

Regulation of Cloned Farm Livestock

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Farm livestock are being cloned by commercial companies in several countries in the world and it is possible that meat and milk from the progeny of these cloned animals will turn up in European food within the next few years. It is not yet clear how regulatory regimes will be applied to these animals and products from them. This lack of clarity both poses a disincentive to the industries wishing to develop these animals and at the same time will risk consumer rejection because of uncertainty as to how their safety and ethical concerns will be met. While the EU has taken the first steps towards addressing safety and ethical concerns, it is important that these are considered in a timely fashion. It is, however, very unlikely that any decision will satisfy all constituencies and all consumers.

THE IMPACT OF FARM ANIMAL CLONING

Cloning in mammals using somatic cell nuclear transfer was brought to public consciousness in 1997 by Dolly the sheep. Subsequently a whole range of species has been cloned using similar techniques, e.g. cow in 1998, goat in 1999 and pig in 2000. A number of companies have been set up to apply the technology commercially. Dolly was originally produced in an attempt to develop a more effective method of genetically modifying animals and to some extent these applications have been continued (e.g. to produce pharmaceuticals in the milk of animals) but they are not considered further in this briefing. Cloning by the somatic cell nuclear transfer (SCNT) method has also been used to reproduce rare species of animals and pets but again the applications have been limited to date and are not considered further in this briefing note.

The application of SCNT to food production has to date mainly involved cattle and pigs and has not involved genetic modification. The technology is not currently widely used, with estimates of some thousands of cloned animals in existence world wide at the time of writing. The birth of a calf, called Dundee Paradise, in the UK in 2006 from semen from a cloned bull in the USA, highlighted the fact that developments in one country can impact on another. The press announcement¹ of the birth of Dundee Paradise made a clear link to genetically modified foods and 'Frankenstein Farming' and alluded to food products from cloned animals appearing in European supermarkets without proper safety checks; uncontrolled, unmonitored and apparently without the knowledge of the regulatory authorities. Whilst the Daily Mail may be pursuing a particular angle on cloned farm livestock, what is the state of current regulation? What issues do cloned farm livestock raise? And might they become widely used in agriculture?

EU REGULATION

At the EU level, a number of different legislative instruments may apply to cloned farm livestock, the key ones being:

- i) Regulation of novel foods and food ingredients (EC regulation 258/97)
- ii) Regulation of commercial release of genetically modified organisms (GMOs) (Directive 2001/18/EC)

“Cloning (somatic cells) is a new technology that is currently not being used by European Breeding Organisations. This is partly for technological and economic reasons, and partly because there is no public approval of such developments at present.”

Statement from the Code of Good Practice for Animal Breeding and Reproduction Organisations in Europe²

- iii) Regulation on breeding animals and imports of breeding stock
- iv) Regulation on welfare of farm animals (Directive 98/58/EC)

Ethical issues have been the subject of attention in several individual EU member states (e.g. Denmark) and are addressed at the community level by the European Group on Ethics (EGE) in science and new technology which consists of a group of specialists who issue opinions to the European Commission.

Regulating cloned animals and their products as novel foods

Food products deemed to be 'novel' are subject to pre-market safety assessment. The European Food Safety Authority (EFSA) is already undertaking an evaluation of the food safety, animal health and welfare and environmental implications of cloned farm animals, their offspring and products derived from these animals. A draft opinion is expected to be available for public consultation by November 2007 and a final (first) opinion in early 2008. At the turn of 2006, the US Food and Drugs Administration (FDA) released their long-awaited draft risk assessment on food from cloned cattle, pigs, sheep and goats and concluded that *"meat and milk from clones and their offspring are as safe as food we eat every day"*. It remains to be seen whether EFSA follows the lead of FDA with respect to cloned animals, although it seems extremely unlikely that any differences can be identified at the next generation level between the progeny of cloned animals and progeny of naturally conceived animals.

RELEASE OF CLONED ANIMALS INTO THE ENVIRONMENT

The relevant regulation governing the commercial release of genetically modified organisms has been developed with crops in mind. Environmental risk assessment is arguably much less of an issue with respect to cloned farm animals as there are usually no 'wild' populations of livestock that they can breed with and even if such populations exist, it is difficult to see how they could be seen to 'contaminate' these populations more than the release of a non-cloned farm animal. It is also not clear if cloned animals would be considered as genetically modified organisms under the current definition in the regulation.

