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October 5, 2020

Jennifer Tucker, Ph.D.
Deputy Administrator, National Organic Program
USDA-AMS-NOP
1400 Independence Avenue SW
Room 2642 – So., Ag Stop 0268
Washington, DC 20250-0268

Re: Strengthening Organic Enforcement
Docket Number: AMS-NOP-17-0065; NOP-17-02
Regulatory Information Number: 0581-AD09

Dear Dr. Tucker,

IOIA strongly supports the proposed rule on Strengthening Organic Enforcement. The proposed rule represents significant progress toward the goal of strengthening organic enforcement and toward improved consistency in application of the organic regulations.

The International Organic Inspectors Association (IOIA) is a nonprofit educational organization. We are a global membership-based association of organic inspectors. We provide quality inspector training and promote consistency and integrity in the organic certification process. We represent about 250 inspectors around the world; 168 of those are located in the USA. Many others in other countries also inspect to the NOP regulations.

Our comments are attached. They include both recommendations for suggested revisions and additional proposed changes to strengthen organic enforcement.

IOIA urges the USDA to move forward with implementation of a final rule as soon as possible.

Thank you for your consideration of these comments.

Sincerely,

Margaret Scoles
Executive Director, on behalf of the IOIA Board of Directors



PUBLIC COMMENT

STRENGTHENING ORGANIC ENFORCEMENT (SOE) *PROPOSED RULE*

DOCKET #: AMS-NOP-17-0065; NOP-17-02
REGULATORY INFORMATION NUMBER: 0581-AD09



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ABOUT IOIA

Who We Are

Since 1991, the International Organic Inspectors Association (IOIA) has been the leading organization offering worldwide training and networking for organic inspectors. Though a United-States based nonprofit, IOIA operates globally with nearly 250 inspector members in over a dozen countries. IOIA has conducted thousands of virtual and on-site training programs and continues to train hundreds of organic inspectors every year. IOIA is recognized for helping establish the procedural, technical, and professional standards by which organic inspectors around the world operate. IOIA inspectors perform inspections for dozens of organic certification programs and their regulations, including the United States' National Organic Program (NOP).

Why We Comment

IOIA's mission is to "address issues and concerns relevant to organic inspectors, to provide quality inspector training, and to promote consistency and integrity in the organic certification process." As the sole global organization representing the voice of the organic inspector—who is frequently the only "face" of organic to a certified company— IOIA takes its mission seriously.

This public comment document was developed by the IOIA Policy Committee with oversight from the IOIA Board of Directors. IOIA might not comment on every aspect of every regulatory proposal or discussion document. However, those that do receive comments have been identified by the IOIA Policy Committee and leadership team as critical to safeguard the interests of organic inspectors, and the integrity of the organic industry.

IOIA is pleased to present these comments on behalf of its membership. For any questions, please contact Margaret Scoles, IOIA Executive Director, at mscoles@rangeweb.net.

OVERVIEW: IOIA COMMENTING STATUS

The following table summarizes the topics in the [Strengthening Organic Enforcement \(SOE\) Proposed Rule](#) on which IOIA is commenting. These areas have been determined to be of most relevance to IOIA, its mission and members.

Item	Commenting?
Applicability and Exemptions from Certification	Yes
Imports to the United States	Yes
Labeling of Nonretail Containers	Yes
On-Site Inspections	Yes
Certificates of Organic Operation	Yes
Continuation of Certification	Yes
Paperwork Submissions to the Administrator	No
Personnel Training and Qualifications	Yes
Oversight of Certification Activities	No
Accepting Foreign Conformity Assessment Systems	No
Compliance – General	No
Noncompliance Procedure for Certified Operations	No
Mediation	No
Adverse Action Appeal Process & General	No
Grower Group Operations	Yes
Calculating the Percentage of Organically Produced Ingredients	Yes
Supply Chain Traceability and Organic Fraud Prevention	Yes
Technical Corrections	Yes

EXEMPTIONS & EXCLUSIONS FROM CERTIFICATION

IOIA supports the restriction of exemptions and the elimination of exclusions in the proposed rule. Inspectors frequently see issues when there are uncertified handlers in the supply chain.

We support the proposed revisions related to exemptions and exclusions. However, the proposed one-year time frame for implementation after final rule publication seems too short for this section.

