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October 1, 2020

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

Docket: AMS-NOP-17-0065; NOP-17-02
Regulatory Information Number: 0581-AD09

Dear Ms. Jennifer Tucker,

Oregon Tilth Certified Organic (OTCO) supports the Strengthening Organic Enforcement (SOE) Proposed Rule.

Without question, closing loopholes, creating consistency among certifiers, correcting vague language, and increasing fraud prevention collaboration are urgent and overdue for the organic sector. OTCO prioritizes oversight and enforcement as the foundation of our work, investing in developing systems, controls, and policies to ensure certified organic businesses and products' unquestionable integrity.

The damaging effects of fraud extend beyond a media headline. The entire organic industry, up and down the supply chain, feels its adverse impacts. From weakening relationships with customers to questioning sources for ingredients, SOE is a necessary and promising step to preserve organic's most critical attribute: trust. Expanded oversight doesn't need to increase costs and require more paperwork. OTCO believes that practical changes alongside clear regulatory language will eliminate many blind spots where fraud is possible.

OTCO brings decades of expertise in reviewing, inspecting, and enforcing organic regulations to its comments. Our goal is to provide the USDA National Program with our perspective as a nonprofit certifier, focusing on word choices that remove ambiguity and offer no opportunity for differences in interpretation. We recommend changes to remove unnecessary and avoidable administrative burdens for certified operators. And we introduce on-the-ground examples of situations found across all certification scopes to provide needed context and understanding for the unintended impact of proposed changes.



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As a nonprofit certifier with 40 years of organic experience, OTCO believes SOE is not just about improving oversight. It moves to protect and preserve the heart of the movement. When someone chooses an organic product, it's not just a choice for sustainability or climate resilience or public health. It's the belief that how we produce food matters. Organic certification provides all of us confidence that our promise to deliver a different food future is well-tested, secured and possible.

1. Applicability & Exemptions from Certification

Except for the callouts below, OTCO is in overall support of the proposed change regarding excluded handlers. We believe it will reduce the potential for fraudulent activities within the organic supply chain.

OTCO responses to NOP questions

Question 1: 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?

- Clarification is needed to define whether or not transloading activities and brand owners fall under handling activities and require certification.
 - The proposed rule's explanatory language indicates that both operation types should be certified based on this revision, but it is not clear from the actual proposed regulatory text. OTCO is highly supportive of required certification for transloaders and brand owners. We request that this be explicitly called out in the regulatory text if this is the NOP's intention to ensure consistent certifiers' application.
- Transporters (who are exempt from certification) can transport combination loads under another certified entity's direction. For example, tanker trucks picking up organic milk from organic dairies and delivering it to organic dairy processors, at the direction of the certified processor, should not be required to be certified since they are acting under the guidance of a certified operation's OSP.
 - The requirement for milk tanker certification would negatively impact the organic dairy industry and is unnecessary to verify compliance. Organic dairy processors can establish contracts with milk haulers that are traceable and verifiable for required sanitation and segregation actions. Contracts would be



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- included in the OSP for the dairy processor and therefore be under their certifier's oversight, sufficiently addressing supply chain concerns.
- We request the NOP include additional definitions to distinguish between transloaders (stationary "brick and mortar" locations) and transport vehicles (mobile). The change will clarify that contract transporters carrying combined loads at a certified operation's direction would not be required to be certified.
- The word "process" is used interchangeably with the word "handle" throughout the proposed rule, but "process" or "processing" is not defined. It is not clear what activities constitute processing. For example:
 - Is a retailer that deposits products from bags into display bulk bins for customer self-service considered to be "processing" that product, or would that activity be covered under the retail exemption?
 - Is a retailer that displays organic sausages in their meat case, then packages and labels the product when a customer selects them for purchase considered "processing," and thereby require certification?
- Additional clarification would help specify that operations that apply additional protective packaging can be excluded from certification. For example:
 - If a shipper adds tough corners to prevent damage to a box of organic chips sold at Costco, provided the additional packaging makes no organic claims *and* the facility does not otherwise repackage or relabel the product, then the facility wouldn't need to be certified.
- While we see certification of transloaders as a huge undertaking in and of itself, we also know that it will create consistencies across certifiers and within the organic supply chain. Overall, it will play a huge role in global organic fraud prevention.
- Mandatory certification of brand owners would promote uniformity in certifier review and approval of products between the co-packers, packagers and brand owners involved. In many instances, the companies in a product supply chain may be certified by different entities (or currently, the brand owner may not be certified).
 - We would request that the NOP provide additional guidance on the functions a brand owner is responsible for, including the types of documentation they need to maintain since nearly all activities (besides sales) will overlap with another certified entity. This means a significant amount of duplicate work could occur in certifying both a brand owner and their co-packers or other contracted entities.



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

No.

Question 3: Are there additional requirements that exempt handlers described in this proposed rule should follow?

No.

Question 4: Activities at ports may present a threat to the integrity of organic products due to the multiple types of handling activities performed in these locations. It is common for independent operations to perform specific physical handling activities within a port (e.g., loading, unloading, or transfer of packaged, unpackaged, or bulk organic product). The proposed rule would require certification of these operations, who are often contractors. What other activities performed at ports should require certification and why?