REGULATION OF BREEDING ANIMALS

The European Union has a number of zootechnical regulations that control the entry of breeding animals into herd books and promoting free trade in breeding animals. Directive 94/28/EC lays down the principles relating to the conditions applicable to imports from third countries of animals, their semen, ova and embryos. This regulation includes the requirement for information on the parents and grand-parents of the imported animal (semen, ova or embryos). There is currently no restriction on entry of cloned animals into herd books. Many European commercial animal breeders have signed up to a voluntary code of practice and this currently states that members will not use SCNT cloning technology.

WELFARE OF FARM ANIMALS

The process of producing SCNT cloned animals involves surgical procedures and hence some harm to the animals involved. In addition, a percentage of cattle, sheep and goat embryos produced by SCNT suffer from a wide-range of defects that become apparent during gestation or soon after birth, including the birth of unusually large offspring. The extent of this problem is debated, however. Some commercial organisations argue that they have now perfected the techniques to the level that is comparable to the use of other reproductive technologies but other stakeholders are sceptical of such commercial claims until the data are published for scrutiny. Once the cloned animals have reached adulthood, they appear to be normal. Limited studies to date indicate that they are normal in health and in behaviour, although it should be noted that the data are currently based on very small numbers of animals and require verification over larger numbers.

EC legislation clearly recognises the value of animals and general rules for good welfare are set out. However, the application of welfare legislation to farmed animals in

*"Based on FDA's analysis of hundreds of peer-reviewed publications and other studies on the health and food composition of clones and their offspring, the draft risk assessment has determined that meat and milk from clones and their offspring are as safe as food we eat every day ...Cloning poses no unique risks to animal health when compared to other assisted reproductive technologies currently in use in U.S. agriculture."*³

the EU does not clearly define what is, and what is not, acceptable welfare. It is therefore likely that the welfare of cloned animals will be disputed and it is not clear how these disputes will be resolved.

INTERNATIONAL TRADE

A survey of producers of cloned farm livestock world-wide which was carried out in 2005 through the European Science and Technology Observatory and co-ordinated by the European Commission Joint Research Centre Institute for Prospective Technological Studies⁴ found a widely held view among industry insiders that products derived from the offspring of cloned cattle and pigs are likely to enter the food chain somewhere in the world before 2010. Several thousand cloned livestock have now been produced globally in a range of commercial enterprises, notably in USA, Australia/New Zealand and China. However, these companies appear to be small and fragile and there has been a lot of turbulence in the sector with a number of companies disappearing or amalgamating.

The main block to the introduction of meat and milk from cloned animals to international markets is a voluntary moratorium by US producers pending marketing approval from FDA. This may well be lifted by the end of 2007 if, as expected, the FDA approved meat and milk from cloned animals (except sheep) to be allowed in the food chain. Meanwhile, there are no clear international agreements covering trade in semen and embryos of cloned farm livestock in place. There must therefore be at least the possibility of trade conflicts related to cloned livestock or products derived from them.

The regulation of world trade is very complex but the main regulatory instruments for international trade in agricultural products are:

- i) Regulation by the World Trade Organisation (WTO)
- ii) Cartagena Biosafety Protocol (CBP)

The WTO is intended to promote free-trade and provides for evidence-based risk-assessment but not discrimination on animal welfare or ethical grounds. The Cartagena Biosafety Protocol is part of the agreements to protect biodiversity and includes a wider definition for the use of the precautionary principle in risk assessment and more scope for inclusion of socio-economic factors. However, the Cartagena Biosafety Protocol applies to Living Modified Organisms and it is not clear if this definition would include cloned animals. It is also noteworthy that it is unclear how contradictions between the WTO and CBP will be resolved, particularly where parties are not all signatories to both agreements.

