

## **Scientific Opinion of the Scientific Committee**

### **Food Safety, Animal Health and Welfare and Environmental Impact of Animals<sup>1</sup> derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals<sup>2</sup>**

(Question No EFSA-Q-2007-092)

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#### **SCIENTIFIC COMMITTEE MEMBERS**

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#### **SUMMARY**

In 2007 the European Food Safety Authority (EFSA) was asked by the European Commission to provide a scientific opinion on the food safety, animal health, animal welfare and environmental implications of animal clones, obtained through somatic cell nucleus transfer (SCNT) technique, of their progeny and of the products obtained from those animals. In view of the multidisciplinary nature of this subject this task was assigned to the EFSA Scientific Committee. The ethical aspects of cloning are outside the remit of EFSA and the European Commission asked the European Group on Ethics in Science and New Technologies to provide an opinion on the ethical aspects of cloning.<sup>3</sup>

Unlike sexual reproduction, in which the fertilized egg is totipotent (capable of becoming all cells in the resulting organism), in SCNT, the activated embryo containing a differentiated somatic cell first must be “reset” to totipotency, so that it then follows the same path as a fertilized embryo and is able to complete embryonic and foetal development. This process called “reprogramming” changes the biochemical signals that control gene expression. Failure of the epigenetic reprogramming, which may occur to varying degrees, is the source of potential adverse health effects which may affect clones and may result in developmental abnormalities. The production of healthy clones is the main indicator of the successful functioning of epigenetic reprogramming.

Cloning by SCNT has been applied to several animal species. Based on current knowledge and given the data available it was only possible to make a risk assessment on clones of cattle and pigs and their progeny.

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<sup>1</sup> The animal species covered in this opinion are cattle and pigs

<sup>2</sup> For citation purposes: Scientific Opinion of the Scientific Committee on a request from the European Commission on Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals. *The EFSA Journal* (2008) 767, 1-49

<sup>3</sup> [http://ec.europa.eu/european\\_group\\_ethics/publications/](http://ec.europa.eu/european_group_ethics/publications/)

Uncertainties in the risk assessment arise from the limited number of studies available, the small sample sizes investigated and the absence of a uniform approach to allow all the issues relevant to this opinion to be addressed.

This opinion considers animal health aspects in relation to the surrogate dams, to clones and their progeny. For surrogate dams, an increase in pregnancy failure has been observed in cattle and pigs and increased frequencies of hydrops 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. These effects have also been observed in surrogate dams carrying pregnancies induced by assisted reproductive technologies not involving SCNT, but at much lower frequencies.

A significant proportion of clones, mainly within the juvenile period for bovines and perinatal period for pigs, has been found to be adversely affected, often severely and with fatal outcome. Most clones that survive the perinatal period are normal and healthy, as determined by physiological measurements, demeanour and clinical examinations. There is no indication of adverse effects for the sexually reproduced progeny of cattle or pig clones. However, clones and their progeny have not yet been studied throughout the whole of their natural life span.

The current welfare assessment is extrapolated from mainly animal health data. The welfare of both the surrogate dam and a significant proportion of clones has been found to be affected by the adverse health outcomes observed.

For the evaluation of the safety of bovine milk and meat from cattle and pigs derived from clones or their progeny, the following aspects were considered: compositional and nutritional data, probability of novel constituents to be present, health status of the animal, available data on toxicity and allergenicity. 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.

At present there is no indication that clones or their progeny would pose any new or additional environmental risks compared with conventionally bred animals.

A number of recommendations is given at the end of the opinion.

**Key words:** Animal Cloning, Animal Health, Animal Welfare, ART, Assisted Reproduction Technology, Bovine, Cattle, Clone, Clones, Environmental Impact, Epigenetic Reprogramming, Food Product, Food Safety, Genetic Diversity, Immunocompetence, Livestock, Offspring, Pig, Progeny, Risk Assessment, SCNT, Somatic Cell Nucleus Transfer, Swine.