

**National Organic Standards Board (NOSB)
Certification, Accreditation, and Compliance Committee (CACC)**

May 2008

APPENDIX: GUIDANCE MATERIALS

Appended to the following Discussion Document:

**Certifying Operations with Multiple Production Units, Sites and Facilities
under the National Organic Program, November 2007**

*[As noted in the November 2007 CACC Discussion Document, “The committee expects to make additional recommendations on **guidance materials** for ACAs that will be developed for attachment to this recommendation as Appendices.”]*

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I. Introduction

For the past 30 years, the organic industry has embraced the concept of people working together to convert more acreage to organic agriculture and create more organic food and products for consumers. One method of people working together has traditionally been called “group certification” or “organic smallholder certification,” and is here referred to as “multi-site certification.” This terminology is consistent with the regulatory language related to inspection found in 7 CFR § 205.403, and serves as shorthand for “operations with multiple production units, sites, and facilities.”

When an operation’s activities are carried out in a similar manner at different sites, production units, and facilities and when the activities of these component parts are under the control of the operation through a well-executed, single Organic System Plan (OSP), it is possible that proper multi-site inspection may be achievable through sampling rather than through direct observation of every member every year.

All multi-site organic operations are subject to the Organic Foods Production Act (OFPA) and 7 CFR Part 205. Therefore, the guidance provided herein focuses on particular items not addressed in the rule, and would serve to codify practices that have existed pursuant to the NOSB 2002 Grower Group recommendation. The intention is not to create a parallel set of organic standards or verification system for multi-site organic operations. Rather, this guidance is provided for topics specifically related to multi-site organic operations.

As of this writing, fundamental questions still exist within the CACC which reflect questions in the larger organic community, about whether uniform criteria can be appropriately applied across all sectors (e.g. growers, producers, handlers and retailers). Members of the CACC are in agreement that the document which follows can be applied to qualified agricultural producers with a beneficial outcome. There is less agreement about applying these “multi-site” principles and criteria to other sectors. It should be noted that the concerns do not call into question the fundamental principles of how an internal control system (described in more detail below) functions; rather the question of whether an even broader application may dilute the strength of what the Rule currently requires for certification in other sectors. A major limiting factor to the growth of the organic industry is supply of raw materials, not those willing to purchase, process, handle, and sell it.

It is the strong desire of the CACC to obtain feedback from the organic community, including the NOP and the public. After having fully read this discussion document and the supporting documents referenced herein, please weigh in on the strength of the model as it applies to grower producers, as well as whether the principles and criteria can be applied across all sectors (growers, producers, handlers and retailers).

II. Prerequisites for a Multi-Site Operation to seek USDA Organic Certification

- The multi-site operation, composed of production units, sites, or facilities, must be organized as a “person” according to 7 CFR 205.2. The Final Rule defines “person” as “an individual, partnership, corporation, association, cooperative, or other entity.”
- The operation must only seek certification with an Accredited Certification Agency (ACA) that is fully qualified to perform certification of operations with multiple production units, sites, and facilities. *(An ACA may be considered qualified if they have produced evidence, upon request by NOP, that is considered by NOP to be satisfactory to affirm the ACA’s fitness to perform the inspection of multi-site operations.)*
- The practices of the multi-site operation must be uniform and reflect a consistent process or methodology, using the same inputs/ processes.
- For growers, participation in the multi-site operation is limited to those growers who sell all of their organic production through the group.
- Multi-site operations must utilize centralized processing, distribution, marketing facilities and systems.
- Record-keeping protocols must be consistent. It is not acceptable that individual production units, sites, or facilities differ in their methodology of record keeping.

III. Organizing the Multi-Site Operation

- Production units, sites, and facilities within a certified organic multi-site operation do not possess individual certificates.
- A “production unit,” “site,” or “facility,” for purposes of ACA inspection, is to be considered the measurement unit of the operation subject to annual inspection. This does not prevent an ACA from determining that direct inspection is necessary within any subparts of a production unit, site, or facility.
- The multi-site operation must establish and implement an Internal Control System (ICS), with supervision and documentation of production practices and inputs used at each member’s/ component’s operation, and collected at each production unit, site, or facility to insure compliance with the USDA’s National Organic Program.

A. Criteria for the clustering of ‘members’ or ‘sub-units’ into a Production Unit

The CACC, in **“Certifying Operations with Multiple Production Units, Sites and Facilities under the National Organic Program, November 2007”** proposed the following definition:

“Production Unit” means:

A portion of a certified production operation identified in the master organic system plan as being managed by a person responsible for the implementation of approved practice standards and required record maintenance and applicable audit trail requirements regarding that portion of the production operation.”