IOIA respectfully responds to items 1-4 in response to the feedback requests/questions posed by the USDA. Items 4 and 5 propose additions to regulatory language.

1. **New “Handler” Definition:** *“Are there additional activities that should be included in the proposed definition of handle (i.e., are there additional activities that require certification)? Are there any activities in the proposed definition of handle that should be exempt from certification?”*

IOIA finds the proposed definition of “Handler” generally adequate. We have proposed additional language regarding ports below in the “Related to Port Activities” section. We also have concerns that private labels might not be adequately addressed. The proposed rule does not make it clear whether private labels are required to be certified. IOIA supports the certification of private labels.

2. **Exempt Operations:** *Are there specific activities not included in the proposed rule that you believe should be exempt from organic certification?*

We support the narrowing of exemptions in the Proposed Rule. No new activities other than those in the proposed rule should be exempt from organic certification.

3. **Additional Handler Requirements:** *“Are there additional requirements that exempt handlers described in this proposed rule should follow?”*

IOIA suggests that exempt operations under 205.101(e) must maintain records sufficient to verify organic status and to verify that quantities produced/sold are reasonable. See proposed language recommended below in the section “Enhance 205.101(e).”

4. **Related to Port Activities:** *“... What other activities performed at ports should require certification and why?”*

A key phrase should be added to the 205.2 “Handling operation” definition.

- a. *Recommendation:* Include the following phrase: “...any operation in a port facility that handles product in other than packaged form (i.e.- bulk), must be certified.”

- i. *Rationale:* The preamble clarifies that grain elevators and ports of entry that are loading, unloading, and/or transferring unpackaged product must be certified, as well as storage facilities that are splitting, combining, and storing lots and loads and/or repackaging or relabeling. It is essential to put this language into the actual regulation. The proposed rule eliminates a distinction between packaged and unpackaged product as relates to receiving, storing, and loading activities that may be exempt. Eliminating this distinction could allow high-risk operations receiving and handling unpackaged organic product, such as grain elevators and ports of entry, to be exempt. To reduce the opportunity for organic fraud, IOIA supports that handling operations that are storing unpackaged product MUST be certified.

5. **Enhance 205.101(e):** The following two changes to 205.101(e) would be important enhancements:

- a. *Recommendation #1:* Re-word 205.101(e) to read: “An operation that only stores, receives, and/or loads packaged agricultural products, but does not sell, process or alter such ~~agricultural~~ products.”

- b. *Recommendation #2:* We suggest adding the following requirements to 205.101(e)

“...must maintain records sufficient to...

(1) Prove that products identified as organic were organically produced and handled; and

(2) Verify quantities produced or sold from such products.”

- i. *Rationale:* The Rule requires that operations producing organic or <70% organic ingredients or exempt retail operations maintain records that prove ingredients identified as organic are organic and sufficient to verify quantities produced. Adding the same language for other exempt operations such as warehouses would strengthen enforcement capacity of the USDA in oversight of these non-certified operations.

IMPORTS TO THE UNITED STATES

IOIA considers that many of the questions proposed by the USDA in this Imports to the United States section (e.g. “30-day time frame”) should be addressed by Accredited Certifying Agencies.

However, IOIA does respectfully submit the following comments.

1. **Online Import Documents Access:** Online access to relevant import documents is not addressed by this section. Requiring online access to these documents would be a significant improvement in the organic regulations.
 - a. *Recommendation:* Include the following (or similar) language in the update to the NOP regulations: “All relevant documents, including any phytosanitary certificates associated with a specific export product, should be accessible electronically to both the certifier and the exporter through the ACE or equivalent database. The exporter and/or certifier should provide this information to purchasers, other certifiers and/or organic inspectors upon request during associated transactions (purchases, during the organic certification process, etc.).”
 - i. *Rationale:* Locating documents such as phytosanitary certificates, customs clearance reports, NOP Import Certificates, transaction certs, etc. has been a challenge for organic operators and inspectors. Having a recognized online repository/database for import documents is critical to maintaining organic integrity, and would benefit the efficiency and costs of organic certification.
2. **Import Certificates:** We are not commenting to the appropriate number of days that should be allowed for issuing NOP certificates.
 - a. *Recommendation:* IOIA supports efforts to minimize the time between arrival of shipments at a U.S. Port of Entry and the issuance of organic import certificates by certifiers.
 - i. *Rationale:* We have concerns that a one-size-fits-all approach is not feasible for high frequency imports by rail and truck from Mexico and Canada.

