TACD

TRANS ATLANTIC CONSUMER DIALOGUE
DIALOGUE TRANSATLANTIQUE DES CONSOMMATEURS

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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 the sheep. Since then, a number of companies have continued to use cloning to produce a wide array of animal clones, and now several are pushing to allow the commercial sale of meat and milk derived from such animals and their progeny.

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.[1] 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 could be impacted if cloned animals or animal products derived from them are used for food. Indeed, there have been limited studies on the safety of cloned animal products for consumption.

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 progeny, essentially asking companies not to market or sell cloned food. The FDA, however, has elected not to put any legally enforceable restrictions on animal cloning.[2] More recently, the FDA has suggested that it will rescind the voluntary moratorium even though a majority of the members of an FDA scientific advisory committee, in a meeting in 2003, had recognized the need for additional food safety data at that time.[3]

In the European Union there is currently no specific binding legislation dealing with animal cloning. Only one of the 27 member states (Denmark) have specific legislation on the cloning of farm animals.[4] There is a lack of clarity as to the extent to which the Novel Foods Regulation, which is under review, will address issues around animal cloning.

Many consumers, in both the U.S. and EU, have significant concerns and 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. An 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.[5] 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.[6] Likewise, polling data in the European Union indicates that animal cloning is a particularly controversial technology.[7] In one poll, 64% of Europeans believe that cloning threatens the natural order and 72% view cloning as unnatural.[8]

TACD believes that, if the U.S. 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 what they are eating.

Reasons of Concern

1. Food Safety Concerns

It is currently unknown whether eating cloned animal products is safe because there have been few studies addressing the issue. In 2002, the U.S. National Academy of Science (NAS) acknowledged the lack of scientific evidence related to food safety and the paucity of data on the safety of food from cloned animals, stating that "[t]here are to date no published comparative analytical data assessing the composition of meat and milk products of somatic cell clones, their offspring, and conventionally bred individuals."[9] In November 2003, an FDA Committee recognized the need for more data to identify the hazards and characterize the risks relating to food consumption, and TACD is currently considering the FDA's recent draft risk assessment concerning the safety of meat and milk from cloned animals, as compared to the safety of food from conventionally bred animals. Recently, a European review concluded that "from an examination of the current state of risk assessment of products from cloned farm animals and their progeny it is apparent that the studies completed so far involve small numbers of animals and that scientific uncertainty still exists."[10]

A. Potential Pathogen Issues

A thorough review of the science reveals that cloning can produce unhealthy animals.[11] This information shows that even cloned animals that appear healthy may suddenly become sick or have concealed illnesses that could affect food safety. The National Academy of Sciences' report, *Animal Biotechnology: Science Based Concerns*, stated the following:

> 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.[12]

B. Intervention such as antibiotics

The questionable health from some clones could raise significant new herd management issues that may affect the quality and state of animal products for consumers. For example, the EU has raised concerns that the widespread use of animal cloning may significant reduce the genetic diversity of livestock to an unacceptable degree.[13] Significantly reduced genetic diversity combined with confined industrial farming practices are likely to 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 Welfare Concerns

Use of cloning techniques raises animal welfare 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 fetuses. 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. Dolly the sheep developed serious health problems that required her to be euthanized at an early age. 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. 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. Others fear 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[14]. Many citizens feel that the continued cloning of animals represents a scientific "transgression"[15] and is a dangerous precedent which will be cited widely by proponents of human cloning as they push for acceptance of the technology.

4. Consumer Right to Know

TACD believes that consumers have a fundamental right to know what they are eating and to be able to avoid consuming food that offends religious or moral sensibilities. In the United States, the FDA has suggested that milk and meat derived from cloned animals will be permitted to be sold without labeling[16]. An EU investigation on the issue states that "[f]rom a consumers' rights perspective … there is a legal gap if foodstuff from cloned animals is covered neither by regulation of novel food nor the regulation of genetically modified food and hence requires more specific labelling requirements."[17] In order to meet consumers' fundamental right-to-know requirements, there should be full disclosure on all aspects of safety evaluations of clone-derived products. While not a substitute for the adoption of mandatory pre-market safety evaluation systems and risk assessments, there should also be clear and truthful labeling if any products come onto the market. At the moment TACD does not believe that it is appropriate to market such products. Currently, U.S. government policy suggests that consumers must accept and consume any product that scientists can create as long as the product meets minimal food safety requirements. There must be an assurance of a right to choose not to purchase and not to consume a particular product. Governments should consider consumer attitudes and values and incorporate them into any decision-making process regarding these foods. Labeling would need to be ensured through traceability and segregation of any cloned-derived products from conventional products.