Further guidance is that all members within a production unit:

- Are bound by a shared training regimen
- Operate together under the same section of the multi-site operation’s single Organic System Plan, including inputs used, fertility management and pest control practices, livestock feeding and health care practices, and record keeping and audit trail system. (This will require an adjustment to the status quo where members may be acting as autonomous members under a single OSP. Going forward, members will need to organize into production units for the sharing of best practices.)
- Share a common input supply
- Share common personnel responsible for managing operations, providing extension services, monitoring and enforcing the functioning of the Internal Control System
- Use a single post-harvest processing system
- Are located within geographic proximity, as defined by access to the same collection or post-harvest handling facility, and/or common soils, water source, slope, topography or other physical features
- Produce unique products or varieties and share the same harvest schedule

Likewise, if any member within a production unit processes or consolidates product from more than one member, it shall be considered a single production unit and must be inspected annually. An upper limit on the number of subunits included in a given Production Unit should be based on the feasibility of effective oversight by management personnel and factors such as size and accessibility of the subunits.

B. The Facility or Site

The CACC, in **“Certifying Operations with Multiple Production Units, Sites and Facilities under the National Organic Program, November 2007”** proposed the following definition:

“Facility or Site” means:

A portion of certified handling or certified retail operation identified in the master organic system plan as being managed by a person responsible for the implementation of approved practice standards and required record maintenance requirements and applicable audit trail requirements regarding that portion of the handling or retailing operation

As consumer confidence in the organic label has grown, so has retailers’ interest in voluntary organic certification. The Organic Trade Association (OTA) has developed a set of guidelines and a detailed manual for retailers who wish to follow Good Organic Retailing Practice (GORP), including how to develop an organic system plan, including practices to prevent commingling and contact with prohibited substances, employee training, and record keeping. The committee is aware of several examples of certified organic multi-site retail operations and, to date, one ACA that is performing multi-site certification of retailers who use an ICS to perform annual review and surveillance at each site. Although certification of retailers is voluntary, they are no less subject to the OFPA or 7 CFR 205 than any other type of certified organic operation.

IV. Inspecting the Multi-Site Operation

A. Initial and Renewal Inspection

In November 2007, the CACC, in **“Certifying Operations with Multiple Production Units, Sites and Facilities under the National Organic Program, November 2007”** proposed the following clarifications to 7 CFR §205.403:

“(i) the initial on-site inspection of any operation consisting of multiple production units, facilities and sites shall include direct observation of each production unit, facility or site;

(ii) each renewal inspection following certification of the operation does not require direct observation of each production unit, facility or site provided an internal control system exists adequate to ensure compliance of each such unit, facility or site with the regulations in this part.”

Additionally, the CACC, in November 2007 proposed the following definitions be added to 7 CFR §205.2

“Initial on-site inspection” means:

Direct observation of each production unit, facility, and site that comprises a certified operation

“Renewal inspection” means:

Direct observation of a certified operation, including a statistically significant number of production units, facilities and sites, as is necessary to ensure the operation’s implementation of approved practice standards and record maintenance requirements and applicable audit trail requirements.

Should the NOP, through rulemaking, enact these clarifications and definitions, the committee expects inspection to be carried out at multi-site operations in the following manner:

Year 1-100%: An initial on-site inspection, involving direct observation, must take place at 100% of the production units, sites or facilities that make up a multi-site operation. To be clear: this means that, for example, every single production unit of a farm or every single retail site in a store chain must be inspected by an ACA in year one.

Subsequent Years: A statistically significant regimen for sampling production units, sites, and facilities should be implemented. The sample size should never be less than is necessary to ensure that the OSP is being implemented by the operation. Any new member to a production unit, or site or facility would need to be inspected during the first year of joining the multi-site operation.

B. Applying the Initial & Renewal Inspection Protocol to Multi-Site Operations

Allowing 36 months from the time NOP adopts this recommendation prior to initiating the first **Year 1-100%** inspections would provide operations the necessary time to organize appropriately for 100% inspection of every production unit, site or facility.

C. Inspection: Sampling and Risk Analysis

The certifying agent shall have policies and procedures for determining how many of the production units, sites, or facilities must receive an annual inspection by the certifying agent after Year 1. The certifying agent shall also have policies and procedures for determining which production units, sites, and facilities present the greatest risks of non-compliance. Various risk assessment methods are used to both determine sample size and select the appropriate production units, sites or facilities to examine. Higher levels of overall risk for a group would dictate a higher proportion of components to be sampled.

The factors below will assist inspectors both in determining the sample size and in deciding which components he/ she should inspect annually.

