



# FARM ANIMAL CLONING

A Compassion in World Farming Report – 2010



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# CONTENTS

	<b>PAGE</b>
<b>EXECUTIVE SUMMARY</b>	<b>05</b>
<b>1. INTRODUCTION</b>	<b>09</b>
<b>2. OVERVIEW OF FARM ANIMAL BREEDING</b>	<b>09</b>
2.1 Dairy cattle	12
2.2 Beef cattle	14
2.3 Pigs	15
2.4 Broiler (meat) chickens	16
2.5 Turkeys	18
2.6 Egg-laying hens	18
<b>3. OVERVIEW OF FARM ANIMAL CLONING</b>	<b>20</b>
<b>4. CURRENT STATUS &amp; POTENTIAL FUTURE APPLICATIONS OF FARM ANIMAL CLONING</b>	<b>24</b>
4.1 Replication of elite breeding animals	24
4.2 Production of transgenic animals	25
<b>5. IMPACT OF CLONING ON THE WELFARE OF FARM ANIMALS</b>	<b>26</b>
5.1 Welfare of clones	26
5.2 Welfare of surrogate dams	29
5.3 Welfare of clone offspring	29
<b>6. THREAT TO LIVESTOCK GENETIC DIVERSITY FROM FARM ANIMAL CLONING</b>	<b>31</b>
<b>7. SAFETY OF FOOD FROM CLONED ANIMALS AND THEIR OFFSPRING</b>	<b>33</b>
<b>8. PUBLIC OPINION ON THE CLONING OF ANIMALS FOR FOOD</b>	<b>35</b>
<b>9. CAN THE CLONING OF ANIMALS FOR FOOD BE JUSTIFIED?</b>	<b>37</b>

10. REGULATORY STATUS OF ANIMAL CLONING FOR FOOD IN THE EU	38
11. CONCLUSIONS & RECOMMENDATIONS	40
REFERENCES	44
GLOSSARY	54

# EXECUTIVE SUMMARY

**Cloning of farm animals for food production has become an increasingly controversial topic of debate, especially within the context of responsibilities to the welfare of farm animals enshrined in European legislation and the growing global demand for meat and dairy production.**

This report examines the consequences of cloning for farm animal welfare, highlights key advice on the issue from scientific and ethical advisory bodies and makes recommendations regarding the future of farm animal cloning.

## **Background**

Human beings have been altering the characteristics of farm animals through selective breeding since the beginning of domestication thousands of years ago. In recent decades, selective breeding has been aided by a number of assisted reproductive technologies such as artificial insemination and embryo transfer. Within the globalised animal breeding industry, a small number of large multinational companies control the vast majority of livestock and poultry breeding. Increasingly, specialised breeds have been developed that produce very high yields of a single commodity (such as meat, milk or eggs). The drive to increase productivity has, in many cases, had serious consequences for the health and welfare of the animals.

## **Farm animal cloning**

Cloning presents severe welfare challenges arising directly from its use and also through exacerbation of the problems caused by selective breeding. Many species have been cloned since Dolly the sheep, the first mammal to be cloned from an adult cell, was born in 1996. There are now estimated to be around 6000 farm animal clones worldwide.

Cloning by somatic cell nuclear transfer (SCNT) is fundamentally different from other established assisted reproductive technologies in that it goes beyond assisting in bringing together the egg and sperm and instead bypasses the requirement for fertilization. SCNT produces animals that are genetically unlike any animal found in nature.

Cloning technology is already being used commercially in some parts of the world for the replication of elite breeding animals, mostly cattle, which are used to produce animals farmed for food production.

## **Impact of cloning on the welfare of farm animals**

Cloning has very serious consequences for animal welfare. The large majority of cloned embryos fail to develop to term and, for those that do, a significant proportion of the animals die during or shortly after birth or at various times over the following days and weeks of life. In its 2008 Opinion on Animal Cloning, the EFSA Scientific Committee, which advises the European Commission, concludes:

*“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.”*

The welfare of animals used as surrogate dams is also adversely affected because of the high rates of pregnancy failure, birthing difficulties and Caesarean section. Although the offspring of the clones that do survive do not appear to suffer any obvious abnormal effects, the use of cloning to replicate elite high-yielding animals for breeding is likely to accelerate the spread of livestock genetics associated with poor welfare, leading to greater suffering from health and welfare problems connected with fast growth and high yields.

## **Threat to livestock genetic diversity from farm animal cloning**

The world’s livestock diversity is currently shrinking, with rapid and uncontrolled loss of unique and often uncharacterised animal genetic resources. The global spread of a small number of specialised breeds has been facilitated by the development of artificial reproductive technologies, particularly artificial insemination. Some suggest that cloning technology could be used to replicate individuals of rare and endangered livestock breeds, which could help to preserve genetic diversity. However, the commercial use of cloning to replicate elite breeding animals is likely to further contribute to the erosion of livestock genetic diversity.

Reduced genetic diversity increases the susceptibility of livestock populations to diseases and other risk factors. This raises the possibility of large numbers of animals succumbing to diseases to which they are susceptible, with potentially serious animal welfare, social and economic consequences.

## **Food safety and consumer concerns**

Risk assessments carried out by the European Food Safety Authority and the US Food and Drug Administration suggest that products from cloned animals and their offspring are unlikely to carry increased food safety risks compared with conventional food products. However, there are limited data available and further studies, including long-term trials, are

warranted to rule out any potential food safety issues from the consumption of products from cloned animals and their offspring.

The majority of EU citizens are opposed to animal cloning for food production purposes and state that they would be unlikely to buy products from cloned animals or their offspring, even if they are shown to be safe. If food products from the offspring of cloned animals were to become available, the vast majority of EU citizens believe that special labelling should be required. It is essential that the freedom and rights of consumers to choose to avoid products from cloned animals and their offspring are respected.

A number of farmers' groups have expressed concern at the threat to the image of the EU livestock industry if products from cloned animals or their offspring are permitted to enter the food chain, potentially leading to a loss of consumer confidence and associated economic consequences.

### **Expert opinion and regulation of farm animal cloning**

The European Group on Ethics in Science and New Technologies (EGE), which advises the European Commission, concludes:

***“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... At present, the EGE does not see convincing arguments to justify the production of food from clones and their offspring.”***

On 3 September 2008, the European Parliament adopted a resolution calling for a ban on:

- The cloning of animals for food supply purposes;
- The farming of cloned animals or their offspring;
- The placing on the market of meat or dairy products derived from cloned animals or their offspring;
- The importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat or dairy products derived from cloned animals or their offspring.

The main concerns cited by the Parliament are threats to animal welfare, genetic diversity, consumer confidence and the image and substance of the European agricultural model.

At present, there is no specific EU legislation governing animal cloning, although various pieces of existing legislation will apply to cloned animals and food products from cloned animals under specific circumstances. Council Directive 98/58/EC states:

***“Natural or artificial breeding or breeding procedures which case [sic] or are likely to cause suffering or injury to any of the animals concerned must not be practised.”***

Compassion in World Farming believes that, if the EU were to allow the cloning of animals for food production, this would be in contravention both of Council Directive 98/58/EC and of the Lisbon Treaty, which requires the EU to “*pay full regard to the welfare requirements of animals*” when formulating and implementing EU policies.

There is an urgent need for the development and introduction of specific EU legislation to govern animal cloning and food products from clones and their offspring.

### **Recommendations on Farm Animal Cloning**

Compassion in World Farming calls on the European Union to follow the Parliament’s wishes and implement: 1) a complete ban on the cloning of animals for food production purposes and the farming of cloned animals or their offspring; 2) a complete ban on the placing on the market of meat or dairy products derived from cloned animals or their offspring; and 3) an embargo on imports of cloned animals and their offspring, semen and embryos from cloned animals or their offspring and meat and dairy products derived from such animals.

# 1. INTRODUCTION

Since 1997, animals are legally recognised as sentient beings in the European Union and it is a legal requirement for the EU and its Member States to “*pay full regard to the welfare requirements of animals*” when formulating and implementing EU policies on agriculture and research. The Lisbon Treaty, which came into force on 1 December 2009, extends this commitment to cover policies in other areas, including fisheries and technological development.

With this in mind, this report will examine the current status, potential uses and welfare consequences of the cloning of farm animals, as well as related biodiversity, food safety and economic concerns, and will seek to answer the question whether animal cloning for food production can be justified.

