Food from Cloned Animals

Background

MPI administers food-related legislation and provides independent policy advice on food and related issues.

MPI applies a risk management framework to ensure any response or regulation is proportional to the risk a situation presents. This is consistent with the New Zealand Biotechnology Strategy which promotes innovation to benefit the wealth, health and environment of New Zealanders.

What is animal cloning?

Animal cloning is a way of producing multiple copies of individual animals. There are a number of forms of animal cloning. The latest and most frequently used technique is termed Somatic Cell Nuclear Transfer. It involves removing the nucleus from an egg or oocyte (recipient) and replacing it with the nucleus of a cell from the animal to be cloned (donor). The donor is usually an animal with desirable traits and, following successful transfer, the cell develops into an embryo which is implanted into a surrogate mother for rearing. The animal born from that embryo will have virtually identical DNA and therefore desirable traits, as the donor animal.

Researchers in New Zealand and around the world have shown the promise of animal cloning in preserving and propagating important animal lines, from elite sires through to endangered species. New Zealand scientists are considered world leaders in many aspects of animal cloning research.

Why use animal cloning?

In farming, animals vary widely in their genetic merit and commercial value. To rapidly multiply animals selected for valuable traits such as milk production, meat quality and healthiness, reproductive technologies such as artificial insemination (AI), embryo transfer and in-vitro fertilisation (IVF) are already used worldwide.

Animal cloning is also a reproductive technology, but unlike artificial insemination, IVF and embryo transfer, cloning allows the direct copying of animals with high genetic or resale value, with less unpredictability than other breeding techniques. The advantage of cloning is that the sex, genetic traits and therefore likely commercial value of the animal are known before birth.

Is cloning used in other industries?

While animal cloning using Somatic Cell Nuclear Transfer is a relatively recent technology, propagation techniques to produce clones have been used in horticulture for hundreds of years with grapes, potatoes, strawberries and many other food plants. Although the same outcome is achieved (producing an organism which is virtually identical to the original), animal cloning is much more ethically and socially complex, with animal welfare considerations.

Are there cloned livestock in New Zealand and do they enter the food supply?

The cloning of livestock animals is still very much at the experimental stage and is restricted to very small numbers of elite breeding stock. AgResearch is the pre-eminent animal cloning research institute in New Zealand and has a voluntary moratorium preventing cloned animals they own entering the food chain.

It is important to note that, at this time, cloning an animal is very expensive and therefore it is not commercially viable to clone animals for direct use as food. Cloned animals are more likely to be used as breeding stock to pass on valuable traits to their offspring, in much the same way artificial insemination and IVF is used. Just like conventionally farmed animals, these clones may enter the food chain at the end of their commercially productive life (although currently this is not the case).

Would food from cloned animals be safe to eat?

If cloned animals were to be used as food, the safety of products from them would be compared with the safety of products from conventionally bred animals. MPI has been looking at this issue for several years and has found no safety reasons to reject food from cloned animals. This position is supported by risk assessments published by the US Food and Drug Administration (US FDA) and by the European Food Safety Authority (EFSA) in 2008.

Scientific studies conducted both internationally and here in New Zealand have concluded that food products from cloned animals and their offspring are as safe as food products from conventionally bred animals.

How will I know if food is from a cloned animal?

Because food from cloned animals is considered as safe as that from conventionally bred animals, there is no safety reason to identify such food differently from conventional food. Labels and warnings on food are typically used to identify ingredients that may cause illness to some people. For example, warning labels for allergens and nutritional information for dietary or health reasons. Contact details of the supplier are required on food labels, however, so for those consumers who wish to know the production history of the food, it is possible to request these details from the supplier.

Food manufacturers can voluntarily label their products with information regarding production status and breeding technique if they wish to meet consumer demand for such labelling. In the case of animal cloning, there is nothing preventing a food manufacturer from making a commercial decision to label their produce as “clone free”. Examples of private labelling regimes that have been developed to meet consumer demand include SPCA-approved free range eggs, organic produce, and the Heart Foundation tick. Such label claims are subject to the provisions regarding false and misleading conduct under the New Zealand Fair Trading Act 1986.

