cloning normally refers to the creation of an organism (the clone) that is a genetic copy of another organism (the donor). A common method of cloning is somatic cell nuclear transfer (SCNT), where genetic material is transferred from the nucleus of a donor adult cell to an egg whose nucleus, and thus its genetic material, has been removed. The reconstructed egg containing the DNA from a donor cell is treated to stimulate cell division. Once the cloned embryo reaches a suitable stage, it is transferred to the uterus of a host where it continues to develop until birth. The surrogate mother needs to be as close as possible, in terms of species, to the donor organism in order for the pregnancy to occur normally.[1]

Clones are not exactly identical to the donor, or each other. There may be a number of differences due to mutations in the DNA of the somatic cells and due to differences in the expression of genes. In addition, the clone will have mitochondrial DNA from the donor egg in its cells—this may give rise to nuclear-mitochondrial incompatibilities, which can lead to death. So far, around a dozen animal species have been cloned via SCNT.[2]

One of the principle aims of cloning is to increase the number of individuals in a population that have certain desirable characteristics. These characteristics might include improved productivity, improved animal health, or resistance to disease. Animal cloning could also be used to repopulate endangered or extinct animals, or animals that are difficult to breed.

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1 DEFRA, *Animal welfare: Government response to FAWC's report on the implications of cloning for the welfare of farmed livestock*, 2003

2 European Group on Ethics in Science & New technologies to the European commission, *Ethical aspects of animal cloning for food supply*, 2008

1.1 Dolly the sheep

The cloning of plants is a common horticultural technique that has been used for thousands of years. While the first vertebrate to be cloned was a tadpole in 1952, it was not until 1996 that the first mammal was cloned from an adult cell. This occurred at Edinburgh's Roslin Institute when Dolly, a cloned sheep, was born.

Dolly was created using SCNT, and lived until the age of six when she died from progressive lung disease and severe arthritis in February 2003.[3] [4] Dolly bred normally on two occasions with a Welsh mountain ram, giving birth to Bonnie in April 1998 and three lambs in 1999.[5]

The Human Genome Project explained the significance of Dolly:

> Dolly's success is truly remarkable because it proved that the genetic material from a specialized adult cell, such as an udder cell programmed to express only those genes needed by udder cells, could be reprogrammed to generate an entire new organism. Before this demonstration, scientists believed that once a cell became specialized as a liver, heart, udder, bone, or any other type of cell, the change was permanent and other unneeded genes in the cell would become inactive. Some scientists believe that errors or incompleteness in the reprogramming process cause the high rates of death, deformity, and disability observed among animal clones.[6]

2 Applications of cloning

2.1 Genetic enhancement

Cloning could be used to increase the number of animals in a population that display certain characteristics—for example, a cow that efficiently produces milk could be cloned to create other cows with the same characteristic. This superior characteristic could then be passed onto the offspring of the cloned cows. Other characteristics that might be selected include robustness, disease resistance and reduced aggression.[7] The European Food Safety Authority (EFSA) said:

> Being a genetic copy of its cell donor, the clone has similar potential productive performances. It should be stressed that besides quantitative/qualitative traits of animal products like milk volume or lean meat, today's selection strategies take into account other relevant parameters, including resistance to the common pathologies (e.g. mastitis, other infectious and parasitic diseases), fertility, mentality and others related to the general robustness of the animal (e.g. lameness). Breeding out such complex traits using the traditional selection schemes is time consuming and might turn out to be complicated and the success is not certain. Cloning could contribute to address these issues in a more rapid manner. The clones are then multiplied using conventional breeding methods.[8]

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3 "Ten years on, has cloning dream died?", *New Scientist*, 1 July 2006

4 I. Wilmut et al, "Viable offspring derived from fetal and adult mammalian cells", *Nature,* vol 385, 27 February 1997

5 "Is Dolly old before her time?", *BBC News*, 27 May 1999

6 "Cloning fact sheet", *Human Genome Project*, 2009

7 Defra, *Government response to the FAWC report on the welfare implications of animal breeding and breeding technologies in commercial agriculture*, 2004

8 European Food Safety Authority, *Update on the state of play of animal cloning*, 2010

Friends of the Earth argued that "creating a livestock population that is genetically identical due to cloning is not sustainable because it reduces genetic diversity, putting the entire livestock population at risk for disease".[9] However, the EFSA rejected this argument. It said:

