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Review of the animal cloning situation in the EU 2008

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Report Highlights:

On July 24, 2008, the European Food Safety Authority (EFSA) adopted their final opinion on animal cloning after the European Parliament (EP) came out against it in June. The EP voted a resolution against animal cloning for food purposes in the EU despite a positive scientific assessment by EFSA in January 2008.

Includes PSD Changes: No
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Scientific Opinions

EFSA adopts final scientific opinion on animal cloning

On July 24, 2008, EFSA published its final [scientific opinion on the implications of animal cloning](#)¹ on food safety, animal health and welfare and the environment. EFSA's opinion follows a request from the European Commission (EC) to EFSA for advice on this issue in February 2007 and public consultation on a draft opinion earlier this year.

Prof. Vittorio Silano, chair of EFSA's Scientific Committee, said in a press conference:

"It is clear there are significant animal health and welfare issues for surrogate mothers and clones that can be more frequent and severe than for conventionally bred animals. For cattle and pigs, food safety concerns are considered unlikely. No clear evidence has emerged to suggest any differences between food products from clones or their offspring, in terms of food safety, compared to products from conventionally bred animals. But we must acknowledge that the evidence base, while growing and showing consistent findings, is still small. That has been one of the challenges throughout this work."

Some of the key conclusions of the opinion include:

- Uncertainties in the risk assessment arise due to the limited number of studies available, the small sample sizes investigated and, in general, the absence of a uniform approach that would allow all the issues relevant to this opinion to be more satisfactorily addressed. Only pigs and cattle are addressed in this opinion: the two species of animals where adequate data were available.
- The health and welfare of a significant proportion of clones, mainly within the juvenile period for cattle and perinatal period for pigs, have been found to be adversely affected, often severely and with a fatal outcome.
- Somatic Cell Nucleus Transfer (the most common technique used to clone animals) has resulted in the production of healthy cattle and pig clones, and healthy offspring that are similar to their conventional counterparts based on parameters such as physiological characteristics, demeanor and clinical status.
- There is no indication that differences exist in terms of food safety for meat and milk of clones and their progeny compared with those from conventionally bred animals. However, such a conclusion is based on the assumption that meat and milk are derived from healthy animals which are subject to relevant food safety regulations and controls.
- No environmental impact is foreseen but there are only limited data available.

FAS/USEU analysis

The conclusions in the final opinion are quite similar as from the draft opinion². However, the focus has shifted from explaining the animal health and animal welfare concerns of this new technology to emphasizing their importance. In the press materials, Prof. Silano, Chair of the EFSA Scientific Committee, pointed out that animals originating from Assisted Reproductive Technologies, such as in-vitro fertilization, showed an even higher percentage of problems than animals produced from cloning. The final opinion maintained the conclusion that no food safety issues were identified, nor that any environmental impact from animal cloning is expected despite limited data. It was highlighted that only sufficient data for the cloning of cattle and pigs were available for this opinion and that it would be completed when more data became available for additional species. It was remarked that

¹ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902019540.htm

² See GAIN [E48006](#) - <http://www.fas.usda.gov/gainfiles/200801/146293472.pdf>

this opinion only assesses animal cloning through Somatic Cell Nucleus Transfer (SNCT) and not any other animal cloning technique.

After the publication of the draft opinion in January, 2008, EFSA had engaged in a [public consultation](#)³ and held a [technical meeting with stakeholders](#)⁴ on February 7, 2008. The final opinion was only drafted after this feedback on the draft opinion was taken into consideration.

Question and answer session

During the Q&A session, it was emphasized that food in the future would not be derived from cloned animals but from their progeny. Because this progeny would have come from conventional reproduction, the animal health and animal welfare issue would not exist at this level. From the aspect of food safety, this conventional reproduction was to be seen as an additional security layer.

When asked about the difference between this EFSA opinion and the FDA assessment of animal cloning, it was pointed out that the FDA assessment included more species⁵, but also that the procedures were different. It was suggested that the aspect of animal welfare was not part of the FDA assessment. Unlike EFSA, FDA covers both the risk assessment and the risk management. On the question if products from animal cloning were already on the market, it was indicated that the panel only knew about developments in the United States, but had no idea about the rest of the world.

Mid-day press conference at the European Commission

Consecutively to the EFSA press conference on the publication of the opinion on animal cloning, the subject was also paramount in the daily mid-day European Commission (EC) press conference. It was highlighted that thus far in the EU, cloned animals and their semen only exist for scientific purposes and that no cloned animal or product had gone to market, nor had been imported into the EU market. When asked whether the EC would ban animal cloning and what procedure would be followed for the approval of such legislation, it was highlighted that the EFSA opinion and the opinion (see below) from the European Group on Ethics of Science and New Technologies (EGE), were just the first steps. In the autumn of 2008, the next Eurobarometer would reveal public opinion about animal cloning and then consultations with the European Parliament and Member States would be held before the EC would draft any proposal to approve or ban animal cloning.

Opinion from the European Group on Ethics of Science and New Technologies (EGE)

The European Group on Ethics of Science and New Technologies (EGE) adopted its [opinion number 23 on "Ethical Aspects of Animal Cloning for Food Supply"](#)⁶ on January 16, 2008. The authors of the EGE report are not convinced that production of food from cloned animals and their offspring is defensible. The opinion states, "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. Whether this applies also to progeny is open to further scientific research." The EGE further called for a Code of Conduct on responsible farm animal breeding, including animal cloning and it also raised concerns about farm animal biodiversity and sustainability, as well as intellectual property issues. The

³ http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178676923092.htm

⁴ http://www.efsa.eu.int/EFSA/efsa_locale-1178620753812_1178685288301.htm

⁵ The FDA assessment also includes goats.

⁶ http://ec.europa.eu/european_group_ethics/activities/docs/opinion23_en.pdf

opinion questioned about the public perception of animal cloning and requested labeling of products derived from cloned animals to ensure the consumer's freedom of choice.

European Parliament voices opposition

On June 2, 2008, the EP held an [oral question and debate session](#)⁷ on animal cloning with the European Commission. The questions raised were principally about whether the EC believed animal welfare of cloned animals and their offspring was sufficient and how the EC intended to secure it. Further questions were about the ethical aspects of animal cloning for food purposes and how the EC would debate this with consumers. Questions were also raised whether the EC was taking measures to prevent imports of cloned animals and their products and if the EC planned to file a proposal to prohibit animal cloning and imports of cloned animals, their offspring and their products.

On June 25, 2008, the Agriculture Committee of the European Parliament (EP) unanimously adopted a [draft resolution](#)⁸ and called on the Commission "to submit proposals prohibiting:

- the cloning of animals for food supply purposes,
- the farming of cloned animals or their offspring,
- the placing on the market of meat or dairy products derived from cloned animals or their offspring, and
- the importing of cloned animals, their offspring, semen and embryos from cloned animals or their offspring, and meat or dairy products derived from cloned animals or their offspring."

Mr. Neil Parish, the president of the EP Committee on Agriculture and Rural Development, had already filed this [Motion for a Resolution](#)⁹ on the cloning of animals for food supply on March 3, 2008.

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⁷ <http://www.europarl.europa.eu/sides/getDoc.do?type=OQ&reference=O-2008-0069&language=EN>

⁸ <http://www.europarl.europa.eu/sides/getDoc.do?type=IM-PRESS&reference=20080623IPR32472&secondRef=0&language=EN>

⁹ <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+MOTION+B6-2008-0107+0+DOC+PDF+V0//EN&language=EN>