Additionally, the proposed one-year time frame for implementation after final rule publication seems too short for US/Mexico/Canada shipments.

LABELING OF NONRETAIL CONTAINERS

IOIA supports the proposed rule to clarify labeling of non-retail containers and to make organic identification mandatory. However, the proposed one-year time frame for implementation after final rule publication seems too short for this section.

IOIA respectfully submits the following comments.

1. **Potential Conflict in 205.307(a)(2) and 205.303(b)(2):** The NOP should address a potential conflict between 205.307(a)(2) and 205.303(b)(2).

a. *Recommendation:* Re-write 205.303(b)(2) to match the proposed language in 205.307(a)(2); this removes any inconsistencies between the two requirements for the required “Certified Organic By” statements on a retail label and a nonretail label.

i. *Rationale:* The way that 205.307(a)(2) has been updated is not consistent with the existing “Certified Organic By” (COB) requirement in 205.303(b)(2).

The requirements in Proposed 205.307(a)(2) effectively prohibit the COB from identifying the certifying agents of operations that handle, but do not process, organic products after production on the nonretail container label. This could restrict which certifiers can be identified in the COB statement on non-retail containers. Additionally, the proposed rule change appears to only allow the certifier of the producer to appear on the nonretail container or the certifier of the last processor of the product being packed in the nonretail container.

By contrast, under 205.303(b)(2), other certifiers can appear in the COB statement (e.g. the Accredited Certifier of a co-packer).

The differing requirements for the COB statement could result in a final product that could identify two different COB statements depending on how the product is packaged: a) The retail label in compliance with 205.303(b)(2) could identify the certifier of the co-packer, and b) the nonretail label will correctly identify the certifier of the last processor of the product.

2. **Maintain Appearance of Traceable Lot Number:** IOIA is concerned that the appearance of lot numbers is no longer required on nonretail containers in the proposed rule. IOIA proposes that the appearance of a traceable lot number on a nonretail container remain a “must” in 205.307(a)(3).

a. *Recommendation:* 205.307(a)(3) should be amended as follows: “205.307 (a) Nonretail containers used to ship or store certified organic product must display the following: ... (3) The production lot number of the product, shipping identification, or other information needed to ensure traceability.

- i. *Rationale:* Visible lot numbers on packaging, containers, and documentation are critical for successful organic audits and maintaining organic integrity. As written, 205.307(a)(3) no longer has the “must” for the appearance of a traceable lot number on a nonretail container as a stand-alone requirement. It now states that alternative information can be substituted for the lot number.

The alternative information that the NOP has as an acceptable substitute could appear on another line separate from the lot number requirement.

- 3. **Name of the Certified Operation and Certifier:** IOIA does not support the proposed rule that leaves the name of the certified operation as optional. IOIA supports mandatory identification of the certifier and the certified operation on nonretail containers.

- a. *Recommendation:* Revise 205.307(a) and (b) as follows: Move “operation name” from paragraph (b) to paragraph (a) so that it becomes mandatory information.

- i. *Rationale:* Strong enforcement rests upon a transparent audit trail and the capacity of inspectors and certifiers to be able to efficiently follow supply chains and identify product source to verify certified status.

ON-SITE/UNANNOUNCED INSPECTIONS

IOIA supports more specific regulations in this area. However, the proposed one-year time frame for implementation after final rule publication seems appropriate for this section.

IOIA respectfully submits the following comments.

- 1. **Unannounced Inspection Percentage:** IOIA supports conducting unannounced inspections at 5% of the certifiers’ operations.

- a. *Recommendation:* n/a - no change recommended.

- i. *Rationale:* Unannounced inspections are a critical component of organic integrity. This proposed change codifies what is already in common practice, based on Instruction 2609 in the Program Handbook. Certifiers have had enough time to implement this practice. The Instruction dates to 2012. Certifiers and inspectors have generally been trained in conducting unannounced inspections.

