



An Insight into cloning farm animals

The Institute of Food Science & Technology has authorised the following Information Statement, date March 2011, which is the first statement on this subject.

Summary

The purpose of this statement is to provide the reader with a brief overview to many of the relevant issues of the current debate. It describes some of the current approaches to cloning together with the implications to the welfare of the cloned animals and their offspring. It considers the regulatory aspects in the UK, the EU and elsewhere and reviews the safety of food from cloned animals. Furthermore the ethics of cloning and the public attitudes to cloning are explored.

Introduction

Animal cloning is about producing an animal that is essentially a copy of the original. This most commonly involves a technique known as somatic cell nucleus transfer (SCNT).

A genetic copy of an animal is produced by replacing the nucleus of an unfertilised ovum (egg cell) with the nucleus of a body (somatic) cell from the animal to form an embryo. The embryo is then transferred to a surrogate dam where it then develops until birth.

Plants have been produced by cloning for many years by taking a small part of a plant and growing another one from it. This has been carried out on a commercial scale for some time with some fruit and vegetables, for example bananas.

The technology has more recently been applied to animals (since 1996 with the birth of Dolly the sheep). Cloning techniques are being used in a number of non-EU countries as well and several food safety authorities have already issued scientific advice on this issue.

Animal breeding and reproductive techniques

Animal Reproductive Techniques (ARTS) have contributed to genetic selection during past decades. These technologies include: artificial insemination from selected sires with its possible extension to sexed semen, oocyte collection from selected dams, embryo selection and transfer from selected genitors, in vitro fertilisation, and the long term storage of gametes and embryos.

In contrast to sexual reproduction, SCNT is intended to reproduce a particular desired phenotype, e.g. disease resistance ability, improved welfare, production or food product quality, with a higher likelihood than sexual reproduction. SCNT allows the replication of the genome of an animal with the intention of producing more animals with a desired trait over a period than might be possible through conventional or assisted breeding. However, as with any other reproductive technique, clones may also develop abnormally and/or possess undesirable traits.

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Somatic cell nucleus transfer (scnt)

In SCNT, the nucleus of a differentiated somatic cell (a non-germ line cell) is transferred, by cell fusion or direct injection, into an oocyte that has had its nucleus removed. In practice, in livestock cloning the whole somatic cell (including the nucleus) is usually transferred. The reconstructed embryo is artificially activated to start its development before implantation into a surrogate dam where it continues to develop and is delivered, in successful cases, as a healthy newborn clone (F0 generation).

Cloned species and cloning efficiency

Since the birth of Dolly the sheep in 1996, SCNT has been applied to livestock and to several other species. Cattle, which are reported to be the animals most frequently used for SCNT, were first cloned in 1998, goats in 1998, pigs in 2000, rabbits in 2001 and horses in 2003. The overall success rate of the cloning procedure to date is low and differs greatly between species. The overall success rate is often measured as the percentage of embryos transferred and the number of live clones born but is often not much above 10%.

Data on clones and their life span

There is no world-wide register of clones; similarly no register is available in individual countries and therefore the number of living clones is difficult to estimate. From information gathered by European Food Safety Authority it is estimated that in 2007 in the EU there were about 100 cattle clones and fewer pig clones alive. The estimated number in the USA is about 570 cattle and 10 pig clones.

Possible use of cloning

With SCNT there is the opportunity to clone those animals that have already shown good productivity, a low incidence of disease and ability to cope with the production environment. As a result there may be an even greater chance that clones will propagate 'good' phenotypes as animals can be selected according to their own individual performance criteria. The primary use of clones (F0 generation) commercially is currently to produce elite animals to be used in breeding, and not to produce animals as a food source.

Animal health

From the available data, mainly concerning cattle, in relation to surrogate dams increased pregnancy failure is observed following the implantation of cloned embryos. Increased frequencies of hydrops, dystocia and consequential Caesarean section are also observed. These effects may affect the future fertility of the surrogate dam. The above-mentioned adverse health effects have all been observed in surrogate dams carrying pregnancies produced by ARTs not involving SCNT, albeit at much lower frequencies.

In relation to clones (F0), although the data are limited and variable, the mortality rate of clones is considerably higher than in sexually produced animals. Increased embryonic and foetal losses occur during pregnancy; increased mortality is observed in the perinatal period for pigs and bovine clones and during the juvenile period for bovine clones; furthermore, a small number of

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studies report an increased mortality in adult clones.