What about the welfare of cloned animals?

New Zealanders are naturally concerned about the care of farmed animals. Although it isn’t the role of MPI to judge issues such as animal welfare or ethics (MPI’s Agricultural Compounds and Veterinary Medicines Group considers animal welfare when administering the ACVM Act) we believe these are important considerations.

New Zealand’s principal animal welfare legislation is the Animal Welfare Act 1999. This covers both farmed and experimental animals, including cloned animals. This legislation is administered by MPI. You can get more information on this from http://mpi.govt.nz/law-and-policy/legal-overviews/animal-welfare.
The negative effects of cloning on the health and welfare of some cloned animals, and the surrogate animals that carry them are well documented. Many of the same abnormalities have been observed, although at a lower frequency, with other related assisted reproductive technologies and occasionally in conventional breeding. These abnormalities may include difficulties giving birth, higher rates of pregnancy loss, increased birth weight and increased rates of post-natal mortality.

In regards to the health of the offspring of cloned animals, a number of studies have shown that the abnormalities observed in some cloned animals are not passed on to sexually reproduced offspring. It is also important to note that only healthy clones would be used for breeding purposes and their offspring would need to be as healthy as conventionally bred animals to be determined as fit for food production.

Listing of Cloned Animals

In June 2010, MPI adopted a regulated control scheme requiring all cloned animals in New Zealand to be listed and identified with a unique cloned animal ear tag. The purpose of the regulated control scheme is to facilitate compliance with any relevant overseas market access requirements that may be imposed by importing countries. The list is maintained by MPI and will form the basis of any assurances that MPI provides to other governments. The listing requirement is not based on food safety concerns and does not extend to the offspring of cloned animals. For more information on the regulated control scheme see www.mpi.govt.nz/dmsdocument/23014

What is MPI's position on animal cloning as a food safety issue, and why?

MPI has been considering this issue for some time, and its policy recommendations are based on completed and peer-reviewed research from many sources.
There is no accepted scientific evidence to suggest that food from cloned animals is any less safe than food from non-cloned animals. On that basis, MPI believes there is no need for specific regulation of such foods, should they ever enter the food chain. As food, they would be subject to general safety requirements under existing legislation.

Research is continuing in this area and MPI will continue to monitor international developments so that if safety issues arise from food derived from cloned animals or their offspring, MPI will consider the need for specific regulation.

Appendix - References

A sample of studies that were available at the time MPI adopted its policy position of food from cloned animals is provide below.

Health status of the offspring of clones

1. Animal Cloning: A Risk Assessment.

FDA DRAFT Executive Summary (2003).

The underlying biological assumption for progeny animals is that generation of the cells that ultimately become ova and sperm naturally resets epigenetic signals for gene expression. This process is thought to effectively "clear" the genome of incomplete or inappropriate signals. The data to confirm this underlying assumption are limited but consistent across species. Cursory reports of normal reproductive function of clone progeny add to the empirical demonstration that clone progeny are as healthy and normal as their conventional counterparts.

2. Review on the current status of the extent and use of cloning in animal production in Australia and New Zealand.

Professor R. F. Seamark (2003).

There are well founded scientific reasons, supported by a mounting body of experimental evidence, to confidently expect that the health profile of any offspring, produced by natural mating, would be entirely normal. Any imprinting anomalies of the cloned parent would be removed during the genetic remodelling process that occurs during gametogenesis (Prather et al., 2003).

There are no scientifically based reasons to view any sexually produced offspring of clones as other than normal in every respect.

3. The safety assessment of foods from transgenic and cloned animals using the comparative approach.

Kelly, L. (2005). Revue scientifique et technique (International Office of Epizootics).

