

**Date:** October 5, 2020

**Docket:** AMS-NOP-17-0065

**Re: Strengthening Organic Enforcement Proposed Rule – Grower Group Operations**

Thank you for this opportunity to provide comment on the United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) National Organic Program (NOP) Proposed Rule on Strengthening Organic Enforcement. The Organic Trade Association is submitting individual comments on each topic in the proposed rule to help NOP in its process of finding and navigating our positions and recommendations. We have also submitted all of our comments bundled into a single PDF including a cover letter. This comment addresses Section #16: Grower Group Operations.

**Summary of the Organic Trade Association’s (OTA) Positions and Recommendation**

- OTA supports certification of group operations and recommends revisions to the new terms and definitions to clarify that the grower group operation is the legal entity that is tied to the legal definition of “person” in §205.2.
- OTA recommends that group operations are identified as such in the NOP Organic Integrity Database.
- OTA recommends that grower group certification become a separate accreditation scope that certifiers must have in order to certify grower group operations.
- OTA does not support limiting group certification only to producers of crop and wild crop products. OTA recommends scope-neutrality regarding the type of products that can be produced and certified under group certification, and recommends that scope limitations are removed from the rule.
- OTA supports scale-neutrality regarding the size of groups and group members that can be certified under group certification. OTA does not support imposing limits on gross sales or field sizes of individual grower group members, nor limiting the maximum number of members allowed in a grower group operation or in a grower group production unit.
- OTA supports geographic proximity of members, and sees no need for more specific limits to further define geographic proximity.
- OTA supports the allowance for members to also have separate individual certification outside of the group should they want to sell organic products outside of the group if they are certified for such products.
- OTA does not support the current proposal that requires certifiers to inspect high-risk members based on the internal control system’s own risk criteria. OTA recommends that certifiers conduct an independent external risk assessment separate from (and in addition to) the internal

risk assessment conducted by the internal control system. OTA also recommends that NOP develop guidance to support certifiers in reaching a common understanding of the criteria that should be used to identify high risk group members and to assess risks of groups as a whole.

- OTA supports many of the specific regulatory requirements for the Internal Control System (ICS), and recommends several critical revisions to the proposed rule that will enhance and clarify the ICS's responsibilities for establishing and maintaining strong oversight and enforcement capabilities.
- OTA recommends regulatory clarifications and guidance to ensure sufficient qualifications of ICS personnel.
- OTA recommends regulatory clarifications to ensure that recordkeeping by the ICS is sufficient to demonstrate compliance.
- OTA recommends regulatory clarifications to elevate and enhance ICS requirements for member training to ensure that all group members understand and can comply with the organic regulations.
- OTA recommends regulatory clarifications and guidance to ensure internal inspections conducted by the ICS are robust, clearly understood, and consistently implemented.
- OTA recommends the development of guidance that clarifies the scenarios that would qualify as a conflict of interest in an ICS.
- OTA supports the sampling method for external inspections that requires the certifier to inspect 1.4 times the square root ( $1.4\sqrt{\phantom{x}}$ ) of members. We also recommend that NOP explore whether to establish a minimum percentage of members (e.g. 2%) that must be inspected that can be used in combination with the  $1.4\sqrt{\phantom{x}}$  method. We also recommend that NOP provide guidance to certifiers that will help ensure that each production unit is well represented in the overall sample of external inspections.
- OTA recommends a modified requirement for external witness audits that requires the certifier to evaluate *at least 25%* of internal auditors to ensure a representative sample of ICS inspectors are evaluated.
- OTA recommends the development of guidance for certifier's external oversight and enforcement of group operations in a manner that focuses on the assessment of the internal control system.
- OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within one year after publication of the final rule.

## **Background**

Grower groups are operations composed of multiple production sites each managed by individual farmer members who collectively market product through a single certified entity. Instead of each member having its own independent certification, the group as a whole is certified based on the group having a strong centralized internal control system that assures compliance of all members through internal inspections and sanctions. The certifier assesses compliance of the internal control system and directly inspects a sample of individual members.

According to a report<sup>1</sup> by the Research Institute of Organic Agriculture (FiBL), there are approximately 5,900 group operations worldwide, including 2.6 million farmers across 58 countries. Group operations are responsible for producing valuable products such as coffee and cocoa. Groups also commonly produce sugar, cotton, tropical fruits, tropical nuts, honey and other specialty crops. The number of members per group varies widely, the average size depending on the geographic region where the group is operating and the type of product produced by the operation. For example, in Latin America, the group sizes are relatively small (typically between 80-250 members; many very small groups with less than 50 members; none over 1,000 members) but individual member's landholdings are relatively large (2.5-4 hectares or greater). In contrast, group operations in Africa are very large (typically between 300-10,000 members; many very large groups over 10,000 members; largest documented group is 80,000 members) but the landholdings for each individual member are very small (< 1 hectare). Groups are also common in India and other parts of Asia.

Grower groups have been and continue to be certified organic under NOP regulations. The definition of "person" in the Organic Foods Production Act includes "groups of individuals" and cooperatives. Therefore, groups that are organized under the legal definition of "person" may apply for certification as a single legal entity. NOP-accredited certifier oversight has been guided by two recommendations from the National Organic Standards Board that were formalized by NOP in 2011 through a policy memo<sup>2</sup> currently maintained in the NOP Handbook.

Simultaneously to NOP formalizing regulatory standards for grower groups, the European Union (EU) is also embarking on formalizing group certification standards for operations certified under the EU organic program. It is common for a groups to hold dual certifications under both EU and NOP, so this is an important opportunity for NOP standards to develop in harmonization with the EU and avoid unnecessary variances that could disrupt the millions of growers worldwide that participate in group certification.

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<sup>1</sup> <https://orgprints.org/35159/>

<sup>2</sup> <https://www.ams.usda.gov/sites/default/files/media/NOP-11-10-GroupGrowerCert.pdf>

## NOP Questions

1. ***Should there be limits on gross sales or field sizes of individual grower group members?***

No. Groups and group members of all sizes should be eligible for group certification provided the group has a strong internal control system and meets other eligibility and regulatory requirements. OTA recommends scale-neutrality in terms of eligibility for group certification, and that any concerns about larger sizes of group members or groups can and should be addressed through risk-assessment. Please see OTA's Positions and Recommendations below for more information about our position on group size limits.

