POSITION STATEMENT ON THE OIE GUIDELINES ON SOMATIC CELL NUCLEAR TRANSFER IN PRODUCTION LIVESTOCK AND HORSES

PREPARED BY THE INTERNATIONAL COALITION FOR ANIMAL WELFARE[1]

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OIE Guidelines for somatic cell nuclear transfer in production livestock and horses appear in the report of the meeting of the OIE Terrestrial Animal Health Commission on 10-14 March 2008.

The International Coalition for Animal Welfare (ICFAW) believes that the OIE Guidelines give insufficient attention to the scientific literature that establishes that cloning entails serious health and welfare problems for animal clones and their surrogate dams. ICFAW respectfully urges the OIE to give further consideration to its Guidelines as we think that they should give greater weight to these health and welfare concerns.

Somatic cell nuclear transfer is a method of cloning, i.e. of artificial reproduction used to produce a genetically identical or almost identical copy of an individual animal. Animal health and welfare problems arise due to:

- The invasive techniques required to produce a clone
- The suffering of surrogate dams who carry cloned foetuses
- High levels of ill health and mortality in the early stages of life of cloned animals.

A paper published in the OIE's *Revue Scientifique et Technique* has identified the serious problems involved in cloning:

> "[A]t present it is an inefficient process: in cattle, only around 6% of the embryos transferred to the reproductive tracts of recipient cows result in healthy, long-term surviving clones. Of concern are the high losses throughout gestation, during birth and in the post-natal period through to adulthood. Many of the pregnancy losses relate to failure of the placenta to develop and function correctly. Placental dysfunction may also have an adverse influence on postnatal health."[2]

The paper added that the incidence of gastrointestinal, umbilical and respiratory infections is increased in cloned livestock.

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[1] The member organisations of the International Coalition for Animal Welfare, representing more than 12 million individual supporters internationally, include: Compassion in World Farming, Eurogroup for Animals, the Humane Society of the United States and Humane Society International, the International Fund for Animal Welfare, the Japanese Farm Animal Welfare Initiative, the National Council of SPCAs, the Royal Society for the Prevention of Cruelty to Animals, RSPCA Australia, and the World Society for the Protection of Animals.

[2] Wells DN. 2005. Animal cloning: problems and prospects. Revue Scientifique et Technique (International Office of Epizootics) 24(1):251-64.

Ian Wilmut, who led the team that cloned Dolly the sheep, is quoted as saying: "The widespread problems associated with clones has [*sic*] led to questions as to whether any clone was entirely normal….There is abundant evidence that cloning can and does go wrong…."[3]

Scientific Opinion of the European Food Safety Authority

In July 2008 the European Food Safety Authority (EFSA) published a Scientific Opinion.[4] This points out that:

- There is an increased proportion of pregnancy failure and disorders in surrogate dams of cloned embryos.
- These disorders and the large size of clones make Caesareans more frequent in cattle carrying clones than in conventional pregnancies.
- The health and welfare of a significant proportion of cloned animals have been found to be adversely affected, often severely and with a fatal outcome.
- The welfare of both the surrogate dam and the clone can be affected by adverse health outcomes.

Opinion of the European Group on Ethics

In January 2008 the European Group on Ethics in Science and New Technologies to the European Commission (EGE) published an Opinion on cloning.[5] This concluded that "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". The EGE added that it "does not see convincing arguments to justify the production of food from clones and their offspring".

Invasive Reproduction Techniques

Once a cloned embryo has been produced, it is implanted into a surrogate mother who carries out the pregnancy. In pigs the transfer of the embryo into the surrogate mother is performed by a surgical procedure. In cattle embryo transfer is sufficiently stressful that UK legislation requires a general or epidural anaesthetic.

Suffering of Surrogate Dams

Large offspring syndrome is common in cloned calves and lambs. Cloned calves are often 25% heavier than normal which leads to painful births for the surrogate mothers and to most deliveries being performed by Caesarean section. The EFSA Opinion points out that "dystocia [abnormal or difficult birth] 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 both the pain of dystocia and the Caesarean section."