There is evidence of increased morbidity of clones compared with sexually produced animals. A proportion of bovine clones show several altered physiological effects, including Large Offspring Syndrome (LOS), that are observed in cattle clones at a higher frequency than with other ARTs. From the data available, there is often no clear indication of the causes of morbidity and mortality, but it has been found that high levels of husbandry care can enhance the survival and health of clones during early life.

Bovine clones that survive the juvenile period and pig clones that survive the perinatal period appear to be normal and healthy as determined by physiological measurements, demeanour and clinical examination. No long-term effects have been observed on the reproductive ability of clones.

As most clones have not yet reached the end of their natural life span for their species; therefore it is difficult to draw any conclusions on possible effects of SCNT on their longevity. Further, the production life of animals is shorter than the natural life span.

In relation to progeny (F1 generation) it is concluded that from the data available there is no indication of any abnormal effects in those species examined.

Food safety

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.

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. However, as information is limited on the immunological competence of clones, it is unclear, in cases where the pathogen is zoonotic in nature, whether or not the prevalence of such infection or infestation (and related public health risk) is the same as that of the conventionally produced animal.

Ethics and public attitudes

Research sponsored by the FSA in 2007 identified that the key areas of concern among representative groups of the public were: whether food from clones would be safe to eat, standards of animal welfare, the lack of tangible consumer benefits, and mistrust in the motives of the key players involved.

Irrespective of their personal views on its acceptability, participants all identified a number of conditions that they would like to be in place if food from cloned animals (and their offspring)

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were to be marketed, including mandatory labelling.

An EU-wide survey was conducted in July 2008 for the European Commission, primarily by telephone interviews. This showed a significant level of opposition to animal cloning for food production. Fifty-eight percent of respondents said that animal cloning is never justifiable for food production and 83% said that special labelling should be required if food products from the offspring of cloned animals became available in the shops. Nevertheless, 45% of 1000 UK respondents said that they were "somewhat" or "very" likely to buy cloned milk or meat, provided that a trusted source confirmed that they were safe, compared with an average of 35% across all Member States.

Regulatory status

There is no specific legislation that regulates the use of cloning technology in food production in the European Union.

The Food Standards Agency have stated that food from cloned animals falls under the general definition of "novel food" in the EU Novel Foods Regulation (Regulation (EC) 258/97) which defines novel foods as foods that have not been consumed in the EU to a significant degree prior to 15 May 1997, and includes foods from animals obtained from non-traditional breeding practices. Novel foods may only be marketed following a pre-market safety assessment and approval.

The EU have not totally agreed with the UK views. The EU Parliament is supporting the establishment of a new law for food from cloned animals, covering ethical as well as safety issues. Meanwhile, the Council has supported inclusion of cloned animals under the existing Novel Foods Regulation, subject to future review.

The wording of the current Novel Foods Regulation 258/97 is not explicit in respect of descendants of non-traditionally bred animals. However, since 2008 and during the ongoing negotiations for a new Novel Foods Regulation, the European Commission has interpreted the regulation to apply only to products from cloned animals themselves, and not to products obtained from animals that are bred conventionally from clones. According to the Commission's interpretation, milk or meat from the offspring of cloned cattle could be marketed without a safety assessment.

Identification and traceability of clones and their progeny.

The regulation of international trade in animals and breeding materials and the movements of animals within the UK are regulated on the basis of harmonised EU rules. These require that imports to be accompanied by a health certificate, but there is currently no requirement to record on the certificate whether the animal has been obtained using cloning technology. Therefore there is no positive indication that a given animal or embryo is a clone, or the descendant of a clone.

The Department of the Environment, Food and Rural Affairs has departmental responsibility in the UK. They have advised that, under the current regulations, the statutory UK cattle passports

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(used for individual cattle identification and movement) could not be amended to indicate that an animal was a clone. There are no passports or their equivalents for other species. Rules for clones and offspring would be difficult to enforce because currently there is no scientific method available to identify whether an animal is derived from a clone. The only methods of identification and tracing are through informal contacts and breed society information.

Uk government position

The UK Government's general view is that all regulation should be proportionate and enforceable, safeguarding the principles of food safety and consumer choice and guided by the principles of better regulation and evidence-based decision making.

