TACD

TRANS ATLANTIC CONSUMER DIALOGUE
DIALOGUE TRANSATLANTIQUE DES CONSOMMATEURS

DOC No. FOOD 31-08 DATE ISSUED: NOVEMBER 2008

TACD Revised Resolution on Food Products from Cloned Animals

Introduction

Animal cloning came to the public's attention in 1996 with the birth of the first mammal clone, Dolly, a sheep. Since then, a number of companies have continued to use cloning to asexually produce a wide array of animal clones, and the commercial sale of meat and milk derived from cloned livestock and their offspring appears imminent.

Cloning is a relatively new technology and its impacts are still not well understood. According to a number of scientific studies the vast majority of cloning attempts fail. Even "successful" clones can have severe health problems, such as metabolic or cardiopulmonary abnormalities, that can result in death or the need for euthanasia. There are concerns that food safety and animal health could be impacted if cloned animals or animal products derived from them are used for food.

In 2003, the U.S. Food and Drug Administration (FDA) requested a voluntary moratorium on the sale of food products from animal clones and their offspring, essentially asking companies not to market or sell cloned food but without any legally enforceable restrictions. However, in January 2008 the FDA published a final risk assessment which concluded that the products from cattle, goat and pig clones posed no additional risk relative to their conventional counterparts[1].

In the European Union there is currently no specific binding legislation dealing with animal cloning. The Novel Foods Regulation, which is currently under review, requires that the products of clones have to be approved before they can go onto the market. However, products from the offspring of clones are not covered and so can legally enter the European market without prior assessment and approval. The European Food Safety Authority (EFSA) and the European Group on Ethics (EGE) have, however, recently issued Opinions on the use of cloned animals for food production. EFSA looked at the food safety, animal health and welfare and environmental impact, whereas the EGE looked at the ethical implications. EFSA[2] highlighted animal health issues for the surrogate dams and the clones. Based on the currently available knowledge, which is limited, it felt that there is no indication that there would be differences in food safety between food products from healthy clones and their offspring compared with healthy conventionally bred animals. The EGE[3] questioned the ethical justification of cloning animals for food considering the current level of suffering and health problems of surrogate dams and animal clones. It highlighted a number of considerations, including the need to ensure traceability if clones did enter the market. These Opinions will inform the approach that is taken by the European Union, along with a European Commission Eurobarometer survey to gauge public opinion in the 27 Member States.

It is already clear that many consumers, in both the U.S. and EU, have significant concerns and

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[1] Animal Cloning: A Risk Assessment, US Food and Drug Administration, January 2008.

[2] Food Safety, Animal Health and Welfare and Environmental Impact of Animals Derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals, Scientific Opinion of the Scientific Committee, 15 July 2008, EFSA Journal (2008) 767, 1-49.

[3] Ethical aspects of animal cloning for food supply, Opinion No 23, the European Group on Ethics in Science and New Technologies to the European Commission, 16 January 2008.

objections to the use of clones in animal agriculture and the sale of milk and meat derived from such clones and their progeny. Recent polls show that most Americans would refuse to buy food from animal clones, and that Americans have serious concerns about the ethics of animal cloning. A recent independent poll found that 79% of Americans are unsure about the safety of cloned food, including 43% who believe that cloned food would be unsafe. A food industry-sponsored poll last year similarly found that 63% of Americans would not buy cloned food, even if the FDA deemed the products safe.

A recent Eurobarometer survey commissioned by the European Commission in 2008[4] found that the vast majority of EU citizens (84%) thought that the long-term effects of animal cloning were unknown. It also found that people were significantly less willing to accept animal cloning for food production purposes with 58 per cent saying that such cloning should never be justified. A majority said that it was unlikely that they would buy meat or milk from cloned animals, even if a trusted source said that such products were safe with 20% saying that it was somewhat unlikely and 43% saying that it was not at all likely. Eight out of 10 (83%) said that special labelling should be required if food products from the offspring of cloned animals became available in shops. A survey conducted by Which? the UK consumer organisation, in February 2008 found that 81 per cent of people were concerned about eating meat from cloned animals and the same percentage for meat from the offspring of cloned animals. Eighty per cent of respondents preferred to buy foods that were not produced using cloned animals and 80 per cent thought that food produced using cloned animals should be clearly labelled[5].

TACD believes that, if the US and EU governments fail to adequately regulate the use of cloned animals and their progeny for food, it could compromise human health and undermine consumers' fundamental right to know and to choose what they are eating.