- Requiring the certification of contractors operating at ports presents difficulties. However, the risk to organic integrity represented by certain activities performed by these contractors is significant, and some level of oversight is warranted. Contractors have no voluntary involvement in the organic industry; they perform required activities for entry ports, regardless of organic status.
- OTCO believes that operations moving unpackaged or bulk organic products represent the greatest potential risk to organic integrity at ports and should be required to be certified.
- Other activities performed by independent operations at ports (e.g. those who load/unload packaged goods) represent a lower potential risk, and therefore certification may not be as essential.
- There may also be an alternative to certification for port operations that the USDA NOP should explore. The U.S. Customs and Border Protection (CBP) agency already has oversight authority of port activities and these independent operations. As USDA NOP develops its partnership with CBP, a Memorandum of Understanding could outline these operations' high-risk activities. Focus can be on operations' handling bulk and unpackaged organic products, and activities would be subject to verification of compliance with organic requirements by CBP agents and representatives.



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OTCO's additional concerns, considerations and recommendations

- The proposed rule uses terms that currently are not defined, including "alter," "transport," "process/processing," "storing," and "combining/splitting." Without clear definitions, the use of these terms in the regulatory text muddy the waters and may lead to inconsistent interpretation by certifiers and certified operations. For example, does this mean that milk/hay haulers are "storing" products that they are combining/splitting?
 - NOP Handbook document 4009 "Who has to be certified" references transport in NOP 5031, which has "transport" more ambiguously undefined. Specifically, it is the language in NOP 5031, section 4.3 that leaves certifiers guessing where handling ends and transporting begins or vice versa. We request an update to Memo 5031 to align with the proposed rule.
- Will all storage facilities of organic products require certification under the proposed rule? Our reading of the explanatory language in the proposed rule indicates that storage facilities that do not handle products should be exempt. Still, the proposed regulatory text does not make this explicitly clear.
- 205.101(b) proposed revision states: "A retail operation or a portion of a retail operation that sells, but does not *process*, organically produced agricultural products." The word "handle" should replace the word "process." If the word "process" is maintained, its definition should be updated to include labeling. While labeling does not alter the organic product's contents within the packaged container, a new label would change the product's representation, and this should be a certified activity.
- The explanatory text of the proposed rule states: "Similarly, uncertified storage facilities may store and split or combine lots and loads. Certifying agents and certified importers may not be informed of the full range of activities conducted at such facilities; however, handlers at these locations have a critical role in maintaining the integrity and traceability of organic products. For this reason, the proposed rule would require the certification of these types of handlers." The addition of 205.101(e) as written contradicts this statement and makes it unclear what the NOP truly expects of storage facilities.
 - We request clarifying the language at 205.101(e) to replace "process or otherwise alter" with "process split or combine lots or loads, or otherwise handle..."
 - An alternative approach would be adding a definition for packaged vs. unpackaged products; that would provide an important distinction to clarify this contradiction.



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- The following clarification provided in the rule's explanatory text should be included in the proposed regulatory text at 205.101(c): "This means that the products must be processed and sold in the same physical location. An operation processing a product for sale at another site would require certification."

Recommendations for timeline and implementation: Minimum of two years.

2. Imports to the United States

OTCO agrees that reforms are necessary to maximize organic fraud prevention in importing products to the U.S. However, the proposed changes pose significant concerns for the organic industry and certifiers which work internationally, both in the short and long term.

Most notably, the proposed changes pose a risk of interrupting international trade (particularly between the United States and Mexico and Canada). The primary concern is In particular, these changes are of concern for imports entering the United States via truck or rail (including perishable goods and raw agricultural commodities such as grains), which are subject to rapid and unpredictable import/export processes that may not align with the proposed timelines for certifiers to issue NOP Import Certificates.

OTCO responses to NOP questions

Question 1: Is the 30-day timeframe for certifying agents to review and issue an NOP Import Certificate appropriate? Why or why not?

If implemented, the 30-day timeframe seems reasonable as long as we are counting from the day that OTCO receives the request and pending the request's completeness.

Question 2: How could the mode of transportation and frequency of shipments affect the use of the NOP Import Certificate?

Regarding proposed rules established through 205.273(a), it may often be impractical for NOP Import Certificates to be issued before export and physically or digitally accompany a product upon entrance to the U.S. or a third country where a NOP operator is located. This is particularly relevant for neighboring countries that share land borders. Land-based or air transportation enables import/export activities to occur within very short timeframes (between



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a few hours and 1-3 days). Here are a few representative examples:

- OTCO certifies approximately 140 organic operations in Mexico, some of which export hundreds or thousands of truck shipments to the United States each year, the vast majority of which are perishable products.
 - The sheer volume of import certificate requests from these operations that would result from this proposed rule change is staggering. It would require OTCO to invest heavily in technically trained administrative staff to field these requests on time. The cost of additional staffing is prohibitive. OTCO would need to charge a sufficient fee for issuing import certificates to cover these costs. This is where the greatest burden lies, as all costs to certifiers and any others in the supply chain will just be passed on, likely resulting in high prices for these products at the end consumer. For other types of transaction certificates, such as TM-11's, NAQS', etc., OTCO charges \$60/request. If OTCO has to implement similar fees for NOP import certificates, it will have a major financial impact on these operations and/or may make businesses opt out of organic.
 - The products and quantities on those shipments are generally not finalized until moments before shipping. This makes it nearly impossible for the operator to request a certificate in advance of shipping. Requests would have to come no sooner than the day the shipment is sent (and often the same day it will cross the border into the United States).
- While OTCO does not currently certify in Canada, we do certify many companies in the United States that purchase organic grain and other raw agricultural commodities from Canada; again, these shipments total in the thousands each year and are primarily transported using rail and trucks.
 - Although these commodities do not have the same time urgency as perishable goods, the proposed changes to the regulations pose similar challenges for these kinds of shipments.
 - Shipping details are generally finalized very shortly before delivery, resulting in a short window of time for the exporter's certifier to issue the necessary documents to be available within 10 days of the shipment. This short timeframe, combined with the volume of shipments that occur each day, will undoubtedly present a significant administrative burden for the exporter's certifier.
 - It is not clear whether a Canadian certifier, which certifies its clients to the Canadian Organic Regime, would issue a NOP import certificate or if they would "provide data through an equivalent data source" as written in the proposed regulatory text. It's also unclear what kind of enforcement authority the NOP has



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over Canadian certifiers should they not provide the necessary documentation or do so in the timeline required, or if they will include this requirement in the revised U.S./Canada Organic Equivalency Arrangement. Without an authority ensuring that these certifiers are meeting the requirements, NOP-certified operations will be the ones who will be penalized by receiving shipments without the necessary documents. Furthermore, NOP operations will need to hold/store them indefinitely until appropriate documentation is received. Railyards and transloading facilities do not have the infrastructure to accommodate longer-term storage, causing a severe bottleneck for these shipments and the supply chain.

- We urge the NOP to consider alternatives to NOP Import Certificates (which must be issued with every shipment) that still achieve the objectives of tracking and verifying organic imports' authenticity into the United States without creating unnecessary trade barriers.
 - One possibility would be to issue permits or licenses to organic importers through the CBP-ACE system; this could be used to track all organic imports handled by a given importer, and then verified by certifiers or the NOP as appropriate and necessary.

OTCO's additional concerns, considerations and recommendations

- Suppose a NOP Import Certificate has not been issued by the time of importation. In that case, a mechanism should exist to allow the product to be released into the importer's segregated custody. Such a provision will protect the product's quality and avoid importers from incurring increased fees due to storage at port of entry.
- The following corresponding alterations are suggested to the varying sub-sections of 205.273, which appear below:
 - 205.273(a) should be updated to indicate that the NOP Import Certificate should be issued within 10 days of shipment (rather than "prior to shipment") per preamble language.
 - 205.273(d) should be updated to indicate that the importer of record must ensure that the shipment is associated with a NOP Import Certificate or equivalent and validated by the Automated Commercial Environment (ACE) Entry Summary process before sale of the product or a processed product which employs the imported ingredient within its formulation as organic.
- The term "accompanied by" should be replaced by "associated with" throughout.



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- The term "equivalent data source" as defined by 205.273(e) remains unclear. Who is responsible for determining what is considered equivalent, and what are the criteria for this determination? This is particularly important to determine who ensures compliance with the NOP's expectations and alignment with the U.S. Customs and Border Protection's ACE system as established in 205.273(c).
- Reference to 205.273(e) should be included anywhere where the term "equivalent data source" occurs within 205.273.
- 205.273(d) establishes that the importer "must verify that the shipment has had no contact with prohibited substances pursuant to 7 CFR 205.272 or exposure to ionizing radiation pursuant to 7 CFR 205.105, since export" and Preamble section - Future harmonization with sanitary and phytosanitary data systems establishes that "the use of health certificates, sanitary certificates, phytosanitary certificates, and other regulatory requirements in place to contain certain plant and animal pests or diseases may offer a possible resource for the NOP and other government agencies to document the movement of organic products across national borders." While the NOP works to harmonize with global sanitary and phytosanitary data systems, it continues to be quite difficult to establish standardized criteria for ensuring compliance to what 205.273(d) requires on a by country of origin basis, as Sanitary Control Systems vary greatly by country. Minimum compliance determination criteria for certifiers to use would be helpful within this section.
- **205.2 — Organic exporter**
If a product is certified to the NOP in a third country and sold to another NOP certified operation outside of the U.S., is an NOP Import Certificate required? This section should make clear the definition of exporter and importer within the context of 3rd country to 3rd country trade under the NOP.
- **205.2 — Organic importer of record**
Multiple entities may be involved in this process, particularly based on the concept of "accepting" and its definition (legal ownership, physical possession, administrative possession, etc.). Which entities involved in import require certification and would be required to apply the considerations of 205.273(d)? It is critical to answer this question clearly in the 205.2 Handle/Handler definitions.

Recommendations for timeline and implementation: As written, certifiers and operators will need a minimum of two years to increase their staff to accommodate the volume of NOP import certificates that will be required.



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3. Labeling of Non-retail Containers

We generally support requiring more comprehensive information on labels for non-retail containers used to ship, and in most cases store, certified products. Clearer, well-detailed information will improve traceability and auditability in the organic supply chain.