2. **Balance & Tracebacks Requirements:** IOIA strongly supports the inclusion of requirements for mass balances and tracebacks during an on-site inspection. **Inspectors are typically the only individuals representing the certifier and the USDA NOP to conduct these audits. Incorporating strong and clear language regarding traceback and mass balance is critical to uniform implementation of the rule and to deterring and detecting fraud.** IOIA has long been concerned about inconsistent rigor of audits and the skill of those conducting the audits and making decisions based upon them. This regulation may create longer inspections, thus creating an increased expense for some operations. However, audits conducted based on scale, scope, and risk will create more consistent scrutiny.

- a. *Recommendation #1:* Revise 205.403(d)(4) as follows “That sufficient quantities of organic product and ingredients are produced or purchased to account for organic product used, stored, sold or transported; based on a mass balance of total raw material/product during a given period.”
 - i. *Rationale:* Many inspectors encounter inventory systems that do not readily provide information about past inventories, making a true mass balance difficult or even impossible. As a result, mass balances are sometimes conducted on single lots, which means they are not true mass balances. These verify raw material usage only for a percentage of actual products used and/or sold at an operation during a given period. A true mass balance must take into account all product under all situations. Inventory (storage) records are a key aspect of calculating total product available. Usage records would include ingredients used in complex production or feed for livestock. Most operations have the capacity to provide the needed documentation for these audits. However, the staff present at inspection are not always versed in this aspect of the database system, or they are not retaining documentation on physical inventory. Most operations have ways to access and/or save this information, thus, increased cost should be negligible for most operations.
- b. *Recommendation #2:* The number of audit exercises should be risk based. This recommendation may be better implemented through guidance than rule-making.
 - For simple, low risk operations, one (1) audit exercise per scope should be required with a minimum of one (1) traceback and one (1) mass balance at each inspection.
 - Certifiers should provide guidance for inspectors pertaining to additional audit requirements based on risk, scale, scope, complexity, ingredient/product risks, and prior history.
 - 1 traceback exercise for imports or exports under each specific trade equivalency agreement as applicable (including at least one [1] if any NOP certified products are being imported) should be required. The exercise may focus on import/purchasing/receiving documentation or export/sales documentation and not a complete audit.

- a. *Recommendation:* Replace the “January 2 of each year” requirement, instead stating “Annually, a list should be submitted by the end of January, including the name...”
 - i. *Rationale:* For many administrative reasons, including regular end-of-year closing activities, holidays, and others, submitting this list on January 2 could prove problematic. However, it is helpful to have the Administrator update records within the first quarter of every year.

4. **INTEGRITY Certificate Information:**

- a. *Recommendation:* Any organic certificate generated by INTEGRITY must state that “This certificate is not valid unless accompanied by [*name of certifier*]’s addendum/summary” which lists the crops, livestock, and/or products.
 - i. *Rationale:* This would clarify to certified operations what information is needed from them as essential to their certification and what can be sold as organic.

CONTINUATION OF CERTIFICATION

IOIA respectfully submits the following comments.

1. **Organic System Plan Updates:** IOIA supports the proposed revision that clarifies that operations are only required to submit sections of their Organic Production System Plan that have changed during the annual certification rather than submitting a full system plan every year.
 - i. *Rationale:* This change is sound and sensible for operators. It also allows inspectors to focus more on issues of organic integrity instead of paperwork.

PERSONNEL TRAINING & QUALIFICATIONS

The complexity of understanding a diverse and expansive global food system is compounded when one must also incorporate a set of regulations. It is imperative that those entrusted with ensuring organic integrity have the knowledge base and experience to accomplish this task.

IN GENERAL, IOIA agrees that minimum requirements for both inspectors and reviewers will strengthen organic integrity. Incorporating some aspects of inspector and reviewer requirements into the Program Handbook as Guidance may be a way to improve the quality and consistency of the profession while maintaining enough flexibility to attract and retain the human capital required in this industry and make changes as we learn what is most effective.

The three requirements listed (minimum field-based experience of one year, 20 hours of continuing education/year, and field evaluations) are easier to verify than some of the intuitive but equally important qualities. **These three very prescriptive requirements still lack clarity and do not fully define a qualified inspector.** There are many other essential characteristics, attributes, and skills (i.e. ethics, communication, curiosity, persistence) that are not addressed.

The proposed one-year time frame for implementation after final rule publication seems appropriate for this section.

To address these issues, IOIA respectfully submits the following comments.

