European Food Safety Authority

EFSA Stakeholder Meeting

7 February 2008

Draft Scientific Opinion on Food Safety, Animal Health and Welfare and Environmental Impact of **Animals Derived from Cloning**

Vittorio Silano, Chair, EFSA Scientific Committee

Commission request for an opinion on Animal Cloning

efsa
European Food Safety Authority

Terms of reference:

…to advise on **food safety**, **animal health**, **animal welfare** and **environmental implications** of live cloned animals, obtained through somatic cell nucleus transfer technique (SCNT), their **offspring** and the **products** obtained from those animals.

Process and Timeframe

- EFSA received draft mandate (Feb 2007) for an opinion by August 2007
- Acceptance of mandate and timeframe after discussion with EFSA Scientific Committee (April 2007)
- Collection of data via web call (April-May 2007)
- Establishment of a working group under the aegis of the Scientific Committee to draft opinion
- Scientific Committee to agree on draft opinion for public consultation (19 Dec 2007)
- Public consultation, from 11 January, Deadline 25 Feb 2008
- Finalisation, adoption and publication of opinion (Expected May 2008)

EFSA Working group

Composed of 14 experts covering the following areas:

- animal reproduction technology
- genetic characterisation
- animal health
- animal welfare
- toxicology
- risk assessment

EFSA Webpage:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178625241264.htm

Sections in the Opinion

- Introduction
- Animal breeding and reproductive techniques
- Epigenetic and genetic aspects
- Animal health and welfare implications
- Safety of meat and milk from clones and their progeny
- Impact on the environment and genetic diversity
- Conclusions and recommendations

Summary – *Breeding and SCNT*

- Cloning by SCNT has been applied to several animal species but, given the available data, it was only possible to make a scientific assessment for cattle and pigs.
- Cloning differs from other modes of reproduction because it is asexual.
- Cloning has its use in animal breeding programs where it allows the introduction of proven desirable characteristics (such as disease resistance) and the propagation of animals regardless of their fertility.
- SCNT allows the reproduction of animals with a known phenotype from a single animal.

Summary – *Epigenetic aspects*

- **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 normal health status of clones is the main indicator of the functioning of epigenetic reprogramming.**

Summary – *Health*

- **For surrogate dams, an increased proportion of pregnancy failure has been observed in cattle and pigs and increased frequencies of hydrops and dystocia have been observed especially in cattle.**

  (These effects have also been observed in surrogate dams carrying pregnancies induced by assisted reproductive technologies not involving SCNT, albeit at a lower frequency and often with less severity.)

- **Mortality and morbidity rates in clones are higher than in sexually reproduced animals**

Summary – *Welfare, Food Safety*

- **The welfare of both the surrogate dam and the clone can be affected due to the adverse health outcomes observed.**

- **No difference exceeding the normal variability have been observed in the composition and nutritional value of meat and milk between healthy clones or the progeny of clones and their conventional counterpart.**

- **Food products from clones of cattle and pigs and their progeny are as safe as food products of livestock derived by conventional breeding.**

Summary – *Environment*

- **No expectation that clones or their progeny would pose any new or additional environmental risks compared with conventionally bred animals.**

Conclusion

Based on current knowledge there is no expectation that clones or their progeny would introduce any new food safety risks compared with conventionally bred animals.

Recommendations

- The Scientific Committee recommends that the health and welfare of clones are monitored during their full natural life.
- It is acknowledged that other food species have also been produced via SCNT and risk assessments should be performed on these species when relevant data become available.
- The Scientific Committee also recommends that this opinion be updated in the light of developments with cloning and/or with new relevant data.
- Additional recommendations arising from the specific sections.

Comments received so far to EFSA public consultation

- EFSA asking for Scientific Comments
- The large majority, received so far are not scientific comments, but personal views, not supporting cloning

- Public Consultation ends February 25

Grazie!