## 2. OVERVIEW OF FARM ANIMAL BREEDING

Human beings have been altering the characteristics of farm animals through selective breeding since the beginning of domestication thousands of years ago. Selective breeding is the process of identifying individuals with particular characteristics and breeding from those animals in order to perpetuate these traits. The primary objective of farm animal breeding has been to increase the yield of meat, milk, eggs, wool or other commodities useful to humans.

In the past it was only possible to make changes relatively slowly using traditional selective breeding methods. In recent decades, selective breeding has been aided by a number of assisted reproductive technologies (ARTs).

The first and most widely used ART is artificial insemination (AI). This involves collecting semen from valuable male animals and using it to impregnate females without the need for the male to be present, hugely increasing the number of offspring that can be sired by an individual male. AI has been used since the beginning of the 20<sup>th</sup> Century and has revolutionised the animal breeding industry, particularly for cattle (Basrur and King, 2005). The development of methods for freezing semen has allowed it to be marketed globally. In recent years, sexed semen has become commercially available. This makes it possible to select the sex of the offspring by using semen which has been processed to separate those

sperm carrying the X (female-producing) chromosome from those carrying the Y (male-producing) chromosome.

By the beginning of the 21<sup>st</sup> Century, AI was used for the insemination of around 110 million cattle, 40 million pigs, 7 million sheep and 0.5 million goats annually (Thibier *et al*, 2004). In cattle, this accounts for 20% of the total global population of breeding females (ranging from more than 60% in Europe to less than 2% in Africa), with dairy breeds accounting for three quarters of the total inseminations (*Ibid.*). In pigs the proportion of sows inseminated artificially in the major pig-producing countries ranges from 85% in the Netherlands and Spain to 10% in Brazil (*Ibid.*)

Embryo transfer is used to increase the number of offspring that can be obtained from valuable female animals and is mostly used in cattle. Embryos for transfer can be produced *in vivo* (inside the body) or *in vitro* (in the laboratory). *In vivo* embryo production using a technique known as MOET (multiple ovulation and embryo transfer) is used for the production of 80% of embryos for commercial purposes worldwide (Schmidt, 2007). Hormones are administered to the donor cow to stimulate the production of multiple eggs (superovulation). The cow is then inseminated and, a week later, the developing embryos are flushed from the uterus. Alternatively, embryos can be produced *in vitro* from immature eggs removed from the ovaries of the donor cow using a procedure known as ovum pick-up (OPU). These eggs are matured and fertilized in the laboratory. The developing embryo is then inserted into the uterus of a surrogate cow for gestation.

The procedures for removing the eggs or embryos from the donor cow and transferring the embryos to the recipient cows are invasive, generally requiring epidural anaesthesia. Cows may be subjected to repeated cycles of MOET or OPU. There is a risk of pain and infection at the epidural injection site, which may extend to the bone and other tissues (McEvoy *et al*, 2006). Arthritis associated with reduced mobility of the vertebrae around the injection site can also occur (*Ibid.*). In other animals, such as pigs and sheep, embryo transfer is usually a surgical procedure, with an incision made in the abdominal cavity to carry out the procedures.



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*Flushing of eggs for the production of embryos for transfer to surrogate cows is an invasive procedure, generally requiring epidural anaesthesia.*

The transfer of over 600 000 *in vivo*-derived cattle embryos from more than 130 000 donor cows was recorded by the International Embryo Transfer Society in 2005, and the actual number transferred globally is estimated to be closer to 1 million embryos (Thibier, 2006). The greatest number of *in vivo*-derived cattle embryo transfers took place in North America, accounting for 45% of the global total, followed by South America (20.5%), Asia (19%) and Europe (14%). In addition, the transfer of over 250 000 *in vitro*-produced cattle embryos was also recorded, mostly in South America (close to 50%), in particular Brazil, and Asia (47%), particularly Korea and China (*Ibid.*). 30 000 pig embryos, 25 000 sheep embryos, 7000 goat embryos and 300 deer embryos were also transferred in 2005 (*Ibid.*).

In Europe in 2008, around 100 000 cattle embryos were transferred (94.5% of which were *in vivo*-derived embryos) (Merton, 2009). In addition, 375 sheep embryos, 75 goat embryos and 28 pig embryos were transferred (*Ibid.*).

Today, farm animal breeding is a globalised industry, with a small number of large multinational companies controlling the vast majority of livestock and poultry breeding across the world. For example, over 90% of world chicken meat production originates from

birds produced by just two breeding companies (Cobb–Vantress, 2010; Avigen, 2010), whilst around 50% of world egg production comes from the hens bred by a single company (ISA, 2010). The largest cattle genetics company in the world disseminates around 13 million doses of semen each year from studs in North and South America, Europe and Australia (Genus, 2010a). More than 100 million slaughter pigs each year contain genetics from the breeding sows, boars and semen produced by the largest pig breeding company in the world (Genus, 2010b).

Selective breeding, aided by assisted reproductive technologies, has led to the development of increasingly specialised breeds that produce very high yields of a single commodity (such as meat, milk or eggs). Breeding companies continue to pursue “genetic gains” in areas such as growth rate, feed conversion efficiency (the amount of feed required for a given quantity of weight gain), age of sexual maturity, number of offspring, yield and quality of meat, milk or eggs. This drive to increase productivity has in many cases had serious consequences for the health and welfare of the animals. Where cloning is used to perpetuate the breeding of farm animals which have been strongly selected for productivity traits (see section 4.1), it has the potential to exacerbate existing welfare problems arising from selective breeding. The impact of selective breeding on some of the major farmed species is summarised in the next sections.

## **2.1 Dairy cattle**

Selective breeding of dairy cattle has led to a dramatic increase in milk yield over recent decades. Milk production per cow has more than doubled in the past 40 years and this increase in yield has been accompanied by declining ability to reproduce, increasing incidence of health problems, and declining longevity in modern dairy cows (Oltenucu and Algers, 2005).

The genetic component underlying milk yield has been found to be positively correlated with the incidence of lameness, mastitis (inflammation of the udder), reproductive disorders and metabolic disorders (AHAW, 2009).

High-yielding dairy cows are generally in negative energy balance in early lactation and mobilise body reserves for milk production (Butler and Smith, 1989). Loss of body condition score is greater and more prolonged for higher yielding cows (Gallo *et al*, 1989). Metabolic or production diseases are a manifestation of the cow’s inability to cope with the metabolic demands of high production (Mulligan and Doherty, 2008).



***Selection for increased milk yield has led to an increased incidence of a number of serious health problems in modern dairy cows, including reproductive failure, a significant problem for the modern dairy industry.***

There is a large body of evidence linking selection for increased milk yield with infertility (Webster, 2000). Higher milk yield is genetically correlated with longer calving interval, increased days to first service and reduced conception at first service (Pryce *et al*, 1997 & 1998). Infertility is the biggest cause of culling in dairy cows (Esslemont and Kossaibati, 1997; Whitaker *et al*, 2000).

The incidence of lameness in dairy cows has increased greatly in recent decades. For example, a farmer-based national survey of lameness in the UK in 1957/58 found an annual incidence of 4% (Leech *et al*, 1960); surveys since the 1990s have reported mean annual incidences ranging from above 20% to over 50% (Clarkson *et al*, 1996; Whitaker *et al*, 2000; Esslemont and Kossaibati, 2002).

A number of studies since the 1990s report a mean annual incidence of mastitis ranging from above 30 to over 70 cases per 100 cows (Esslemont and Kossaibati, 1996; Kossaibati *et al*, 1998; Esslemont and Kossaibati, 2002, Bradley *et al*, 2007).

The European Food Safety Authority (EFSA) Panel on Animal Health and Welfare, which advises the European Commission, concludes (AHAW, 2009):

***“Long term genetic selection for high milk yield is the major factor causing poor welfare, in particular health problems, in dairy cows.”***

Another consequence of breeding for specialised milk breeds is that the male calves are often not considered suitable for beef production and may be killed at birth.

## **2.2 Beef cattle**

Beef cattle have been selectively bred for large muscles (large meat yield). This has resulted in a greater incidence of leg disorders and calving problems. Some breeds have a “double-muscling” gene which causes them to have grossly oversized muscles. Animals may carry one copy (heterozygous) or two copies (homozygous) of the double-muscling gene. Calving is particularly difficult for those animals with two copies of the gene and calves often have to be delivered by Caesarean section (SCAHAW, 2001). These animals are also more susceptible to stress (*Ibid.*).

