



Policy Memorandum

To: Stakeholders and Interested Parties

From: Miles McEvoy, Deputy Administrator

Subject: Retained Memos: NOP Statements on Cloning and Organic Livestock Production

Date: Original Issue Date – January 31, 2011

Attached are the January 31, 2007 “NOP Announcement on Cloning and Organic Livestock Production”, and the January 15, 2008 “NOP Cloning and Organic Livestock Production Talking Points” and “NOP Cloning and Organic Livestock Production Q and A’s” memos issued by the National Organic Program (NOP). These memos are being retained by the NOP as a new policy memo and remain in effect. This document has been assigned the control number “PM 11-11”.

Enclosures: “NOP Announcement on Cloning and Organic Livestock Production” January 31, 2007 memo, “NOP Cloning and Organic Livestock Production Talking Points” January 15, 2008 memo, and “NOP Cloning and Organic Livestock Production Q and A’s” January 15, 2008 memo

National Organic Program Cloning and Organic Livestock Production

Recently, FDA announced its approval of a draft risk assessment of cloning as a production technique in agriculture. Since that announcement, many questions have been raised about cloning and animals produced using cloning technology (called clones) respecting organic production and their allowance under the National Organic Program (NOP) regulations. The following questions and answers explain the position of the NOP regarding cloning and animals produced using cloning technology for organic livestock production.

Q. Is cloning as a livestock production practice allowed under the NOP regulations?

A. No. Cloning as a production method is incompatible with the Organic Foods Production Act (OFPA) and is prohibited under the NOP regulations.

Q. May animals produced using cloning technology, or clones, be considered organic under the NOP regulations?

A. No. Animals produced using cloning technology are incompatible with OFPA and cannot be considered organic under the NOP regulations.

Q. What about the progeny of animals produced using cloning technology, or clones – can they be organic under the NOP regulations in organic livestock production?

A. AMS intends to work with the National Organic Standards Board (NOSB) to develop a rulemaking proposal to determine the organic status of the progeny of animals derived using cloning technology, or clones.

January 31, 2007

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- Since the Dec. 2006 announcement of FDA's approval to conduct a risk assessment, questions have been raised about cloning and clones related to organic production and their allowance under the National Organic Program (NOP) regulations.
- Public statements against cloning in organic production have been issued by the Organic Trade Association, Organic Valley, Organic Consumers Association, and the Center for Food Safety.
- On Jan. 31, 2007, USDA's NOP issued a statement on its web site that cloning as a production method is incompatible with the Organic Foods Production Act (OFPA) and is prohibited under the NOP regulations. Q&A's on cloning in connection with organic programs were published along with the statement on the NOP website.
- Although not specifically identified, the basis for excluding cloning technology from organic production stems from the definition of an excluded method in the NOP regulations:

*“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.”* [Emphasis added.]

- The prohibition on the progeny of clones is less clear. The NOP asked its advisory committee, the National Organic Standards Board, to discuss the issue at their March 2007 meeting. After discussion and public comment, on March 29, 2007, the Board voted to accept the following Livestock Committee recommendation:

“To strengthen and clarify existing rules, the National Organic Standards Board 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.” [Emphasis added.]

- Work has been initiated on a National Organic Program origin of livestock public rulemaking that will encompass the National Organic Standards Board's recommendation regarding cloning and the progeny of clones.

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On Jan. 15, 2008, FDA released final versions of three documents on animal cloning: A Risk Assessment, a Risk Management Plan, and Guidance for Industry. These documents are the final versions of drafts released for public comment in December 2006. These documents represent FDA's conclusions regarding the health of animals involved in the cloning process, and the safety of food from four species of livestock that have been cloned, as well as food from the offspring of clones from any species traditionally consumed as food.

FDA's Final Risk Assessment and Risk Management Plan on Animal Clones and their Progeny concludes that according to all available science, food from clones of cattle, swine, and goats, and the offspring of clones from any species traditionally consumed as food, are as safe to eat as food from conventionally bred animals. FDA concludes that it has insufficient information to reach a conclusion on the safety of food from clones of other animal species, such as sheep.

Last year, when FDA announced its approval of the draft risk assessment of cloning as a production technique in agriculture, many questions were raised about cloning and animals produced using cloning technology (called clones) respecting organic production and their allowance under the National Organic Program (NOP) regulations. The following questions and answers explain the position of the NOP regarding cloning and animals produced using cloning technology for organic livestock production.

Q: When consumers hear that USDA will *not* certify products from cloned animals or their offspring as ORGANIC, doesn't that indeed send the signal that the products are not healthy?

A. No, it simply reflects the fact that organics is a marketing program. As such, by consensus of the market participants, many production methods and materials are excluded from use.

Q: Is cloning as a livestock production practice allowed under the USDA National Organic Program regulations?

A. No. Cloning as a production method is incompatible with the Organic Foods Production Act and is prohibited under the NOP regulations.

Q: Can animals produced using cloning technology, or clones, be considered organic under the National Organic Program regulations?

A. No. Animals produced using cloning technologies are incompatible with Organic Foods Production Act and cannot be considered organic under the National Organic Program regulations.

Q: What about the progeny of animals produced using cloning technology or clones – can they be organic under the NOP regulations in organic livestock production?

A. Based on a recommendation of the National Organic Standards Board, USDA's Agricultural Marketing Service is preparing the necessary public rulemaking to address the organic status of the progeny of animal clones.