2. ***Should there be a limit on the maximum number of members allowed in a grower group operation or in a grower group production unit?***

No. Groups and group members of all sizes should be eligible for group certification provided the group has a strong internal control system and meets other eligibility and regulatory requirements. OTA recommends scale-neutrality in terms of eligibility for group certification, and that any concerns about larger sizes of group members or groups can and should be addressed through risk-assessment. Please see OTA's Positions and Recommendations below for more information about our position on group size limits.

3. ***Should there be a limit to the geographical distribution of members?***

No. The regulations should allow for groups to define geographic proximity based on the unique context and the geographic conditions of the region within which the group is operating. Please see OTA's Positions and Recommendations below for more information about our position on geographic distribution.

## OTA's Positions and Recommendations

- **OTA supports certification of group operations.** NOP's regulatory definition of "person" provides a pathway for groups of individuals to be certified as a single legal entity. Groups legally organized as a "person" can accommodate common structures of group operations worldwide, including farmer-led groups and processor/trader-affiliated groups.
- **OTA recommends revisions to the new terms and definitions to clarify that the grower group operation is the legal entity that is tied to the legal definition of "person" in §205.2.** The eligibility requirements in the proposed rule are sufficient to require that groups are legally organized as a person. However, the terms and definitions in §205.2 would benefit from increased clarity to ensure consistent implementation. For instance, the proposed rule uses the term "person" in the definition of group *member* but not in the definition of group *operation*. This could result in confusion about which entity is tied to the legal definition of person in §205.2. "Person" is legal justification for certifying the

group operation, not individual members of a group. Furthermore, we recommend that the new terms and definitions proposed for §205.2 be improved by avoiding use of the term “single” in reference to a producer or product. “Single” would be more appropriate to describe the legal entity, or the Organic System Plan, or the certificate. Referring to “single producers” could create confusion and misrepresentation, so we recommend its removal.

- ➔ **Recommendation:** Revise the terms and definitions in §205.2 to accurately and clearly define relationships between group/member, make better use of existing term “person,” and to improve clarity and consistency. *See OTA’s requested revisions in Table 11 below.*
- **OTA recommends that grower group operations be identified as such in the NOP Organic Integrity Database.** Currently, the status of an operation as being a grower group is not visible in the Organic Integrity Database, so it is not possible to determine if an operation is a grower group or how many grower groups are certified to the NOP organic standards. This is an important point of data transparency. Ideally, the Organic Integrity Database should identify if an operation is certified as a group operation and identify how many members are in the group. The total certified acreage of the group should already be captured in requirements for operations to report certified acreage to the Administrator, because group operations would need to report data just as any other certified operation. *See also OTA’s Comments on Organic Certificates & Data Reporting.*
  - **OTA recommends that grower group certification become a separate accreditation scope that certifiers must have in order to certify grower group operations.** The ability for groups to be certified under NOP regulations while maintaining organic integrity and assuring organic compliance is dependent on the group having a strong internal control system and the certifier having a strong understanding and ability to assess compliance of group operations. The assessment and verification process for a group operation’s internal control system is significantly different from that of an individual operation. Certifiers need specific skills and training to effectively provide certification services to group operations, which requires unique additional elements of conformity assessment and auditing management systems. It is critical that certification agencies are qualified in this regard, and that NOP oversight ensure continued qualifications through accreditation audits. There doesn’t appear to be anything in OFPA that would preclude this from becoming a new accreditation scope for certifiers.
- ➔ **Recommendation:** Develop a new accreditation scope for group certification and implement a requirement that certifiers must be accredited under the new scope in order to provide certification services for group operations. *See OTA’s requested revisions in Table 11 below.*

- **OTA does not support limiting group certification only to producers of crop and wild crop products. OTA recommends scope-neutrality regarding the type of products that can be produced and certified under group certification, and recommends that scope limitations are removed from the rule.** All producers, including livestock producers, should be eligible for group certification provided the group has a strong internal control system and meets other eligibility and regulatory requirements. The regulations should fairly and consistently apply group certification procedures across all scopes of production, just like procedures for individual certification which can be for any scope provided that the practice standards and other requirements are met. Scope-neutrality will align with the forthcoming EU organic regulations that will allow group certification for group of producers of crops, livestock, apiculture, algae, and aquaculture.

The group certification model should not discriminate against or penalize producers of livestock and livestock products. Prohibiting livestock would also exclude honey producers because apiculture is certified under the livestock scope. OTA is not able to justify (and NOP has not articulated in the preamble) a case as to why livestock should be excluded from group certification. Livestock operations do not embody an inherent incompatibility or inability to comply with organic regulations. **Concerns about increased risk of livestock operations can and should be addressed through risk-assessment.** Scope-neutrality of the regulations does not preclude certifiers from using scope as a risk factor and imposing stronger controls on high-risk groups.

→ **Recommendation:** Revise proposed rule to remove limitations to crop and wild crops and ensure fair and consistent applicability of the regulations. All producers should be eligible for group certification provided the group has a strong internal control system and meets other eligibility and regulatory requirements. *See OTA's requested revisions in Table 11 below.*

Furthermore, the proposed terms defined and other parts of the proposed rule need better consistency in their references to production and/or handling. Both production and handling are activities that may be performed within a group or by a group member. There are several instances where production and handling are not consistently referenced, and this needs to be clarified.

→ **Recommendation:** Revise proposed rule to ensure consistent references to production and handling activities. *See OTA's requested revisions in Table 11 below.*

- **OTA supports scale-neutrality regarding the size of groups and group members that can be certified under group certification. OTA does not support imposing limits on gross sales or field sizes of individual grower group members, nor limiting the maximum number of members allowed in a grower group operation or in a grower group production unit.** Groups and group members of all sizes should be eligible for group certification provided the group has a strong internal control system and meets other eligibility and regulatory requirements. The regulations should fairly and consistently apply group certification procedures across all sizes and scales of production, just like procedures for individual certification which can be applied to any size or scale provided that the practice standards and other requirements are met. No other part of the regulations disqualify operations from organic certification based only on gross sales or field size or number of production sites.

Setting limits on size or scale may not necessarily lead to reduced risk or better fraud prevention. These variables in and of themselves are not an indicator of inherent incompatibility or inability to comply with organic regulations; smaller size or scale does not automatically mean less risk. **Concerns about larger sizes of group members or groups can and should be addressed through risk-assessment.** Scale-neutrality of the regulations does not preclude certifiers from using size as a risk factor and imposing stronger controls on high-risk groups. Furthermore, it would be very difficult to determine a non-arbitrary limit on size or scale that would work for a variety of production systems and geographic regions worldwide, without creating unintended negative consequence. The Indian National Programme for Organic Production (NPOP) is the only organic certification scheme that currently enforces a maximum limit (500 member per group) and appears to have resulted in data transparency challenges and no substantive evidence of strengthened organic integrity. According to the FiBL Report, these size limits have made systems less accountable and less transparent rather than improve quality. A large group that functionally operates a single group operation is split ‘on paper’ into multiple smaller groups to comply with NPOP’s size limit, but there not any change in actual practices (members in all groups are still marketing through the same centralizes system), there is less transparency in how the smaller groups are connected to each other, and it inflates the data on how many groups are operating under the scheme.

