#### Eurogroup for Animals Submission to EFSA on the "Draft Scientific Opinion on Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by SCNT and their Offspring and Products Obtained from those Animals"

#### 1. Introduction

Eurogroup for Animals is a pan-European animal welfare organisation. It represents all 25 Member States through its Member Organisations and Observers. It therefore represents a significant proportion of EU public opinion.

This submission summarises Eurogroup's concerns about the impact that cloning by SCNT has, or is likely to have, on animal health and welfare throughout Europe. These concerns are based on the fact that the development and commercial application of animal cloning by SCNT to food production:

- involves procedures that have great potential to cause animals pain, suffering or distress;
- are hugely inefficient and use a very large number of animals;
- increase the perception of animals as commodities for human use and/or gain, such as units of production, rather than as sentient beings;
- could greatly reduce genetic diversity within livestock populations, increasing the chances of whole herds being wiped out by disease to which they would all be equally susceptible
- are being pursued without public awareness of, and in spite of well-documented public concerns relating to, the use of biotechnology in food production (eg. GM foods).

The comments in the following sections are specific to the content of the EFSA draft Opinion and detail our concerns regarding:

- How the animal welfare concerns are presented
- The animal health and welfare conclusions and recommendations

## 2. Concerns relating to Section 4 - Animal health and welfare implications of SCNT

### 2.1. General points

 Section 4, line 603: "As the literature on cloning is based upon reports of work carried out in highly monitored populations and environments, the effects observed and recorded may not reflect the conditions of husbandry that exist in everyday production systems."

This statement makes a very important point given the problems that occurred when BST use in cattle moved from the laboratory to the farm. Eurogroup believes this statement should be reiterated in the conclusions, and that the Opinion should include a recommendation that further research be undertaken to inform a future discussion on the risks associated with the introduction of cloning into 'everyday' / commercial livestock production systems, before any policy decisions are taken.

## 2.2. Source animals for oocytes

• Section 4.2.1, line 925: "The cloning procedure itself does not normally affect the welfare of the somatic cell nucleus or oocyte source animals."

We believe this statement to be unsubstantiated in the case of oocyte source animals because ovum pickup as a non-therapeutic surgical intervention has been cited as a particular area of concern (FAWC, 2004). Ovum pickup (in cattle) involves passing a needle through the wall of the vagina under ultrasound guidance to collect oocytes directly from the ovarian follicle (Banner, 1994), whilst in pigs endoscopy is used (Brussow et al., 2000). This is therefore a very skilled technique and as such is classified as an act of veterinary surgery under UK law (Banner, 1994).

### 2.2. Surrogate Dams

• Section 4.2.2, line 929: "the welfare of the dam is likely to be affected".

This statement is true, however no mention is made in the Opinion of the procedure required to transfer the cloned embryos into the surrogate dams, in either the animal health or welfare sections. This is a worrying omission because embryo transfer requires an epidural in cattle, and a general anaesthetic in sheep, goats and pigs (Banner, 1994; Brussow et al., 2000). The repeated use of epidural anaesthesia in cattle has previously been raised as an animal welfare concern in the UK "Code of Recommendations for the Welfare of Livestock: Cattle" (DEFRA, 2003). There are also no current rules governing the number of embryos which may be implanted into sheep or cattle, or the number of times such a procedure may be performed (FAWC, 2004).

### 2.3. Clones

 In the EFSA Opinion on the "Aspects of the biology and welfare of animals used for experimental and other scientific purposes" (EFSA 2005) it is acknowledged that there is a risk that "mammals in utero may sometimes be aware before parturition". It is also stated that "when a procedure is performed on a fetus in utero that is likely to cause pain in a newborn of that species....., protection should be given against pain and suffering" (EFSA 2005).

In section 4.2.3 of the current draft Opinion there is no discussion of the impact of cloning on the welfare of cloned animals before birth. Eurogroup therefore believes that EFSA should expand the draft Opinion to incorporate a discussion of the welfare of clones during gestation and the perinatal period in relation to the health problems raised in Section 4.1.3.1.

### 2.4. Progeny of clones

• Section 4.2.4, line 1034: "No studies on the welfare of the progeny of clones have been reported in livestock species."

We believe this statement is sufficiently important to warrant its inclusion within the Opinion conclusions, together with a recommendation that any decision on the commercial use of SCNT cloning for food production purposes is delayed until such time as this information is available. Such a recommendation would be in

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keeping with the EFSA Scientific committee opinion relating to the early identification of emerging risks (EFSA, 2006), which states that "*The Authority shall establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission*", where an emerging risk is "*an issue that in the future may pose a risk to the health of the consumer, animals, or the environment*" (EFSA, 2006). Eurogroup believes that EFSA has a responsibility to delay a decision until information is available given that it is the progeny of clones that it is anticipated will enter the human food chain.

# 3. Concerns relating to Section 6 - Impact on the environment and genetic diversity

 Section 2.4, line 333: "Cloning provides a way in which selected characteristics can be propagated into production herds more rapidly. For example, if an animal with a genetic resistance to a disease has been identified, that animal could be expanded by cloning into several genitors, which could then be used to introduce the disease resistance trait via sexual reproduction into the production herd."

Eurogroup is concerned that the converse of this statement could be true meaning that cloning could actually increase rather than decrease animal health problems. Experience from conventional selective breeding indicates that there can be unintended negative consequences of highly focussed selection for one desired trait. The same could be true for selection via cloning, thus by creating a herd of animals with genetic resistance to one disease these animals could unintentionally be being selected to be highly susceptible to another disease. In addition, selection for a specific trait could also result in other beneficial genetic traits being bred out and lost. Indeed following the introduction of the UK National Scrapie Plan, in which sheep with greater genetic resistance to Scrapie were selected for breeding, there have been a number of concerns raised about possible detrimental effects on health and production traits ().

### 4. Concerns relating to the Overall Opinions and Recommendations

- European Directive 98/58/EC states that "natural or artificial breeding procedures which cause, or are likely to cause, suffering or injury to any of the animals concerned shall not be practiced" (Annex, point 20). Given that the EFSA opinion identifies a number of animal health and welfare concerns, Eurogroup believes that one of the key recommendations of this Opinion should state that the application of SCNT cloning technology for food production should not be permitted until such time as the animal health and welfare concerns have been effectively addressed.
- Eurogroup urges EFSA to make it clear to the European Commission that the sections on Animal Health and Welfare should be given equal weight to those on Food Safety, and the Environment, when considering future policy developments.
- EFSA states that "SCNT technology as such is not expected to adversely affect the genetic diversity of domestic species. However as with other ARTs, SCNT could, by extensive or inappropriate use, increase homogeneity of a genotype within a population, and therefore increase susceptibility of the

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animal population to infectious agents and other risk factors." (Section 6.1, line 1220). Given this statement, which concurs with the issue we raised in point 3 above, Eurogroup believes that the current recommendation that SCNT technology be used "*in such a way as to prevent the reduction of genetic diversity*" (Page 32, line 1306) should be amended to state that *the use of SCNT technology for food production should be subject to strict regulation and control to ensure it does not reduce genetic diversity*.

#### References

Banner (1994) Report of the Committee to Consider the Ethical Implications of Emerging Technologies in the Breeding of Farm Animals. Ministry of Agriculture, Fisheries and Food, HMSO.

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Council Directive 98/58/EC of 20 July 1998 concerning the protection of animals kept for farming purposes (1998) *Official Journal L.* **221** 0023 - 0027

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