

# 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

Recommendation October 1, 2007

### I. Introduction

Congress determined that national organic standards would facilitate commerce and assure consumers that products marketed with an organic claim meet a “consistent standard.”<sup>1</sup> To achieve this commercial consistency Congress authorized the USDA to develop a federal organic certification program<sup>2</sup> in consultation with the National Organic Standards Board.<sup>3</sup> 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 2007 recommendation “Certifying Operations with Multiple Production Units, Sites and Facilities” is a new recommendation that accepts and extends the logic of the NOSB’s 2002 recommendation to accommodate developments in the industry since that time.<sup>4</sup> 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. While we expect to develop further guidance for ACAs regarding implementation of this recommendation, the first and most critical step regarding the continuation of group certification is to clearly connect the act of certifying groups to the OFPA and existing NOP regulations. This recommendation suggests minor amendments to the regulations. The OFPA and the NOP authorize certification of operations with multiple production units, sites or facilities-- including operations consisting of groups--based on their organic system plan, their internal control systems and other oversight provided by certifying agents.

Two key developments underpin this recommendation. Commerce in organically produced and handled products has grown dramatically since the 2002 NOSB recommendation and certifying agents have developed and implemented certification models that are tailored to the various types of operations seeking certification. At the NOP these certification models were based on the NOSB’s 2002 recommendation and are now extended to reach all links in the organic value chain from farm, to handler to final retailer. Second, by an informal decision dated October 27, 2006 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.<sup>5</sup>

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<sup>1</sup> 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.” )

<sup>2</sup> 7 USC §6503(a)

<sup>3</sup> 7 USC §6503(c)

<sup>4</sup> The rationale described in the 2002 recommendation remains applicable and is revisited here only where necessary.

<sup>5</sup> National Organic Program Appeal Decisions 2005-07 (March 12, 2007)

<http://www.ams.usda.gov/NOP/Compliance/AppealsSummaries/Sept05-Mar07.pdf>

Although the decision involved review of the practices of one producer group, the decision has been cited by the NOP as applicable to handlers as well as final retailers. The perspective, then, of this recommendation, is to broadly look at the entire organic supply chain.

There are today producers, handlers, and final retailers<sup>6</sup> 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 in the case of a producer-- or multiple sites in the case of a handler or final retailer. 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. It has also encouraged the voluntary participation of final retailers in organic certification thus helping to bring all of the links in the seed to table organic value chain under one organic program. 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. This recommendation updates the 2002 NOSB recommendation by seeking a rule change to clarify and accommodate these desirable certification services.

The committee expects to make additional recommendations on guidance materials for ACAs that will be developed for attachment to this recommendation as Appendices. The Documents Consulted section at the end of this document, in addition to being excellent resources for developing guidance materials for ACAs, should reinforce the concept that group certification is a well recognized certification model around the world.

## 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 or eliminate 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."<sup>7</sup> 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.<sup>8</sup> The Administrator affirmed the certifying

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<sup>6</sup> Although Congress excepted final retailers from being treated as handlers under the statute, it did not exempt retailers from the purview of organic certification. **See** Final Rule at pg. 20 ("Retail food establishments, not exempt under the Act, could at some future date be subject to regulation under the NOP.") The term "retail food establishment" was defined for purposes of certifying facilities that are not "handlers" but that sell "ready-to-eat food." 7 CFR §205.2 Final retailers meeting the terms of 7 CFR 205.101(b)(1) are also routinely certified in the U.S.

<sup>7</sup> 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."

<sup>8</sup> Pg. 10

agent's decision, concluding that there had been a "failure of internal oversight mechanisms" thus the certification denial was justified.<sup>9</sup> 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).<sup>10</sup> 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."<sup>11</sup>

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)

## B. The Role of the Organic System Plan

The OFPA authorizes persons<sup>12</sup> 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[.]<sup>13</sup>

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.*<sup>14</sup>

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.*<sup>15</sup>

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.<sup>16</sup>

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<sup>9</sup> Pg. 10

<sup>10</sup> Pg. 11

<sup>11</sup> Pg. 12

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

<sup>13</sup> 7 USC §6513(a); §6506(a)(2)

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

<sup>15</sup> 65 Fed. Reg. at 80558 (emphasis added).

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

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.<sup>17</sup>

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 or eliminate the need for direct observation by inspection of each unit or site.

### 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."<sup>18</sup> The statute does not define "inspection" and the fact that it occurs but once a year indicates that Congress considered 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.<sup>19</sup>

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.<sup>20</sup>

#### 1. Distinguishing Initial On-Site Inspections and Annual or Renewal Inspections of Operations Involving Multiple Production Units, Sites and Facilities

The NOP implemented the statutory requirement for an annual inspection by adopting an on-site inspection rule that makes two key distinctions relevant to this recommendation.