The EU Scientific Panel on Animal Health and Animal Welfare concludes (SCAHAW, 2001):

***“Beef breeds have been selected for a high meat production. These breeds are often associated with a hypermuscularity which can cause leg disorders, increase calving difficulties and decrease cow longevity... Among hypermuscular animals, the homozygous carriers of myotrophin defective gene, or double-muscled animals, need much more care due to their higher susceptibility to stress. A high proportion of caesareans are carried out in these animals... Homozygous double-muscled animals have a wide range of problems and should not be used in beef production. The use of heterozygous animals bearing the double-muscling gene would still entail welfare problems in the stock of parental homozygous animals.”***



*Belgian Blue cattle carry the “double-muscling” gene which is associated with an increased incidence of leg disorders and calving difficulties and increased susceptibility to stress.*

### 2.3 Pigs

Pigs are bred for fast growth, efficient feed conversion and high levels of lean meat in the carcass. This has led to serious health problems, including leg disorders and cardiovascular problems.

The incidence of leg weakness, particularly osteochondrosis, is genetically correlated with both growth rate and leanness (Rauw *et al*, 1998; AHAW, 2007a).

Modern pigs have a reduced ability to exercise and to cope with stressful situations without having cardiovascular problems (AHAW, 2007a).

The EFSA Panel on Animal Health and Welfare, which advises the European Commission, concludes (AHAW, 2007b):

*“The genetic selection of pigs for rapid growth and lean meat without enough consideration of other factors has led to some widespread and serious problems, in particular leg disorders, cardiovascular malfunction when high levels of activity are needed or stressful conditions are encountered, and inadequate maternal behaviour.”*

Pigs are also bred for increased litter size. Larger litter size is associated with lower piglet birth weight and higher piglet mortality (Weber *et al*, 2007; AHAW, 2007c). Competition for access to teats is increased in larger litters (AHAW, 2007c) leading to a greater risk of injuries to the piglets and to the sow's teats. Piglets are often subjected to tooth clipping to reduce the risk of injuries. Tooth clipping causes acute pain and distress (Noonan *et al*, 1994; Rand *et al*, 2002) and can also result in chronic pain (Hay *et al*, 2004; Prunier *et al*, 2002). The number of piglets in a litter may exceed the number of functioning teats, necessitating the use of "cross-fostering", where some of the piglets are moved to other litters or to sows whose piglets have recently been weaned, which can raise further welfare issues for both the sow and the piglets (AHAW, 2007c). The EFSA Panel on Animal Health and Welfare (AHAW, 2007d) recommends that genetic selection for litter size should not aim at exceeding 12 piglets born alive per litter.

#### **2.4 Broiler (meat) chickens**

Broiler (meat) chickens are bred for fast growth, efficient feed conversion and large breast meat yield. Modern commercial broilers reach a slaughter weight of 2– 2.5kg in 35–40 days (Cobb Vantress, 2008; Aviagen, 2007) compared with 12 weeks 30 years ago (Broom, 2009). This has resulted in serious health problems, including lameness and cardiovascular disorders.



*Painful lameness is common in fast-growing broiler chickens.*

Fast-growing broiler chickens suffer from a number of cardiovascular disorders that can cause sudden death and are responsible for a major portion of flock mortality (Julian, 2005).

Leg disorders are a major cause of pain and poor welfare in broiler chickens. Lamé birds will self-select feed containing the anti-inflammatory drug carprofen (Danbury *et al*, 2000). Danbury *et al* concluded that birds with a gait score of 3 or above consumed more carprofen, indicating that they are in pain. A re-analysis of the data from this study suggests that all birds with a gait score of 1 or above had significantly higher carprofen intakes (Webster, 2005). Webster concludes that *“all lameness hurts”*.

A large-scale study into leg disorders in broilers (Knowles *et al*, 2008) found that on average 97.8% of chickens showed some degree of gait abnormality (gait score 1 or higher) and 27.6% had a gait score of 3 or higher. Given the conclusions of Danbury *et al* (2000) and Webster (2005) above, this suggests that at least more than a quarter, and probably the vast majority, of commercially reared fast-growing broilers are likely to experience pain as a result of lameness. Knowles *et al* (2008) conclude:

***“[T]he primary risk factors associated with impaired locomotion and poor leg health are those specifically associated with rate of growth.”***

Another consequence of breeding for fast growth rate is that the birds kept for breeding are subjected to severe feed restriction in order to reduce mortality and health problems associated with excessive weight gain, causing them to be *“chronically hungry, frustrated and stressed”* (Savory *et al*, 1993).

The EU Scientific Committee on Animal Health and Animal Welfare concludes (SCAHAW, 2000):

***“It is clear that the major welfare problems in broilers are those which can be regarded as side effects of the intense selection mainly for growth and feed conversion. These include leg disorders, ascites, sudden death syndrome in growing birds and welfare problems in breeding birds such as severe food restriction. It is apparent that the fast growth rate of current broiler strains is not accompanied by a satisfactory level of welfare including health”***.

## 2.5 Turkeys

Turkeys are also bred for fast growth, efficient feed conversion and large breast meat yield and suffer from similar problems to broiler chickens.

Like broiler chickens, turkeys suffer from a number of cardiovascular disorders that can cause sudden death and are responsible for a major portion of flock mortality (Julian, 2005).

Lameness is a serious welfare issue in growing turkeys (*Ibid.*) and painful degeneration of the hips and other joints is common in male breeding turkeys (Duncan *et al*, 1991).

Male turkeys are now too heavy and broad-breasted to mate naturally without risking injury to the female. Artificial insemination is therefore standard practice. The 1995 report of the Banner Committee on the ethical implications of emerging technologies in the breeding of farm animals concluded:

***“The breeding of birds who are physically incapable of engaging in behaviour which is natural to them is fundamentally objectionable”.***

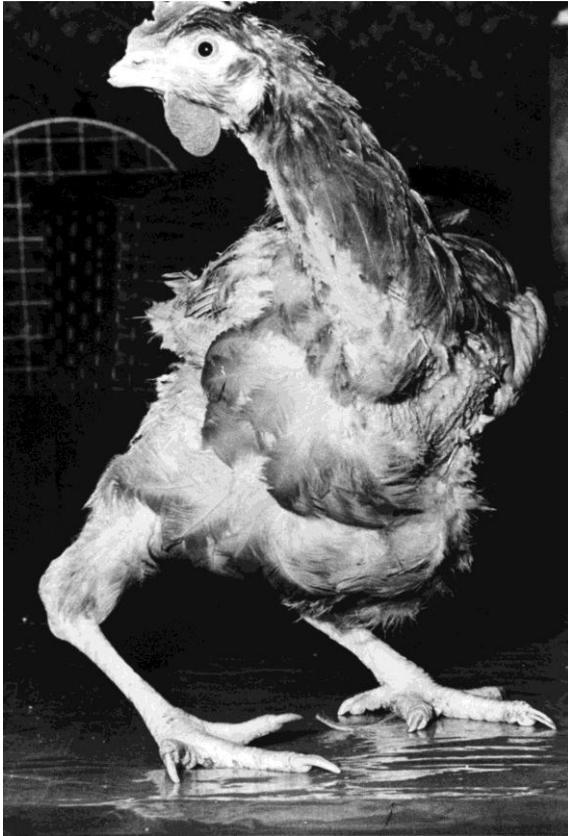
As with broiler chickens, breeding turkeys are subjected to severe feed restriction in order to reduce mortality and health problems.

## 2.6 Egg-laying hens

Laying hens have been selectively bred to produce very high numbers of eggs – a typical commercial hen now lays around 300 eggs in a year (Defra *et al*, 2008). Genetic selection of commercial layers for increased egg production has resulted in much weaker bones compared with traditional breeds (Budgell and Silversides, 2004). This is because egg shell quality is maintained in genetically selected lines at the expense of bone strength and density (Hocking *et al* 2003).

The lack of opportunity for exercise in cage systems further contributes to weakened bones and caged hens may develop “caged layer osteoporosis” (also known as “caged layer fatigue”). Osteoporosis accounts for 30 to 35% of deaths in caged laying hens and many of these deaths will be lingering and likely to involve emaciation and pain (McCoy *et al*, 1996; Webster, 2004). The affected bird becomes paralysed and, if the condition goes unnoticed, the hen often dies a slow death at the back of the cage from dehydration and starvation because they are unable to reach water and food (Abdul-Aziz, 1998). By the time they come to be slaughtered, the birds’ bones have become so weak that many hens suffer broken

bones during removal from the cages, transport and slaughter (Gregory & Wilkins, 1989; Gregory *et al*, 1990).