- The number of operations participating in the multi-site operation
- The size of the average component in the operation
- The degree of uniformity among the production units, sites or facilities
- The complexity of the production system
- The management structure of the internal control system.
- Prohibited materials applied adjacent to a member within the previous year
- New entrants to the multi-site operation
- Significant expansion of size of the member's plot or site
- Split or parallel production
- The number of years the multi-site operation has functioned
- The rate of growth in new members
- Any previous problems with functioning of the ICS
- Staff turnover
- Potential conflict of interest
- Complexity of types of subunits and/or products marketed
- The prevalence of conventional production of the same type in the region
- Whether a handling or livestock facility of any kind is included
- Compliance with Internal Training

From the sample of production units, sites and facilities to be inspected, at least 25% should be selected randomly. This helps to prevent the complacency that might be inadvertently encouraged by a certifier focusing only on higher-risk production units, sites, and facilities.

The objective of using risk assessment methodology is to determine whether the Internal Control System (or ICS, see below) is functioning and to detect and correct noncompliances before they compromise the certification of the group. Moreover, the direct observation of a given member is not a guarantee that an instance of deliberate or fraudulent noncompliance will be detected. While detection is more likely if such a member is directly observed, an operator who wishes to hide the use of prohibited substances, for example, could do so. It is reasonable to expect that a well functioning Internal Control System, whose personnel visit each member at least once a year, will be effective in detecting such instances of noncompliance.

D. The Role of the Internal Control System (ICS)

An Internal Control System may also be called an Internal Quality System, and is analogous to the function of the Quality Assurance department of a large operation. Its mandate is to maintain consistency in compliance with the regulations as well as more traditional product quality concerns. The various components of a multi-site operation all are governed by the same Organic System Plan, and the ICS must maintain sufficient oversight to ensure that all personnel, are consistently following the plan. It is in the interest of this body to safeguard the organic status of the entire operation and the eligibility of the group as a whole for organic certification.

Within a production unit, the Internal Control System personnel are charged with conducting surveillance and reviews of every smallest divisible part of the production unit, site or facility every year. For instance, for a single sub-unit of a farming operation that is made up of multiple production units, the ICS surveillance and review should

focus on critical organic control points (analogous to a HACCP Plan) such as buffer areas, condition of growing crops, soil quality indicators, input and equipment storage areas, and level of understanding of organic requirements by the operator.

While it is the ACA's role to inspect at the level of production units, sites, and facilities and ensure that the ICS is functioning properly, the Internal Control System peers deeper into each of these production units, sites or facilities. For the person seeking organic certification to be in compliance with the NOP, all non-compliances detected at the production unit, site, or facility or at the sub-unit or member level are required to be reported to the *certifier* (not just the ICS) per 205.400 (f).

i. How the ICS Works

The internal reviewers carry out at least one annual direct observation and review of each individual operator, including visits to fields and facilities.

The Internal Control System keeps appropriate documentation, including at least a description of the farms and the facilities, the production plans, the products harvested, the contractual arrangement with each individual member and internal inspection reports.

The Internal Control System must include the application of sanctions to individual members who do not comply with the organization's OSP, the OFPA or the NOP Regulations. It must inform the ACA of the irregularities and non-compliances found. It must communicate back to the source of the non-compliance the corrective actions imposed, with agreed time for completion.

ii. Internal Control System Personnel

At minimum, the ICS personnel team should include internal inspectors, the internal evaluation committee, the director of ICS, the director of training and capacity building, representatives from the technical committee, representatives from the marketing committee, and the board of trustees. While primary responsibility would remain with the directors, the internal inspectors, and the internal evaluation committee, coordination and input from other personnel is crucial for a well-functioning ICS process.

The ICS operator needs to develop an organizational chart to provide a clear picture of how the various duties among the ICS staff are divided and to make clear the reporting structure among personnel. Additionally, the staff hired to fulfill the roles within an ICS should possess the following qualifications:

- Be fluent in the local language and dialect of the farmers
- Possess the ability to read and write and report in the chosen ICS language
- Be well versed in the National Organic Program, especially in the sections of the regulation that relate to the subunits and members, sites or facilities that they review
- Be familiar with the local agricultural production systems.
- Be familiar with the principles and practice of organic agriculture

- Be familiar with the principles and practices of organic handling and GORP, in the case of retailers
- Be able to demonstrate competence in internal control procedures and an understanding of the internal regulations

iii. Addressing Potential Conflicts of Interest

Any employee of an organization empowered by that same organization to determine compliance with a regulation carries the potential to be conflicted about whether or not to report non-compliances. This is true at single site operations and at multi-site operations. In order to mitigate the potential for noncompliances to go unreported, the Internal Control System personnel must receive contractual (in-writing) assurances that under no circumstances are they to be admonished in any way because they have detected and reported a noncompliance. In essence, this written assurance from the organization or “person” creates a firewall of protection for Internal Control System personal to implement the operation’s OSP. Additionally, these personnel must also be required to disclose, in writing, any potential conflicts in advance of surveillance and review.