- **OTA supports geographic proximity of members and sees no need for more specific or prescriptive limits to further define geographic proximity.** The proposed rule already requires group members to be in geographical proximity, and requires the internal control system to describe its criteria for defining geographic proximity. The regulations should allow for groups to define geographic proximity based on the unique context and the geographic conditions of the region within which the group is operating.

It would be very difficult to determine a non-arbitrary limit on geographic proximity that would work for a variety of production systems and geographic regions worldwide. Setting limits on geographic proximity may not necessarily lead to reduced risk or better fraud prevention. Distance among members is not itself an indicator of inherent incompatibility or inability to comply with organic regulations; short distance



does not automatically mean less risk. **Concerns about geographic proximity of group members or groups can and should be addressed through risk-assessment.** The regulations do not preclude certifiers from using geographic proximity as a risk factor and imposing stronger controls on high-risk groups.

OTA recommends that NOP develop guidance to support certifiers in reaching a common understanding across groups and certifiers regarding criteria that is commonly accepted for defining geographic proximity. The guidance could incorporate examples from the 2008 NOSB Recommendation that defines geographic proximity as having access to the same collection or post-harvest handling facility, and/or common soils, water source, slope, topography or other physical features.

➔ **Recommendation:** Develop guidance that supports common understanding across groups and certifiers regarding criteria that is commonly accepted for defining geographic proximity.

- **OTA supports the allowance for members to also have separate individual certification outside of the group should they want to sell organic products outside of the group if they are certified for such products.** Group members are rightly prohibited from using the group's certification to individually market their own product as organic outside of the group. Group certification applies to the group operation as a single legal entity and must not be used to represent individual members. However, individual members likely produce many more types of products than are sold through the grower group. Therefore, we agree with the proposed rule that allows group members to seek separate additional individual certification should they want to sell organic products outside of the group if they are certified for such products. Since group operations often only market one type of product from its members, the option of additional individual certification would let individual members sell their other products, such as organic rotational crops, which might not be included in the group certification. It would also allow individuals to sell excess/bumper crops that might be over the group's quota for individual members. The FiBL Report cites many benefits of allowing members to have additional individual certification, such as supporting crop diversity and rotations, and supporting socioeconomic development of members.

We recognize that members that participate both in a group and also have separate individual certification may present an elevated risk. Such members would have dual certification for the same area of production and perhaps also the same type of product. We also recognize that a dual certified group member would also have more direct oversight than a typical group member because it will receive direct certification oversight and inspections from its certifier. **Increased risks that are associated with a farm being both a group member and individually certified can and should be addressed through risk assessments.** Strong systems of recordkeeping and management are essential in these operations to ensure that organic products are properly accounted for under each certification. If the member seeks individual certification



from a certificate agency other than the one certifying the group, the certification agencies should have strong communication and cooperation to ensure risks are managed appropriately.

- **OTA does not support the current proposal that requires certifiers to inspect high-risk members based on the internal control system's own risk criteria. OTA recommends that certifiers conduct an independent external risk assessment separate from (and in addition to) the internal risk assessment conducted by the internal control system.** ICS's should have their own system for describing its criteria for identifying high-risk members and managing those risks as appropriate. When it is time for the certifier to conduct its external inspections of the ICS and a sample of members, the certifier should conduct an independent risk assessment based on its own criteria for identifying high risk group members. Certifiers should not be required to use the group's risk assessment criteria, as is currently required in the proposed rule. Certifiers should continue to inspect all members that are considered high-risk according to the certifier's own risk assessment criteria. The preamble already includes a list of criteria that certifiers should consider when determining which grower group members to assess, which clearly shows that the regulations are intended to have the certifier conduct their own risk assessment based on their own criteria.

➔ **Recommendation:** Revise §205.201(c)(4) to add a requirement that the ICS have a procedure for assessing and managing risks appropriately. Revise §205.403(a)(2)(iii) to remove the reference to §205.201(c)(4), clarify that the risk assessment is conducted by the certifier, and require the certifier to have documented criteria for identifying high risk group members. *See OTA's requested revisions in Table 11 below.*

OTA recommends that NOP develop guidance to support certifiers in reaching a common understanding of the criteria that should be used to identify high risk group members and to assess risks of groups as a whole. The guidance should capture the list of risk factors identified in the preamble for individual members, such as having split or parallel production, noncompliance history, geographic proximity to other members, and whether the member also has additional individual certification. Risk assessments for group operations should also address concerns about increased risk of livestock operations, larger sizes of group members or groups, and larger geographic distribution of members. The certifier's risk assessment should also be harmonized as appropriate with other provisions for risk-assessment as proposed in the Strengthening Organic Enforcement Proposed Rule (See Section #18: Supply Chain Traceability & Fraud Prevention) that would require certifiers to have criteria to identify high-risk operations and products.

➔ **Recommendation:** Develop guidance to support common understanding and consistent implementation on the risk criteria that certifiers should use to determine which high-risk group members must be inspected.

- **OTA supports many of the specific regulatory requirements for an Internal Control System (ICS) and recommends several critical revisions to the proposed rule that will enhance and clarify the ICS’s responsibilities for establishing and maintaining strong oversight and enforcement capabilities.** We also encourage NOP to development guidance for group operation and their internal control systems to support clear understanding and consistent implementation of the new regulatory requirements. Several of the responsibilities and requirements of an Internal Control System will require enhanced explanation and examples to support a clear understanding of the regulatory text and to prepare organic operations to readily implement and comply with the regulations. OTA has identified several issues throughout this comment where regulatory revisions and additional guidance are needed to enhance and clarify the ICS’s responsibility to ensure clear understanding and consistent implementation of the new regulatory requirements.

For starters, the proposed definition of Internal Control System in §205.2 should be expanded to encompass all critical elements and responsibilities of a strong well-functioning internal control system. The 2008 NOSB Recommendation included specific references to personnel, procedures, practice standards, recordkeeping, and audit trail requirements. Additionally, the proposed list of eligibility requirements in §205.400(g) is missing a basic requirement to have an Internal Control System. The ICS is which is the most fundamental eligibility requirement for groups and needs to be directly referenced.