*Bone fractures are a major welfare problem in laying hens selected for increased egg production.*

Even in non-cage systems, where bone strength is improved by the greater opportunities for exercise, many birds have old healed fractures by the end of lay. Recent data suggests that the problem of bone fractures is getting worse, with various studies from cages, floor housing, aviary and free-range systems reporting incidences ranging from 50% to almost 90% (Friere *et al*, 2003; Wilkins *et al*, 2004; Rodenburg *et al*, 2006).

Another consequence of breeding for specialised egg-laying strains is that the male chicks are not commercially useful. The males do not lay eggs and only fast-growing, heavy-muscled chickens are considered suitable for meat production. As a result, the chicks are sexed at hatching and the males are killed.

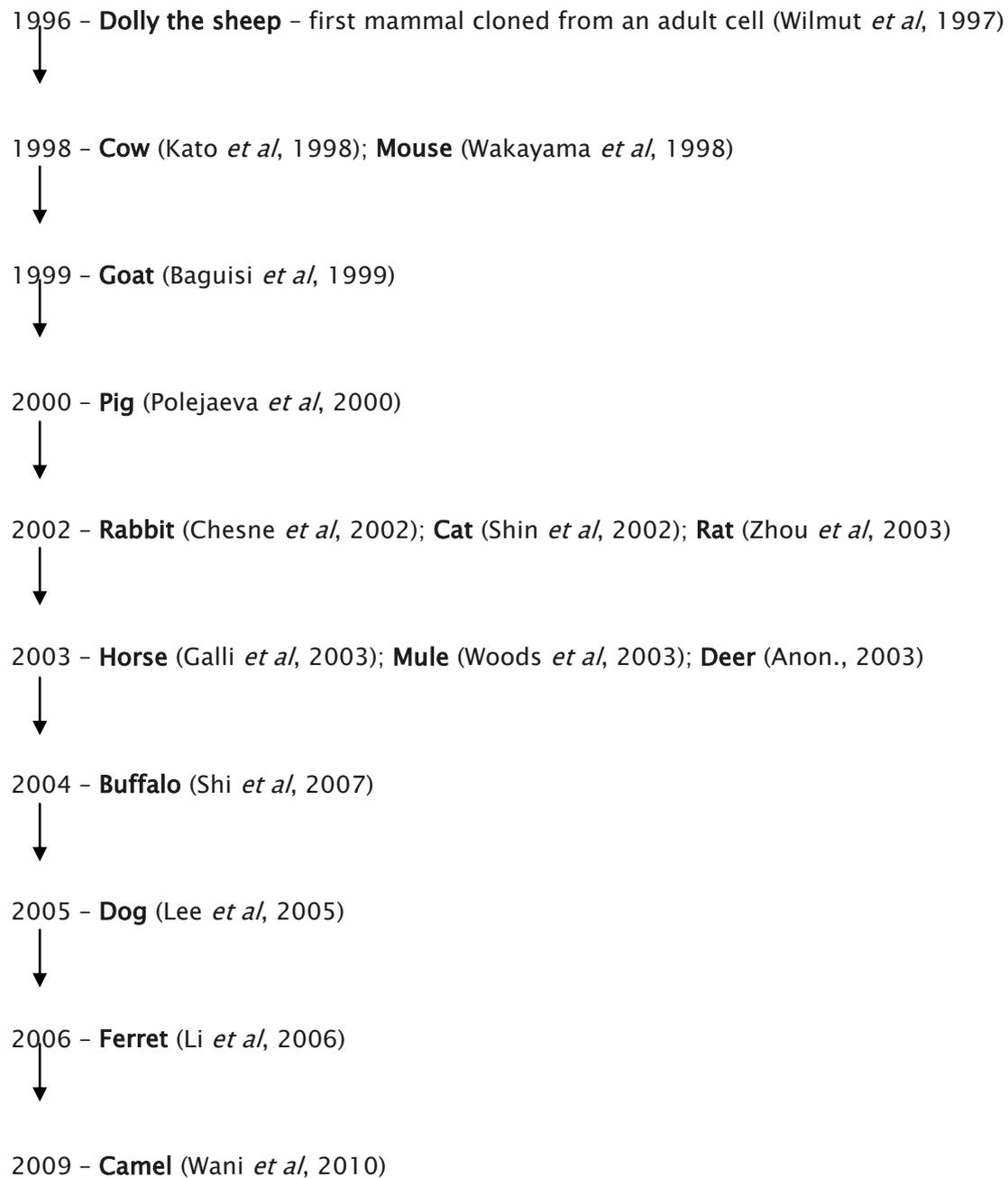
### 3 OVERVIEW OF FARM ANIMAL CLONING

The first mammal cloned from an adult cell was Dolly the sheep in 1996 (Wilmut *et al*, 1997). The process that created Dolly is called somatic cell nuclear transfer (SCNT). Since then, many other species have been cloned (Figure 3.1). Today, there are estimated to be around 6000 farm animal clones worldwide (Plume, 2009).



*Dolly, the first mammal to be cloned from an adult cell, was born at the Roslin Institute in 1996. She was euthanised in 2003 because she was suffering from a progressive lung disease. She had also been suffering from arthritis for over a year before she died. Both of these conditions are unusual in a sheep of her age and may have been a result of cloning.*

**FIGURE 3.1: TIMELINE OF DOMESTIC SPECIES CLONED.**



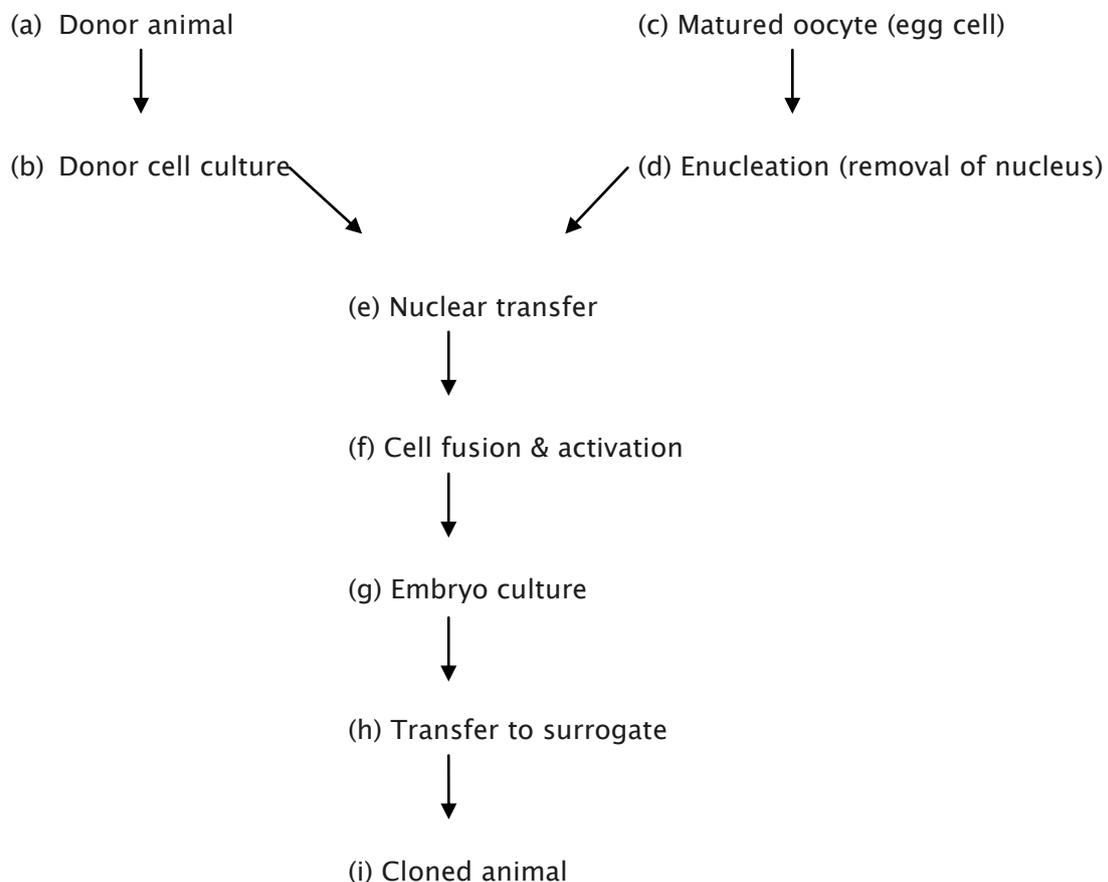
Some suggest that cloning is a simple extension of existing assisted reproductive technologies (ARTs) which are already in widespread use in farm animals. However, this is not the case as cloning by somatic cell nuclear transfer is fundamentally different from other established ARTs for a number of reasons:

- Cloning by SCNT goes beyond assisting reproduction through the bringing together of egg and sperm and instead bypasses the requirement for fertilization;
- SCNT produces animals that are genetically unlike any animal found in nature: unlike identical twins produced through conventional reproduction or embryo splitting techniques, animals cloned by SCNT are not true copies of another individual because they contain the nuclear DNA sequence of one individual (from the donor) as well as mitochondrial DNA from another individual (from the recipient egg).