General Recommendations

1. **“Complexity” of Operations:** “Complexity” of an operation is a key stumbling block for under-qualified and inexperienced inspectors and reviewers.
 - a. *Recommendation:* Include “Complexity” when referring to the characteristics of scope and scale. 205.501(a)(4)(i); 205.501(a)(4)(i)(C); 205.501(a)(4)(ii);
 - i. *Rationale:* In defining operations, scope and scale are important, but complexity is also a crucial factor. For example, a small produce operation often has significantly more inputs, seeds, and management components than a large scale commodity farmer of corn, soybeans, and hay. Likewise, inspection of a small bakery or importer of soy may require significantly more skill than a large scale facility that repacks a single ingredient into retail packaging. Inspectors or reviewers who are not trained or experienced in degrees of complexity may not be qualified to identify the threat of organic fraud or other organic integrity concerns.

Reviewer Requirements

1. **Similar Minimum Requirements:** IOIA believes that reviewers should meet requirements similar to inspector qualifications, including the following:
 - a. *Recommendation #1:* Reviewers should be required to attend or conduct at least one (1) inspection per year for each scope of operations that they review.

- i. *Rationale:* Inspections not only provide insight into an operation, but also offer valuable understanding of the general process of verifying organic compliance in person. Understanding the logistics of reviewing documentation in real time to verify audits and other pertinent records will facilitate reviewers’ better understanding all aspects of both operation and inspection reports.
- b. *Recommendation #2:* Reviewer requirements should cover both complexity and scale for the scopes they review. Like inspectors, this may be achieved through a scaled requisite number of hours of training and commensurate field experience.
 - i. *Rationale:* Reviewers arguably hold more responsibility than inspectors as they make the final decision that affects all aspects the operation— and to a larger degree, the overall industry. Creating similar expectations for reviewers and inspectors ensures that reports are understood and documentation used to verify compliance is adequate.

Field-Based Experience for Scale and Scope

We **support** qualified staff, both reviewer and inspector, being paired with operations of reasonable size and complexity to fit their capabilities.

1. **One Year of Field Experience:** Further clarity is needed in the requirement regarding “one year of field-based experience.”
 - a. *Recommendation:* “One year” should be changed to a quantifiable number of hours of field experience, and to better acknowledge the need for formal training and mentorship.
 - i. *Rationale:* The proposed change “...1 year of field-based experience related to both the scope and scale of operations they will inspect.” is simultaneously too prescriptive and yet not clear enough. For example, one year of ‘field-based experience’ does not clarify whether it is one calendar year, or one year of full-time work. Neither does it clarify what type of work meets the requirement. It also does not account for the math and writing skills required to perform a good inspection, as well as soft skills such as emotional intelligence.

Requiring hours of specific types of experience would be more reliable as a guarantee of qualified personnel. An example: One year of picking produce is less likely to provide the skills imperative to inspecting, compared to 200 hours of working on a local produce farm, 100 hours of

ag related webinars, 5-10 shadow inspections, and an IOIA basic inspection course.

- b. *Recommendation:* The ability of inspectors to add another inspection scale, complexity, and scope should be obtainable through focused, structured mentorships, training, and/or credentialing program, rather than being limited to “one year” of field-based experience in each scope and scale.
 - i. *Rationale:* Recognized training, mentorship, and credentialing programs could provide a path for inspectors wishing to expand their expertise in order to inspect operations of increased scale and complexity.

Continuing Education

IOIA believes continuing education is critical.

1. **Scope and Hours of Continuing Ed 205.501(a)(4)(i)(B):** Additional guidance is needed to clarify the required number of hours of Continuing Education. *A more robust requirement should be added for entry-level inspectors, which are not addressed at all in the proposed rule.*
 - a) *Recommendation #1:* Hours of annual continuing education should be based on the number of scopes inspected for a minimum of 10-15 hours if an inspector is doing one scope. More training (3-5 hours) should be required for each additional scope. Training hours should focus on regulations changes, new guidances, areas the inspector would like to branch out to, and areas of needed improvement based on the certifier evaluations.
 - i. *Rationale:* 20 hours for those doing simple crop operations may be too much. For those doing large complex operations for all three (3) scopes or adding a new scope, 20 hours may not be adequate.
 - b. *Recommendation #2:* IOIA does *not support* 20 hours as adequate for initial entry into the industry and believes that a more robust initial training of 75-100 hours (i.e. IOIA basic training plus field training) is a more realistic expectation to produce a qualified inspector at the onset.
 - i. *Rationale:* Initial introduction to the organic regulations and inspection requires a significantly higher investment of time than yearly upkeep regarding regulation changes and focus on areas of improvement.