Cloned embryos exhibit abnormal patterns of expression, leading to high rates of embryonic, foetal, perinatal and neonatal deaths, as well as offspring with various abnormalities. Such unintended effects, however, are not unique to cloning. May of the same abnormalities have been observed albeit at a lower frequency, with techniques such as in vitro fertilisation and other related assisted reproductive technologies, which suggests that some of the observed effects may not be solely the result of cloning by nuclear transfer per se, but may also be due to the use of in vitro embryo culture techniques.

4. Risks and benefits related to livestock cloning applications.

French Food Safety Agency Report (2005).

In-depth studies conducted at a molecular level, particularly in mice but also in cattle, indicate that the few differences sometimes observed in clones have disappeared in their progeny. The tests that have long been applied to conventional animals for the marketing of their carcasses should protect consumers from any risk.

5. Animal Cloning: problems and propects.

Wells, D.N. (2005). Revue scientifique et technique (International Office of Epizootics).

Observations indicate that the clone-associated phenotypes are not transmitted to offspring following sexual reproduction, i.e. the offspring of clones are phenotypically normal. This indicates that most epigenetic errors are reset during gametogenesis. Nonetheless, it is still possible that epigenetic errors could be inherited by the offspring of clones.

Conception, pregnancy, parturition and survival are all within the normal ranges, as is the subsequent fertility of these clones. More discriminatory, is the mating of cloned females with cloned males. With these matings in sheep, cattle and mice there is no evidence of placental abnormalities and large birth weights. The most convincing evidence for the lack of transmission of any obvious deleterious or recessive trait has been provided following the mating of cloned male and cloned female mice (derived form XY and XO embryonic stem cells) obtained from the same cell line. The resulting offspring were phenotypically normal.

6. Abnormalities in cloned mice are not transmitted to the progeny

Shimozawa, N., Ono, Y., Kimoto, S., Hioki, K., Araki, Y., Shinkai, Y., Kono, T. and Ito, M. (2002). Genesis 34, 203–207.

Phenotypically normal offspring have resulted following the mating of cloned male and cloned female mice derived from XY and XO embryonic stem cells, respectively, obtained from the same cell line.

7. Progeny of Somatic Cell Nuclear Transfer (SCNT) Pig Clones Are Phenotypically Similar to Non-Cloned Pigs.

Mir, B., Zaunbrecher, G., Archer, G.S., Friend, T.H. and Piedrahita, J.A. (2005). Cloning and Stem Cells 7 (2), 119-125.

The data presented and previous results in mice strongly support the hypothesis that the offspring of clones are similar to the offspring of naturally bred animals, and as such there should not be any increased risks associated consumption of products from these animals.

8. The Health of Somatic Cell Cloned Cattle and Their Offspring

Wells, D.N., Forsyth, J.T., McMillan, V. and Oback, B. (2004). Cloning and Stem Cells 6 (2), 101-110.

AgResearch Ltd., Ruakura Research Centre, Hamilton, New Zealand.

The viability of offspring derived from somatic cell cloned cows following either natural mating or artificial insemination using conventional bulls appears completely normal when managed under standard seasonal New Zealand pastoral farming conditions.

No deaths beyond weaning have so far been encountered with the offspring of clones where the oldest animals are 3 years of age.

In contrast to the cloned generation, the offspring of clones produced following sexual reproduction are phenotypically normal. An increasing body of international data indicates that the major abnormalities in the clones are probably epigenetic in nature and do not appear to be transmitted to offspring even when male and female clones are mated together. However, there is the need for molecular confirmation to distinguish between possible trans-generational epigenetic or genetic effects that will be important to provide confidence in large-scale breeding applications of genetically elite cloned livestock. Moreover, it is a critical requirement to better understand and control the epigenetic reprogramming of somatic donor nuclei following nuclear transfer to develop a robust and safe procedure. This in turn will increase the utility and acceptability of cloning technology and improve the health and viability of the animals produced.