In addition, the SCNT process is more invasive than established ARTs, involving direct manipulation of the recipient egg cell to remove its nucleus (containing the primary DNA sequence) and replace it with the nucleus of the donor cell. The SCNT process is summarised in Figure 3.2.

**Figure 3.2: The process of cloning by somatic cell nuclear transfer.**

Cells are collected from the donor animal (the animal to be cloned) **(a)** and cultured *in vitro* **(b)**. An oocyte (egg cell) is collected and matured either *in vitro* (collection from dead animal and maturation in the laboratory) or *in vivo* (collection from live animal following superovulation) **(c)**. The oocyte is enucleated (removal of the nucleus containing the primary DNA sequence) **(d)**. A donor cell is transferred into the enucleated oocyte **(e)**. The donor cell and the oocyte are fused by application of an electrical pulse and the reconstructed embryo is activated by electrical or chemical stimulation **(f)**. The reconstructed embryo is cultured *in vitro* or *in vivo* **(g)** and then transferred to a surrogate animal for gestation **(h)**. The offspring is a clone of the donor animal **(i)**. Source: Adapted from Tian *et al* (2003) & Campbell *et al* (2007).



## 4 CURRENT STATUS & POTENTIAL FUTURE

### APPLICATIONS OF FARM ANIMAL CLONING

Cloning technology is already being used commercially in some parts of the world for the replication of elite breeding animals, mostly cattle, which are used to produce animals farmed for food production. Cloning can also be used in the production of genetically modified animals for biomedical, research and food production purposes.

#### 4.1 Replication of elite breeding animals

Cloning is already being used commercially in the livestock industry in some parts of the world for the replication of elite breeding animals. It has been widely reported in the media that products from the offspring of cloned animals have already entered the human food chain in the United States and elsewhere (Weiss, 2008; Bethge, 2009; Plume, 2009).

Following the decision by the US Food and Drug Administration (FDA, 2008) that products from cloned animals are safe, food from clones and their offspring can freely enter the marketplace in the US and there is no requirement for these products to be labelled. There remains a voluntary moratorium in place for clones of species other than cattle, pigs and goats until more information is available on these species (FDA, 2010).

A number of companies in the US offer cloning services to the livestock breeding industry, primarily for cattle and also for pigs (ViaGen, 2009; Trans Ova Genetics, 2009; Cyagra, 2009). Bovance, a joint venture between ViaGen and Trans Ova Genetics, states (Bovance, 2009):

*“For more than eight years, cloning has been a successful tool for those clients who have chosen to create genetic twins of their elite cattle.”*

The situation in Asia is less clear but it is likely that products from the offspring of clones have entered the food chain in at least some Asian countries. As early as 2002, calves cloned from an elite Holstein dairy bull were sold to China by Australian-based company, Clone International (BBC, 2002). Cloning of livestock is also being undertaken within China by Yangling Keyuan Cloning (People’s Daily, 2001).

While Bovance (2009) considers that *“cloning will remain a technology suited exclusively for the most elite tier of genetics, and cloned individuals will represent only a fraction of a*

*percentage of tomorrow's cattle breeding foundation*", some authors have suggested that there will be a transition from the commercial use of semen and offspring of clones to the production of food products from cloned animals themselves over the next few years (Suk *et al*, 2007).

#### **4.2 Production of transgenic animals**

Genetic modification of animals involves altering an animal's genetic make-up by adding foreign genes or disabling existing genes. Transgenic animals can be created by microinjection of foreign DNA into recently fertilized eggs. Typically only a very small percentage of the animals produced will express the foreign gene and, even in those that do, the foreign gene may not be expressed in all cells.

Although the SCNT process is very inefficient (see Section 5), cloning is more efficient than the process of creating transgenic animals by microinjection of foreign DNA (Vajta and Gjerris, 2006). Cloning can be used to increase the efficiency of production of transgenic animals using nuclear transfer of cultured transgenic cells. The foreign DNA is introduced to cultured cells, which can then be screened to identify those cells that have successfully incorporated the foreign DNA. These transgenic cells are used as the nuclear donor in the SCNT process to create cloned transgenic animals. Cloning could also be used to create multiple copies of an existing transgenic animal.

The use of cloning technology is therefore facilitating the development and commercialisation of genetically modified animals for food production purposes. Potential applications include::

- The production of animal products with altered characteristics, for example, milk with higher levels of proteins called caseins (to increase the yield of cheese that can be obtained) or lower levels of lactose or lactoglobulin (substances in milk which can cause allergic reactions in some people) (Heyman, 2001); and
- The production of cloned transgenic male animals who produce mono-sex sperm – the animals are modified to disrupt the development of either X- or Y-chromosome-bearing sperm so that single-sex offspring are produced (Forsberg, 2005).

# 5. IMPACT OF CLONING ON THE WELFARE OF FARM ANIMALS

## 5.1 Welfare of clones

The large majority of cloned embryos fail to develop to term and, for those that do, a significant proportion of the animals die during or shortly after birth or at various times over the following days and weeks of life from cardiovascular failure, respiratory problems, liver or kidney failure, immuno-deficiencies or musculoskeletal abnormalities.

Clones may be born unusually large and with a range of associated health problems, termed “large offspring syndrome” (LOS). This is a common problem in cattle and sheep clones and gives rise to increased perinatal mortality, excess foetal size, abnormal placental development, enlarged internal organs, increased susceptibility to disease, sudden death, reluctance to suckle and difficulty in breathing and standing (EFSA, 2008). LOS was first described in pregnancies with *in vitro*-fertilized embryos but its incidence is much higher in clone pregnancies (*Ibid.*). In contrast to cattle and sheep clones, with cloned piglets there is an increased incidence of growth retardation during development in the uterus, resulting in low birth weight (*Ibid.*).

Panarace *et al* (2007) reviewed commercial experience of cattle cloning over five years in the US, Argentina and Brazil. Overall, only 9% of transferred embryos resulted in the birth of live calves. Continual losses during gestation were documented, with 37% of recipient cows being pregnant 30 days into gestation, falling to 11% at term. On average, 42% of cloned calves died between delivery and 150 days of age. 18% died during birth, 10% died within the first 24 hours and a further 14% died up to 150 days of age. The most common abnormalities were enlarged umbilical cord (37%), contracted flexor tendons (21%), calves depressed/prolonged recumbency (20%), respiratory problems (19%), hyper/hypothermia (17%) and persistent urachus (failure of the connection between the bladder and the naval to close) (10%). 37% of calves required treatment with antibiotics.

Watanabe and Nagai (2009) reviewed mortality in cloned cattle and their offspring in Japan. 16.4% of cloned calves were stillborn and a further 14.4% died within the first 24 hours. 24.1% of cloned cattle died due to disease during the first 30 days of their life. The main problems identified in dead calves two to three days after birth were respiratory problems (35.3%) and deformed hearts (11.8%). After four days the major cause of death was pneumonia. By 200 days of age, mortality in cloned cattle reached the same level as

conventionally bred cattle. Mortality in the offspring of cloned cattle did not differ significantly from mortality in conventionally bred cattle.

Loi *et al* (2004) reviewed experience of sheep cloning over six years in Europe. While early development of clone embryos appeared similar to control embryos produced by fertilization, the majority of clone pregnancies established at day 30 were lost over the following months and problems were observed in the few pregnancies that were carried to term. Only 13% of clone pregnancies reached term. Around 40% of the surrogate animals carrying clones developed acute hydroallantois (rapid accumulation of fluid in the placenta during the latter stages of pregnancy) and 45% showed a premature placental ageing (post-mature placenta). In both cases, the offspring were born alive but died at various times after delivery. Post-mortem investigations revealed that the ultimate cause of death was a direct consequence of placental abnormalities. Overall, placental abnormalities were observed in 67% of live clone births. The abnormalities leading to pre- and post-natal mortality in the large majority of clones that developed to term were hardly seen in *in vitro*-derived fertilized embryos and were totally absent in naturally mated ewes. At the time of the review no cloned sheep remained alive.