→ **Recommendation:** Revise §205.2 to expand the definition of internal control system to encompass critical elements, and also add a reference in §205.400(g) to explicitly require group to have an ICS in order to be eligible for group certification. *See OTA’s requested revisions in Table 11 below.*

- **OTA recommends regulatory clarifications and guidance to ensure sufficient qualifications of ICS personnel.** The proposed regulations require the ICS to describe the roles and responsibilities of all personnel, but are lacking an explicit requirement for such personnel to be sufficiently qualified to perform such roles and responsibilities. OTA recommends that the ICS must have a written description of the minimum qualifications of each role within the ICS. Furthermore, the ICS must ensure that it maintains a sufficient number of qualified personnel to carry out all ICS procedures and responsibilities.

→ **Recommendation:** Revise §205.201(c)(1) to require the ICS to describe qualifications for all roles and to require that the ICS has a sufficient number of qualified personnel to carry out all ICS procedures and responsibilities. *See OTA’s requested revisions in Table 11 below.*

OTA also recommends that NOP establish guidance that will ensure a common understanding of qualifications that are expected of ICS personnel. ICS personnel are different from a certifier's review or inspector staff. Rather, the ICS is equivalent to an internal Quality Assurance department at an individually certified operation. Extending the same qualification and training requirements of certification agent personnel to the personnel of a certified operation is not appropriate. ICS personnel must be allowed to have qualifications that are adapted to the needs and availability of training within the unique context within which the group is operating. The guidance can capture the suggested qualifications and training requirements for ICS personal as written in the 2008 NOSB Recommendation. (*See also OTA position below on conflict of interest.*)

→ **Recommendation:** Provide guidance to ensure a common understanding of qualifications that are expected of ICS personnel.

- **OTA recommends regulatory clarifications to ensure that recordkeeping by the ICS is sufficient to demonstrate compliance.** Records are essential for documenting and maintaining a well-functioning internal control system and demonstrating compliance to auditors. The proposed rule is lacking an explicit requirement for the ICS to describe the records that it maintains to demonstrate compliance of the group and all group members. OTA recommends that, at minimum, the regulations specifically require the ICS to maintain the following records:
  - List of each group members, locations, products, acreage
  - Formal agreement between each group member and group's legal entity that commits the group member to complying with the internal control system's policies, the organic system plan, and the USDA organic regulations.
  - Copies of internal inspection reports
  - Copies of internal sanctions and corrections

→ **Recommendation:** Revise §205.201(c)(1) to include the specific recordkeeping requirements needed to demonstrate compliance of the group and all group members. *See OTA's requested revisions in Table 11 below.*

- **OTA recommends regulatory clarifications to elevate and enhance ICS requirements for member training to ensure that all group members understand and can comply with the organic regulations.** It is critical that individual members receive education, training, and technical assistance about how to implement and comply with the internal control system’s policies, the organic system plan, and the USDA organic regulations. The FiBL Report emphasizes that training and regular contact with farmer members are among the most if not *the most* important element of successful assurance of group compliance. The ICS should be providing information and training to all members, at least annually, to maintain their understanding, interest and commitment to compliant organic production practices.
  - ➔ **Recommendation:** Revise §205.201(c) to include a new provision that requires the ICS to describe procedures for providing training, education, and technical assistance to grower group members to ensure understanding of and compliance with ICS, OSP, and Organic Regulations. *See OTA’s requested revisions in Table 11 below.*
- **OTA recommends regulatory clarifications and guidance to ensure internal inspections conducted by the ICS are robust, clearly understood, and consistently implemented.** It is crucial that group members are present onsite during their internal inspection so that the ICS personnel can interact with and ask questions of the member to ensure a full understanding of the activities on that member’s production site. Additionally, the ICS procedures should include a description of the procedures for accepting new members and must ensure that an onsite inspection is completed by the ICS prior to accepting the new member into the group. There should also be attention paid to consistency in terminology used throughout the grower group regulations. The terms “surveillance” or “internal inspection” or some combination are used. The regulations must ensure a clear distinction between the internal inspections conducted by the ICS and the *external* inspections conducted by the certification agency.
  - ➔ **Recommendation:** Revise §205.201(c) and §205.400(g) to include provisions needed to ensure that internal inspections are robust, clearly understood, and consistently implemented. *See OTA’s requested revisions in Table 11 below.*

OTA also recommends that NOP establish guidance that will ensure a common understanding of key elements that are expected to be addressed during an ICS internal inspection of group members. Such guidance should include best practices such as ensuring that inspections are conducted at appropriate times of the year so that active production can be observed.

- ➔ **Recommendation:** Provide guidance to ensure a common understanding of internal inspection requirements expected of ICS inspectors.

- **OTA recommends the development of guidance that clarifies the scenarios that would qualify as a conflict of interest in an ICS.** The proposed rule at §205.201(c)(8) requires the ICS to protect against potential conflicts of interest. NOP must clarify what does and does not constitute a conflict of interest for ICS personnel. Guidance should take in to account the fact that ICS personnel are equivalent to internal staff at an individually certified operation that may give education and training to other colleagues, (*see OTA position above on ICS personnel qualifications*), so extending the same conflict of interested policies used by certifiers to individual operations is not appropriate.

OTA recommend that the guidance must protect the ability of ICS personnel to provide education, training, and technical assistance to members. If an internal inspector gives technical support and guidance about organic compliance to their members during an inspection, this should not be classified as a conflict of interest. As described above (*see OTA's position above on member training*), training and regular contact with farmer members are among the most if not *the most* important element of successful assurance of group compliance. NOP should clarify these points through guidance and ensure that group members are not deprived of ICS's technical support, information, education, and training.

→ **Recommendation:** Provide guidance to ensure a common understanding of scenarios that would qualify as a conflict of interest within an internal control system.

- **OTA recommends a modified requirement for external witness audits that requires the certifier to evaluate at least 25% of internal auditors to ensure a representative sample of ICS inspectors are evaluated.** It is important that multiple ICS inspectors are witnessed to ensure representative review of the ICS inspector activity and competency. To ensure that an appropriate sample of internal inspectors receive witness audits from the certifier, the regulations should specific a minimum number of percent of auditors that must be witnessed.