9. Zootechnical Performance of Cloned Cattle and Offspring: Preliminary Results

Heyman, Y., Richard, C., Rodriguez-Martinez, H., Lazzari, G., Chavatte-Palmer, P., Vignon, X. and Galli, C. (2004). Cloning and Stem Cells 6 (2), 111-120.

Mean birth weight in the clone group (50 females) was statistically higher than that of 68 contemporary female controls obtained by artificial insemination. Growth rate was within normal values for Holstein and daily gain was not influenced by the high or low birth weight of clones.

Semen production from three cloned bulls was within the parameters expected for young bull of the same age. Frozen semen from one clone bull was used for an AI trial, resulting in 65% pregnancies, 25 live calves were naturally delivered.

Concerning the offspring of both female and male clones, the phenotypical and clinical observation of the calves in the first week of age did not reveal any clinical abnormality, suggesting that the deviations observed in clones are not transmitted to the progeny.

Milk and/or meat composition of clones and their offspring

1. Animal Cloning: A Risk Assessment.

FDA DRAFT Executive Summary (2003).

States that “the current weight of evidence suggests that there are no biological reasons, either based on underlying scientific assumptions or empirical studies, to indicate that consumption of edible products from clones of cattle, pigs, sheep or goats poses a greater risk than consumption of those products from their non-clone counterparts”.

2. The Health of Somatic Cell Cloned Cattle and Their Offspring.

Wells, D.N., Forsyth, J.T., McMillan, V. and Oback, B. (2004). Cloning and Stem Cells 6 (2), 101-110.

AgResearch Ltd., Ruakura Research Centre, Hamilton, New Zealand.

Milk composition of six 2-year-old cloned Friesian cows in their first lactation was directly compared to the single donor cow from which they were cloned, in her third lactation. Overall, milk composition of the clones was very similar to the donor and comparable to what would be expected to be produced by healthy cows. Some components varied, however, particularly leakage of bovine serum albumin (BSA) into milk and linoleic and linolenic fatty acids, which are greatly influenced by blood lipids, but were still within normal limits.

3. Comparison of milk produced by cows cloned by nuclear transfer with milk from non-cloned cows

Walsh, M.K., Lucey, J.A., Govindasamy-Lucey, S., Pace, M.M. and Bishop, M.D. (2003). Cloning Stem Cells 5, 213–219.

Report (Walsh et al., 2003) comparing the composition of milk produced from cloned animals with milk from non-cloned animals. This report concludes there are no obvious differences in

milk composition produced from cloned cows compared to non-cloned cows (Walsh et al., 2003).

4. Performance of Dairy Cattle Clones and Evaluation of Their Milk Composition.
Norman, H.D. and Walsh, M.K. (2004). Cloning and Stem Cells 6 (2), 156-164.

Milk composition (total solids, fat, fatty acid profile, lactose, and protein) was compared for nuclear-transfer clones (Brown Swiss, Holstein, and Holstein-Jersey cross) with non-cloned cows and literature values; no differences were found for gross chemical composition of milk.

5. Meat and milk compositions of bovin clones.
Tian, X.C., Kubota, C., Sakashita, K., Izaike, Y., Okano, R., Tabara, N., Curchoe, C., Jacob, L., Zhang, Y., Smith, S., Bormann, C., Xu, J., Sato, M., Andrew, S. and Yang, X. (2005). Proceedings of the National Academy of Science USA 102 (18), 6261-6266.

Tested over 100 parameters comparing the composition of meat and milk from beef and dairy cattle derived from cloning to those of genetic- and breed-matched control animals from conventional reproduction. The composition of meat and milk from clones were largely not statistically different from those of matched comparators, and all parameters examined were within the normal industry standards or previously reported values.

6. Evaluation of Meat Products from Cloned Cattle: Biological and Biochemical Properties.
Takahashi, S. and Ito, Y. (2004). Cloning and Stem Cells 6 (2), 165-171.

This study was carried out in Japan as part of Operation of Urgent Research for Utilization of Clone Technology (supported by Ministry of Agriculture, Forest and Fisheries and Japanese Livestock Technology Association (JLTA)).