Cloning – The Process

Cloning or Somatic Cell Nucleus Transfer (SCNT) involves replacing an egg's nucleus with the nucleus from the adult cell or from an embryo or foetus to be cloned using cell fusion or direct injection. The egg is then manipulated so that it develops without fertilisation and the embryo clone is implanted into a surrogate female animal.

There is interest in cloning because it allows more offspring to be produced from animals that have particularly desirable traits than would be possible through other methods of reproduction. It is likely, for this reason, that cloning will be used in combination with genetic modification (GM), although the recent Opinions do not address this. Clones are also more likely to be used for breeding. It is, therefore, the offspring of clones that are most likely to be used for food production.

Reasons for Concern:

1. **Food Safety Concerns**

There are limited studies assessing the safety of cloned animal products. Both EFSA and the FDA have taken the view that the indications are that food products from healthy clones are unlikely to raise different concerns to conventionally bred healthy animals. They regard the issues for the offspring of clones as being no different to conventional animals.

However, EFSA is clear that uncertainties arise from the limited number of studies available, the small sample sizes investigated and the absence of a uniform approach to allow all of the relevant issues to be addressed. They felt that the data on cloned sheep was too limited and they therefore could not include them within the Opinion.

Both opinions acknowledge the adverse animal health effects that result from cloning, but take the view that these should be identified and affected animals removed from the food chain. Unusually, the risk assessment is predicated on assumptions about the effectiveness of food safety controls, including ante- and post-mortem inspection.

[4] Europeans' attitudes towards animal cloning, Analytical Report, Flash Eurobarometer 238, European Commission, October 2008.

[5] 2061 people representative of the general population of the UK were interviewed by telephone in February 2008.

A. Potential Pathogen Issues

The US National Academy of Sciences' report, Animal Biotechnology: Science Based Concerns, stated that:

'*A number of data sets suggest that the health and well-being of neonatal and young somatic cell clones often are impaired relative to those of normal individuals. Direct effects of any abnormalities in patterns of gene expression on food safety are unknown. However, because stress from these developmental problems might result in shedding of pathogens in fecal material, resulting in a higher load of undesirable microbes on the carcass, the food safety of products, especially such as veal, from young somatic cell cloned animals might indirectly present a food safety concern'.*

EFSA also recommends that there should be further investigation into the immunocompetence and susceptibility of clones and their offspring to diseases and transmissible agents when reared and kept under conventional husbandry conditions. It advises that: '*Should evidence become available of reduced immunocompetence of clones, it should be investigated whether, and if so, to what extent, consumption of meat and milk derived from clones or their offspring may lead to increased human exposure to transmissible agents'.*

B. Intervention such as antibiotics

The questionable health of some clones could raise significant new herd management issues that may affect the quality and state of animal products for consumers. Significantly reduced genetic diversity combined with confined industrial farming practices could make herds more susceptible to widespread disease issues. Sicker herds, in turn, might result in more interventionist approaches to herd management including new and increased subtherapeutic and therapeutic uses of antibiotics.

2. **Animal Health Concerns**

Use of cloning techniques raises animal health concerns. Because of the high failure rate of cloning, surrogate animals can be subjected to repeated surgical operations to implant cloned embryos and extract cloned foetuses. Most cloned animals exhibit a condition known as "large-offspring syndrome," which results in overly stressful deliveries for surrogates and newborns. For the few cloning attempts that result in a live birth, the cloned animal's health is often so poor that many die within 24 hours due to respiratory distress, increased birth weight and major cardiovascular abnormalities. Even apparently "healthy" clones often suffer unexpected health consequences and will require a lot of husbandry care. As well as any food safety implications arising from sick animals, many consumers do not wish to use food products derived from techniques that cause such problems to farm animals.

3. **Unresolved Ethical Considerations**

There are significant ethical issues associated with cloning that are of varying degrees of concern to consumers and reinforce the need to trace clones, their offspring and enable choice. Some consumers believe that asexual production such as cloning fundamentally alters the natural status of the animal and raises serious concerns as to the extent to which society should allow humans to further objectify and commodify animals. Consumer research conducted by the Food Standards Agency in the UK[6], for example, found that most participants saw animal cloning as a quantum leap 'from giving mother nature a helping to hand to interfering with mother nature' and people struggled to identify convincing benefits. There is also a fear by some that animal cloning is merely a stepping stone in the path to human cloning and eugenics. Leading scientists acknowledge that cloning procedures developed on mammalian animals would remain essentially the same if utilized to produce human clones. Many citizens feel that the continued cloning of animals represents a scientific "transgression" and is a dangerous precedent which will be cited widely by proponents of human cloning as they push for acceptance of the technology.