In its 2008 Opinion on Animal Cloning, the EFSA Scientific Committee, which advises the European Commission, concludes (EFSA, 2008):

***“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.”***

In June 2009, the EFSA Scientific Committee examined further evidence and confirmed that these conclusions are still valid (EFSA, 2009).

In order for the SCNT process to be successful, the donor cell must be correctly reprogrammed so that gene expression is properly controlled in order to allow normal development. The major cause of abnormalities in clones appears to be incorrect reprogramming of the donor cell genome. EFSA (2008) states:

***“Epigenetic dysregulation [abnormal control of gene expression] is considered to be the main source of adverse effects that may affect clones and result in developmental abnormalities.”***

The effects of these reprogramming failures are obvious in the majority of cloned animals, resulting in a range of physical abnormalities and illnesses which clearly cause suffering and

often death. Even those clones that survive and appear normal may have underlying abnormalities. During early development in mammal embryos, the majority of genes on the X chromosome are repressed (switched off) in a process called “X inactivation”. This is one of the epigenetic processes that may not happen properly in clone embryos. Research by Cao Geng-Sheng *et al* (2009) suggests that even apparently normal clones may have subtle epigenetic abnormalities. The authors state:

***“Our data also indicate that epigenetic modifications... that are associated with gene repression, are all aberrant to some extent in live cloned cattle.”***



© Photo courtesy: AP Photo/Wade Payne

***Even clones who appear healthy may have underlying abnormalities. Millennium, known as Millie, a cloned Jersey calf seen here in 2000, was found dead at 9 months of age in a pasture at the University of Tennessee Agricultural Experiment Station in Knoxville, Tennessee. A bacterial infection was blamed for killing Millie, who had appeared healthy until her sudden death.***

There is insufficient data available to date to be able to draw firm conclusions about the long-term health of cloned livestock. However, studies of cloned mice suggest that surviving clones may suffer long-term health problems, including obesity and abnormalities in a number of organs and early death (Ogonuki *et al*, 2002; Tamashiro *et al*, 2002; Inui, 2003; Shimozawa *et al*, 2006).

## 5.2 Welfare of surrogate dams

Pregnancy failure and abnormal or difficult delivery (dystocia) are common in clone pregnancies and delivery is often by Caesarean section (EFSA, 2008). Initial pregnancy rates in cattle used as surrogate dams are similar between those carrying clones and those carrying embryos produced by artificial insemination or *in vitro* fertilization. However, there is a continued pregnancy loss throughout the entire gestation period in those carrying clones which is not observed with other ARTs and embryo survival is only one third of that following *in vitro* embryo production (*Ibid.*). The high rate of pregnancy failure is linked to placental abnormalities (Hill *et al*, 2000; Oishi *et al*, 2006; Kim *et al*, 2009).

In its 2008 Opinion on Animal Cloning, the EFSA Scientific Committee, which advises the European Commission, states (EFSA, 2008):

*“For surrogate dams, an increase in pregnancy failure has been observed in cattle and pigs and increased frequencies of hydrops [abnormal accumulation of fluid in the foetus] and dystocia have been observed especially in cattle. This together with the increased size of the offspring (large offspring syndrome) makes Caesarean sections more frequent in cattle carrying a clone than with conventional pregnancies... [D]ystocia carries the risk of unrelieved “extra” pain during birth due to the large offspring. If the dam has to have a Caesarean section then that itself carries the risk of pain and anxiety due to the procedures involved, including a failure to provide adequate post-operative pain relief. If the Caesarean section is not planned then there is the added burden of the pain of both the dystocia and the Caesarean section.”*

## 5.3 Welfare of clone offspring

From the limited data available, it appears that the offspring of cloned animals do not suffer from any obvious abnormal effects. However, cloning of farm animals for food production is likely to focus on the replication of elite high-yielding animals for breeding (see Section 4.1). Such animals already suffer from a range of serious health and welfare problems associated with selection for high productivity (see Section 2). The use of cloning in commercial livestock breeding is therefore likely to accelerate the spread of genetics that are associated with poor welfare, leading to greater suffering from health and welfare

problems connected with fast growth and high yields. It is increasingly being recognised that livestock breeding must pursue different goals, aimed at producing more robust animals, if farm animals are to have an acceptable quality of life (Rauw *et al*, 1998; Sandøe *et al*, 1999).

The European Parliament (2008) states:

*“While the principal purpose of cloning is to produce multiple copies of animals with fast growth rates or high yields, traditional selective breeding has already led to leg disorders and cardiovascular malfunction in fast-growing pigs, and lameness, mastitis and premature culling in high-yielding cattle... cloning the fastest-growing and highest-yielding animals will lead to even higher levels of health and welfare problems.”*

The large majority of cloned embryos fail to develop to term and, for those that do, a significant proportion of the animals die during or shortly after birth or at various times over the following days and weeks of life. In its 2008 Opinion on Animal Cloning, the EFSA Scientific Committee, which advises the European Commission, concludes:

*“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.”*

The welfare of animals used as surrogate dams is also adversely affected because of the high rates of pregnancy failure, birthing difficulties and Caesarean section.

Although the offspring of clones do not appear to suffer any obvious abnormal effects, the use of cloning to replicate elite high-yielding animals for breeding is likely to accelerate the spread of genetics associated with poor welfare, leading to greater suffering from health and welfare problems connected with fast growth and high yields.

## 6. THREAT TO LIVESTOCK GENETIC DIVERSITY FROM FARM ANIMAL CLONING

The world's livestock diversity is currently shrinking, with rapid and uncontrolled loss of unique and often uncharacterised animal genetic resources (FAO, 2007). If breeds become extinct before their unique adaptive attributes and disease-resistance qualities have been identified, genetic resources which could greatly contribute to improving animal health are lost forever (*Ibid.*).

The objectives of commercial breeders tend to be short-term profitability, and their interests centre on the limited range of livestock breeds that can achieve high levels of output in large-scale production systems. This has increasingly led to the worldwide spread of a few specialized breeds, especially for poultry, pig and dairy cow production, rather than the development of a broad range of genetic material (*Ibid.*).

This global spread of a small number of specialised breeds has been facilitated by the development of assisted reproductive technologies. In principle, all artificial breeding could reduce biodiversity (Bulfield, 2000). The use of artificial insemination (AI) has restricted the male side of breeding, especially for dairy cattle, to a few elite individuals who are considered to have outstanding characteristics (*Ibid.*). Thus, AI is one of the main causes of genetic erosion in farm animals (Basrur & King, 2005).

Along with other assisted reproductive technologies, some suggest that cloning could be used to help preserve rare indigenous breeds of livestock (Wells *et al*, 1998) or individual animals within a breed who possess unique characteristics (Westhusin *et al*, 2007) in order to prevent the loss of unique traits, such as resistance to a particular disease or adaptability to local environments, from the global gene pool (Wells, 2003). However, the commercial use of cloning to replicate elite breeding animals is likely to further contribute to the erosion of livestock genetic diversity. EFSA (2008) concludes:

***“Cloning does not appear to have a direct effect on genetic diversity in that no new genetic modifications are introduced, but there could be an indirect effect due to overuse of a limited number of animals in breeding programmes. An increased homogeneity of a genotype within a population may increase the susceptibility of an animal population to infection and other risk factors.”***

The European Parliament (2008) states:

*“[C]loning would significantly reduce genetic diversity within livestock populations, increasing the possibility of whole herds being decimated by diseases to which they are susceptible.”*

Such a possibility could have very serious consequences, not only for animal welfare, but also for rural communities and economies.

The world’s livestock diversity is currently shrinking, with rapid and uncontrolled loss of unique and often uncharacterised animal genetic resources. The global spread of a small number of specialised breeds has been facilitated by the development of assisted reproductive technologies, particularly artificial insemination.

Some suggest that cloning technology could be used to replicate individuals of rare and endangered livestock breeds, which could help to preserve genetic diversity. However, the commercial use of cloning to replicate elite breeding animals is likely to further contribute to the erosion of livestock genetic diversity.

Reduced genetic diversity increases the susceptibility of livestock populations to diseases and other risk factors. This raises the possibility of large numbers of animals succumbing to diseases to which they are susceptible, with potentially serious animal welfare, social and economic consequences.

