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

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

August 25, 2008

I. Overview

Congress determined that national organic standards would facilitate commerce and assure consumers that products marketed with an organic claim meet a "consistent standard."¹ To achieve this commercial consistency Congress authorized the USDA to develop a federal organic certification program² in consultation with the National Organic Standards Board.³ On October 20, 2002, the NOSB submitted its recommendation "Criteria for Certification of Grower Groups" to the Secretary. (2002 recommendation) The National Organic Program (NOP) approved the 2002 recommendation in May 2007 for interim use by certifying agents.

This 2008 recommendation "Certifying Operations with Multiple Production Units, Sites and Facilities"⁴ is a new recommendation that accepts and extends the logic of the NOSB's 2002 recommendation.⁵

The OFPA and the NOP authorize certification of operations with multiple production units, sites or facilities-- including operations consisting of legally-constituted groups-based on their organic system plan, their internal control systems and other oversight provided by certifying agents. *In short, this recommendation supports the continued expansion of opportunity to certify groups worldwide that supply many organic products and ingredients without compromising or diluting the strict requirements of the Organic Foods Production Act (OFPA) and NOP.*

The key development that underpins this recommendation is an informal decision dated October 27, 2006 in which the AMS Administrator determined that a certifying agent's policy of inspecting "only a percentage of producers" in a group instead of annual inspections of each producer in the group was inconsistent with 7 CFR §205.403.⁶ The NOP allowed the continuation of group certification under the guidance of the 2002 NOSB recommendation on May 2nd 2007

³ 7 USC §6503(c)

¹ 7 USC §6501; §6505(b) (imported products may be sold in interstate commerce if certified under an "organic certification program ...[that] provides safeguards and guidelines ...equivalent to the requirements for this chapter.")

² 7 USC §6503(a)

⁴ This terminology is consistent with the regulatory language related to inspection found in 7 CFR § 205.403.

⁵ The rationale described in the 2002 recommendation remains applicable

⁶ National Organic Program Appeal Decisions 2005-07 (March 12, 2007) http://www.ams.usda.gov/NOP/Compliance/AppealsSummaries/Sept05-Mar07.pdf

There are today producers operating under certifications based on implementation of strong internal control systems that guide the implementation of a single organic system plan across multiple production units. This method of organic certification has assisted producers and handlers from less developed areas in reaching organic markets and in expanding the purchasing options of organic consumers. The use of an internal control system as part of an organic system plan that integrates multiple sites and production units is consistent with the OFPA and, provided additional assurances are met, may reduce or eliminate the need for direct observation by inspection of each unit or site operated under that OSP.

II. Legal Background

The committee agrees with and adopts the 2002 NOSB approach that the NOP may authorize its certifying agents to develop requirements for internal control systems designed to assist in certifying operations that consist of multiple production units, sites and facilities operating under a single organic system plan and that may reduce the need for direct observation by inspection of each unit or site. We begin with the October 2006 Decision in APL-011-06 (the decision) because it partially frames the ultimate issue addressed by this recommendation.

A. The Decision

In October 2006 the AMS Administrator issued a decision regarding a "community grower group" that was denied certification largely because it lacked a "well defined internal control system."⁷ The group had sought review only of the certification denial, appealing "the magnitude of the sanction" and not the underlying finding of an inadequate internal control system.⁸ The Administrator affirmed the certifying agent's decision, concluding that there had been a "failure of internal oversight mechanisms" thus the certification denial was justified.⁹ The decision went further however and concluded the use of an internal control system that required annual inspection of only a "percentage of producers for initial and annual on-site inspections" did not comport with 7 CFR 205.403(a)(1). ¹⁰ Other deficiencies were identified and taken together caused the Administrator to conclude that an "internal inspection system [cannot be used] as a proxy for the mandatory on-site inspections by a certifying agent." ¹¹

We understand the decision to say that the system under review in the case failed to comply with section 205.403(a)(1). But the decision does not preclude internal control systems that reduce or eliminate the need for direct observation of each portion of an operation under the annual on-site inspection rule appearing at section 205.403(a)(1)

¹¹ Pg. 12

⁷ Docket APL-011-06, Pg. 5, fn. 9 (defining a community grower group for purposes of the administrative decision) The 2002 NOSB recommendation also describes the organizational form its recommendation addresses calling it a "grower group."