Mortality During Pregnancy

A substantial proportion of clones die during pregnancy, often from placental and foetal abnormalities, or are stillborn. The EFSA Opinion states that there is a high rate of pregnancy failure in surrogate dams and that this has been linked to abnormal and/or poorly developed placental formation. Such placental defects have been associated with early embryonic loss, abortions, stillbirths, dystocia and pre- and post-natal deaths. A 2007 study reported that 25% of cows pregnant with cloned embryos at day 120 of gestation develop hydroallantois (abnormal fluid accumulation in the allantoic cavity of the placenta) and their pregnancies have to be terminated.[6]

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[3] Leake J. 2002. Gene defects emerge in all animal clones. The Sunday Times (UK), April 28.

[4] European Food Safety Authority, 2008. Scientific opinion on food safety, animal health and welfare, and environmental impact of animals derived from cloning by somatic cell nuclear transfer (SCNT) and their offspring and products obtained from those animals (Question No EFSA-Q-2007-092). The EFSA Journal (2008) 767, 1-49.

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

[6] Laible, G. and Wells, D. N. 2007. Recent advances and future options for New Zealand agriculture derived from animal cloning and transgenics. *New Zealand Journal of Agriculture Research* **50**: 103-124.

Inefficiency and Wastage of Life

Cloning is a wasteful process. A 2004 paper reported that only 13% of cloned calf embryos implanted into surrogate dams results in calves delivered at full term.[7] A 2003 review of cloning procedures reported that less than 5% of all cloned embryos transferred into recipient cows have survived.[8]

A recent paper refers to the cloning process as "inefficient and highly prone to epigenetic errors".[9] Due to the low efficiency of the cloning process, a high number of surrogate dams are required to produce a low number of clones.

Perinatal Problems and Post-natal Mortality of Cloned Animals

Many clones die in the early stages of life. In a 2007 paper researchers from the U.S. Food and Drug Administration noted "that perinatal calf and lamb clones have an increased risk of death and birth defects".[10] The EFSA Opinion states that changes observed in late gestation in clones from cattle and sheep give rise to an increase in perinatal deaths, excess foetal size, abnormal placental development, enlarged internal organs, increased susceptibility to disease, sudden death, reluctance to suckle and difficulty in breathing and standing.

The EGE Opinion states that around 20% of calves do not survive the first 24 hours after birth, and an additional 15% die before weaning. Similar findings were reported by Panarace *et al* in 2007 who summarised five years of commercial experience of cloning cattle in three countries.[11] On average 42 % of cattle clones died between delivery and 150 days of life and the most common abnormalities were enlarged umbilical cords (37 %), respiratory problems (19 %), depressed or weak calves displayed by prolonged recumbency (20 %) and contracted flexor tendons (21 %).

The high rates of mortality and ill health are due to a range of factors including:

- Immune deficiencies
- Respiratory problems
- Cardiovascular failure
- Liver failure
- Kidney abnormalities
- Musculoskeletal abnormalities.

Examples of these problems can be seen in two cases of piglet mortality. In 2003 three cloned pigs out of a group of four died of heart attacks before the age of 6 months; the fourth had died a few days after birth. In another case, of seven cloned piglets, two died shortly after birth from breathing problems and a third died after 17 days from heart failure. Of the survivors, one had heart and lung abnormalities, one had eye and ear abnormalities and one had a leg joint abnormality.

Loi *et al* published an account of the death of a group of cloned lambs in 2006. Out of 93 clones transferred to surrogate dams, only 12 reached full-term development. Of these twelve, three were stillborn and five died within 24 hours, displaying degenerative lesions in the liver and kidneys. Another two died 24 hours after birth from respiratory distress syndrome. The final two cloned lambs showed respiratory dysfunction and died at around one month due to a bacterial complication.[12]