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 U.S. Governments:

1. Prior to any cloning for commercial purposes, TACD calls for the EU and U.S. 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 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

2. Prior to any use of animal cloning for commercial purposes, which TACD believes is currently inappropriate, TACD calls for the EU and U.S. governments to establish a system of mandatory approval that will assess the safety of all foods produced or derived from cloned animals and/or their offspring. Such a pre-market mandatory approval process should be transparent and allow for public input before any safety determination is made. Until a particular 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).

3. 3.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 the impact on agricultural management practices. Furthermore, appropriate regulatory agencies shall conduct a thorough safety assessment, including a cost/benefit assessment as well as an assessment concerning the impact on sustainable agriculture. It must be guaranteed that this assessment for a particular cloned animal be conducted in a transparent and participatory manner, and publicly-available information must be used.
4. Consistent with existing principles, regulations and practices, the governments of the EU and U.S. should maintain prohibitions on the use of cloned animals and their progeny in organic production.

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

Endnotes

[1] See e.g. Jonathan R. Hill et al., *Development Rates of Male Bovine Nuclear Transfer Embryos Derived From Adult and Fetal Cells*, 62 BIOLOGY REPROD., 1135 (2000)

[2] Press Release, FDA, FDA Issues Draft Executive Summary of its Assessment of Safety of Animal Cloning; Current Voluntary Moratorium on Releasing Animal Clones Remains in Effect (Oct. 31, 2003), *available at* www.fda.gov/bbs/topics/NEWS/2003/NEW00968.html

[3] FDA Veterinary Medicine Advisory Committee meeting, November 4, 2003, Transcript at 206-216, *available at* www.fda.gov/cvm/Documents/03VMACTrans.doc

[4] Danish Centre for Bioethics and Risk Assessment (CeBRA), Regulating Farm Animal Cloning: Three Scenarios (2006) at 6, available at www.sl.knl.dk/cloninginpublic/index-filer/Page460.htm

[5] Pew Initiative on Food and Biotechnology Poll: Pew Initaive Finds Public Opinion About Genetically Modified Foods Remains 'Up For Grabs' Ten Years After Introduction of Ag Biotech (Dec 6, 2006) *available at* http://pewagbiotech.org/research/2006update/

[6] *See Dairy Industry Support Continued FDA Ban on Selling Cloned-Cow Milk*, WASHINGTON TIMES, July 12, 2005 (citing poll by International Food Information Council), *available at* www.organicconsumers.org/Toxic/clone.cfm

[7] *See* Danish Centre for Bioethics and Risk Assessment (CeBRA), Public Perceptions of Farm Animal Cloning in Europe (2006), available at www.sl.knl.dk/cloninginpublic/index-filer/Page460.htm

[8] Id. at 12

[9] NATIONAL ACADEMY OF SCIENCES, ANIMAL BIOTECHNOLOGY: SCIENCE BASED CONCERNS, BOARD ON AGRICULTURE AND NATURAL RESOURCES, 65 (2002), *available at* www.nap.edu/books/0309084393/html/ [hereinafter "NAS 2002 study"]; *See also id.* at 8-9, 64-5

[10] Danish Centre for Bioethics and Risk Assessment (CeBRA), Legal Aspects of Research on the Use of Farm Animal Cloning Within the EU - A synthesis (2006) at 9, available at www.sl.knl.dk/cloninginpublic/index-filer/Page460.htm