Inspector Evaluations

1. **Evaluation Methods:** IOIA supports regular inspector evaluations as a critical tool for professional improvement and to safeguard organic integrity. IOIA supports the use of field evaluations AND recommends more regular certifier feedback on inspection reports.
 - a. *Recommendation:* Field evaluations should occur annually until two (2) satisfactory evaluations have been conducted, after which evaluations may occur once every three (3) years. If a subsequent evaluation produces an unsatisfactory result, field evaluations should resume annually until two (2) successful consecutive evaluations occur.
 - i. *Rationale:* Field evaluations have proven to be an effective way to measure performance in the field. It is imperative for inspectors to understand what they are doing well and where they need to improve.
 - b. *Recommendation:* **Certification agencies** should be required to provide feedback on a minimum number or certain percentage of inspection reports. For persistent areas of concern, requirements for improvement should include specific trainings conducted by a qualified training institute (NOP Organic Integrity Learning Center, certifier, IOIA, etc.).
 - i. *Rationale:* Inspection reports are also an important and accessible way to evaluate inspector knowledge and competence. The inspection report provides an insight to inspectors' skill sets on a regular basis. Many inspectors do not receive timely or detailed evaluations of their work from certification agencies.

Certifier observations of traceback and mass balance practices, proficiency in citing regulations, thoroughness of showing work, as well as evaluating if time on site was appropriate to the operation, are all means to evaluate the inspector. These feedback loops can provide the inspector insight on areas of improvement and recommendations on continuing education to address deficiencies that lead to improvement.

Costs of Training

1. **Financial Support for Training:** IOIA supports the government's involvement in the development of financial mechanisms to support inspectors and reviewers in obtaining training thresholds.
 - a. *Recommendation:* Work with our federal representatives, the Organic Trade Association, and other advocacy organizations to carve out portions of the federal

budget that can be used in a cost-sharing, grant, or similar program to defray training costs for organic inspectors and reviewers.

- i. *Rationale:* The educational investment cost involved for initial requirements to meet qualifications, as well as annual continuing education, is a concern. There is currently very little financial assistance available (i.e. student loans, grants, scholarships, reimbursement, etc.) for acquiring the training and skills required. The more limited funds are to achieve and maintain minimum training levels, the more challenging it will be to recruit and retain a dynamic, educated workforce of organic inspectors and reviewers.

GROWER GROUP OPERATIONS

IOIA supports the proposed addition of grower group operations into the regulation.

In items 1-2, IOIA respectfully responds to the feedback requests/questions posed by the USDA in the proposed rule. Additionally, IOIA has commented on two other items.

1. **Maximum Number of Members:** There is no reason the rule should be so prescriptive as to limit the number of growers in a group

- a. *Recommendation:* the rule should not limit the number of growers in a group.

- i. *Rationale:* As long as the operator can demonstrate that the Internal Control System (ICS) staff on hand are adequately ensuring organic integrity, the number of members should not be a concern. Relatedly, there are economies of scale and professionalism that grow out of larger grower group ICS systems. Arguably this scale and professionalism can help reduce incidents of organic fraud or other concerns with organic integrity.

2. **Geographical Distribution of Growers:**

- a. *Recommendation:* The geographical distribution of grower groups should only be limited to the extent to which groups can reasonably aggregate raw product, as opposed to finished products.

- i. *Rationale:* We do not feel very strongly about this, except to recognize that the size of the geographical area should be defined by post-harvest

considerations of the crop in question. For example, distinct zones should be close enough to a central collection point to allow for the aggregation of raw, possibly perishable raw materials. Aggregation of raw materials is a key component of a grower group.

3. **Risk Factors:** IOIA does NOT BELIEVE that growers with incomes greater than \$5,000, or with mixed crop/livestock operations or a specified size should be considered “high risk,” and require individual inspections.

- a. *Recommendation:* Do not automatically require individual inspection of growers who earn >\$5,000 or who have mixed crop/livestock operations or a specific size.