OTCO responses to NOP questions

Question: AMS seeks comment regarding the proposed amendments to the labeling of non-retail containers, specifically whether or not the certified operation that produced or last processed the product must be listed (i.e., not optional) on all non-retail container labels.

We support the requirement to list the applicable certification categories on non-retail container labels.

We support adding the name of the certifier to non-retail container labels, with the following to be taken into consideration:

- Listing the name and contact information for the final handler or distributor, or a unique identifier such as the operation's NOP ID, should be a MUST, not a MAY. A certifier should not be listed on a non-retail label without including the certified operation.
- Certifiers cannot easily trace a product to a producer based solely on a lot code and the designation of a certification category. Excluding the name of the final handler or distributor, or a unique identifier such as the NOP ID, and only including the certifier does not provide adequate information to increase traceability or prevent potential fraud.

OTCO's additional concerns, considerations and recommendations

- The proposed text does not differentiate or allow for a reasonable approach for on-site storage containers posing little to no risk to audit trail integrity.
 - For example, a small blueberry farm may pick into buckets to be stored in on-farm freezers for future production into jam. Provided audit trail systems are in place to adequately track the product. It would be an unnecessary burden to require such an operation to include labels on these non-retail containers used for storage when they do not leave the operation's premises and the harvest amounts are trackable. By adding an "if applicable" or "as necessary" clause to the MUST text would allow for a realistic approach for certifiers to take to accommodate a wide diversity of operations.



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- The proposed regulatory text does not explicitly exempt "large" non-retail containers, as described in the proposed rule explanatory text. This would create inconsistencies among certifiers determining when a non-retail container is "large" and, therefore, not need the labeling requirements. We request additional clarification of "large" non-retail containers in the regulatory text.
- This proposed change will likely affect thousands of labels in the industry. We recommend careful consideration of a reasonable and adequate implementation period for current labels to be updated.

Recommendations for timeline and implementation: One year

4. On-Site Inspections

OTCO supports requiring a 5 percent minimum for unannounced inspections. We also support requiring mass balance *and* traceback audit exercises during all annual inspections. OTCO already follows both of these practices; we do not anticipate any impacts to our staff or certified operations by implementing this requirement. In general, NOP-certified operations may experience a minor increase in inspections costs due to the required "additional" time to conduct audit trail exercises by certifiers who do not require these at each annual inspection.

This proposal ensures high integrity and will benefit the overall organic community and label.

- OTCO recommends rephrasing 205.403(d)(4) to say, "That sufficient quantities of organic product and ingredients are produced or purchased to account for organic product sold, transported, services rendered, or otherwise consumed on site; and..."
 - The current language doesn't cover the use of organic products produced on-farm and used on the farm (e.g., harvested crops fed to livestock) since they are not "sold or transported."
- OTCO would like clarification on the proposed 205.404(d)(5), regarding traceability requirements. What does "back to the source per 205.501(a)(21)" mean? As a certifier, we would have difficulty explaining this to our clients and inspectors.

Recommendations for timeline and implementation: One year

5. Certificates of Organic Operation

OTCO supports the proposed rule's intent in this section. We recognize the benefits that would come with increased uniformity and consistency in certificates.



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However, we have some significant concerns about and are in strong opposition to the NOP's plan to achieve this intent, as currently written in the proposed rule. Requiring certifiers to issue certificates from INTEGRITY poses several substantial problems.

OTCO responses to NOP questions

Question 1: How frequently should accredited certifying agents update the information in an operation's organic certificate?

Certificates should be updated any time there is a change that needs to be reflected on the certificate (e.g., crop/product addition or removal, new field/facility, after review of the annual inspection, etc.). Updates should be timely to ensure the accuracy of a client's certificate.

Question 2: Should a minimum reporting frequency (e.g., monthly, quarterly, etc.) be added to the regulations?

Only with implementing a close to real-time, automatic updating API linking INTEGRITY with certifiers' databases would OTCO support a minimum reporting frequency of less than monthly. If manual updates are required, we would support monthly reporting as the maximum frequency.

Question 3: Should an expiration date be included on all certificates of organic operation? Would this make them more useful?

- Adding expiration dates on certificates, when the certification of an operation does not expire, does not appear to serve any purpose. The inclusion would require additional certifier workload in generating new certificates when old ones expire. We also anticipate that expiration dates would be confusing to the industry.
- If the intent is to ensure that the operation's information is current, then the NOP should point the industry towards verifying the information in INTEGRITY. The overall goal is to ensure that certifiers maintain accurate information for operations.

OTCO's additional concerns, considerations and recommendations

- What appears on the surface to be a simple requirement is not. The administrative burden is overwhelming, particularly for larger certifiers with a diverse client base. Even



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under the best circumstances, it will require certifiers who have already invested time, staff, and millions of dollars into their database systems to manage data in two places.

