Formal Recommendation by the National Organic Standards Board (NOSB) to the National Organic Program (NOP)

Date: December 2, 2011

Subject: Unannounced Inspections

Chair: Tracy Miedema

The NOSB hereby recommends to the NOP the following:

Guidance Statement

Statement of the Recommendation (Including Recount of Vote):

Recommendation to provide draft guidance language to NOP as per attached CACC Recommendation. Passed by a vote of 14 yes, 0 no.

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

CACC recommendation is attached.

NOSB Vote:

Moved: Joe Dickson			Second:	John Foster				
Yes:	14	No:	0	Abstain:	0	Absent:	0	Recusal: 0

National Organic Standards Board Certification, Accreditation and Compliance Committee Proposed Recommendation Unannounced Inspections

December 2, 2011

Background

On June 23, 2011, the Deputy Administrator of the National Organic Program (NOP) issued a memorandum to the chair of the National Organic Standards Board (NOSB) requesting a proposal on best practices for unannounced inspection. The Certification, Accreditation and Compliance Committee (CACC) has reviewed this request and, in consultation with representatives from the organic community, developed this proposal.

Currently, unannounced inspections are allowed, but not required, under the NOP regulations. Some Accredited Certification Agencies (ACA's) conduct many unannounced inspections, often to fulfill international requirements, while others may conduct none. We believe that it would be appropriate for the NOP to issue guidance to ACA's on this subject and respectfully submit our recommendations below.

Relevant Regulatory Text

7 CFR § 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 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.

(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 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.
- (c) Verification of information. The on-site inspection of an operation must verify:
 - (1) The operation's compliance or capability to comply with the Act and the regulations in this part;
 - (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;
 - (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.
- (d) Exit interview. The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.
- (e) Documents to the inspected operation.
 - (1) At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.
 - (2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.

Discussion

The CACC believes that unannounced inspections are one of the most powerful and useful tools in the NOP regulations to ensure compliance across certified operations and give consumers additional reasons to trust the organic label. We believe that all ACA's should be conducting unannounced inspections of a significant portion of their clients every year.

Unannounced inspections serve the dual purpose of giving the ACA the opportunity to observe the activities of a specific operation without the advance notice provided in the annual monitoring inspections, but also acts as a deterrent factor to other operations who may consider acting in noncompliance with the NOP. ACA's who already conduct significant unannounced inspections report that word of unannounced inspections tends to spread among groups of organic operations. A consistent approach to unannounced inspections is essential in order to ensure organic integrity, reinforce the public trust in the organic label and create an even playing field for certifiers and certified operations alike.

We strongly recommend that the NOP provide guidance that includes a specific percentage of operations which must have unannounced inspections every year. We are proposing a five percent requirement across the board for all ACA's. This will ensure fair and equitable application of unannounced inspections by certifiers of all sizes and will not unfairly or impact small or large ACA's. Because ACA's have the option of charging certified operations for unannounced inspections (either on a per inspection basis or as part of their overall fee structure), we do not believe that requiring ACA's to conduct unannounced inspections will have a negative financial impact on ACA's. The proposal for five percent of operations per year is in line with IFOAM and COR. As these international organic standards already require unannounced inspections, a number of NOP ACA's have experience in conducting these types of inspections and are already performing at least the 5% proposed.

ACA's may be disinclined to conduct unannounced inspections in remote geographic areas or areas where they do not have regular inspection services or inspectors. While we understand the financial and operational considerations, we believe that an ACA should and must be able to conduct an unannounced inspection in any area they offer certification services or they are failing to maintain adequate resources to effectively and equally apply this oversight. At this time, we are not proposing that the ACA be required to conduct annual unannounced inspections in each country, of each product type, or each certification scope. Such requirements could result in a single operation having an unannounced inspection every year, while the majority of a certifier's operations would not receive an unannounced inspection in any year, which predictably leads to absurd outcomes. Instead, we recommend that ACA's have a systematic plan for equitably distributing unannounced inspections across their clients to ensure a reasonable representation of certified operators.