> [I]f used appropriately, in connection with suitable management measures, cloning is not expected to adversely affect the genetic diversity among domestic species (EFSA 2008). It is appropriate to recall that the last century has seen a dramatic reduction of animal species, mostly large mammals, mainly caused by human-related activities. The obvious consequence of such phenomenon is the progressive contraction in biodiversity. Paradoxically, this problem does not involve wild species only, but also domestic ones, often local breeds perfectly adapted to particular ecotypes, being substituted by a few more productive phenotypes. According to the Food and Agriculture Organization of the United Nations, 1491 (around 20 %) of the reported 7616 livestock breeds are classified as being critically endangered, critical-maintained, endangered, or endangered-maintained (FAO, 2007).[10]

2.2 Food

If productive animals can be cloned and their characteristics passed on to their offspring, animal cloning may have the potential to increase food supply. This issue is one of the most controversial aspects of animal cloning, partly due to fears about the safety of such food.[11] Food from cloned animals has been referred to as 'frankenfood' in the press.[12]

While animal cloning does not play a large role in current food systems, the Foresight Future of Food and Farming Report indicated that the technology might have a role to play in meeting future world food security. It said that when appraising new technologies in the food system:

> ● New technologies (such as the genetic modification of living organisms and the use of cloned livestock and nanotechnology) should not be excluded a priori on ethical or moral grounds, though there is a need to respect the opinions of people who take a contrary view.
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> ● Investment in research on modern technologies is essential in the light of the magnitude of the challenges for food security in the coming decades.
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> ● The human and environmental safety of any new technology needs to be rigorously established before its deployment, with open and transparent decision-making.
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> ● Decisions about the acceptability of new technologies need to be made in the context of competing risks (rather than by simplistic versions of the precautionary principle); the potential costs of not utilising new technology must be taken into account.
>
> ● New technologies may alter the relationship between commercial interests and food producers, and this should be taken into account when designing governance of the food system.
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> ● There are multiple approaches to addressing food security, and much can be done today with existing knowledge. Research portfolios need to include all areas of science and technology that can make a valuable impact – any claims that a single or particular new technology is a panacea are foolish.

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9 *What it Means to Eat Meat and Dairy from Cloned Animals*, Friends of the Earth, viewed 14 December 2010

10 European Food Safety Authority, *Update on the state of play of animal cloning*, 2010

11 "Son of Frankenfood? The food industry", *The Economist*, 19 January 2008

- Appropriate new technology has the potential to be very valuable for the poorest people in low income countries. It is important to involve possible beneficiaries in decision-making at all stages of the development process.[13]

Regulation

Foods produced from cloned animals fall under European Regulation (EC) No 258/97 (the 'Novel Foods Regulation'). A novel food is defined as a food or food ingredient that did not have a significant history of consumption within the European Union before May 1997. Under the regulation, meat, milk or eggs from cloned animals have to be subjected to a safety evaluation and approved by all European Union (EU) Member States as a novel food before they could be legally marketed. To date no applications for the authorisation of food from cloned animals or their offspring have been made.

The European Commission does not believe that the Novel Foods Regulation should apply to the offspring of clones, if they have been bred normally. However the UK body charged with evaluating novel foods, the Food Standards Agency (FSA), had interpreted the regulation to include offspring.[14] [15] This meant that products from clone offspring could only be sold in the UK if they had been scientifically assessed and specially licensed.[16]

The FSA is seeking views on whether to "adopt the position that foods obtained from the descendants of clones of cattle and pigs do not require authorisation under the novel foods regulation… in line with the current view of the European Commission and others". Before making a change the FSA sought views from interested parties by 10 February 2011.[17] An announcement is expected soon.

Changes to regulation—potential ban on clones

Although no applications for the use of cloned animals in food have been made, in January 2008 the European Commission presented a proposal to update novel foods rules.[18] The European Parliament and Council could not agree on a final text, mainly due to disagreements on food from cloned animals and nanotechnology. The different institutions have found it hard to agree on the extent to which cloning should be regulated.[19]

In March 2010 the European Council stated that the regulations should apply to the offspring of clones.[20] The European Parliament called "for a total ban on the cloning of animals; on imports of live clones and their offspring; on the marketing of food from clones and their offspring; and on the import of semen and embryos of clones".[21] The European Commission disagreed with aspects of this.[22]

In order to break the deadlock the European Commission produced a report to inform the debate on how to proceed. It recommended that there should be a temporary ban on the use