- Updating data in INTEGRITY any more frequently than monthly will only be reasonable with the use of an Application Program Interface (API) that will allow certifiers' databases to exchange information with INTEGRITY on-demand or in real-time. Without an API, issuing certificates via INTEGRITY will generate significant additional administrative work for our organization. It far outweighs any reduction in the administrative burden of verifying other certifier's certificates.
- For example, in the first half of 2020, OTCO issued over 4,500 certificates to clients. Certificates were issued *any* time there was a change to a client's information that needed to be reflected on the certificate. Issuing certificates from INTEGRITY does not allow for the inclusion of international equivalency on certificates. The result is that any client with international equivalency would HAVE to have an addendum generated from our internal database. Extra administrative steps and duplicative work would multiply the amount of staff time required to issue certificates. Additionally, there will be a need for supplementary staff training to maintain both systems.
- Even with additional training, the opportunity for human error always increases when information must be manually managed and stored in two places. Overall, increases in time to facilitate certificate generation is a disadvantage for certified operations and the industry.
- Issuing certificates from INTEGRITY will restrict certifiers to using only the taxonomy in INTEGRITY. The limitations will not allow for the customization of listing products to meet client needs. Without providing any additional organic integrity to the supply chain, it also introduces unnecessary constraints.

We propose many alternative solutions for NOP to consider fulfilling the proposal's intent while avoiding the introduction of administrative burden.

- Mandate the use of standardized organic certificate templates by all certifiers. Templates could be implemented by each certifier using its database system. Certificates will be generated internally, along with any necessary addendums. The templates will eliminate the need to manage information in two systems and avoid many of the above concerns.
- If INTEGRITY could receive real-time updates (without the need for manual entry), OTCO poses the question: why do we need to issue paper certificates at all? Instead, wouldn't



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it be most secure to refer to the information in INTEGRITY to verify organic compliance for products? OTCO sees this as the way of the future.

- Paper/PDF certificates are easily manipulated and provide no guarantee against fraud. Certifiers can point to numerous examples of alterations of their certificates to represent non-organic companies and products as organic. In all instances, we encourage our certified operations to refer to INTEGRITY and check with a supplier's certifier for verifiable and current certification information.
- Future editions of INTEGRITY could include a robust history feature that would show how an operation's certification/products have changed over time. The historical view will support the verification of transactions that occurred months or years before viewing the data.
- Repurpose INTEGRITY's certificate generator to enable printed representations of a certified operation's INTEGRITY data to provide a snapshot in time. The data could accompany shipments of organic goods and demonstrate verification of suppliers' certification status in a supply chain. Additionally, for operations that do not use technology (e.g., the Plain communities), the representations could be generated on demand.

Recommendations for timeline and implementation: Although we do not support this proposed regulatory change as currently presented, if the NOP moves forward with requiring issuance of certificates through INTEGRITY, we would need at least two years to successfully modify our systems to implement it.

6. Continuation of Certification

OTCO aims to inspect all clients on an annual, calendar-year basis. We support requiring annual inspections to ensure more robust and complete oversight of organic operations. Requiring annual inspections in the regulation makes clear that all clients must be inspected each calendar year.

We would note that periodically, it can be challenging to arrange/schedule an inspection on time due to a certified operation's lack of cooperation or response. Recognizing that it takes the cooperation of the operator and the certifier to schedule an inspection successfully, we would encourage the following revision to §205.406(b):



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- "The certifying agent and the operation must arrange and conduct an on-site inspection, pursuant to §205.403, of the certified operation at least once per calendar year."

OTCO supports the clarification that operations should only submit the sections of the OSP changed, along with eliminating the need to provide a status update on the correction of noncompliances. The explanation in the proposed rule explanatory text for removing this section is accurate. Furthermore, it will eliminate needless administrative burden from the annual update process.

OTCO notes that the revised language effectively separates the annual update requirement from the annual inspection. The proposed regulatory text does not require the certifier to receive the annual update before scheduling the annual inspection each year. The removal of this requirement simplifies scheduling annual inspections and the process for inspectors (one less thing to confirm). However, it's important to call out that many annual updates include changes to the OSP that require an inspection (e.g., land/facility additions and new types of production or processing). Certifiers may need to establish their annual update requirements before annual inspections to ensure efficient certification procedures.

Recommendations for timeline and implementation: One year

7. Paperwork Submissions to the Administrator

We support the removal of the requirement at 205.405(c)(3) and 205.501(a)(15) to provide the NOP with copies of official certification notifications. In our experience, copying the NOP on these notifications has not offered any enforcement benefit. Removal of this requirement eliminates an unnecessary bureaucratic step in the certification process.

While we are generally supportive of the proposed revision at 205.501(a)(15), we have some concerns and are seeking clarification about NOP's expectations for certifiers to "maintain current and accurate data in INTEGRITY for each operation which it certifies;" specifically:

- How often are certifiers expected to update data in INTEGRITY for it to be considered current? Certifiers' success in meeting this requirement will depend on whether the NOP will provide an API to facilitate data exchange with INTEGRITY.
 - If an API is provided and proves to be functional, daily or weekly updates could be achievable. We see this as the best solution to achieve close to real-time updates to INTEGRITY, but potentially complicated to manage in practice.



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Certifiers use different database systems, and the NOP would need to ensure that their API worked across multiple platforms. Additionally, any updates to INTEGRITY would need to ensure the API remains functional.

- If no is API provided and certifiers must manually update INTEGRITY, then we would anticipate that no more than monthly updates would be reasonable to achieve. There would be a significant burden on our staff to conduct duplicate data management in two databases.
- The NOP should provide clear guidance and expectations for all certifiers in the timeliness of updates to INTEGRITY. Timeliness should also account for the impact on both large and small certifiers, each of which will face unique challenges in meeting this requirement.