[11] *See generally, e.g.,* Merritt McKinney, *Flawed Genetic 'Marking' Seen in Cloned Animals*, REUTERS HEALTH, May 29, 2001; Yong-Kook Kang et al., *Aberrant Methylation of Donor Genome in Cloned Bovine Embryos*, 28 NATURE GENETICS 173 (2001), *available at* http://www.nature.com/ng/journal/v28/n2/full/ng0601_173.html; Rick Weiss, *Clone Study Casts Doubt on Stem Cells*, WASH. POST, July 6, 2001, at A-1

[12] NAS 2002 study, at 64-5

[13] Opinion of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission, No. 9 (May 28, 1997) at 1.13

[14] Rudolf Jaenisch, *Human Cloning – The Science and Ethics of Nuclear Transplantation*, 351 NEW ENG. J. MED. 2787 (Dec. 2004)

[15] *See, e.g.*, The President's Council on Bioethics, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY (July 2002), *available at* www.bioethics.gov/reports/cloningreport/pcbe_cloning_report.pdf. However, this committee did not address animal cloning.

[16] See *FDA to Consider Morals, Ethics in Animal Cloning*, FDA WEEK (Sept 23, 2005)

[17] Danish Centre for Bioethics and Risk Assessment (CeBRA), Legal Aspects of Research on the Use of Farm Animal Cloning Within the EU - A synthesis (2006) at 10, available at www.sl.knl.dk/cloninginpublic/index-filer/Page460.htm

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[3] FDA Veterinary Medicine Advisory Committee meeting, November 4, 2003, Transcript at 206-216, *available at* http://www.fda.gov/cvm/Documents/03VMACTrans.doc.

[4] Danish Centre for Bioethics and Risk Assessment (CeBRA), Regulating Farm Animal Cloning: Three Scenarios (2006) at 6, available at http://www.sl.knl.dk/cloninginpublic/index-filer/Page460.htm .

[5] Pew Initiative on Food and Biotechnology Poll: Pew Initaive Finds Public Opinion About Genetically Modified Foods Remains 'Up For Grabs' Ten Years After Introduction of Ag Biotech (Dec 6, 2006) *available at* http://pewagbiotech.org/research/2006update/

[6]*See Dairy Industry Support Continued FDA Ban on Selling Cloned-Cow Milk*, WASHINGTON TIMES, July 12, 2005 (citing poll by International Food Information Council), *available at* www.organicconsumers.org/Toxic/clone.cfm

[7] *See* Danish Centre for Bioethics and Risk Assessment (CeBRA), Public Perceptions of Farm Animal Cloning in Europe (2006), available at http://www.sl.knl.dk/cloninginpublic/index-filer/Page460.htm .

[8] Id. at 12.

[9] NATIONAL ACADEMY OF SCIENCES, ANIMAL BIOTECHNOLOGY: SCIENCE BASED CONCERNS, BOARD ON AGRICULTURE AND NATURAL RESOURCES, 65 (2002), *available at* http://www.nap.edu/books/0309084393/html/ [hereinafter "NAS 2002 study"]; *See also id.* at 8-9, 64-5.

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[12] NAS 2002 study, at 64-5.

[13] Opinion of the Group of Advisers on the Ethical Implications of Biotechnology to the European Commission, No. 9 (May 28, 1997) at 1.13.

[14] *See, e.g.*, The President's Council on Bioethics, HUMAN CLONING AND HUMAN DIGNITY: AN ETHICAL INQUIRY (July 2002), *available at* www.bioethics.gov/reports/cloningreport/pcbe_cloning_report.pdf. However, this committee did not address animal cloning.*See FDA to Consider Morals, Ethics in Animal Cloning*, FDA WEEK (Sept. 23, 2005).

[15] See *FDA to Consider Morals, Ethics in Animal Cloning*, FDA WEEK (Sept 23, 2005)
[16] See *FDA to Consider Morals, Ethics in Animal Cloning*, FDA WEEK (Sept 23, 2005)

[17] Danish Centre for Bioethics and Risk Assessment (CeBRA), Legal Aspects of Research on the Use of Farm Animal Cloning Within the EU - A synthesis (2006) at 10, available at http://www.sl.knl.dk/cloninginpublic/index-filer/Page460.htm.