→ **Recommendation:** Revise §205.403(a)(2)(ii) to add a minimum requirement for 25% of internal auditors that must be witnessed. *See OTA's requested revisions in Table 11 below.*

- **OTA supports the sampling method for external inspections that requires the certifier to inspect 1.4 times the square root ( $1.4\sqrt{\phantom{x}}$ ) of the total number of grower group members.** We also recommend that NOP explore whether to establish a minimum percentage of members (e.g. 2%) that must be inspected that can be used in combination with the  $1.4\sqrt{\phantom{x}}$  method. In other words, the certifier would inspect  $1.4\sqrt{\phantom{x}}$  or 2%, whichever is higher. We understand that 2% is a minimum sample size that is being considered by international group certification schemes, so it is used here as an example. Establishing a minimum percentage to kick-in once the sample exceeds  $1.4\sqrt{\phantom{x}}$  will ensure that as group size increases, the sample for external inspections increases at a rate that is more appropriate for larger size groups. The minimum percentage may also disincentivize groups from becoming very large because of the greater number of external inspections that would be required. Without the minimum percentage, very large groups may not receive a sufficient number of external inspections to properly assess compliance. (See Figure 1 below, and note that the  $1.4\sqrt{\phantom{x}}$  method increases very little, never above 400, even though the total group size is increasing by tens of thousands.) The  $1.4\sqrt{\phantom{x}}$  methodology is still important for sampling groups on the smaller size (See Figure 2 below, and note that the  $1.4\sqrt{\phantom{x}}$  results in larger sample sizes for groups under 5,000 members, approximately. Especially for very small groups,  $1.4\sqrt{\phantom{x}}$  methodology results in a larger and more appropriate sample size compared to the 2% methodology.)

→ **Recommendation:** NOP should further explore whether to establish a minimum percentage of members to be used in combination with the  $1.4\sqrt{\phantom{x}}$  method in determining the minimum sample size (e.g.,  $1.4\sqrt{\phantom{x}}$  or 2%, whichever is higher).

The proposed rule currently requires certifiers to individually inspect each handling facility and at least one grower group member in each grower group production unit. As written, this does not guarantee that the total inspected members will be representative of the group across its production units. OTA initially considered whether the sampling methodology should be applied *to each production unit* to ensure representative sampling in each production unit. However we no longer see that as a viable solution, because it puts too much reliance on how the group defines its own production units and may create an incentive for groups to manipulate the number of production units to mathematically influence the number of inspections. Furthermore, if the  $1.4\sqrt{\phantom{x}}$  methodology were used for production units, it may result in *too many* inspections overall, since the square root would be taken of a smaller number (each production unit) rather than a larger number (whole group). Instead, we recommend that NOP provide guidance to certifiers that will help ensure that each production unit is well represented in the overall sample of external inspections.

→ **Recommendation:** Develop guidance regarding the procedures that certifiers can use to ensure that each production unit is well represented in the overall sample of external inspections.



Figure 1: Comparison of sample methodologies

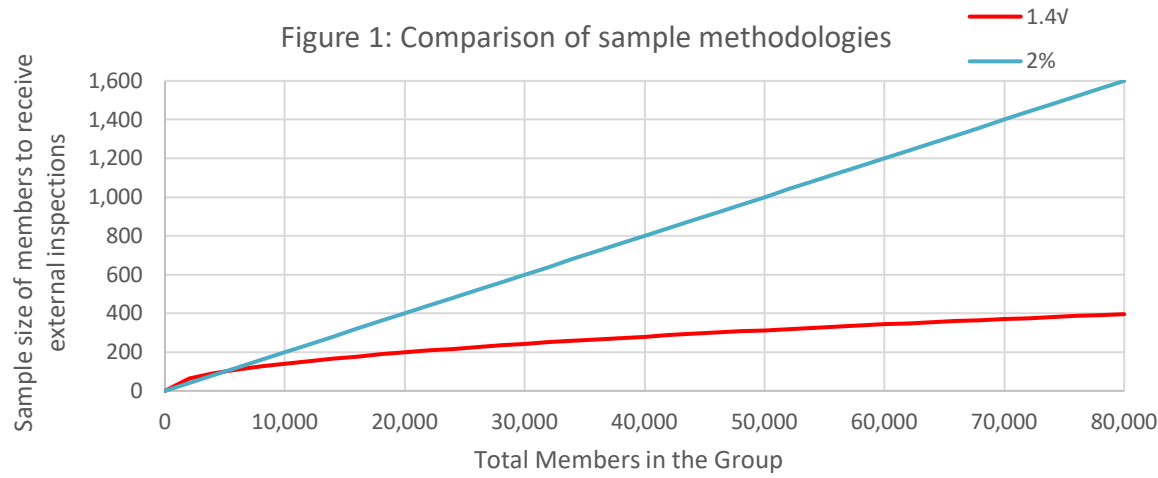
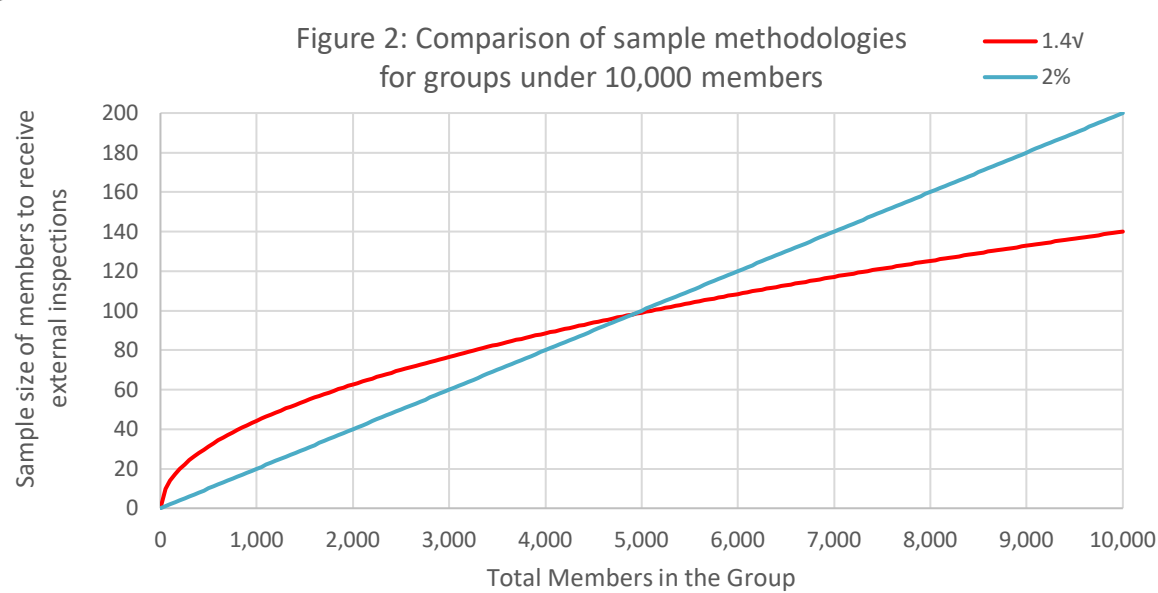


