March 16, 2007

Ms. Valerie Frances, Executive Director
National Organic Standards Board, USDA-AMS-TMP-NOP
1400 Independence Ave., SW.
Room 4008-So., Ag Stop 0268
Washington, DC 20250-0268
http://www.regulations.gov

Re: Docket No. AMS-TM-07-0032; TM-07-05, Notice of Meeting of the National Organic Standards Board [Federal Register: March 12, 2007 (Volume 72, Number 47) Page 10971-10973], National Organic Standards Board Cloning Recommendation.

Dear Ms. Frances:

The Biotechnology Industry Organization (BIO) provides the following comments on the above referenced docket. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. BIO appreciates the opportunity to comment on the Cloning Recommendation currently under consideration by the National Organic Standards Board (the NOSB or the Board).

BIO members provide industry leadership for the ethical application of animal biotechnology to improve animal and human well-being. The industry seeks to improve global food supply and quality through the application of animal cloning, and thereby to provide solutions to issues important to humankind—hunger and health.

The USDA National Organic Program (NOP) provided a statement on January 31, 2007, stating that cloning technology is prohibited under NOP regulations. Despite that statement, a recommendation is currently before the Board to formalize the exclusion of the use of cloning technology as a production method under the NOP. We respectfully oppose the recommendation and offer the following general and specific comments.

General Comment

Somatic Cell Nuclear Transfer (SCNT) and other forms of animal cloning are an assisted reproductive technology (ART), which fall on a continuum of breeding methods used today in animal agriculture, including artificial insemination, embryo transfer and in vitro fertilization, all of which are allowed under the NOP. Animal cloning allows farmers and ranchers to produce healthy, productive animals and healthful foods for human consumption. Animal cloning allows for rapid distribution of the best genetics from

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proven animals to provide consistent, healthful, and safe meat and milk for human consumption.

A clone is a genetically identical twin to a donor animal, which naturally exhibits desirable traits. Progeny (offspring) of clones are not clones; they are sexually produced from the mating of one or more animal clones, after undergoing a normal gestation period and birthing process.

Based on all available scientific information, animal cloning technology is shown to be safe and produces safe food. On December 28, 2006, the U.S. Food and Drug Administration (FDA) stated in its science-based draft Risk Assessment (FDA, CVM. 2006. Animal Cloning: A Draft Risk Assessment, http://www.fda.gov/cvm/Documents/Cloning_Risk_Assessment.pdf) that edible products from healthy clones and progeny of clones pose no additional food consumption risks relative to corresponding products from other animals. FDA agrees with the National Academy of Sciences (2002 Animal Biotechnology: Science-Based Concerns. www.nap.edu/books/0309084393/html/), which concluded that "The products of offspring of clone(s)…were regarded as posing no food safety concern because they are the result of natural matings," and "In summary there is no current evidence that food products derived from adult somatic cell clones or their progeny present a food safety concern."

The U.S. companies that provide cloning technology for agricultural animals are leaders in the production of healthy livestock clones. This industry has continuously improved the technology, collaborated in research, been transparent with federal agencies in providing all data, and openly provided information about the animals and the technology to many different stakeholder groups.

Specific Comments

1) The Organic Foods Production Act of 1990 (7 USC §6501 to 6522)

Livestock clones and their progeny can be raised in accordance with the Organic Foods Production Act (OFPA), specifically 7 USC §6502 Definitions, §6504 National standards for organic production, and §6509 Animal production practices and materials.

In particular, 7 USC §6509 Animal production practices and materials, Breeder stock, states that breeder stock may be purchased from any source if such stock is not in the last third of gestation. Since breeder stock may be purchased from any source, livestock clones and their progeny could be breeder stock and meet the statutory requirements, as defined in the Act. In fact, cloned animals will be used primarily for breeding purposes with only nominal amounts winding up in the food supply after the animal's useful breeding life.

