National Organic Standards Board
Livestock Committee
February 20, 2007

Cloning Recommendation

I. Introduction

The Center of Veterinary Medicine at the US Food and Drug Administration (FDA) issued a draft risk assessment on meat and milk from cloned animals. A Federal Register notice was issued by the FDA on January 3, 2007, which requested comments on the draft risk assessment on animal cloning. On January 31, 2007 the National Organic Program (NOP) posted a short series of questions and answers on its website, clearly stating that cloning technology is prohibited in organic production, and that the NOP will be working with the NOSB to determine the organic status of the progeny of animals derived using cloning technology, or clones.

The NOSB concurs with the NOP and believes that the existing federal organic rules prohibit animal cloning technology and all its products To strengthen and clarify the existing rules, the NOSB recommends that the NOP amend the regulation to ensure animal cloning technology, and all products derived from such organisms be excluded from organic production. Furthermore, the NOSB is very concerned with the issues involving the progeny of animals that are derived using cloning technology, and will work with the NOP on further rulemaking recommendations as issues are identified.

II. Background

Cloning, defined by FDA as somatic cell nuclear transfer, is a process by which animals are reproduced asexually by introducing a differentiated somatic cell (a non-germ line cell from an existing animal) to an oöcyte (a cell which is the immediate precursor of a mature egg) that has had its nucleus removed, and then, following some manipulations, is induced to start replicating. Cloning can also be accomplished without cell fusion by injecting the DNA from the skin cell directly into the egg cell.

The FDA concluded that animal cloning results in an increased frequency of health risks to animals involved in the cloning process, including late gestation complications and an increase of mortality. Many cloned animals develop abnormally due to misarranged genetic code, with some abnormalities so subtle that they would not be visibly noticeable, but which may have health implications for humans if consumed.

The organic industry has expressed concern to the NOSB that cloned animals, or products of cloned animals could enter into the organic production stream and harm the perception of organic food products. Giving credence to those concerns, a December 2006 poll by the Pew Initiative on Food and Biotechnology found that 64 percent of consumers said they were uncomfortable with animal cloning, with 46 percent saying they were “strongly uncomfortable,” which indicates most consumers are uncomfortable with clones and do not want them to be part of their food supply. If the FDA does not require clones to be tracked, consumers are very likely to turn to organic products, under the assumption that clones are not allowed in organic production.

The NOP rule requires organic farmers to accommodate the health and natural behaviors of animals, along with encouraging genetic biodiversity. The rule also states that an organic animal's growth and development must not be influenced by means "that are not considered compatible with organic production." Clearly, animal cloning technology was not intended to be allowed in organic production.

III. Regulatory Framework

The Organic Food Production Act (OFPA) does not specifically mention reproductive techniques or practices suitable for organic production, but the OFPA does authorize the NOSB to make relevant recommendations.

Under OFPA:

> **SEC. 2110. [7 USC 6509] Animal Production Practices and Materials.**
> (d) HEALTH CARE.—
> (2) STANDARDS.--- The National Organic Standards Board shall recommend to the Secretary standards in addition to those in paragraph (1) for the care of livestock to ensure that such livestock is organically produced.

At the time of the implementation of the regulation, the NOP Rule was thought to be sufficiently clear regarding the exclusion of cloning technologies in organic production.

From NOP Rule **Subpart A – Definitions**

> **§ 205.2 Terms defined.**
>
> Excluded Methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

From NOP Rule **Subpart B – Applicability**

> **§ 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.**
>
> To be sold or labeled as "100% organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:
>
> (e) Excluded methods, except for vaccines, Provided, That, the vaccines are approved in accordance with § 205.600(a);

From NOP Rule **Subpart C – Organic Production and Handling Requirements**

> (b) The following are prohibited:
>
> (1) Livestock or edible livestock products that are removed from an organic operation and subsequently managed on a non-organic operation may not be sold, labeled, or represented as organically produced.
>
> (2) Breeder or dairy stock that has not been under continuous organic management since the last third of gestation may not be sold, labeled, or represented as organic slaughter stock.

IV. Recommendation

The Livestock Committee recommends that the NOP implement rule change to clarify that cloning technology and all its products be excluded from organic production. The Livestock Committee recommends the following change to existing regulation:

> **§ 205.2 Terms defined.**
>
> Excluded Methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, somatic cell nuclear transfer (or other methods of animal cloning), and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, artificial insemination, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

The Livestock Committee and the NOSB will work in collaboration with the NOP on further rule making recommendations as issues are identified.

Committee vote

Moved: Kevin Engelbert Second: Hubert Karreman

Committee Vote: Yes- 6 No- 1 Abstentions- 0 Absent- 0

Minority opinion

The dissenting vote (Kevin Engelbert) reflects a belief that the Livestock Committee should also recommend a rule change under **§ 205.236 Origin of Livestock,** to prohibit livestock, progeny of livestock, reproductive materials, or any other products derived from animals produced using animal cloning technology (includes somatic cell nuclear transfer or other cloning methods) from being used as a source of organic livestock.

Conclusion

To strengthen and clarify the existing rules, the NOSB Livestock Committee recommends that the NOP amend the regulations to add animal cloning technology to the definition of “Excluded Methods” and that the NOP update other sections of the rule to ensure that animal cloning technology is excluded, and that products derived from organisms subjected to such technology be excluded from organic production.