- i. *Rationale:* If the final document carries the suggestion that grower group members with incomes over \$5,000 should be considered higher risk, it would defeat the effectiveness of the grower group model to address and mitigate poverty in many countries around the world. Five thousand dollars, especially for a family, is a very meager income in any country. Requiring the grower group to pay for these growers to receive individual inspections would completely negate the wide-ranging positive effect that community grower group models can have in developing countries.

Larger growers should not, by their nature, be automatically assumed to be high risk. There are other risk criteria that should outweigh the size of a grower in making the “high risk” determination (e.g. mixed or parallel operations, proximity to conventional operations).

Relatedly, suggesting that “integrated crop-livestock systems” are higher risk would serve to penalize growers who are better off (cattle and other livestock being a sign of wealth in many areas) and/or those who are substituting external inputs with locally produced ones.

4. **Percentage of Inspected Growers:** IOIA believes that the percentage of growers inspected annually by an accredited certifier should be manageable and reasonable cost for the grower group, and in line with the integrity of their ICS. The proposed re-inspection rate in 205.403 (1.4 v) is the rate currently used in the IFOAM Accreditation Requirements for “high-risk” groups.

- a. *Recommendation:* The minimum number of community members inspected by an accredited certifier every year should be consistent with the industry standard. We can support the proposed rate of 1.4v as the number of farms to be inspected by the certifier. However, we also support a recommendation of IFOAM – Organics International that an additional minimum percentage rate is important. Otherwise,

the sample size for external inspection can become too small for large groups. (i.e. IFOAM is recommending 2-3% re-inspection rate as a minimum). IOIA recommends 3-4% inspection rate as a minimum.

Lower numbers should be considered for groups that have a history of strong ICS oversight and compliance.

We support that a lower percentage of members may be inspected in subsequent years of certification, if the grower group as a whole demonstrated a good record of compliance through their ICS.

- i. Rationale:* The minimum number of community members required to be inspected by an accredited certifier every year should be consistent with common industry practice of our trading partners and recommendations of industry topic experts (like IFOAM).

Although the above represents IOIA's formal position, IOIA does publicly note that some members expressed interest in seeing a higher minimum percentage of inspections carried out by the accredited certifier.

CALCULATING THE % OF ORGANICALLY PRODUCED INGREDIENTS

IOIA agrees that the revised text at 205.302(a)(1), 205.302(a)(2) and 205.302(a)(3) will reduce confusion and ensure consistent determination of organic content when calculations are based on the weight of ingredients at the time of formulation.

IOIA respectfully submits one recommendation for further clarification with rationale.

The proposed one-year time frame for implementation after final rule publication seems appropriate for this section.

1. **Label Nonretail Containers with "% Organic":** An opportunity exists to improve organic integrity and facilitate organic audits if nonretail bulk containers of organic ingredients/multi-ingredient food/feed products are labeled with the actual % of organic products it contains. This requirement would need to be harmonized across various labeling standards.
 - a. *Recommendation:* Display the percentage of organic ingredients on nonretail containers to facilitate future audit processes that help prevent and detect

organic fraud. Update all impacted standards with this language, which include but are not limited to: 205.303, 205.304, 205.305, 205.306, and 205.307

- i. *Rationale:* When displaying the % organic on nonretail organic ingredient labels would, this makes inspection processes more efficient and reduces the risk of fraud by creating additional checkpoints in complicated supply chains.

SUPPLY CHAIN TRACEABILITY AND ORGANIC FRAUD PREVENTION

In general, IOIA supports the proposed changes, including additional a definition for organic fraud, the requirement for fraud vulnerability assessments and fraud prevention plans, the requirement for certifiers to share information to verify supply chains and conduct investigations, and requirement for certifiers to conduct risk-based supply chain audits.

Items 1-2 address question one proposed by the USDA. IOIA also has identified additional areas of consideration. Comments respectfully submitted below.

1. **Adequacy of 205.2 Definitions & Additions:** *“Does the proposed definition of organic fraud encompass the types of fraudulent activities you witness in the organic supply chain?”*

IOIA is generally in agreement with the new proposed revisions and additions to definitions at § 205.2. We believe that the proposed definition for organic fraud seems to encompass the types of fraudulent activities inspectors witness along the organic supply chain. Regarding fraud issues centered around uncertified handlers, we think opportunities for fraud would be reduced by instituting the proposed revised definitions for 'handle' and 'handler', and by the proposed rules to increase the number of businesses that may need certification to include brokers, traders, importers, and exporters in the supply chain.