⁸ Pg. 10

⁹ Pg. 10

¹⁰ Pg. 11

B. The Role of the Organic System Plan

The OFPA authorizes persons¹² to seek certification for their operations by submitting an organic system plan.

"[O]rganic plan" means a plan of management * * * that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling[.]¹³

Congress envisioned the OSP as a collaborative written management plan that reflected the unique characteristics of the operation. The Final Rule reflects this guidance.

The organic system plan must be negotiated, enacted, and amended through an informed dialogue between certifying agent and producer or handler, and it must *be responsive to the unique characteristics of each operation.*¹⁴

The organic system plan is the forum through which the producer or handler and certifying agent collaborate to define, on a site-specific basis, how to achieve and document compliance with the requirements of certification. The organic system plan *commits the producer or handler to a sequence of practices and procedures resulting in an operation that complies with every applicable provision in the regulations.*¹⁵

OSPs are the key management document for certified operations. Additional documentation may be ordered by the certifying agent to ensure the OSP is consistent with the OFPA and NOP.

[C]ertifying agents are competent to determine the specific documentation they require to review and evaluate an operation's organic system plan.¹⁶

Such records must be adapted to the particular business that the certified operation is conducting, *** and be sufficient to demonstrate compliance with the Act and regulations.¹⁷

The organic certification process envisioned by Congress and embedded in the Final Rule demonstrates that an OSP is a management plan that is responsive to the operation's particular needs and that certifying agents may impose additional documentary requirements to ensure a particular operation is compliant. This is adequate authorization to use the organic system plan as a vehicle for development of internal control systems that improve the results of third-party inspections by bringing the various units and sites under one governing compliance scheme that may reduce the need for direct observation by inspection of each unit or site.

¹² 7 USC §6502 (15) A person may be an individual or any other form of legally recognized entity.

¹³ 7 USC §6513(a); §6506(a)(2)

¹⁴ Final Rule at p. 41, http://www.ams.usda.gov/NOP/NOP/standards/FullText.pdf

¹⁵ 65 Fed. Reg. at 80558 (emphasis added).

¹⁶ Final Rule, at pg. 44, http://www.ams.usda.gov/NOP/NOP/standards/FullText.pdf

¹⁷ Pg. 21 Final Rule, http://www.ams.usda.gov/NOP/NOP/standards/FullText.pdf

C. The Role of Inspections

Inspections play an important role in determining whether an OSP is being properly implemented, and Congress mandated that all certified farms and handling operations receive an "annual inspection."¹⁸ The statute does not define "inspection" and the fact that it occurs but once a year indicates that Congress considered the organic inspection to be more a part of the OSP collaboration between the farmer and the certifying agent than as part of the government's policing of the organic label. The NOP's definition of "inspection" and statements in the Final Rule support this approach:

The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.¹⁹

An inspection is a tool based on examination and evaluation of site-specific activity to verify that the organic system plan "accurately reflects the practices used" and that the operation may be seen to comply with the rules and statute.²⁰

III. Recommendation

The committee recommends that the NOP accept the following **suggested definitions changes** and **prepare guidance materials for ACAs** that describes the implementation of these changes regarding certification of operations with multiple production units, sites or facilities. This may require a rule change to Section 205.403 and 205.2 that specifically allows multi-site certification based on a single OSP and functioning ICS.

Recommended new definitions for addition to 7 CFR205.2

"Production Unit" means:

The portion of an organic operation where products are produced and/or handled, including any sub-units located within geographic proximity. A production unit, including any sub-units located within geographic proximity, operates under the operation's organic system plan, and is managed through an internal control system to ensure compliance with all applicable provisions of the regulations. Each production unit within a production or handling operation has defined location, practices, management and/or products.