## 7. SAFETY OF FOOD FROM CLONED ANIMALS

The European Food Safety Authority evaluated the safety of foods from cloned animals and their offspring (EFSA, 2008). Due to the limited data available, only the safety of products from cattle (milk and meat) and pigs (meat) were evaluated, considering compositional and nutritional data, the probability of the presence of novel constituents, toxicity and allergenicity, and the health status of the animals. EFSA concludes (*Ibid.*):

*“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.”*

The US Food and Drug Administration (FDA) reached a similar conclusion in their assessment of the safety of products from cloned cattle, pigs and goats and their offspring (FDA, 2008).

*Based on the limited data currently available, the European Food Safety Authority and the US Food and Drug Administration have concluded that there is unlikely to be any increased food safety risk associated with eating meat and milk from cloned animals. However, further studies are warranted to rule out any potential food safety issues from the consumption of products from cloned animals and their offspring.*

However, EFSA acknowledges that there is limited information on the immune competence of clones and that it is therefore unclear whether there may potentially be an increased public health risk from cloned animal products if clones are more susceptible to infection by pathogens that can also infect humans. EFSA recommends that the susceptibility of clones and their offspring to disease should be investigated further and, if evidence of reduced immune competence of clones becomes available, it should be investigated whether consumption of meat and milk derived from clones or their offspring may lead to an increased human exposure to pathogens (EFSA, 2008).

Other authors have also highlighted the need for further research. For example, Heyman *et al.* (2007) concluded that the quality and safety of milk and meat from healthy adult cloned cattle are broadly similar to those from normal animals but they advise:

*“Cloned animals, although apparently normal, are however significantly different from contemporary controls maintained in the same conditions, and we feel that more studies on clones and offspring of clones are necessary to evaluate the safety of their use for human consumption.”*

Butler (2009) argues that a risk assessment approach incorporating the assumption that cloning does not put any new substances into an animal (because the primary DNA sequence is unchanged) is flawed. She points out that animal clones produced by SCNT are fundamentally different from conventionally bred animals and are unlike any found in nature. She therefore argues that the entire cloned animal should itself be treated as a new substance and be subject to long-term studies to assess the safety of eating food products from clones.

**Risk assessments carried out by the European Food Safety Authority and the US Food and Drug Administration suggest that products from cloned animals and their offspring are unlikely to carry any increased food safety risks compared with conventional food products. However, there are limited data available and further studies, including long-term trials, are warranted to rule out any potential food safety issues from the consumption of products from cloned animals and their offspring.**

## 8. PUBLIC OPINION ON THE CLONING OF ANIMALS FOR FOOD

A Eurobarometer survey of the attitudes of EU citizens to animal cloning, carried out in 2008, found that the majority of EU citizens are opposed to animal cloning, particularly for food production purposes (European Commission, 2008):

- 58% said that cloning for food production would never be justified;
- A further 28% said that cloning for food production would only be justified under certain circumstances;
- 84% agreed that we don't have enough experience about the long-term health and safety effects of using cloned animals for food;
- 75% agreed that cloning animals for human consumption could be seen as unacceptable on ethical grounds;
- 69% agreed that animal cloning for food production isn't acceptable because it would treat animals as commodities rather than as creatures with feelings;
- 63% said that it was unlikely that they would buy meat or milk from cloned animals, even if a trusted source stated that such products were safe to eat: 20% said it was somewhat unlikely and 43% said it was not at all likely;
- Respondents did not view products from the offspring of clones any more favourably than the products of clones themselves, with 62% saying that it was unlikely that they would buy meat or milk from animals where one of the parents was a clone.

When presented with a number of statements regarding the ethics of animal cloning, the majority of EU citizens agreed that (*Ibid.*):

- The long-term effects of animal cloning on nature are unknown (84%);
- Animal cloning might lead to human cloning (77%);
- Cloning might decrease the genetic diversity within livestock populations (63%);
- Animal cloning is morally wrong (61%).

The survey also highlights the importance of labelling to EU citizens (*Ibid.*):

- Nine out of 10 EU citizens considered it important that, if food products from offspring of cloned animals became available, that these products should be clearly labelled: 83% said this should certainly be the case and an additional 7% said this should probably be so.

In its 2008 Opinion on Ethical Aspects of Animal Cloning for Food Supply, the European Group on Ethics in Science and New Technologies (EGE) stresses the importance of protecting consumers' freedom and rights by ensuring that consumers are provided with sufficient information to enable them to choose the kind of products they want (EGE, 2008).

If products from cloned animals or their offspring are permitted to enter the food chain in the EU, there is a risk of serious damage to the image of the European livestock industry, leading to a loss of consumer confidence and associated economic risks. The European Parliament (2008) states:

***"[C]loning poses a serious threat to the image and substance of the European agricultural model, which is based on product quality, environment-friendly principles and respect for stringent animal welfare conditions."***

A number of livestock industry organisations in Europe and around the world have expressed similar concerns regarding the introduction of food from cloned animals, including the European Farmers Coordination (Van Tichelen *et al*, 2008), the Italian farmers' group Coldiretti (BBC, 2008) and the Dutch farmers' organisation LTO (Smet, 2008). Klaas-Johan Osinga, policy official of the LTO, is quoted as saying (*Ibid.*):

***"We are opposed to cloning because consumers do not want it. Also, cloning does not help us improve the genetic quality of our livestock, as well as being too expensive"***.

The New Zealand Meat Industry Association (MIA) and Deer Industry New Zealand (DINZ) have expressed concern at the "*serious market risks associated with the use of cloned animals [that] arise from [negative] consumer perceptions... toward clones and the offspring of clones*" (MIA/DINZ, 2009). In a letter to the New Zealand Food Safety Authority, MIA and DINZ stress the importance of mandatory registration and tagging, both of clones and of the offspring of clones, so that these animals can be reliably identified to allow them to be excluded from products (*Ibid.*).

The majority of EU citizens are opposed to animal cloning for food production purposes and state that they would be unlikely to buy products from cloned animals or their offspring, even if they are shown to be safe. If food products from the offspring of cloned animals were to become available, the vast majority of EU citizens believe that special labelling should be required. It is essential that the freedom and rights of consumers to choose to avoid products from cloned animals and their offspring are respected.

A number of farmers' groups have expressed concern at the threat to the image of the livestock industry if products from cloned animals or their offspring are permitted to enter the food chain, potentially leading to a loss of consumer confidence and associated economic consequences.

## 9. CAN THE CLONING OF ANIMALS FOR FOOD BE JUSTIFIED?

Compassion in World Farming believes that the cloning of animals for food should not be permitted due to a number of serious concerns outlined in this report, namely:

- There are very serious welfare problems affecting a large proportion of clones and surrogate dams;
- The use of cloning to replicate elite high-yielding animals for breeding is likely to accelerate the spread of genetics associated with poor welfare, leading to greater suffering from health and welfare problems connected with fast growth and high yields;
- The cloning of elite animals for breeding is likely to further contribute to the erosion of livestock genetic diversity;
- There is strong public opposition to the cloning of animals, particularly for food production purposes.

This view is supported by the European Group on Ethics in Science and New Technologies (EGE), which advises the European Commission, and by the European Parliament.

The European Group on Ethics in Science and New Technologies states (EGE, 2008):

*“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.”*

And concludes (*Ibid.*):

*“At present, the EGE does not see convincing arguments to justify the production of food from clones and their offspring”.*

On 3 September 2008, the European Parliament adopted a resolution calling for a ban on (European Parliament, 2008):

- The cloning of animals for food supply purposes;
- The farming of cloned animals or their offspring;
- The placing on the market of meat or dairy products derived from cloned animals or their offspring;
- The importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat or dairy products derived from cloned animals or their offspring.

The main concerns cited by the Parliament are threats to animal welfare, genetic diversity, consumer confidence and the image and substance of the European agricultural model.

## 10. REGULATORY STATUS OF ANIMAL CLONING FOR FOOD IN THE EU

At present, there is no specific EU legislation governing animal cloning, although various pieces of existing legislation will apply to cloned animals and food products from cloned animals under specific circumstances.

EU animal welfare legislation states (Council Directive 98/58/EC):

*“Natural or artificial breeding or breeding procedures which cause [sic] or are likely to cause suffering or injury to any of the animals concerned must not be practised.”*

There is substantial evidence that the SCNT procedure causes suffering due to the high levels of mortality and health problems seen in cloned animals, as well as the impact on the welfare of surrogate dams (see Section 5). Compassion in World Farming believes that, if the EU were to allow the cloning of animals for food production, this would be in contravention both of Council Directive 98/58/EC and of The Lisbon Treaty, which requires the EU and its Member States to “*pay full regard to the welfare requirements of animals*” when formulating and implementing EU policies.