Furthermore, it should be noted that there is currently no scientific method (and no obvious basis) for distinguishing between the milk and meat of cloned and non-cloned animals (or their offspring). Thus any labelling requirements placed on the products from cloned animals (and their offspring) would need to rely on traceability regimes that may be more feasible in small, niche markets than in international commodity markets.

DRIVERS FOR USE OF CLONED FARM LIVESTOCK

The main justifications for using SCNT cloning technology in livestock farming is economic as the technology allows elite animals to be used more widely than using natural breeding. Environmental benefits may also accrue as the improvement in production from using these elite animals mean less resources are required to produce a given quantity of meat or milk. Cloned animals may also be used as 'insurance' against the premature death or injury of a valuable elite animal and clones of elite bulls may be used to export to countries where Artificial Insemination (the more common method used for international transfer of breeding stock) is not widely used.

Evidence (all be it limited) suggests that the European publics are likely to react negatively to products from cloned animals, particularly if a degree of poor animal welfare is involved. The data suggest that European publics may accept a degree of

“The animal was born as the majority of the 220,000 animals that we register in the UK every year are born – as a result of artificial insemination”⁵

Simon Gee, Holstein UK
quoted by BBC, referring to the birth of Dundee Paradise from the semen of a cloned bull

animal suffering as long as there is a clear benefit to be gained but economic benefit for producers of breeding stock is unlikely to provide sufficient justification.

CONCLUSIONS

Companies have been established and are producing cloned animals for livestock production (although not in the EU). There is a widely held view by industry insiders that cloned livestock (especially pigs and cattle) will be used within the food chain somewhere in the world before 2010. The expectation is that clones will be used as parents or grand-parents of slaughter pigs, beef cattle and dairy cows rather than the clones themselves being consumed. The main argument for the use of cloned parents is economic benefit. The US FDA is expected to approve the use of cloned animals (except sheep) in the food chain by the end of 2007. Semen from cloned cattle has already been exported to the UK and at least one calf produced as a result. There is at least the prospect of food products from the progeny of cloned animals to enter into the EU, although the speed and extent of adoption of cloning technology is difficult to predict. There is no clear regulation on international trade in cloned animals, their progeny and products from them and there is therefore the potential for trade disputes in this area.

One of the aims of regulation is to ensure the safety of food products and the EFSA is already in the process of gathering data on cloned animals and their progeny. Ensuing animal welfare is also a key issue and again EFSA has been charged with evaluating this aspect of cloned animals. However, it is not immediately obvious that EFSA historically has the background to make such judgements and is therefore likely to require a degree of institutional learning to take place. Setting clear targets for good animal welfare is notoriously difficult, although in the case of cloned animals (but not their progeny) there are some clear welfare issues which may or may not be deemed acceptable.

However, the main issues are likely to be different preferences or ideologies regarding agricultural production practices and ethical issues related to the cloning method per se. The EGE have already been asked to advise on the ethical aspects of cloned farm livestock and have initiated a consultation. The question remains how decisions made regarding ethics at the EU level are legitimated. EGE members are appointees of the President of the Commission, rather than a democratically elected representative body.

The number of regulatory instruments available to the EU (should the EU wish to use these) are also somewhat limited. It may be possible to use zootechnical legislation for control of imports and production of cloned animals and semen. Labelling of products of cloned animals (let alone progeny or grand-progeny of cloned animals) may be impossible to enforce and likely to be unacceptable to exporters of commodity meat and milk due to cost considerations, although possibly desirable from a consumer point of view. This information may therefore become incorporated in e.g. organic standards or branded products. An alternative approach by objectors is to avoid animal products all together but it is not clear how many people will feel strongly enough to adopt a vegetarian diet in response to these developments.

There are likely to be a plurality of opinions about cloning and therefore it will be impossible to satisfy everyone. Regulators may be faced with the dilemma of how to make evidence-based decisions about value-based issues and it may be that the key issue is how any decision is legitimated. However, there is a need to arrive at a conclusion in a timely manner to maintain public confidence and provide regulatory certainty for industry.

“The history of cloning is littered with examples of animals that are unhealthy or die quite early and the whole process involves invasive procedures that cause suffering”

Peter Stevenson,
policy advisor
for Compassion
in World
Farming quoted
in *The Scotsman*⁶

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