The EGE raised concerns that the use of cloning in the food supply raises a number of specific ethical concerns relating to clones and their offspring, humans, the environment and society more broadly.

[6] Animal Cloning and Implications for the Food Chain, Findings of Research Among the General Public, Food Standards Agency, May 2008.

The first relates to the moral status of animals and the recognised principles as defined by the World Organisation for Animal Health (OIE): freedom from hunger, thirst and malnutrition; fear and distress; physical and thermal discomfort; pain, injury and disease and to express normal patterns of behaviour. Other considerations include: the importance of considering issues around sustainable agriculture; the potential that use of cloning in animal production will open the door for possible human uses, what they call the 'slippery slope argument'; religious considerations as the relationship between humans and animals will vary according to religious beliefs; public perception and the consumer's right to know, free choice and labelling and concern that patents might be extended to specific genes or to animals leading to a concentration of resources that are important for breeding.

4. **Consumer Right to Know**

Consumers have a fundamental right to know what they are eating and to make informed choices about what they eat. For the reasons outlined above, and based on the available consumer research, it is likely that many consumers will wish to avoid the products of clones and their offspring. Traceability is, therefore, fundamental to ensuring that consumers can make this choice, but also that the effects of cloning – whether in terms of food safety, animal health or environmental impact – can be monitored.

However, in the United States, the FDA has suggested that milk and meat derived from cloned animals will be permitted to be sold without labelling. The EU is currently considering what approach to take to cloning.

Once clones and their offspring are introduced on to the market in one country, traceability will be challenging – particularly as many clones will be used for breeding and so the available products will come from their offspring. It is already the case that the semen from clones is being traded and some breeders have planned to export embryos from cloned livestock.

Conclusions and Recommendations

With regard to the use of animal clones and their progeny in the food supply, the TACD makes the following recommendations to the EU and US Governments:

1. We consider it is premature to permit the use of cloning and the offspring of clones for food production while there are unresolved issues around food safety, animal health and how an effective consumer choice could be maintained.

2. Prior to any cloning for commercial purposes, TACD calls for the EU and US governments to sponsor an open and transparent public discourse on the economic, ethical and social impacts and issues associated with the use of such technologies. Such discourse should fully analyze the risks and any purported benefits of animal cloning, should inform the governments and the public about whether and why cloning should be allowed and, if so, how it should be used.

3. TACD calls for the EU and US governments to reassess the safety of all foods produced or derived from cloned animals and/or their offspring, and to insist on studies designed specifically to assess safety of clones that look at animals over their entire lifetime and include sufficiently large study populations to draw valid conclusions. Such a pre-market assessment process should be transparent and allow for public input before any safety determination is made. Until a particular species of cloned animal and its progeny has been evaluated under such a regulatory process, products from those cloned animals and their progeny should not be allowed into the food supply. As well as a safety assessment, the approval process should utilize the precautionary principle and include an analysis of other legitimate factors, such as social and ethical considerations (see TACD resolution Food-16-00, www.tacd.org/docs/?id=18). TACD reiterates that the precautionary principle applies in cases where the scientific evidence is not conclusive to determine the level of protection but there is a necessity to take measures for the purposes of protecting public health, safety, or the environment. (See TACD position paper Food 9PP-99, www.tacd.org/docs/?=15).

4. TACD currently believes that there is a paucity of publicly available scientific evidence concerning the safety of cloning on the welfare of animals, food products derived from those animals and their progeny, and the impact on agricultural management practices. Furthermore, appropriate

regulatory agencies should conduct a thorough assessment, including a cost/benefit assessment as well as an assessment concerning the impact on sustainable agriculture. It must be guaranteed that this assessment be conducted in a transparent and participatory manner, and publicly available information must be used.

5. Consistent with existing principles, regulations and practices, the governments of the EU and US should maintain prohibitions on the use of cloned animals and their progeny in organic production.

6. If cloned animals or their offspring are used for food production, TACD calls upon the EU and US governments to establish mandatory labelling and traceability of such products. Such information should allow consumers to exercise their choice to eat or not eat food made from this technology.