Figure 2: Comparison of sample methodologies for groups under 10,000 members



Total Members	1.4V Sample	2% Sample
50	10	1
100	14	2
500	31	10
1,000	44	20
2,000	63	40
3,000	77	60
4,000	89	80
5,000	99	100
6,000	108	120
7,000	117	140
8,000	125	160
9,000	133	180
10,000	140	200
15,000	171	300
20,000	198	400
25,000	221	500
30,000	242	600
40,000	280	800
50,000	313	1,000
60,000	343	1,200
70,000	370	1,400
80,000	396	1,600

- **OTA recommends the development of guidance for certifier’s external oversight and enforcement of group operations in a manner that focuses on the assessment of the internal control system.** Certifiers need guidance on the procedures to be used when assessing compliance of a group and issuing noncompliance or other adverse actions to a group operation. Groups require a very different approach to compliance assessments compared to individual operations. For example, if the ICS is properly issuing sanctions to members, then there is not a need for a certifier to issue an adverse action. The certifier should be issuing adverse actions to the group if the ICS is failing to assure compliance. Certifiers need guidance to ensure a common understanding of the situations that would indicate a failure of the ICS. Certifiers need guidance to evaluate when internal sanctions issued by an ICS should be elevated to a noncompliance or adverse action issued by the certifier. The increased responsibility and unique assessment skills are the very reason underlying OTA’s recommendation to establish group certification as a separate accreditation scope for certifiers (*see above for OTA’s position on accreditation scope*).

Group operations also need to have guidance to understand the expectations for when the ICS must notify the certifier of internal sanctions or noncompliant activities. For example, the ICS may issue internal sanctions and maintain documentation of subsequent corrections to have available for the certifier’s external inspection to demonstrate that the ICS is functioning properly. However, there may be circumstances when the ICS must notify the certifier immediately and not wait until their next inspection. These scenarios may include: when a group member is removed from the group, or when a member applies a prohibited substance.

➔ **Recommendation:** Provide guidance to ensure a common understanding of a certifier’s responsibilities for external oversight and enforcement of group operations in a manner that focuses on the assessment of internal control system.

We also recommend that NOP further explore whether a new subsection is needed at §205.662 (Noncompliance procedure for certified operations) to address noncompliance procedures for group operations. This new subsection could compliment the new subsection for inspections of group operations that has already been proposed for addition to §205.403(a) (On-Site inspections).

- OTA supports the implementation of the proposals in this section (with OTA requested revisions and recommended guidance) within one year after publication of the final rule.

**Table 11: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance**

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity or utility of the proposed rule
<p>205.2 Add new terms</p>	<p><i>Grower group operation.</i> A single producer consisting of grower group members in geographical proximity governed by an internal control system under an organic system plan certified as a single crop and/or wild crop production and handling operation.</p> <p><i>Grower group member.</i> A person engaged in the activity of growing or gathering a crop and/or wild crop as a member of a grower group operation.</p> <p><i>Grower group production unit.</i> A defined subgroup of grower group members in geographical proximity as a part of a single grower group operation that use similar practices and shared resources to grow or gather similar crops and/or wild crops.</p> <p><i>Internal control system.</i> An internal quality management system that establishes and governs the review, monitoring, training, and inspection of the grower group operation and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations as a single producer.</p>	<p><b>Revisions needed</b> in the terms and definitions in §205.2 to accurately and clearly define relationships between group/member, make better use of existing term “person,” and to improve clarity and consistency. See OTA’s Position on <b><u>legal entity</u></b>.</p> <ul style="list-style-type: none"> <li>• Remove “person” from the definition of group member and add it to the definition of group operation. The group operation is the entity that is tied to the legal definition of person in §205.2.</li> <li>• Avoid the terms “single” in reference to a producer or product, to avoid confusion and misrepresentation.</li> </ul> <p><b>Revisions needed</b> to implement OTA’s Position on <b><u>scope-neutrality</u></b>. The regulations should not limit group certification only to producers of crops and wild crops.</p> <ul style="list-style-type: none"> <li>• Remove “crop and or/wild crop” and “growing or gathering”</li> <li>• Clarify that both production and handling are activities that may be performed within a group or by a group member</li> </ul> <p><b>Revisions needed</b> to the definition Internal Control System to include personnel, procedures, and reference to practice standards, recordkeeping, and audit trail requirements. See OTA’s Position on <b><u>regulatory requirements for an Internal Control System (ICS)</u></b>.</p> <p><b>Guidance needed</b> to support common understanding across groups and certifiers regarding criteria that is commonly accepted for defining geographic proximity. See OTA’s Positions on <b><u>geographic proximity</u></b>.</p>

**OTA Requested Revision:**

*Grower group operation.* A ~~single~~ producer legally organized as a person consisting of grower group members in geographical proximity governed by an internal control system under an organic system plan ~~certified as a single crop and/or wild crop production and handling operation implemented across multiple production sites and facilities.~~

*Grower group member.* ~~An person individual engaged in the activity of growing or gathering a crop and/or wild crop as a~~ member of a grower group operation.

*Grower group production unit.* A defined subgroup of grower group members in geographical proximity as a part of a ~~single~~ grower group operation that use similar practices and shared resources ~~to grow or gather similar crops and/or wild crops.~~

*Internal control system.* An internal quality management system consisting of both personnel and procedures that establishes and governs the review, monitoring, training, recordkeeping, and internal inspection and enforcement of ~~the all~~ grower group operation members, and the procurement and distribution of shared production and handling inputs and resources, to verify and maintain compliance of the grower group operation with the USDA organic regulations ~~as a single producer.~~

205.201(c)  
 Add New  
 Section

In addition to paragraph (a) of this section, a grower group operation’s organic system plan must describe its internal control system. The description of the internal control system must:

- (1) Define the organizational structure, roles, and responsibilities of all personnel;
- (2) Identify grower group production units and locations;
- (3) Define geographical proximity criteria for grower group members and grower group production units;
- (4) Describe characteristics of high-risk grower group members and grower group production units;
- (5) Describe shared production practices and inputs;

**Revisions needed** to clarify ICS personnel qualifications in §205.201(c)(1). See OTA’s Position on qualifications of ICS personnel.