Recommendations for timeline and implementation: Minimum two years for regular/frequent updates of INTEGRITY - this could be implemented sooner if a functional API is available at the time of final rule publication.

8. Personnel Training and Qualifications

OTCO supports the proposed clarification's intention for training and expertise and the need for a consistent baseline of knowledge and skill for certification work. The result will be the production of required high-level training for certification staff and inspectors, leading to more consistent contract inspector-led enforcement across operations.

OTCO responses to NOP questions

Question 1: Is 20 training hours a year an appropriate amount of continuing education for organic inspectors and certification review personnel?

- In regards to 205.501(a)(4)(i)(B), OTCO believes 20 hours of training is reasonable to require for all inspectors.
- In regards to 205.501(a)(4)(ii)(B), OTCO believes that 20 hours of annual training is achievable for certification review staff as long as this training can include procedural training for operational tasks directly related to providing certification services.
- Certifiers must be allowed to conduct continuing education training for certification review staff and inspectors internally—reliance on external third parties is not feasible. A combination of high-quality internal and external training resources will be most beneficial and provide increased flexibility/access.



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Question 2: Should organic inspectors be evaluated on-site more frequently than once every three years?

- OTCO supports conducting annual performance evaluations of all certification reviewers and inspectors. We already perform evaluations as a regular part of our workflow.
- OTCO supports conducting on-site evaluations of inspectors once every three years, except for new inspectors and/or concerns are raised/found during an assessment. For the inspector's first three years of inspecting, OTCO recommends that they receive annual on-site evaluations. If the inspector is conducting inspections for multiple certifiers, OTCO suggests that certifiers be allowed to share inspector evaluations to meet these requirements.
- OTCO agrees with proposed section 205.501(a)(6)(ii) that only qualified individuals should evaluate inspectors.

Question 3: Should any other types of knowledge, skills, and experience be specified?

- OTCO believes that an effective organic inspector must possess excellent technical computer skills and be well-versed in investigative techniques. Additionally, experience using various recordkeeping methods to conduct mass balance and traceback audits, and calculate dry matter intake (DMI) from pasture, is essential for success.
- OTCO recommends training for inspectors in relevant safety and biosecurity measures often required at certain operations.
- Inspectors should be required to maintain documentation to support their ongoing training; such documentation should be made available to certifiers upon request for verification, as necessary.

OTCO's additional concerns, considerations and recommendations

- OTCO recommends revising proposed 205.501(a)(4)(i)(A) to state (additions in red), "Certifying agents must demonstrate that inspectors continuously maintain adequate knowledge and skills about the USDA organic standards, applicable production and handling practices, certification requirements, inspection requirements, import and export requirements (if applicable), auditing practices and skills (including mass balance and traceability audits), communication skills (both oral and written), sample collection, investigation techniques, and preparation of technically accurate inspection documents..."



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- OTCO takes exception with proposed 205.501(a)(4)(i)(C); one year of field-based experience is vague, and requiring this for both scope and scale of operations is overly prescriptive. The directive further limits the pool of qualified inspectors to draw from and is impractical. For example, would a potential inspector need to have one year of experience working on a large dairy before being allowed to inspect this operation? Having cross-trained inspectors for various scopes is vital. Maintaining and developing a wide pool of inspectors is important, notably if we increase the number of unannounced inspections in the future.
- OTCO recommends that in place of one-year field-based experience in the scope and scale of the operation they will inspect, a mentoring and evaluation system is allowed. For example, certifiers must establish procedures for inspector training and evaluation. The goal is to demonstrate how protocols ensure that inspectors are competent and address any identified deficiencies or needs for retraining.
- OTCO recommends revising 205.501(a)(4)(i)(C) to state, "Certifying agents must demonstrate that inspectors have evidence of formal education, training, or professional experience in the fields of agriculture, science, or organic production and handling that directly relates to the scope of operations they will inspect before assigning inspection responsibilities."
- OTCO urges the NOP to ensure the language is not overly prescriptive, prohibiting the development and growth of new organic inspectors.
- OTCO urges the NOP to recognize certifying agency-specific metrics for continuous evaluation of and providing feedback to inspectors year-round.

Recommendations for timeline and implementation: Certifiers and inspectors will need a minimum of two years to address the necessity to develop the human capital required to meet the qualifications. It will take one year to implement the 20 hours training requirements for inspectors/staff.

9. Oversight of Certification Activities

We understand that the new definitions intend to ensure that satellite offices that operate under their own oversight structure are included in the scope of accreditation for each certifier.

- We have identified a couple of concerns with the proposed definitions of "certification activity" and "certification office."
 - These definitions are tied to physical locations and do not consider virtual, all-remote models for certification work. In the face of the changes occurring due to



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the current pandemic, the NOP should expect to see more certification staff and offices moving to all-remote work structures. These definitions will lag behind these changes in workforce trends.