A fundamental principle of EU food law, set out in Regulation (EC) No 178/2002, stipulates that food must not be placed on the market if it is unsafe. In addition, animal cloning is considered a novel food production process in the EU, and therefore any food or ingredient from a cloned animal requires prior authorisation under the Novel Food Regulation (EC) No 258/97 before being placed on the EU market.

A major concern is the possibility of imported products from clones or their offspring entering the food chain in the EU, especially as there is no requirement in the US for such products to be identified or labelled. The import and export of food products from clones and their offspring will be subject to World Trade Organisation (WTO) rules on trade and barriers to global trade. Compassion in World Farming believes that any WTO challenge could be successfully resisted. The Community could, in our view, successfully contend that a marketing or import ban fell to be considered under GATT Article III (internal regulations) rather than Article XI (import restrictions) and further, that cloned animals and products derived from them are not “like” sexually produced animals and products obtained from them. If this argument were to fail, the Community could justify marketing or import restrictions under Article XX (a) [public morals] or (b) [animal health].

There is an urgent need for the development and introduction of specific EU legislation to govern animal cloning and food products from clones and their offspring. Compassion in World Farming calls on the European Union to follow the Parliament’s wishes and implement 1) a complete ban on the cloning of animals for food production purposes and the farming of cloned animals or their offspring, 2) a complete ban on the placing on the market of meat or dairy products derived from cloned animals or their offspring and 3) an embargo on imports of cloned animals and their offspring, semen and embryos from cloned animals or their offspring and meat and dairy products derived from such animals.

# 11. CONCLUSIONS & RECOMMENDATIONS

- Selective breeding, aided by a number of assisted reproductive technologies (ARTs), has led to the development of increasingly specialised livestock breeds that produce very high yields of a single commodity (such as meat, milk or eggs). The drive to increase productivity has in many cases had serious consequences for the health and welfare of the animals.
- Cloning by somatic cell nuclear transfer (SCNT) is fundamentally different from other established ARTs in that it goes beyond assisting in bringing together the egg and sperm and instead bypasses the requirement for fertilization. SCNT produces animals that are genetically unlike any animal found in nature.
- Many species have been cloned since Dolly the sheep, the first mammal to be cloned from an adult cell, was born in 1996. There are now estimated to be around 6000 farm animal clones worldwide.
- Cloning technology is already being used commercially in some parts of the world for the replication of elite breeding animals, mostly cattle, which are used to produce animals farmed for food production.
- Cloning can be used to increase the efficiency of production of transgenic animals using nuclear transfer of cultured transgenic cells. The use of cloning technology is therefore facilitating the development and commercialisation of genetically modified animals for biomedical, research and food production purposes. Compassion in World Farming is opposed to the genetic modification of farm animals.
- Cloning has very serious consequences for animal welfare. The large majority of cloned embryos fail to develop to term and, for those that do, a significant proportion of the animals die during or shortly after birth or at various times over the following days and weeks of life. In its 2008 Opinion on Animal Cloning, the EFSA Scientific Committee, which advises the European Commission, concludes:

***“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.”***

- The welfare of animals used as surrogate dams is also adversely affected because of the high rates of pregnancy failure, birthing difficulties and Caesarean sections.
- Although the offspring of clones do not appear to suffer any obvious abnormal effects, the use of cloning to replicate elite high-yielding animals for breeding is likely to accelerate the spread of livestock genetics associated with poor welfare, leading to greater suffering from health and welfare problems connected with fast growth and high yields.
- The world's livestock diversity is currently shrinking, with rapid and uncontrolled loss of unique and often uncharacterised animal genetic resources. The global spread of a small number of specialised breeds has been facilitated by the development of ARTs, particularly artificial insemination.
- Some suggest that cloning technology could be used to replicate individuals of rare and endangered livestock breeds, which could help to preserve genetic diversity. However, the commercial use of cloning to replicate elite breeding animals is likely to further contribute to the erosion of livestock genetic diversity.
- Reduced genetic diversity increases the susceptibility of livestock populations to diseases and other risk factors. This raises the possibility of large numbers of animals succumbing to diseases to which they are susceptible, with potentially serious animal welfare, social and economic consequences.
- Risk assessments carried out by the European Food Safety Authority and the US Food and Drug Administration suggest that products from cloned animals and their offspring are unlikely to carry any increased food safety risks compared with conventional food products. However, there are limited data available and further studies, including long-term trials, are warranted to rule out any potential food safety issues from the consumption of products from cloned animals and their offspring.
- The majority of EU citizens are opposed to animal cloning for food production purposes and state that they would be unlikely to buy products from cloned animals or their offspring, even if they are shown to be safe. If food products from the offspring of cloned animals were to become available, the vast majority of EU citizens believe that special labelling should be required. It is essential that the freedom and rights of consumers to choose to avoid products from cloned animals and their offspring are respected.

- A number of farmers' groups have expressed concern at the threat to the image of the EU livestock industry if products from cloned animals or their offspring are permitted to enter the food chain, potentially leading to a loss of consumer confidence and associated economic consequences.
- The cloning of animals for food production is not ethically justifiable. The European Group on Ethics in Science and New Technologies (EGE), which advises the European Commission, concludes:

***“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... At present, the EGE does not see convincing arguments to justify the production of food from clones and their offspring”***

- The European Parliament has adopted a resolution calling for a ban on the cloning of animals for food supply purposes, the farming of cloned animals or their offspring, the placing on the market of meat or dairy products derived from cloned animals or their offspring, and the importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat or dairy products derived from cloned animals or their offspring.
- At present there is no specific EU legislation governing animal cloning, although various pieces of existing legislation will apply to cloned animals and food products from cloned animals under specific circumstances. Council Directive 98/58/EC states:

***“Natural or artificial breeding or breeding procedures which cause [sic] or are likely to cause suffering or injury to any of the animals concerned must not be practised.”***

- Compassion in World Farming believes that, if the EU were to allow the cloning of animals for food production, this would be in contravention both of Council Directive 98/58/EC and of the Lisbon Treaty.
- There is an urgent need for the development and introduction of specific EU legislation to govern animal cloning and food products from clones and their offspring.

Compassion in World Farming calls on the European Union to follow the Parliament's wishes and implement: 1) a complete ban on the cloning of animals for food production purposes and the farming of cloned animals or their offspring; 2) a complete ban on the placing on the market of meat or dairy products derived from cloned animals or their offspring; and 3) an embargo on imports of cloned animals and their offspring, semen and embryos from cloned animals or their offspring and meat and dairy products derived from such animals.



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*The birth of this cloned calf was reported in 1999 by the French National Institute for Agricultural Research (INRA). She appeared healthy until six weeks of age when she developed severe anaemia and died. Post-mortem examinations revealed that her immune system had not developed properly.*

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# GLOSSARY

<b>Caesarean section</b>	Birth by surgical intervention
<b>DNA</b>	The material which carries the genetic code of an organism
<b>Dystocia</b>	Abnormal or difficult delivery (birth)
<b>Enucleation</b>	Removal of the nucleus from a cell
<b>Epigenetic dysregulation</b>	Abnormal control of gene expression
<b>Hydroallantois</b>	Abnormal accumulation of fluid in the allantoic cavity of the placenta
<b>Hydrops</b>	Abnormal accumulation of fluid in the foetus, sometimes leading to spontaneous abortion
<b>In vitro</b>	Occurring outside of a living organism (especially in a laboratory)
<b>In vivo</b>	Occurring within a living organism
<b>Genome</b>	The entire genetic make-up of an organism
<b>Mitochondria</b>	Structures inside a cell that contain DNA other than the primary DNA sequence
<b>Multiple ovulation and embryo transfer (MOET)</b>	Procedure for the production of multiple embryos for transfer to surrogates
<b>Nuclear</b>	Of or relating to the nucleus
<b>Nucleus</b>	Structure inside a cell that contains the primary DNA sequence
<b>Oocyte</b>	Egg cell
<b>Ovum pick-up (OPU)</b>	Procedure for collecting immature eggs from the ovaries
<b>Perinatal</b>	Of or relating to the period around birth (in livestock generally the period 7 days before and 7 days after birth)
<b>Somatic cell</b>	Cell of the body other than the eggs or sperm
<b>Surrogate</b>	Animal carrying the embryo/foetus of another animal
<b>Transgenic</b>	Containing foreign DNA



# FARM ANIMAL CLONING

A report by Compassion in World Farming

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2010

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