- Add requirement that ICS describes qualifications for all roles.
- Add requirement that ICS has a sufficient number of qualified personnel to carry out all ICS procedures and responsibilities

**Revisions needed** to clarify ICS risk assessment procedures. See OTA’s Position on risk assessment.

- Add requirement in §205.201(c)(4) that the ICS has a procedure for assessing and managing risks appropriately

	<p>(6) Describe the internal monitoring, surveillance, and auditing methods used to assess the compliance of all grower group members;</p> <p>(7) Describe the system of sanctions for noncompliant grower group members, including procedures to address noncompliances detected among grower group members, impose sanctions, and remove grower group members when warranted, and procedures for reporting noncompliances to the certifying agent;</p> <p>(8) Describe measures to protect against potential conflicts of interest;</p> <p>(9) Describe how training, production and handling inputs, and other resources are procured and provided to all grower group members and personnel;</p> <p>(10) Have clear policies and procedures to verify the grower group operation's and grower group members' compliance with the USDA organic regulations; and</p> <p>(11) Address any other terms or conditions determined by the Administrator to be necessary to enforce compliance with the USDA organic regulations and the Act.</p>	<p><b>Revision needed</b> to clarify recordkeeping requirements for ICS to demonstrate compliance of the group and all group members. See OTA's Position on <b><u>recordkeeping</u></b>.</p> <ul style="list-style-type: none"> <li>• Include list of individual members, locations, products, acreage</li> <li>• Copies of inspection reports, sanctions and corrections to be available during inspection by the certifier</li> <li>• Formal agreement for each group member with the group that commits them to complying with ICS, OSP, and organic regulations</li> </ul> <p><b>Revision needed</b> to clarify the provision of education, training, and technical assistance to members. See OTA's Position on <b><u>member training</u></b>.</p> <ul style="list-style-type: none"> <li>• Remove "training" from §205.201(c)(9) and add it to a new provision that requires the ICS to describe procedures for providing training, education, and technical assistance to grower group members to ensure understanding of and compliance with ICS, OSP, Organic Regulations.</li> </ul> <p><b>Revision needed</b> to clarify procedure for onboarding new members. See OTA's Position on <b><u>internal inspections</u></b>.</p> <ul style="list-style-type: none"> <li>• Add requirement in §205.201(c) for ICS to describe procedures for onboarding new members into the group in a manner that assures new members are not added until an internal inspection is complete.</li> </ul> <p><b>Revision needed</b> in §205.201(c)(6) to add specific reference to "inspections." Otherwise it would be unclear what "surveillance" is referring to. Need to ensure that internal inspections, as described</p>
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		<p>throughout the proposed rule and preamble, are included in this regulatory section. See OTA’s Position on <b><u>internal inspections</u></b>.</p> <p><b>Revisions needed</b> to clarify that both production and handling are activities that may be performed within a group or by a group member. See OTA’s Position on <b><u>scope-neutrality</u></b>.</p> <ul style="list-style-type: none"> <li>• Add “and handling” to §205.201(c)(5)</li> </ul> <p><b>Guidance needed</b> to support a common understanding of qualifications that are expected of ICS personnel. See OTA’s Position on <b><u>qualifications of ICS personnel</u></b>.</p> <p><b>Guidance needed</b> to clarify what does and does not constitute a conflict of interest for ICS personnel. See OTA’s Position on <b><u>conflict of interest</u></b>.</p> <p><b>Guidance needed</b> to ensure that inspectors are conducting internal inspections at times of the season when they can observe production of certified organic products. See OTA’s Position on <b><u>internal inspections</u></b>.</p>
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**OTA Requested Revisions:**

(1) Define the organizational structure, roles, qualifications, and responsibilities of all personnel and the procedure to ensure that a sufficient number of qualified personnel are available to carry out all internal control system procedures and responsibilities;

(4) Describe characteristics of high-risk grower group members and grower group production units and the procedure to assess and manage risks appropriately;

(5) Describe shared production and handling practices and inputs;

(6) Describe the internal monitoring, surveillance inspections, and auditing methods used to assess the compliance of all grower group members



(9) Describe how ~~training~~, production and handling inputs, and other resources are procured and provided to all grower group members and personnel;

(New) Describe how training, education, and technical assistance is provided to grower group members to ensure understanding of and compliance with internal control system’s policies, the organic system plan, and the organic regulations.

(New) Describe the procedure for verifying, inspecting, and accepting new members into the group that includes an onsite inspection prior to addition to the group

(New) Maintain records sufficient to demonstrate compliance of the group and all group members, including but not limited to:

- Current list of individual members, locations, products, and acreage
- Formal agreements from each group member that commits them to complying with the internal control system’s policies, the organic system plan, and the organic regulations
- Copies of internal inspection reports
- Copies of sanctions and corrections

205.400(g)  
 Add New  
 Section

In addition to paragraphs (a) through (f) of this section, a grower group operation must:

- (1) Be a single producer organized as a person;
- (2) Sell, label, or represent only crops and/or wild crops as organic;
- (3) Use centralized processing, distribution, and marketing facilities and systems;
- (4) Be organized into grower group production units;
- (5) Ensure that all crops and/or wild crops sold, labeled, or represented as organic are from grower group members only;
- (6) Ensure that grower group members do not sell, label, or represent their crops and/or wild crops as

**Revisions needed** to implement OTA’s Position on **scope-neutrality**.  
 The regulations should not limit group certification only to producers of crops and wild crops.