- If taken as written, the definition of "certification office" could be interpreted to include the home office of any remote employee of a certification agency. They conduct "certification activities" from that location, albeit on an entirely virtual platform shared across the certification agency.
- We recommend including an exception in the definition of "certification office" to expressly exclude "telecommute locations" where remote employees perform certification activities under the authority and oversight of the certification agency's central office (virtual or physical).
 - This ensures that satellite offices, which may operate under a separate oversight structure from the main office, are included explicitly as "certification offices" but clarifies that telecommute locations (e.g., remote employees' home offices) are not included.
 - Clarifying this definition would also confirm that certification agencies do not need to report to the NOP every time they hire a remote worker using a home office. To be clear, this does not appear to be the NOP's intent but would be required in the rule as written with the current definitions.
- We also recommend revising the definition of "certification office" to address the potential for an entirely virtual certification agency with no physical headquarters.
- Suggested language change: "Certification office. Any site, facility, *physical or virtual location, other than an employee's telecommute location, where a certification agency manages oversight of and/or conducts* certification activities are conducted... except for certification activities that occur at certified operations..."

Recommendations for timeline and implementation: One year

10. Accepting Foreign Conformity Assessment Systems

OTCO supports the proposed revisions to the regulatory text, as presented. The proposed rule language codifies existing practice and would not change how equivalency or recognition occurs.



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On multiple occasions, OTCO has encountered organic shipments from India that do not include TraceNet TC. A mechanism that reinforces the responsibility of the third-party country accrediting body regarding Recognition Agreement requirements would be a welcome addition to the regulation. We do not foresee a major impact on OTCO or clients.

Recommendations for timeline and implementation: One year

11. Compliance—General

OTCO supports the proposed revisions to the regulatory text, as presented. We regularly encounter organic claims made by uncertified entities that require investigation. Reinforcement of the NOP's authority to conduct such investigative enforcement activity is a welcome addition to the regulation. These efforts will not only support OTCO's work but contribute to increased organic integrity.

Recommendations for timeline and implementation: One year

12. Noncompliance Procedure for Certified Operations

We recognize the value of up-to-date information in INTEGRITY, particularly regarding suspensions, revocations, and surrenders, and are generally supportive of reasonable measures to accomplish this. However, the prescriptive requirement in the proposed revision of 205.662(e) (3) of requiring updates to be made within three (3) business days is not feasible.

- The impact of data updates that rely either on manual input or integrated reports within a short period would cause an undue burden on the administration of this requirement (*unless* NOP implements an API that automates data transfers). A period of less than one business week would prevent certifiers from establishing a regular and consistent reporting schedule.
- A reasonable approach would be to establish a more extended reporting period with a minimum of 10 business days. This allows certifiers of different sizes with different data systems and resources to develop and execute a regular reporting schedule.
- Pending the outcome of the proposed updates to proposed revision at 205.501(a)(15), the best outcome would be to establish a practical process to ensure INTEGRITY is kept reasonably up to date and encompass all of the required updates into one regular reporting cycle.



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We recognize and generally support that the proposed changes to 205.662(f)(1) will facilitate closing a loophole, preventing responsibly connected persons related to a suspended operation from receiving certification as a different entity. Implementation of this proposed regulation as written, however, may be problematic.

- The definition of "responsibly connected person" pertains to a wide range of individuals, including partners, officers, directors, holders, managers, or owners of 10 percent or more of the voting stock.
- The explanation of this proposed change indicates that certifiers would be expected to identify all responsibly connected persons in the proposed suspension. Certifiers do not necessarily have access to information to include an exhaustive list of responsibly connected persons that may fall under the broad definition provided in the regulation. That said, we agree that listing known responsibly connected persons in a proposed suspension would help close the loophole in preventing a suspended person from entering into certification without undergoing reinstatement.
- It is not clear what the impact of the suspension of a responsibly connected person for one operation would have if that same individual were considered a responsibly connected person for an unrelated certified operation. For example, suppose an individual is deemed ineligible for organic certification due to the suspension of an operation where they're a 10 percent owner. This person is also an owner or a board director for another certified operation. In that case, it is not clear if there would be an impact on these other operations' certification. It would be problematic to suspend other operations without clear evidence of OFPA violations related to that specific operation.

In the proposed change to 205.662(f)(1), it is not clear to whom eligibility requests should be submitted. Nor is it evident who is responsible for determining eligibility. Clarification is needed on if this would be the responsibility of the Secretary or of certifiers to decide whether or not the corrective actions taken comply with the regulations, and if an operation or responsibly connected person can demonstrate the ability to remain in compliance.

- If this proposed change is allowing a step for a suspended operation or responsibly connected person to get approved for eligibility from the Secretary prior to going through the certification and reinstatement process, this may be beneficial, saving the time and resources of not going through the reinstatement process if the Secretary will not grant reinstatement.



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- If the intent of this proposed change is that certifiers would be responsible for determining eligibility for reinstatement, this does not appear to have any additional benefit over an initial review of an application for reinstatement.

Recommendations for timeline and implementation: One year, provided our comments are considered and suggestions are implemented, we see this to be feasible.

13. Mediation

We support the addition of mediation expectations in the regulation. These updates codify general practices derived from the NOP Handbook.