A series of studies of properties of meat derived from cloned cattle was carried out to collect data for the safety assessment of cloned cattle products. Meat samples obtained from embryonic cloned, somatic cloned and non-cloned cattle were analyzed for chemical composition, as well as amino acids and fatty acids. Digestibility, allergenicity, and mutagenicity of meat were also examined. There were no significant differences in these properties among embryonic cloned, somatic cloned and non-cloned cattle. The analyses and tests revealed that there were no significant biological differences in meat from a non-cloned, an embryonic cloned, or a somatic cloned animal.

This together with the feeding trial discussed below, suggests that the meat from cloned animals studies should not pose any food safety risks not encountered in the products from non-cloned counterpart animals.

7. Report on safety of food products from cloned cattle by the Japan Research Institute for Animal Science in Biochemistry and Toxicology (2002).

Revealed no biologically significant differences in the component analysis testing and feed additive animal testing between products of BNT cloned cattle and SCNT cloned cattle (milk and meat), and the products of ordinary cattle.

Animal Feed Studies

1. Nutritional Value of Milk and Meat Products Derived from Cloning.

Tome, D., Dubarry, M. and Fromentin, G. (2004). Cloning and Stem Cells 6 (2), 172-177.

Paris-Grignon National Agronomics Institute, France.

Preliminary results obtained from rats fed cow's milk or meat-based diets prepared from control animals or from animals derived from cloning did not show any difference between control and cloning-derived products.

2. Evaluation of Meat Products from Cloned Cattle: Biological and Biochemical Properties.

Takahashi, S. and Ito, Y. (2004). Cloning and Stem Cells 6 (2), 165-171.

Involved a 14-week feeding trial in which rats were feed meat from cloned or non-cloned animals. No abnormalities in body growth, general condition, locomotor activity, reflexes, sexual cycle, urinalysis, hematology, blood biochemistry, and histology. This study showed for the first time that the biological/biochemical properties of meat of cloned cattle are similar to those of non-cloned cattle.

Safety of Cloned Animal as Foods

1. Animal Cloning: A Risk Assessment.

FDA Draft Executive Summary (2003).

The current weight of evidence suggests that there are no biological reasons, either based on underlying scientific assumptions or empirical studies, to indicate that consumption of edible products from clones of cattle, pigs, sheep or goats poses a greater risk than consumption of those products from their non-clone counterparts. Edible products from the progeny of healthy clones are likely as safe to eat as similar products from the progeny of non-clone animals, based on underlying biological assumptions, compelling evidence from the mouse model system, and limited data in the species evaluated.

2. Risks and benefits related to livestock cloning applications.

French Food Safety Agency Report (2005).

The very great majority of calves that survive the first few months after birth without any damage have similar lives to those of animals observed by fertilisation. Composition studies conducted on a small number of animals do not reveal any difference between cloned animals and their conventional counterparts.

The data suggests that animals descended from clones can be treated in the same way as their equivalents produced using conventional reproductive methods.

3. Food Consumption Risks Associated with Animal Clones : What should be investigated?

Rudenko, L., Matheson, J.C., Adams, A.L., Dubbin, E.S. and Greenlees, K.J. (2004). Cloning and Stem Cells 6 (2), 79-93.

The Centre for Veterinary Medicine (CVM) of the US FDA developed an approach for evaluating food consumption risk associated with animal clones. The risk assessment developed is a qualitative, comparative analysis, in which outcomes are expressed relative to comparators of know or inferred safety (the comparator being food derived from conventional animals). This approach assumes animal clones from species used for foods and their progeny to be subject to the same regulatory restrictions as conventional animals and that edible products from clones and progeny would also be subject to the same scrutiny as products from their conventional counterparts.

This translates to:

i. Healthy animals are likely to produce safe food, and
ii. If there is no material difference between the foods derived from cloned animals and their conventional alternatives then no additional risk is likely to be countered from the foods from cloned animals.