- Remove “crop and or/wild crop” and “growing or gathering”
- Clarify that both production and handling are activities that may be performed within a group or by a group member
- If NOP rejects our requested revision to §205.400(g)(2), we ask that NOP please clarify the text in §205.400(g)(2) to avoid unintended prohibition on split production. Language in the current proposed rule is unclear and could lead to interpretation that product can only be sold as organic, thereby prohibiting any product from being sold as conventional. However NOP preamble explains that split production is allowed and that conventional production could be a risk factor (indicating that it

<p>organic outside of the grower group operation unless they are individually certified;</p> <p>(7) Report to the certifying agent on an annual basis the name and location of all grower group members and grower group production units, and the crops, wild crops, estimated yield, and size of production and harvesting areas of each grower group member and grower group production unit;</p> <p>(8) Conduct internal inspections of each grower group member, at least annually, by internal inspectors, which must include mass-balance audits and reconciliation of each grower group member's and grower group production unit's production yield and group sales;</p> <p>(9) Document and report to the certifying agent the use of sanctions to address noncompliant grower group members, at least annually; and</p> <p>(10) Implement procedures to ensure all production and handling by the grower group operation is compliant with the USDA organic regulations and the Act, including recordkeeping requirements to ensure a complete audit trail from each grower group member and grower group production unit to sale and distribution.</p>	<p>is intended to be allowed and managed through risk-based controls).</p> <p><b>Revisions needed</b> to avoid the terms “single” and “single producer” to avoid confusion and misrepresentation. See OTA’s Position on <b><u>legal entity</u></b>.</p> <p><b>Revisions needed</b> to clarify conditions under which individual certification is permitted. See OTA’s Position on <b><u>individual certification</u></b>.</p> <p><b>Revisions needed</b> to specify need for member to be present during their internal inspection. See OTA’s Position on <b><u>internal inspections</u></b>.</p> <ul style="list-style-type: none"> <li>• Add requirement in §205.400(g)(8) for the group member to be present during the internal inspection</li> </ul> <p><b>Revision needed</b> to explicitly require group to have an ICS in order to be eligible for group certification. See OTA’s Position on <b><u>regulatory requirements for an Internal Control System (ICS)</u></b>.</p> <ul style="list-style-type: none"> <li>• Add requirement in §205.400(g) for the group to have an Internal Control System</li> </ul> <p><b>Guidance needed</b> regarding the instances when the ICS must contact the certifier. See OTA’s Position on <b><u>external oversight and enforcement</u></b>.</p>
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**OTA Requested Revision:**

(1) Be a **single** producer organized as a person;

~~(2) Sell, label, or represent only crops and/or wild crops as organic;~~

(6) Ensure that grower group members do not sell, label, or represent their ~~crops and/or wild crops~~ products as organic outside of the grower group operation unless they are individually certified for such products;

(8) Conduct internal inspections of each grower group member, at least annually, by internal inspectors with the member present, which must include mass-balance audits and reconciliation of each grower group member's and grower group production unit's production yield and group sales;

(New) Establish and implement an internal control system that ensures compliance of the group operation with NOP regulations

205.403(a)(2)  
 Redesignate  
 as  
 205.403(a)(3);  
 add new  
 paragraph  
 (a)(2)

Initial and annual on-site inspections of a grower group operation as defined in §205.2 must:  
 (i) Assess the compliance of the internal control system of the organic system plan, or its capability to comply, with the requirements of §205.400(g)(8). This must include review of the internal inspections conducted by the internal control system.  
 (ii) Conduct witness audits of internal control system inspectors performing inspections of the grower group operation.  
 (iii) Individually inspect at least 1.4 times the square root of the total number of grower group members. This must include an inspection of all grower group members determined to be high risk according to criteria in 205.201(c)(4). At least one grower group

**Revision needed** to clarify the requirements for witness audits. See OTA's Position on **external witness audits**.

- Add a requirement in §205.403(a)(2)(ii) to identify the minimum 25% of internal auditors that must be witnessed.

NOP should further explore whether to establish a minimum percentage of members (e.g. 2%) that must be inspected that can be used in combination with the 1.4<sup>√</sup> method as part of the sampling method in §205.403(a)(2)(iii). See OTA's Position on **sampling method for external inspections**.

**Revision needed** to allow certifiers to conduct an independent risk assessment using their own risk criteria and to require certifier to have criteria for high risk group members. See OTA's Position on **risk assessment**.

	<p>member in each grower group production unit as defined in §205.2 must be inspected.          (iv) Inspect each handling facility.</p>	<ul style="list-style-type: none"> <li>Remove the reference to §205.201(c)(4) from §205.403(a)(2)(iii) and add requirement for the risk assessment to be conducted “by the certifier”</li> <li>Add new section to require certifiers to have criteria for identifying high risk group members.</li> </ul> <p><b>Revision needed</b> to clarify “handling facility” in §205.403(a)(2)(iv):</p> <ul style="list-style-type: none"> <li>Avoid use of “handling facility” because it is not defined. There are already many other existing terms that we can use: handle, handling operation, and handler. Avoid creating another version.</li> </ul> <p><b>Revision needed</b> in §205.403(a)(2)(i) to correct in-text reference:</p> <ul style="list-style-type: none"> <li>Replace §205.400(g)(8) with a more appropriate reference. Must comply with all elements of ICS, OSP, and organic regulations.</li> </ul> <p><b>Guidance needed</b> regarding the procedures that certifiers can use to ensure that each production unit is well represented in the overall sample of external inspections. See OTA’s Position on <b><u>sampling method for external inspections</u></b>.</p> <p><b>Guidance needed</b> regarding the risk criteria that certifiers should use to determine which high-risk group members must be inspected. See OTA’s Position on <b><u>risk assessment</u></b>.</p> <p><b>Guidance needed</b> regarding the procedure of certifiers to issue non-compliances and adverse actions to groups. See OTA’s Position on <b><u>external oversight and enforcement</u></b>.</p>
<p><b>OTA Requested Revision:</b></p>		

- (i) Assess the compliance of the internal control system of the organic system plan, or its capability to comply, with the requirements of §205.400(g)(8) this part. This must include review of the internal inspections and internal sanctions conducted by the internal control system.
- (ii) Conduct witness audits of at least 25% internal control system inspectors performing inspections of the grower group operation.
- (iii) Individually inspect at least 1.4 times the square root of the total number of grower group members. This must include an inspection of all grower group members determined to be high risk by the certifier according to criteria in 205.201(e)(4). At least one grower group member in each grower group production unit as defined in §205.2 must be inspected.
- (iv) Inspect each handling facility operation.
- (New) A certifying agent must have documented criteria for identifying high-risk group members.

**OTA Requested Revision:**

§205.500 Areas and duration of accreditation. (a) The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, ~~or~~ handling, or grower groups, or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.

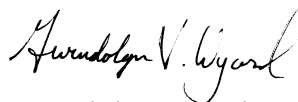
**Revision needed** to establish grower group operations as a separate accreditation scope. See OTA's Position on accreditation scope.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Program for your commitment to protecting organic integrity.

Respectfully submitted,



Johanna Miranda  
Farm Policy Director



Gwendolyn Wyard  
Vice President, Regulatory and Technical Affairs

cc: Laura Batcha  
Executive Director/CEO