Some of the past concern regarding conflict of interest at multi-site operations may have arisen from a misuse of the word “inspection” as referring to the Internal Control System’s use of surveillance and review as part of its oversight function. These internal surveillance and compliance reviews should be clearly distinguished from the inspections conducted by the certifying body, and should not be represented as serving as proxies for, or in lieu of, the organic inspection. In other words: only ACAs conduct Inspections.

While internal staff could be considered to have an inherent conflict of interest, their obligation is to ensure that the entire group maintains its organic status. The use of internal staff to ensure compliance by all group members is analogous to the QA department of a large, complex operation. Groups may mitigate any conflict of interest by assigning staff to review subunits in different regions or villages, and similar measures. The NOP requires an individual operator to report any changes that might affect the operation’s compliance, including drift or applications of prohibited substances, and a certifier should also expect to receive this information from ICS personnel.

V. Comments on Training

The success of an ICS is greatly enhanced by consistent and continuous training for all members and all ICS personnel. For most organizations, internal personnel will carry out the majority of training, but at least one training per year by an external specialist is recommended. For multi-site operations, the internal surveillance and review is a rigorous and time-consuming process for ICS personnel. Training maximizes the efforts of the personnel devoted to the ICS, and therefore the entire internal review process.

Training is roundly considered to be the key to ensuring that members understand and comply with organic standards. The responsibility of NOP in regards to certifier qualifications, in addition to reviewing a certifier’s evidence of fitness to certify multi-site operations, is to promote and

assist in the implementation of certification training specific to multi-site operations, particularly the training in the evaluation of Internal Control Systems.

VI. Pending Issues

The CACC seeks constructive input to help us design the best solution for the organic industry. As part of your evaluation, we want to be certain to receive comment on the following pending issues:

1. Should group certification apply to retailers, handlers, processors and/or restaurants if they meet this stringent criteria?
2. Should it be limited to only small farmers (holders)? What defines small?
3. Does a process of random external inspection levels based on risk criteria provide enough oversight of individual locations or is there a need to guarantee all locations are externally inspected at some minimum frequency?
4. Should the qualification and inspection criteria be different for each sector of the organic industry eligible to apply for multi-site certification? If so, what are the specific criteria that are not included in this document?
5. What is the advantage of including other sectors in the multi-site model? Disadvantages?
6. Will the multi-site model increase our ability to detect non-compliance?
7. How will consumers react knowing that the certification model does not require annual inspections of each group member?
8. How will the multi-site model improve the National Organic Program?
9. Would it be worth pursuing the development of the multi-site model for other sectors separately from grower groups?
10. As this is an international regulation, are there additional concerns with multi-site certifications, beyond producers/grower groups, in other countries?
11. How will extending multi-site certification affect small businesses in each sector that may not choose or qualify for consideration as multi-site?
12. What means can be adopted to insure that the Internal Control System does not become a proxy for rigorous third party annual inspections for all production units?
13. If multi-site is included in all sectors, what economic issues should be evaluated to make sure it is fair for large and small operations?

VII. Suggested Resources

The Organic Foods Production Act of 1990

7 CFR Part 205 National Organic Program

IFOAM Training Manuals: ICS Training Kit for Group Certification, For Producer Organizations

IFOAM Training Manuals: ICS Training Kit for Group Certification, For Inspectors and Certification Personnel

Certifying Operations with Multiple Production Units, Sites and Facilities under the National Organic Program, November 2007. CACC Discussion Document

NOSB Recommendation, "Criteria for Certification of Grower Groups," adopted October 20, 2002.

International Accreditation Forum, Inc. (IAF), "IAF Guidance on the Application of ISO/IEC Guide 62:1996, Annex 3, Multisite Certification/Registration," April 12, 2000

IFOAM, "Smallholder Group Certification: Compilation of Results," March, 2003

ISO/IEC 17021: "Conformity Assessment—Requirements for bodies providing audit and verification of management systems," First edition 2006-09-15.

Pyburn, Rhiannon. "Final Report on Internal Control Systems and Management Systems: Public Summary," Social Accountability in Sustainable Agriculture (SASA), August 3, 2004

Public Input: OTA Group Certification Task Force 2007-2008 White Papers and Public Comments collected to www.regulations.gov. Search for all documents related to AMS-TM-07-0118

Committee Vote:

The CACC accepts and submits this discussion document for the May 2008 NOSB Meeting.

First: Bea James Second: Julie Weisman Yes – 6 No – 0 Absent – 0 Abstain - 0