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[7] Wells, D.N. 2004. *The integration of cloning by nuclear transfer in the conservation of animal genetic resources*. In: Simm G *et al*.(Eds). Farm animal genetic resources. British Association of Animal Science, pp 223-241.
[8] Oback B and Wells DN. 2003. Cloning cattle. Cloning and Stem Cells 5(4):243-56.
[9] As 5.
[10] Rudenko L and Matheson JC. 2007. The U.S. FDA and animal cloning: risk and regulatory approach. Theriogenology 67(1):198-206.
[11] Panarace, M., Aguero, J. I., Garrote, M., Jauregui, G., Segovia, A., Cane, L., Gutierrez, J., Marfil, M., Rigali, F., Pugliese, M., Young, S., Lagioia, J., Garnil, C., Forte Pontes, J. E., Ereno Junio, J. C., Mower, S. and Medina, M. 2007. How healthy are clones and their progeny: 5 years of field experience. *Theriogenology* 67 (1): 142-51.
[12] Loi, P., Clinton M., Vackova I., Fulka J Jr., Feil R., Palmieri C., Della Salda L., Ptak G., 2006. Placental abnormalities associated with post-natal mortality in sheep somatic cell clones. *Theriogenology* **65** (2006) 1110-1121.

A study undertaken at the US Department of Agriculture and published in October 2005 suggested that clones may be born with defective immune systems. The finding could explain why clones often die from infections soon after birth.[13] Team leader Jeff Carroll says: "I've looked at the immune response of hundreds of young pigs and I've never seen anything that low until I looked at a clone".[14]

Some abnormalities may not show up until later in life. Writing in the OIE *Revue Scientifique et Technique* a leading cloning scientist pointed out that the development of musculoskeletal problems, such as chronic lameness and severely contracted flexor tendons, in these high-production animals "emphasises the point that any underlying frailties in cloned animals may not be fully revealed until the animals are stressed in some manner."[15] Wells *et al* found that the most common cause of death of cattle they cloned were late developing musculoskeletal problems so severe that the cows needed to be euthanized.[16]

Likely Suffering of Cloned Animals and Their Offspring When Raised On-farm

To correctly assess the long-term impact of cloning on the welfare of cattle and pigs, ICFAW believes that it is important to consider the ways in which cloning is likely to be used within the livestock sector. The likelihood is that cloning will be used to multiply the highest yielding cows and fastest growing pigs .Yet research shows that these animals are likely to suffer from metabolic and physiological disorders associated with fast growth and excessive muscle or udder development.

Traditional selective breeding has already led to major health problems for such animals. Fast growing pigs suffer from leg disorders and cardiovascular malfunction[17] and high yielding cattle from lameness, mastitis and premature culling; the cloning of the most fast growing and high yielding animals will lead to an even higher proportion of animals suffering from the same health and welfare problems.

Increased Susceptibility to Disease

A herd of cloned animals or their offspring will have less genetic diversity than a conventional herd and so will have increased vulnerability to a disease challenge. The EGE said that the use of a limited number of breeding lines in intensive animal farming may affect the biodiversity of farm animals and create inbreeding problems.

It is claimed that it will be mainly offspring of clones that will be used on-farm, with the clones themselves being used for breeding. It is further argued that the offspring of clones do not suffer from unusual health problems. However, few studies have been carried out on the health of the offspring of clones and none have been reported on their welfare. Moreover, even if the offspring of clones are as healthy as normal animals, the fact remains that the clones themselves and their surrogate dams often experience substantial suffering and health problems.

ICFAW believes that cloning of farm animals is taking us in the wrong direction - towards perpetuating industrial farming when all other societal trends point towards sustainable farming and respect for animals as sentient beings.

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[13] Carroll, J.A., Bart Carter, D., Korte, S.C., Prather, R.S. 2005. Evaluation of the acute phase response in cloned pigs following a lipopolysaccharide challenge. *Domestic Animal Endocrinology* **29**: 564-572.
[14] New Scientist News Staff. 2004. The problem with clones. *New Scientist* 06/11/04, page 20.
[15] As 1.
[16] Wells DN, Forsyth JT, McMillan V, and Oback B. 2004. The health of somatic cell cloned cattle and their offspring. Cloning and Stem Cells 6(2):101-10.
[17] Scientific Opinion of the Panel on Animal Health and Welfare on a request from the Commission on Animal health and welfare in fattening pigs in relation to housing and husbandry. *The EFSA Journal* (2007) 564, 1-14.