"Sub-unit" means:

A smaller discrete portion of a production unit, such as a field, plot, wild-crop harvest area, or distinct processing area.

"Internal Control System" means:

¹⁸ 7 USC §6506(a)(5) and 6502 (definitions)

¹⁹ 7 CFR §205.2 (definitions)

²⁰ Pg. 158 Final Rule, http://www.ams.usda.gov/NOP/NOP/standards/FullText.pdf

A written quality assurance system included in a master organic system plan that sets forth the practice standards, recordkeeping and audit trail requirements applicable at each production unit, facility or site and that identifies the internal verification methods used.

"Site" means:

The location of management activities for a given production unit.

Recommended guidance materials that NOP should create for Accredited Certifying Agencies

A. 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 "producer group certification." 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 risk assessment and sampling rather than through direct observation of every member of the producer group every year.

All producer group 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 intent here is to provide guidance for topics specifically related to producer group organic operations, not to create a parallel set of organic standards or verification system for producer group organic operations.

B. Prerequisites for a Producer Group Operation to seek USDA Organic Certification

- The producer group 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."
- <u>The certification is owned by the group, not any individual member or subunit, which</u> may not represent itself as certified other than through the group.
- 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, which is considered by NOP to be satisfactory to affirm the fitness of the ACA to perform the inspection of multi-site operations.)
- The practices of the producer group operation must be uniform and reflect a consistent process or methodology, using the same inputs/ processes.

- Participation in the producer group operation is limited to those group members who market their organic production only through the group, unless the member is individually certified.
- Producer group 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.

C. Organizing the Producer Group Operation

Production units, sites, and facilities within a certified organic producer group 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 includes direct inspection of sub-units of a production unit based on both risk assessment and random sampling.

The producer group operation must establish and implement an Internal Control System (ICS), with supervision and documentation of production practices and inputs used at each subunit, and collected at each production unit, site, or facility to insure compliance with the USDA's National Organic Program.

Criteria for the clustering of 'members' or 'sub-units' into a Production Unit

The ACA must approve the designation of specific members or subunits as belonging to a single production unit according to the following criteria, as applicable to the group, the geographic location, and the type(s) of product being produced. All members or sub-units within a production unit:

- Are unified by a shared training regimen
- Operate together under the same section of the producer group 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 must be considered a single production unit and must be inspected annually. An upper limit on the number of members or 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.

D. Inspecting the Producer Group Operation

An inspection, as defined by the NOP, is "the act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part." The applicant or certified entity is the legal business or association whose Organic System Plan (OSP) must be verified by examining each "production unit, facility, and site" where organic products are produced or handled.

Verification of the OSP is largely accomplished by a thorough audit of the functioning of the Internal Control System, accompanied by a physical examination of every Production Unit (generally the headquarters or common regional handling or collection facility) and a meaningful sample of subunits within any given Production Unit. In a producer group operation, the Production Unit is the smallest portion of the operation that must be inspected every year.

1. Inspection: Sampling and Risk Analysis

The certifying agent must have policies and procedures for determining how many of the sub-units within a production unit must receive an annual inspection by the certifying agent. The certifying agent must also have policies and procedures for determining which sub-units present the greatest risks of non-compliance. Various risk assessment methods are used to both determine sample size and select the appropriate sub-units to examine. Higher levels of overall risk for a production unit 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. It is the responsibility of the ACA to instruct the inspectors on which high-risk sub-units must be inspected and the number of lower-risk sub-units that should be sampled based on their determination of the group's over-all risk. The ACA will ensure that this protocol is transparent

- The number of production units and sub-units, sites and facilities participating in the producer group operation
- The size of the average production unit and sub-units
- The degree of uniformity among the sub-units within a production unit
- The complexity of the production system
- The management structure of the internal control system.
- Prohibited materials applied adjacent to a sub-unit within the previous year
- New entrants to the producer group operation
- Significant expansion of size of the sub-unit
- Split or parallel production
- The number of years the producer group 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
- Frequency of minor non-compliances

The high-risk sample is identified and inspected. Twenty five percent (25%) of the remaining subunits to be inspected should be selected randomly. The ACA must develop a random selection protocol that limits repeat inspections. This helps to prevent the complacency that might be inadvertently encouraged by a certifier focusing only on higher-risk sub-units.

