

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

Date: November 30, 2007

Subject: Guidance on Temporary Variance for Research

Chair: Andrea Caroe

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: _____

Guidance Statement: X

Other: _____

Statement of the Recommendation (including Recount of Vote):

The approval of Guidance on Temporary Variance for Research.

NOSB Vote: **Motion: R. Delgado** **Second: J. Moyer**

Board vote: Yes - 15 No- 0 Abstain- 0 Absent - 0

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

This guidance will provide consistency and clarity regarding temporary variances allowed for research purposes.

Response by the NOP:

National Organic Standards Board

Final Recommendation for

Guidance on Temporary Variance for Research

Date: 11/30/07

I. List: (where in FR rule example 205.606)

N/A

II. Committee Summary:

Rule section § 205.290(a)(3) allows the Administrator of USDA's Agricultural Marketing Service (AMS) to establish temporary variances with the purpose of conducting research. However, confusion exists regarding the types of variances that are allowed. The intent of this guidance is to provide consistency and clarity regarding temporary variances allowed for research purposes.

The recommendation provides a framework for the assessment of research variance requests based on these general principles:

1. A variance implies a compromise to the regulation and benefits to the organic community are expected in return. The results of the research must be made public.
2. Variances must be for legitimate research purposes and designed to expand knowledge that is valid in the context of organic production and handling systems.
3. All research must be conducted taking into account the organic integrity of the site used for research and the humane treatment of animals in the study.

The Crops, Livestock and Policy Development committees encourage the NOSB to respectfully request that the NOP and the Administrator accept this recommendation as early as possible. The committee members look forward for an opportunity to work with the NOP and the Administrator on finding ways to implement this important recommendation.

III. Board Recommendation

The approval of Guidance for Certification of Operations Participating in Crop Production Research.

Board vote:

Moved: R. Delgado Second:

Board vote: Yes- 15 No- 0 Absent- 0 Abstain-0 Recuse -0

National Organic Standards Board (NOSB)
Joint Policy Development, Crops, and Livestock Committees
Guidance on Temporary Variance for Research

September 30, 2007

Introduction:

National Organic Program rule section § 205.290(a)(3) allows the Administrator of USDA's Agricultural Marketing Service (AMS) to establish temporary variances from certain regulatory provisions for conducting research. Researchers, farmers, and certifying agents are aware that the regulation allows for research variances, but confusion exists as to the types of variances that are allowed. In order to bring consistency and clarity, the NOSB recommends that the USDA issue guidance concerning temporary variances allowed for research purposes.

The NOSB recognizes the critical role that agricultural research plays in the expansion of organic agriculture and encourages the continuous development of appropriate technology. The nature of research design, however, demands experimentation under the conditions of organic systems. It is possible that some experiments could involve concessions which conflict with organic principles. Research variances allow scientists the flexibility they need to obtain results relevant to organic growers and consumers and it is expected that these results justify the research methods. This document presents a framework for evaluating each variance request.

Background:

A core principle of organic agriculture is the adoption of best sustainable and ecologically sound practices and inputs as they become available. Organic agricultural research is used to assess and develop emerging practices and inputs. It is a dynamic field with new information available regularly. Organic producers, handlers, and consumers all receive benefits from research on new methods, practices, varieties, and breeds.

National Organic Program rule section § 205.290 allows the Administrator of USDA's Agricultural Marketing Service (AMS) to establish temporary variances from certain regulatory provisions for conducting research. The same section defines what is eligible for variance and what is excluded.

Relevant areas in § 205.290 include:

- (a) Temporary variances from the requirements in §§ 205.203 through 205.207, 205.236 through 205.239, and 205.270 through 205.272 may be established by the Administrator for the following reasons:
 - (3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.
- (b) A State organic program's governing State official or certifying agent may recommend in writing to the Administrator that a temporary variance from a standard set forth in subpart C of this part for organic production or handling operations be established.
- (c) The Administrator will provide written notification to certifying agents upon establishment of a temporary variance applicable to the certifying agent's certified production or handling operations and specify the period of time it shall remain in effect, subject to extension as the Administrator deems necessary.
- (d) A certifying agent, upon notification from the Administrator of the establishment of a temporary research variance, must notify each production or handling operation it certifies to which the temporary variance applies.

A specific restriction found in § 205.290(e) is:

- (e) Temporary variances will not be granted for any practice, material, or procedure prohibited under § 205.105."

