

**FORMAL RECOMMENDATION BY THE  
NATIONAL ORGANIC STANDARDS BOARD (NOSB)  
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

**Date:** 3-29-07

**Subject: Cloning Recommendation**

**Chair: Andrea Caroe**

**Recommendation**

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: XXX

Guidance Statement: \_\_\_\_\_

Other: \_\_\_\_\_

**Statement of the Recommendation (including Recount of Vote):**

The NOSB recommends the attached document be adopted to establish standards regarding the issue of cloning.

**NOSB Vote: Motion:** Kevin Englebert    **Second:** Jeff Moyer

*Board vote: Yes - 12    No - 0    Abstain - 1    Absent - 2*

**Rationale Supporting Recommendation (including consistency with OFPA and NOP):**

The NOSB is proposing to amend 205.236 Origin of Livestock to be used by the NOP, certifying agents, and industry to ensure that cloned animals, their progeny and any derived products there from will not be used in the organic industry. This is consistent with OFPA language of not using excluded methods.

**Response by the NOP:**

**Cloning Recommendation**  
**National Organic Standards Board**  
**March 29, 2007**

## **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 National Organic Program and believes that the existing federal organic rules (NOP) prohibit animal cloning technology and all its products, including all progeny and succeeding generations of those progeny in organic production. To strengthen and clarify the existing rules, the NOSB recommends that the NOP amend the regulations to ensure animal cloning technology, all generations of progeny from cloned animals, 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.

## **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. Likewise, 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). Excluded 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**

**§ 205.236 Origin of Livestock.**

(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, including all progeny and succeeding generations of those progeny, 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, 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, conjugation, fermentation, hybridization, in vitro fertilization, artificial insemination, or tissue culture.

The Livestock Committee recommends the following addition to the regulation:

**§ 205.236 Origin of Livestock**

(b) The following are prohibited:

(3) Livestock, progeny and all succeeding generations from cloned livestock, reproductive materials, or any other products derived from animals produced using animal cloning technology.

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

Moved: Hubert Karreman      Second: Kevin Englebert

**Committee vote**

Yes – 6    No – 0    Abstentions – 0    Absent - 1

**Minority opinion**

**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, including all generations of progeny of cloned animals. ~~and that products derived from organisms subjected to such technology be excluded.~~