(a) On-site inspections. (1) A certifying agent must conduct an *initial* on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be *conducted annually thereafter for each certified operation* that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.<sup>21</sup>

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

<sup>18</sup> 7 USC §6506(a)(5) and 6502 (definitions)

<sup>19</sup> 7 CFR §205.2 (definitions)

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

<sup>21</sup> 7 CFR §205.403

The on-site inspections rule distinguishes between a certified operation and the various sites, production units and facilities that are under the control of the certified operation.<sup>22</sup> It also distinguishes between the “initial” inspection that includes all of the different units, sites and facilities and annual renewal inspections thereafter that do not.<sup>23</sup> The rule thus establishes a two-tiered inspection system---one for initial inspections and one for each year thereafter for renewal of the certification. The annual renewal inspection does not include the requirement that each part of the certified operation be subject to an on-site inspection. Most inspections under the NOP are renewal inspections thus the vast majority of inspections undertaken today *do not* require direct observation of each site, production unit or facility. Drawing the distinction between the initial inspection and renewal or annual inspections is important because it demonstrates that the NOP’s existing policy recognizes that one operation may consist of many units or sites, and that there is no requirement beyond the initial inspection that each unit or site be directly observed by inspection annually.

D Acceptance of Certifications of Operations Currently Certified under Different Forms of Group Certification<sup>24</sup>

The October 2006 AMS decision is one example demonstrating that the organic value chain within the purview of the NOP today includes certified producers, handlers and retailers that consist of multiple units and sites operating under a single organic system plan. It is appropriate that any certified operation that currently operates multiple units or sites under an single approved organic system plan and that has not received direct observation by inspection of each unit or site, continue to be certified unless a reasonable and justifiable belief exists that the internal control system is inadequate. We expect to develop additional guidance describing the factors a certifying agent should consider to determine that an existing certification needs, or needs not to be revisited because each production unit, site or facility was not directly observed by inspection.

Conclusion

The statutory definition of “person” and the explicit identification in the OFPA of producers, handlers, and final retailers as links in the organic value chain by Congress authorizes rules regarding their certification, and imposes a duty on the NOP and NOSB to develop a uniform approach to certification services provided to each. The overarching concept of the organic system plan is sufficiently robust to include internal control systems that reduce or eliminate the need for annual direct observation by inspection of each production unit, site or facility of an organic operation, without regard to its area of operation (production, handling, retail).

These suggested rule changes are authorized by the statute and constitute little in the way of new policy but instead harmonizes and clarifies the existing approach to providing certification services to

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<sup>22</sup> Similarly, the word “field” is defined as a “discrete unit” of a certified operation. 7 CFR 205.2

<sup>23</sup> It is important to note that nothing in the existing rule or this recommendation would alter the authority of any certifying agent to inspect any production unit, site or facility it determined was reasonably necessary to ensure compliance.

<sup>24</sup> The committee believes it is reasonable to assume the vast majority of such certifications are based on the 2002 NOSB recommendation and other international guidance materials on the subject that have been developed since that time. Additionally, the committee is aware of no credible evidence that the use of such certification mechanisms has been shown to pose any material increase in the risk that organic products are mislabeled. Thus we see little reason to disrupt the existing certifications absent a showing of substantial need.

operations involving multiple production units, sites and facilities under 7 CFR §205.403. To minimize the need for substantial rewriting of the rules, we retain and clarify the distinction between the initial and annual inspections to make clear that a sufficiently robust internal control system, that is described in sufficient detail in the master OSP, may reduce or eliminate the need for direction observation by inspection of each unit, site or facility.

Some stakeholders in the group certification issue have focused their attention on specific guidance to ACAs. However, the approach of this committee is to first ensure that groups unequivocally can exist within the regulatory framework of the NOP. The development of guidance materials for ACAs is assumed to be the next phase in this process and, other than the Documents Consulted section, is not part of the recommendation per se.

### III. Recommendation

The committee recommends that the NOP accept the following suggested rule changes and prepare a guidance document for ACAs that describes the implementation of these changes regarding certification of operations with multiple production units, sites or facilities.

#### A. New Definitions for addition to 7 CFR §205.2

“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.

“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

“Initial on-site inspection” means:

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

“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.

“Internal Control System” means

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.

B. Clarification of On-Site Inspections (bold indicates recommended language to be added)

§ 205.403 On-site inspections.