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 non-compliances before they compromise the certification of the group. Moreover, the direct observation of a given sub-unit is not a guarantee that an instance of deliberate or fraudulent noncompliance will be detected. It is reasonable to expect that a well functioning Internal Control System, whose personnel visit each sub-unit at least once a year, will be effective in detecting such instances of noncompliance.

2. 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 producer group 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 sub-units 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 minor non-compliances found. It must communicate back to the source of the minor non-compliance the corrective actions imposed, with agreed time for completion.

The Internal Control System must provide for the suspension or exclusion of members or subunits who are found to have major non-compliances, including a plan for corrective action that must be implemented before the member or subunit can be readmitted. It must inform the ACA of all such actions, and a member who willfully or fraudulently violates the NOP should not be permitted to rejoin the group until the ACA approves the measures taken to ensure that the violation is not repeated.

ii. Internal Control System Personnel

Ideally, the ICS personnel team should include field staff 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.

Regardless of the number of ICS personnel, the ICS director 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. ICS personnel must have clear roles and responsibilities assigned by management and the resources and training to fulfill their roles and responsibilities. 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 group members
- 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
- 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 individual producer operations and at producer group operations. In order to mitigate the potential for non-compliances 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 producer group 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, carried out by the operation's field staff, 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 field 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 field 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.

3. Training Requirements

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 of members, but at least one training per year by an external specialist is recommended for ICS personnel. For producer group 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 considered to be the key to ensuring that members understand and comply with organic standards. The responsibility of NOP with regard 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 producer group operations, particularly the training in the evaluation of Internal Control Systems.

V - VI (Reserved)

References:

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

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 <u>www.regulations.gov</u>

COMMITTEE VOTE:

The CACC moves to accept this document as the recommendation:

Moved: Julie Weisman; Second: Tracy Miedema

Yes: <u>3</u> No: <u>2</u> Abstain: <u>0</u> Absent: 1

MINORITY OPINION - Multi-site Certification

The recommendation for "Certifying Operations with Multiple Production Units, Sites and Facilities under the National Organic Program" rests on a solid foundation of thorough consideration of the integrity of organic certification and the reality of some foods produced by incredibly similar, and often quite small businesses that can, by meeting rigorous requirements, band together as multiple independently owned operations under a single umbrella of performance and inspection.

Undertaken and enforced correctly, multi-site certification for growers continues a practice that has worked well. By this recommendation, it becomes not only common practice, but also a sanctioned method of organic business cooperation and resulting inspection. A strong internal control system provides an important and reliable system of self-governance with a balance of external oversight, as noted.

While there is agreement with the majority of items included in this recommendation for growers, one aspect of it falls short of providing the public with the confidence they need and deserve as it regards the process of USDA National Organic certification. In section,

- D. Inspecting the Producer Group Operation 1. Inspection: Sampling and Risk Analysis
 - New entrants to the producer group operation

This list of risk-assessment considerations helps define the secondary inspections the ACA will complete. Based on an unweighted score of all the variables listed in this section, the sub-units receiving on-site external inspections will be identified.

All new entrants to a producer unit should automatically qualify as a high-risk location, with an automatic external inspection for each new member. This process would train all new entrants immediately as to the importance of organic certification and prevent any new and less familiar producers in the group from not passing.

The multi-site recommendation posted for consideration at the November 2008 NOSB meeting would be much stronger with the requirement that all new entrants to a production unit undergo an external 3rd party inspection prior to official inclusion as a group/production unit member. In all years subsequent to their successful inspection and organic certification, the production sub-units can be effectively monitored through the ICS.