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12 ibid
13 *Foresight: The Future of Food and Farming*, Government Office for Science, 2011
14 *The history of the FSA*, Food Standards Agency, viewed 14 December 2010
15 Food Standards Act 1999
16 *FSA statement on cloned animals and their offspring*, Food Standards Agency, 2 August 2010
17 *Food from descendants of cloned animals*, FSA, 13 January 2011
18 *Q&A on the novel foods regulation update*, European Parliament, 19 October 2010
19 *Commission to allow imports of cloned food*, Euractiv, 20 October 2010
20 European Commission, *Report from the Commission to the European Parliament and the Council on animal cloning for food production*, 19 October 2010
21 ibid
22 COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, *COM(2010)124 final*, 24 March 2010

of clones, but that the ban should not apply to clone offspring. It said that "banning imports of food from the offspring of clones… is unnecessary and would disrupt global trade"[23]:

> The European Commission has today announced that it will propose a temporary suspension of animal cloning for food production in the EU. The Commission also plans to suspend temporarily the use of cloned farm animals and the marketing of food from clones. All temporary measures will be reviewed after five years. The establishment of a traceability system for imports of reproductive materials for clones, such as semen and embryos of clones is also envisaged. The system will allow farmers and industry to set up database with the animals that would emerge from these reproductive materials.
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> Commissioner in charge of Health and Consumer Policy, John Dalli, said: *"The Communication adopted today is a response to calls from the European Parliament and Member States to launch a specific EU policy on this sensitive issue. I believe that the temporary suspension constitutes a realistic and feasible solution to respond to the present welfare concerns ".* The commissioner underlined that the proposal will not suspend cloning for uses other than food, such as research, conservation of endangered species or use of animals for the production of pharmaceuticals. In conclusion, he expressed the hope that *"with the adoption of this report, the Council, the Parliament and the Commission will move forward on the proposal on Novel Foods which is an important contribution to consumer protection and innovation".*[24]

The Coalition Government rejected the European Commission's proposal, saying that a ban was not justified:

> Following consideration by interested Government Departments and advice from the Food Standards Agency, the Government consider that a ban or a temporary suspension on cloning, the use of clones and the marketing of food from clones is disproportionate in terms of food safety and animal welfare. Insufficient evidence has been provided to justify a ban and any ban would require an impact assessment that demonstrated the need for and benefit of new regulation.[25]

The European Commission is likely to go ahead and publish legislative proposals for the new rules in 2011, but these would still have to be approved by the Council and Parliament.[26]

Safety

A number of food safety bodies have concluded there is no difference between products from clones and animals that are bred normally. Therefore they suggest that there is no particular food safety risk associated with such products.[27] For example, in November 2010 the Advisory Committee on Novel Foods and Processes (ACNFP)[28] found that there was no difference between meat and milk "of conventional animals, clones or their progeny and is therefore unlikely to present any food safety risk":

> The committee noted that:

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23 *Commission to allow imports of cloned food*, Euractiv, 20 October 2010

24 *Commission favours temporary suspension of animal cloning for food production in the EU*, European Commission, 19 October 2010

25 HC Deb, 10 January 2011, c167W

26 *Commission to allow imports of cloned food*, Euractiv, 20 October 2010

27 With certain provisos – see European Food Safety Authority, *Update on the state of play of animal cloning*, 2010

28 The ACNFP is a non-statutory independent body of scientific experts that advises the Food Standards Agency on matters relating to novel foods.

- the evidence showed no differences in composition between the meat and milk of conventional animals, clones or their progeny and is therefore unlikely to present any food safety risk

- the current evidence on the composition of meat and milk is relatively limited, and further evidence is required on how the rearing of animals in different environments may affect the meat and milk

- any potential differences between conventional cattle and the progeny of a clone were unlikely to exist from the second generation onwards

- that consumers may want to see effective labelling of products from clones and their offspring

> In responding to the committee's discussion, Food Standards Agency Chief Scientist Andrew Wadge said: 'In considering this hypothetical application, the ACNFP has confirmed that meat and milk from cloned cattle and their offspring shows no substantial difference to conventionally produced meat and milk and therefore is unlikely to present a food safety risk.
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> 'The FSA Board will discuss this issue at its December meeting. The Board will consider the opinion of the ACNFP, the recent European Commission proposal to ban meat and milk from clones, and any other developments, before providing further advice to ministers.'[29]

The European Food Safety Authority (EFSA) has also found "no indication of any differences in food safety for the meat and milk of clones and their progeny compared with conventionally bred animals":[30]

> [N]one of the studies… 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. [31]

Animal welfare

Animal cloning could improve animal welfare if traits such as robustness and disease resistance were propagated more widely in farm animals. However, there are significant animal welfare concerns about cloning due to the high disease and mortality rate experienced by cloned animals. The EFSA said:

> The health and welfare of a significant proportion of clones, mainly within the juvenile period for bovines and perinatal period for pigs, have been found to be adversely affected, often severely and with a fatal outcome. Epigenetic dysregulation is considered to be the main source of adverse effects that may affect clones and result in developmental abnormalities. The use of SCNT in cattle and pigs, however, has also produced healthy clones and healthy offspring that are similar to their conventional counterparts based on parameters such as physiological characteristics, demeanour

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29 *Cloned meat is safe—hypothetically speaking*, Food Standards Agency, 25 November 2010

30 European Commission, *Report from the Commission to the European Parliament and the Council on animal cloning for food production*, 19 October 2010

31 European Food Safety Agency, *Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals*, 15 July 2008

> and clinical status. The production of clinically healthy clones provides evidence in those cases that the epigenetic reprogramming has taken place successfully.[32]

There are also welfare implications for the surrogate mother of the clone, which "suffer from late gestational losses, more difficult delivery (dystocia) and large offspring".[33] Further to this, there are concerns that highly productive animals might be cloned in spite of any negative health problems they may suffer from.

Due to these welfare concerns the European Group on Ethics in Science and new Technologies, a European Commission advisory body, stated that cloning animals for food supply might not be ethically justified, although it called for more research:

> 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. Whether this applies also to progeny is open to further scientific research. At present, the EGE does not see convincing arguments to justify the production of food from clones and their offspring.[34]

It set out a number of recommendations.

Recent controversy

There was controversy in August 2010 when it was found that the offspring of a cloned cow had entered the UK food chain. The FSA found that 8 embryos produced by a cloned cow were imported to the UK from the US, and that meat from two of these animals, and the meat from a calf of one of these animals, entered the food chain:

> The Agency last week traced animals born in the UK from eight embryos produced by a cloned cow in the US. Four of these embryos were male calves and four were female. All were Holstein animals, a breed mainly used for dairy production.
>
> Since the previous update published on 4 August, the Agency has received assurances from the local authorities that visited the farms, the dairy industry and the farmers involved that no milk from the remaining two dairy cows has entered the food chain. This is in addition to similar assurances received in relation to the other dairy cow, Dundee Paradise.
>
> The fourth female calf died at less than a month old. No meat or products from this young animal entered the food chain and its carcass was disposed of in accordance with the law.
>
> As part of this investigation, the Agency has established that five of the eight animals are known to have had offspring. All of this next generation is too young to be milked or to be used for breeding purposes. However, one animal, a male calf of less than a month old, was slaughtered on 16 June 2010 and meat from this animal entered the food chain. The meat was sold in a butcher's shop in London and will have been eaten.
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> In summary, as part of this investigation, the Agency has established that, in total, meat from three animals has entered the food chain without authorisation under the Novel Food Regulations.

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[32] European Food Safety Authority, *Update on the state of play of animal cloning*, 2010

[33] European Commission, *Report from the Commission to the European Parliament and the Council on animal cloning for food production*, 19 October 2010

[34] The European Group on Ethics in Science and New Technologies to the European Commission, *Ethical aspects of animal cloning for food supply—Opinion No 23*, 16 January 2008

> The Agency can confirm meat from the first animal, Dundee Paratrooper, slaughtered in 2009, was sold to consumers via four butchers' premises in Scotland and a single butcher's shop in north east England. Meat from the second animal, Parable, slaughtered on 5 May 2010 was sent to Belgium. The Agency has informed its equivalent in Belgium of this.
>
> While there is no evidence that consuming products from healthy clones, or their offspring, poses a food safety risk, meat and products from clones and their offspring are considered novel foods and would therefore need to be authorised before being placed on the market [although this position has now changed – see previous section].[35]

2.3 Endangered species

Reproductive cloning could be used to repopulate endangered and extinct species, or species that are difficult to breed. The first clone of an endangered wild animal was born in 2001—a wild ox called a gaur. It died from an infection about 48 hours after birth.[36] The first extinct animal, the Pyrenean ibex, was reported to have been cloned in 2009. The young animal also died soon after birth.[37]

Some conservation biologists and environmentalists are opposed to cloning endangered species. This is because cloning is expensive and funds may better be spent on addressing the underlying causes of biodiversity loss such as habitat loss. In addition, clones would have to be made from genetic material from a large enough number of different individuals in order to create a viable breeding population. Failure to do this would lead to inbreeding and the likely continued decline of the species. Genetic material may not be available from a large enough number of individuals.

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[35] *Summary of investigation on cloned animals*, Food Standards Agency, 11 August 2010
[36] "Cloning fact sheet", *Human Genome Project*, 2009
[37] "Extinct animal cloned for the first time", *New Scientist*, 2 February 2009