(a) *On-site inspections.* (1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An **annual** on-site inspection shall be conducted ~~each year annually~~ thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.

(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.**

(2) (i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.

(ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.

(iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.

(b) *Scheduling.* (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: *Except*, that, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

(2) All on-site inspections **whether designated as initial or renewal** must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.

Documents Consulted

The Organic Foods Production Act of 1990

7 CFR Part 205 National Organic Program

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.

**Committee Vote:**

**Moved:** Tracy Miedema

**Second:** Julie Weisman

Yes: 3

No: 2

Abstain: 1

Absent: 0

## Minority Opinion – Multi-Site Operations/ Grower Group Certification

The following minority opinion suggests further consideration and clarity in the proposed recommendation for Multi-Site operations, specifically:

- Retain the scope of the October 2002 Grower Group recommendation which is focused and limited to Grower Groups (farmers only).
- Require complete inspections of all sites, facilities and production units annually for all operations, with certain considerations granted to farms meeting specific criteria for grower (farmer) groups.
- Specific details to the criteria for grower groups to provide guidance on internal inspection should be included in the proposed recommendation. For example, farm groups that market similar crops through one outlet, utilize the same inputs, are geographically proximate, and are organized into a legal business entity could be eligible for grower (farmer) groups.
- The introduction makes several assumptions and generalizations regarding the interpretation of OFPA. For example in paragraph five the following statements are not based in quantifiable facts and should be eliminated; *“It (a single OSP) has also encouraged the participation of final retailers in organic certification thus helping to bring all of the links in the seed to table organic value chain under one organic program. 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”*.
- The following statement is also incorrect and should be struck. *“...certifying agents have developed and implemented certification models that are tailored to the various types of operations seeking certification. At the NOP these certification models were based on the NOSB’s 2002 recommendation and are now extended to reach all links in the organic value chain from farm, to handler to final retailer.”* NOP has not approved any new certification “models” that some certifiers have developed. One unapproved model has permitted retail stores to be certified without annual inspection of each site.
- The addition of the recommended new definitions dilutes and corrupts the meaning of OFPA and the final rule. The following definitions should not be added to 7 CFR §205.2 “Renewal inspection”, “Facility or Site”, “Production Unit”.

The current problem NOSB has been asked to address involves the ability of certifiers to certify growers (farmers) that are organized in groups in order to consolidate and market a specific crop. This has been historical practice in many developing countries, particularly for crops like coffee, bananas, cocoa, tea and other tropical fruits.

This committee recommendation unnecessarily increases the scope of the previous 2002 NOSB recommendation to include all “multi-site operations.” Currently, handling and processing and large farm operations may be certified as complex multi-site operations under one certification application. However, all sites, facilities, and production units must be annually inspected under the current regulations. If there are current examples in the industry where handling and processing operations are not being inspected in their entirety annually this is a violation of the rule, and not a “model” for how it can be done. There is no need to change the requirements or procedures that are well established for these operations, and important in order to provide adequate monitoring.

Handlers and other processors, including retailers who chose to be certified, must have their central headquarters audited, operate under one Organic System Plan, and be subject to **annual** inspection of each site, facility and production unit, as required at 205.403(a)(1).

This CAC recommendation interprets the language at 205.403 very narrowly to mean that complete inspections are only required the first year of certification, which is contrary to the OFPA, current regulations, and the practice of organic certification in the US. Annual inspection should be done consistently and with the same criteria each year, a renewal is not a lessening of the annual inspection. The CAC recommendation conflicts with OFPA, which states:

6506(a) In General – A program established under this title shall –

(5) provide for annual on-site inspection by the certifying agent of each farm and handling operation that has been certified under this title;

6502 Definitions

(4) Certified organic farm – The term “certified organic farm” means a farm, or portion of a farm, or site, where agricultural products or livestock are produced, that is certified by the certifying agent under this title as utilizing a system of organic farming as described by this title.

(5) Certified organic handling operation – The term “certified organic handling operation” means any operation, or portion of any handling operation, that is certified by the certifying agent under this title as utilizing a system of organic handling as described by this title.

The handling and processing of organic food introduces a greater level of complexity to the certification process, for instance, often there are many sources of ingredients, frequent changes in product lines and labels, change in personnel, all of which add risks to organic integrity. It is one thing to permit cooperative farmers with tightly managed internal quality systems producing a similar crop to group their production in units and have a reduced inspection protocol, but quite another to propose to alter the current scheme for processors and handlers. An allowance for reduced inspection after the first year of certification for all processors, handlers, and farmers will introduce unacceptable risks to organic integrity and should not be considered.