- a. *Recommendation:* Revise the proposed definition in § 205.2 as follows: Intentional deception, for ~~illicit~~ economic gain using the USDA organic label.

- i. *Rationale:* Some inspectors voiced concern regarding the possible difficulty proving 'illicit economic gain'.

2. **Full Supply Chain Audits:** *“Should certifying agents be required to perform a minimum number of trace-back audits each year?”*

IOIA supports and agrees with an increased focus on the full supply chain that crosses both operation and certification agencies. Several types of considerations for these audits should

be considered as final rule or in a guidance document published by the NOP. This allows the industry to learn in such a way that changes may be made based on industry experience.

- a. *Recommendation:* A portion of supply chain audits should include product that is processed or handled by retail operations (i.e. Organic baked goods, bulk products, repacked goods, etc.)
 - i. *Rationale:* Currently, there is no accountability at the largest link to the consumer, retail operations. Why does a bakery need to be certified if they are selling to a retailer, while the exact same process can occur within the store and does not need to be certified? Though we recognize that certifying all retail operations would create a large burden both in human capital and in cost, a small sampling conducted through traceback will provide some insight into a largely hidden, yet major link in the food chain.
- b. *Recommendation:* The number of audit exercises conducted should be risk based. 3-7% of each agency's operations should be involved in a full supply chain audit. To reduce costs and effectively distribute human capital, the agency that certifies an operation involved in any supply chain audit, despite who initiated it, should have access to the audit and be able to count that toward their minimum requirements. The agency that initiated the supply chain audit may require financial compensation.
 - i. *Rationale:* Full and/or partial supply chain audits strengthen organic integrity tremendously. This process is likely to create a financial burden for both certifiers and certified operations. 3-7% is enough to be effective and improve overall compliance, yet attainable.
- c. *Recommendation:* Specific audits to be conducted should be representative of risk and consider the resource impact of particular industries in the supply chain. A certification agency should be able to provide justification that clients that have been involved in three (3) successful supply chain audits in a calendar year are exempt from participation unless the request is an investigation of potential fraud.
 - i. *Rationale:* In some industries and/or regions, a small percentage of companies may be responsible for a large percentage of commerce. This may put undue financial burden on select companies.

3. Training and Qualifications- Supply Chain Audits: IOIA supports including minimum qualification requirements for personnel involved in full supply chain audits.

- a. *Recommendation:* All inspectors who conduct full supply chain audits should be trained specifically for supply chain audits, including lead auditor training.

- i. *Rationale:* Full supply chain audits are complex. In the spirit of increasing organic integrity, minimum qualifications for personnel handling these complex audits should be established.

4. **Housekeeping on 205.201(a)(3) Language:** The text of 205.201(a)(3) for Organic System Plans could be modified to reduce redundancy.

- a. *Recommendation:* Update 205.201(a)(3) to read: “A description of the monitoring practices and procedures to be performed and maintained to verify that the plan is effectively implemented. Include the frequency with which each will be performed. Provide information adequate to verify suppliers in the supply chain, verify the organic status of products received, and to prevent organic fraud, as appropriate to the certified operation's activities;”

- i. *Rationale:* In the proposed language, there is some redundancy of the use of “monitoring” and other words that can be combined to be less redundant and clearer. *Original Language:* “A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented. This must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of products received, and to prevent organic fraud, as appropriate to the certified operation’s activities;”

5. **Independent Contract Inspectors:** IOIA notes the value of Independent contract organic inspectors in performing full supply chain audits for the following reasons:

- They often work with both the buyer and seller of different commodities and raw materials in the supply chain.
- They often work for multiple certification agencies and would therefore potentially be able to conduct several segments of a full supply chain while simultaneously conducting aspects of an annual inspection, reducing costs.
- Many work primarily in regional areas for multiple certifiers and are able to make initial risk assessments of potential fraud based on local observations, inconsistent/inaccurate/incomplete documentation from suppliers, etc.
- Contract inspectors will not generally have conflict of interest when auditing an operation certified by a competitor.

TECHNICAL CORRECTIONS

IOIA supports all proposed text for technical corrections listed for 205.301, and for 205.400(b) and 205.401(a) to correct the reference to organic system plans (205.201).