The Government recognises that cloning is not a traditional breeding technique and, as such, accepts that, under the EU Novel Foods Regulation 258/97, approval should be sought before food from clones themselves can be marketed. However, the Food Standards Agency is minded 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. This would be in line with the current view of the European Commission and others.

Eu considerations

The European Commission proposed a temporary ban on animal cloning for food production in the European Union at a meeting of the European Commission, Council and Parliament held in Strasbourg in October 2010. The proposals would also temporarily suspend the use of cloned farm animals and the marketing of food from clones, and establish a tracing system for imported genetic material, such as semen and cloned embryos.

The meeting served as a precursor for discussion between the European Parliament and the Council with the aim of coming to an agreement on whether food from cloned animals (and their offspring) should be covered by novel foods legislation.

However, at the time of writing (March 2011), agreement between the European legislative institutions on the wording of a new novel foods regulation, which would incorporate legal controls on animal cloning and the food products, has not yet been announced.

United states position

In January 2008 after years of detailed study and analysis, the US Food Drug Administration (FDA) concluded that meat and milk from clones of cattle, swine, goats and the offspring of clones from any species traditionally consumed as food are as safe to eat as food from conventionally bred animals. Furthermore there is no basis to require labelling of food products from clones or their progeny.

The FDA says it has insufficient information to reach a conclusion on the safety of food from clones of other animal species, such as sheep.

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Glossary

Animal clones

Animals derived via somatic cell nuclear transfer techniques. The terminology employed in this assessment did not use "cloned animals." The phrase "cloned animals" does not clearly differentiate between the animal serving as the source of genome being propagated, or the animal that has been generated from a particular source. For example, the sentence "That field contains several cloned animals" does not specify whether the animals had been used as a source of material for SCNT or whether they had been generated by that technology.

ARTs

Assisted reproductive technologies.

clone

A group of cells or individuals that are genetically identical as a result of asexual reproduction including nuclear transfer.

cloning

Asexual reproduction of animals using somatic cell nuclear transfer (SCNT).

DNA

Abbreviation for deoxyribonucleic acid; one of the two types of nucleic acids that constitutes the genetic material of most known organisms; usually in double helix form.

dystocia

Abnormal or difficult labour.

embryo

In mammals, the term is restricted to the structure present in the early part of gestation that develops into a foetus.

F0

Abbreviation for the initial parent generation in a multi-generation reproduction study.

F1

Abbreviation for filial generation 1 (first generation). The initial hybrid generation resulting from a cross between two parents.

gamete

A mature reproductive cell capable of fusing with a cell of similar origin but of opposite sex to form a zygote from which a new organism can develop. Gametes normally have haploid chromosome content. In animals, a gamete is a sperm or egg.

genitor

The natural mother or father

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genome

The full set of genes in an individual, either haploid (the set derived from one parent) or diploid (the set derived from both parents).

hydrops

Oedema. Hydrops refers to a set of conditions relating to abnormal fluid accumulation in one or more compartments of the placenta and/or the foetus itself, and are alternatively referred to as hydroallantois, hydramnios or hydrops fetalis, depending on where the oedema occurs.

Large Offspring Syndrome (LOS)

A morphologic syndrome presumably expressed at the molecular and physiological level due to some alterations in embryonic gene expression. Animal clones with LOS may experience difficulties in developing and maintaining the placenta. An LOS foetus is unusually large for its species, has longer than usual gestation periods, and often has immature lungs or heart abnormalities. Kidneys and liver may also be affected.

nucleus

The most conspicuous organelle of a eukaryotic cell; it contains the chromosomes and is the site of genomic DNA replication and or RNA synthesis in the cell.

oocyte

A cell of an animal ovary that undergoes meiosis to form an ovum.

ovum

The female reproductive cell which, after fertilisation, becomes a zygote that develops into a new member of the same species. Also called an egg.

phenotype

The totality of the observable functional and structural characteristics of an organism as determined by its genotype and its interaction with its environment.

progeny

An animal derived from sexual reproduction that has at least one cloned animal as a parent (but could result from two cloned animals mating).

SCNT

Acronym for Somatic Cell Nuclear Transfer. The process of generating a live organism asexually by transferring the diploid nucleus of a somatic cell from a donor animal to the enucleated embryo of a recipient animal.

sexual reproduction

The production of offspring by the fusion of male and female gametes (in contrast to 'asexual reproduction').

somatic cell

Any cell of an organism other than a germ cell.