From §205.290(a), the following are eligible for consideration for temporary variances:

- §205.203 Soil fertility and crop nutrient management practice standard.
- §205.204 Seeds and planting stock practice standard.
- §205.205 Crop rotation practice standard.
- §205.206 Crop pest, weed, and disease management practice standard.
- §205.207 Wild-crop harvesting practice standard.
- §205.236 Origin of livestock.
- §205.237 Livestock feed.
- §205.238 Livestock health care practice standard.
- §205.239 Livestock living conditions.
- §205.270 Organic handling requirements.
- §205.271 Facility pest management practice standard.
- §205.272 Commingling and contact with prohibited substance prevention practice standard.

Relevant terms found in § 205.2:

“Administrator. The Administrator for the Agricultural Marketing Service, United States Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.”

Discussion

Since no other section numbers are listed in §205.290(a), other sections of the regulation, such as those pertaining to recordkeeping (§205.103), allowed and prohibited substances (§205.105), organic system plans (§205.201), land requirements (§205.200 and §205.202), labeling (Subpart D), certification (Subpart E), and administrative requirements (Subpart F), are not eligible for consideration.

The intent of the present recommendation is to provide a framework for the assessment of research variance requests based on three overall principles. First, a variance implies a compromise to the regulation and benefits to the organic community are expected in return. Therefore, the results of the research must be made public. Second, variances must be for legitimate research purposes and designed to expand knowledge that is valid in the context of organic production and handling systems. Third, all research must be conducted taking into account the organic integrity of the site used for research and the humane treatment of animals in the study.

Recommendation:

To bring consistency and clarity concerning temporary variances allowed for research purposes, the NOSB recommends the USDA issue the following guidance.

A. Scope:

- 1) Research variances only apply to requirements in §§ 205.203 through 205.207, 205.236 through 205.239, and 205.270 through 205.272, provided that the operation is certified and it complies with all other regulatory requirements;
- 2) Practices, materials, or procedures listed under § 205.105 will not be considered for research variances.

B. Request for temporary variances involving research should be submitted by the principal investigator/research facility to an accredited certifying agent that includes, as part of the Organic System Plan, the following information:

- 1) A specific description, including citation, of the practice standard, origin of livestock, feed, living condition, or handling requirement involving the research variance;
- 2) A thorough justification of the need for a variance;
- 3) A valid research plan including background, literature review, experimental design, projected benefits, and an outreach plan;
- 4) A description of the specific location (field number, plot plan, building, etc.) where the research will be conducted, and, if applicable, animals involved;
- 5) A timeframe for the duration of the study and the research variance;
- 6) A description of care standards, recognized by animal welfare organizations, that will be followed during the experiment in order to eliminate the possibility of abuse of animals;
- 7) For variance requests not involving §205.272, a description of how non-certified products will be kept separated from certified organic products to prevent contamination or commingling;
- 8) A description of how the land, animals, or facilities will be managed to regain full certification after the variance has expired;
- 9) A description of how land, animals, or facilities not considered for recertification will be handled after the variance has expired;
- 10) A plan to provide progress reports to the NOP. Such reports should relate to specific activities involving the implementation, management and control of the variance and should be provided, at minimum, on a yearly basis in conjunction with the review of the organic plan;
- 11) A brief description of the professional background of key research personnel and conflict of interest statement.

- C. The assessment of a research variance request should be made based on the following criteria:
- 1) Justification of the variance request and potential benefit to the community.
 - 2) Quality of the research plan.
 - 3) Appropriate care for research animals.
 - 4) Level of experience of key personnel involved in the research project.
 - 5) Existence of potential conflict of interests.
- D. The Administrator should take into account the time sensitivity of each research project in order to provide a final determination to the request. The final decision on the variance request should be made public.
- E. In order to monitor the correct implementation of a proposed experimental design, and depending on the nature of the research, a variance on temporary research could be granted contingent on continuous monitoring by the certifying agent or an independent third party. Costs resulting from the required monitoring should be covered by the variance requestor.
- F. Research variances should not be granted to exceed five years, but, if justified, an extension should be allowed. An application for extension should be presented at least one year prior to the expiration of the variance.

All progress reports provided to the NOP (as requested in point B. 10 above) must be published in the NOP website. All research results, regardless of type of findings, must be made public no later than 12 months after the completion of the study.

Committee vote:

Yes 6 No Abstain Absent 1