

## STATEMENT OF EFSA

### Update on the state of play of animal cloning<sup>1</sup>

European Food Safety Authority<sup>2, 3</sup>

European Food Safety Authority (EFSA), Parma, Italy

#### SUMMARY

The European Food Safety Authority (EFSA) received in May 2010, a request from the European Commission for an update on the state of play of the possible scientific developments on the issue of cloning of farmed animals for food production purposes and taking into consideration existing data from European research centres about the health and welfare of clones during their production life and natural life span.

The present statement follows the EFSA 2009 statement and EFSA 2008 scientific opinion and is based on a review of identified peer reviewed scientific literature up to 1 July 2010, information made available to EFSA following a call for data, discussion with experts in the field of animal cloning and a peer review by external experts. The focus of the statement has been to evaluate information related to aspects of food safety, health and welfare of animal clones and their offspring.

The EFSA 2008 scientific opinion concluded that epigenetic dysregulation is considered to be the main source of adverse effects that may affect clones and result in developmental abnormalities. 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 use of cloning by SCNT (Somatic Cell Nuclear Transfer) in cattle and pigs, has also produced healthy clones and healthy offspring that are similar to their conventional counterparts based on parameters such as physiological characteristics, demeanour and clinical status. In relation to food safety, there is no indication that differences exist for meat and milk of clones and their progeny compared with those from conventionally bred animals. The EFSA 2009 statement confirmed that the conclusions and recommendations of the EFSA 2008 scientific opinion were still valid.

Based on the literature search and information provided in the framework of the present statement, it is concluded that there is still limited information available on species other than cattle and pigs which would allow for assessment of food safety and animal health and welfare aspects.

Information, published over several years, indicate that cloning efficiency in cattle (currently around 10 %) and pigs (currently around 6 %) is lower than by natural breeding (cattle calving rate 40-55 %) as well as from assisted reproductive technologies (ART), such as artificial insemination. However,

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1 On request from the European Commission, Question No EFSA-Q-2010-00887, issued on 14-09-2010

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compared with *in vitro* produced embryos and embryo transfer in pigs, cloning has similar efficiency (~ 6 %).

*In vitro* fertilisation technologies can deliver healthy animals using similar *in vitro* handling steps (e.g. maturation, culture) to those used in cloning, but at a higher rate, especially in cattle. This suggests that the reprogramming of the somatic donor cell nucleus (epigenetic dysregulation) is a major factor affecting cloning efficiency. If the success rate of the epigenetic reprogramming is improved it is expected that the pathologies and mortalities observed in a proportion of clones would decrease (EFSA 2009).

No new information has become available, since the EFSA 2009 statement and the EFSA 2008 scientific opinion that would lead, at this point in time, to a reconsideration of the conclusions and recommendations related to the food safety, animal health and welfare aspects of animal cloning as considered in the 2008 scientific opinion and the EFSA 2009 statement.

#### **KEY WORDS**

SCNT, Somatic Cell Nuclear Transfer, Efficiency, Safety, Cattle, Pig