We believe that ACA's can appropriately use unannounced inspections either for targeted, risk based investigation purposes or simply randomly. We do not believe that ACA's should be limited to performing either one type of unannounced inspection or the other, and will be able to determine the appropriate balance of the two types. We

recommend that ACA's develop risk assessment systems to document the operations who they have determined to be most at risk for noncompliance, and therefore a higher priority for an unannounced inspection. While we have provided some elements of a risk assessment guide, we believe that this is not comprehensive, and that ACA's will be able to use other criteria for determining whether an operation is a good candidate for an unannounced inspection. ACA's are encouraged to share their risk assessment criteria among themselves to facilitate this process.

Some ACA's may use unannounced inspections in conjunction with sampling visits. Collecting samples during the course in order to fulfill the (currently draft) requirements for pesticide residue testing can be an efficient use of ACA and inspector resources. While we do not discourage this practice, we want to be clear that a sample collection alone is not sufficient to fulfill an unannounced inspection requirement. The inspector must also observe some aspects of an operation's activities or fields, facilities or products. An unannounced inspection must include the creation of an inspection report by the inspector and review by the ACA, even though the inspection may be limited in scope. Especially if the operator's representative was not present at the inspection, it is important that the ACA document the visit and the observations of the inspector and supply a copy of this report to the inspected operation.

While operations are required by the NOP to make all documents relevant to certification available during normal business hours, in practice, many operations (particularly small farmers) may not be able to make all records available during an unannounced inspection. When an operation is able to make all records available, and the operator's representative is able to spend the necessary time with the inspector. there is no reason why an unannounced inspection cannot fulfill the annual on-site monitoring requirements of NOP 205.403. If the ACA conducts unannounced inspections at their own expenses, as some do, it may even be preferred by the operation to have the unannounced inspection be a full annual inspection. While we think it is reasonable for inspectors to show up unannounced and require some time from the operation, we expect that ACA's respect the business realities of the certified operations. Inspectors should not make unreasonable demands on their time, such as expecting an operation to stop all activity and spend an entire day with the inspector. Especially in cases where the unannounced inspection is being conducted randomly, as opposed to based on risk factors, or in the case of small businesses and sole proprietorships, unannounced inspections can be done relatively quickly and without too much interruption in daily activities. We discourage ACA's, inspectors or certified operations from expecting all or most unannounced inspections from fulfilling the annual inspection requirements.

The issues of trespassing and property access can be controversial. ACA's must provide specific, written guidance to their inspectors and their clients describing their policies on having inspectors access certified operations when a representative of the operation is not present. While laws may vary from state to state (and country to country), we strongly recommend that ACA's instruct inspectors never to enter on to private land or roadways without permission. Even if an operation has signed a certification contract stating that they allow access at any time, we are concerned that inspectors could be in violation of trespassing laws if they do so. At many operations, there are observations that can be made by an inspector from public property, such as roadways and parking lots.

At some operations, such as closed facilities or biosecure chicken houses, it may be absolutely essential that a representative be present to allow access to the facilities in order for an unannounced inspection to provide any kind of meaningful observation by the inspector. In these cases, we believe that it may be useful to provide some advance notice to the operation so that they can ensure a representative is present. ACA's currently have a number of different approaches to pre-inspection notification. Some ACA's may provide as long as 48 hours advance notice before an "unannounced" inspection. We believe that the latter is excessive notice and could allow a fraudulent operation sufficient time and warning to clean or obscure elements of their facilities, storage areas, ledgers, and so on. We suggest that a limit of no more than four hours pre-inspection notice provides reasonable time for an operation to make a representative available, while limiting the amount of pre-inspection preparation that can occur. We recognize that this is a somewhat arbitrary time limit, and we suggest feedback from ACA's on this requirement. In any event, The ACA must include notice to applicants of their policies regarding notice and expectations for compliance.