2) 7 CFR Part 205.2 Terms defined

a) The cloning recommendation before the Board would characterize SCNT and other methods of animal cloning as methods used to genetically modify organisms or influence their growth and development. SCNT and other methods of animal cloning do not genetically modify organisms, nor do they influence the growth and development of organisms. Therefore, they should not be considered excluded methods.

b) The original definition of "Excluded Methods" as provided in the NOP amended proposed rule (65 Fed. Reg. 13,512 (March 13, 2000)), was specifically inserted to prohibit the intentional use of recombinant DNA technology. There is no recombinant DNA technology involved in the process of cloning; no genes are inserted or changed. Cloning simply produces a genetic twin. Therefore, the recommendation is inconsistent with the intent and purpose of the definition of Excluded Methods.

c) ARTs are not excluded under the NOP. It is a scientific fact that SCNT and other forms of cloning are ARTs. Other ARTs, such as in vitro fertilization, artificial insemination, and tissue culture are not excluded methods. Therefore the recommendation creates inconsistencies in how ARTs are treated under the NOP, and the inclusion of SCNT as an excluded method is inconsistent with similar organic production practices.

ARTs, such as artificial insemination, embryo transfer, and in vitro fertilization, are widely used in the livestock industry including organic production. It is estimated that 75 percent of milk and 80 percent of pork is produced from the use of artificial insemination, which includes milk and pork labeled organic under the NOP. The use of embryo transfer has been valuable in capturing the desirable traits of superior females. In vitro fertilization is increasingly being used in production of superior animals eventually used as founder sires. These ARTs have been successfully practiced in the agriculture sector, including organic production. Cloning is simply another ART, a fact supported by the FDA (FDA, CVM. 2006. see previous citation), which will continue to improve the health of agricultural animals that produce safe meat and milk.

3) Progeny of Clones

BIO interprets that the proposed amendment to the definition of Excluded Methods does not exclude progeny of clones, or the products thereof, from organic production practices. Progeny of clones are not clones. Without prejudice to our position that cloning should be allowed under the NOP, if the NOSB disagrees with that position, progeny of clones and products thereof certainly should be allowed in organic production practices. Livestock clones, because of their highly desirable traits and genetic merit, will be the superior founder breeding animals for organic production. They are produced through sexual reproduction under normal conditions of gestation and parturition and therefore are compatible with organic production. FDA has concluded that progeny of clones are not clones (FDA, CVM. 2006. see previous citation), which is in agreement with the

National Academy of Sciences (National Academies. 2002. see previous citation). Offspring of clones, born under normal conditions of sexual reproduction, gestation and parturition, and which may be raised according to the requirements of the OFPA and the NOP regulations, should be allowed under the NOP to produce animal food products and be labeled in accordance with the NOP.

7 CFR Part 205.236 Origin of Livestock (3) Breeder Stock specifically allows that breeder stock may be brought from a non-organic operation onto an organic operation. Therefore, progeny of animals produced by SCNT should be allowed to be used as breeders for organic livestock. There is nothing restricting the kinds of "non-organic" breeders that can be brought into an organic production facility. An animal from a non-organic farm, even one that had been produced by SCNT, could convert to producing offspring that would be in compliance with the organic standards. Thus, food products derived from those offspring would meet all the NOP regulatory requirements and labeling them as such should be legal.

Conclusion

The Organic Foods Production Act does not prohibit the use of assisted reproductive technologies in organic production. BIO does not support the proposed amendment, which would exclude one type of assisted reproductive technology, SCNT (or other methods of animal cloning), from the NOP. Further, BIO does not support exclusion of animal clones or their progeny from organic production. Just as with other forms of assisted reproductive technologies, organic livestock producers should have the option to select the best genetics and reproductive technology, including SCNT, which result in an organic food product consistent with the NOP.

BIO appreciates this opportunity to comment on the cloning recommendation currently before the Board. We look forward to further deliberation, and would be pleased to work with the Board and USDA to provide further input or clarification of our comments or on the cloning technology, as needed.

Sincerely,

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Managing Director, Animal Biotechnology
Food & Agriculture Section