Proposed Guidance

- 1. ACA's are required to conduct periodic unannounced inspections at minimum of five percent (5%) of their total certified operations per year. For calculation purposes, the number of operations will be counted as the number reported by the ACA to the NOP during the annual update each January. For ACA's with less than 20 certified operations, they are required to conduct one (1) unannounced inspection each year.
- 2. The ACA should strive to conduct unannounced inspections broadly across all certified operations, including a broad spectrum of production types, products and locations. ACA's should not limit unannounced inspections to nearby operations or certain production types. ACA's should have a long term plan for conducting unannounced inspections across their client base, including geographic location and certification scope. ACA's shall not accept applications for certification from locations where they are unable or unwilling to conduct unannounced inspections.

- **3.** ACA's may choose operations for periodic unannounced inspections may be random, risk based, or the result of a complaint or investigation. The ACA is not required to disclose to the operation the reason for the unannounced inspection.
 - a. Risk factors for conducting an unannounced inspection of an operation may include, but are not limited to:
 - i. Previous noncompliance issues
 - ii. Complaints
 - iii. Organic and non-organic production, especially of visually indistinguishable varieties
 - iv. Likelihood of drift or contamination potential
 - v. Product market value or prevalence
- 4. Unannounced inspections may fulfill the requirements for annual on-site monitoring inspections required by section 205.403 only if the inspector is able to conduct a full inspection of the operation as required by this section. Unannounced inspections may be limited in scope, depth and breadth, and may cover only certain aspects of the operation such as parcels, facilities, products, etc. ACA's may direct the inspector to a portion of the operation to review during an unannounced inspection.
- **5.** An inspection report must be written by the inspector, sent to the client and reviewed by the ACA and a decision communicated to the clietnas per NOP 205.403 and the ACA's internal protocols.
- 6. Inspectors may conduct sampling during an unannounced inspection. Such an inspection may count towards both the number of samples and towards the number of unannounced inspections an ACA is required to take annually. However, if a visit of the operation is to count as both an instance of sample collection and an unannounced inspection, the inspector must review some aspects of the operation besides simply collecting a sample.
- **7.** An unannounced inspection may occur even if no representative of the operation is present.
 - a. Wherever possible, an unannounced inspection should include no prior notification of the operation to be inspected before the inspector arrives on site. In special cases or where extenuating circumstances make it impossible to conduct any type of observation of the operation without prior notification (such as biosecurity issues), the ACA may notify the operation up to four (4) hours prior to the inspector arriving on site to ensure that appropriate representatives are present.
 - b. If a representative of the operation is not present, observations of the operation including, but not limited to, the following may be observed:
 - i. Condition of soil fertility
 - ii. Health of the plants
 - iii. Condition of soil and water
 - iv. Erosion issues
 - v. Evidence of, or lack of, herbicide, fungicide or pesticide use

- vi. Condition of facilities, including pest control and contamination risks
- vii. Condition of pastures and indicators of grazing
- **8.** ACA's are responsible for providing adequate training to their inspectors to ensure that inspectors do not trespass or break any other laws during unannounced inspections. Inspectors should not enter private property without explicit permission of the operation. Inspectors must have adequate identification, such as a business card and/or explanatory letter from the ACA, to demonstrate that they are acting on behalf of the ACA. ACA's must have a written policy on unannounced inspections and inspector access to certified facilities that is provided to all clients and to inspectors.
- 9. If an operation refuses to allow an inspector access to any part of an operation, including the non-organic portions of the operation, during normal business hours, the operation shall be considered non-compliant with NOP section 205.403 and the ACA should promptly issue a Notice of Noncompliance to the operation.
- **10.** ACA's must clearly disclose to their clients their protocols for unannounced inspections. ACA's may charge their clients fees for unannounced inspections as long as these fees are clearly disclosed to all clients preemptively.

Committee Vote

Motion by: John Foster Second: Barry Flamm

Yes: 6 No: 0 Absent: 0 Abstain: 0 Recuse: 0