OTCO's additional concerns, considerations and recommendations

We advocate for changing the requirement that the request for mediation must be submitted within "30 calendar days of receipt" to "30 calendar days from the date of issuing the applicable notice." The following provides context for this recommendation:

- Operators are responsible for providing contact information for correspondence regarding certification-related business. While it is necessary to send adverse action notices to enable receipt tracking, operators may choose not to open an email or sign for a registered notice. Certifiers should demonstrate due diligence in informing the operation an adverse action has been issued.
- Mediation requested within 30 days from receipt slows down enforcement/stoppage of adverse actions. Noncompliant activities must not be allowed to continue for an unreasonable amount of time.
- Certifiers may not be in a position to defend taking further action in the process (e.g., denial, suspension, or revocation) if they cannot document an operation's refusal to receive a notification.
- Provided certifiers can demonstrate due diligence to notify an operator of an adverse action, changing the language from "date of receipt" to "date of issue" provides a concrete and enforceable deadline for certifiers to take the next step against adverse actions.

Recommendations for timeline and implementation: One year



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14. -15. Adverse Actions—General, Appeals

We advocate for changing the requirement that the filing for appeal must be submitted within "30 calendar days from the date of issuing the applicable notice," rather than the date of receipt. The following provides context for this recommendation:

- Operators are responsible for providing contact information for correspondence regarding certification-related business. While it is necessary to send adverse action notices to enable receipt tracking, operators may choose not to open an email or sign for a registered notice. Certifiers should demonstrate due diligence in informing the operation an adverse action has been issued.
- Certifiers may not be in a position to document an operation's refusal to receive a notification.
- Provided certifiers can demonstrate due diligence in efforts to notify an operator of an adverse action, changing the language from "date of receipt" to "date of issue" provides a concrete and enforceable deadline.

Recommendations for timeline and implementation: One year

16. Grower Group Operations

We urge the NOP to keep in mind the origins of allowing grower group certification: to provide a way for small farmers with limited means to gain access to the organic market. Establishing arbitrary limits on grower group certification may lead to breaking up existing well-functioning grower groups. Furthermore, it may lead to eligible farmers being denied membership to an at-capacity nearby grower group (therefore having no access to the organic market).

OTCO believes the primary focus of grower group regulations should be on verifying the effectiveness of each group's Internal Control System.

OTCO responses to NOP questions

Question 1: Should there be limits on gross sales or field sizes of individual grower group members? If yes, please describe these limits.

No. There should not be limits on gross sales or field sizes of individual grower group members.



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- Of all the developing countries of Latin America, Mexico has a robust agricultural sector and connected economy due to its close export relationship with the United States. Here we've seen the emergence of an innovative model of grower group directly associated with land-based export, as well as higher-income organic markets (including vegetables, herbs, and fresh and processed fruits). Any sales or parcel size limitations must be designed to prevent discrimination and increase economic development opportunities for grower groups.
- Sales and field size limitations established by standards, such as EU 848/2018, reinforce a cyclical poverty model. Structures for this grower group model use high membership with low-value production (e.g., grower groups with 1000+ members with production in low-value crops like coffee). Income rates are comparably low and can be certified. Under this grower group model, EU 848/2018 acts as a barrier to real economic growth and prosperity for small scale rural farmers. It prevents access to the education, social organization, market access support, and technical development opportunities that grower group models often offer when forced to remain small and comparably unproductive to independent operators. The NOP mustn't establish similar restrictions on grower group certification and further disenfranchise highly vulnerable participants in the global organic marketplace.
- Eligibility for inclusion in a grower group MUST not be restricted based on operator size or economic potential. Such restrictions deepen non-size related barriers such as access to technical support, education, input/machinery, and market development. These are just as limiting for rural farmers, regardless of their size.
- Grower groups of a different model with lower member numbers (20-250 members) and higher value export crops can access international markets. These opportunities would not be possible if they operated independently, and small grower groups are disadvantaged under the current EU criteria.
- On average, OTCO sees an 85 percent decrease in certification costs per farmer when certified as part of a grower group versus as an individual operator. The majority of members in OTCO's certified grower groups are small. On their own, certification costs would be prohibitive. Additionally, they are unable to produce sufficient volume to access international organic market opportunities. By spreading certification costs across grower group members and collectively aggregating their production yields, economic opportunities and prosperity are made possible. Of note, savings realized in certification fees via grower group structures are reinvested in personnel to manage and implement the grower group's Internal Control System. Field representatives visit individual member farms to ensure organic integrity and oversight.



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- The proposed limits would break apart existing, well-functioning grower groups. Some operators may survive and become individually certified entities, while many others would no longer access the organic marketplace. The possible increase in the number of operations requiring certification would be burdensome, creating significant administrative work to supply certification for individual operations sharing the same organic system plan.
- If the proposed limits were established, we urge them to be flexible and adjust according to crop types and/or the number of growers.

Question 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? If yes, please describe these limits.

No. There should not be a limit to how many members can form part of a grower group.

- Rather than limiting the number of members in a group, place greater emphasis on inspection measures to ensure representative sampling at each production unit annually. In some cases, a single member from each unit may not be truly representative, as is currently implied in the proposed regulations.
- Establish risk-based criteria for certifier inspections by assessing grower group structure and complexity and Internal Control System (ICS) effectiveness (through annual risk factor assessments). Such an approach would allow a certifier to appropriately determine inspection sample sizes based on ICS functionality, which is the heart of grower group certification and maintains focus on this regulation.
- Increased grower group size (greater member/parcel volume) is often equal to increased benefits from an operator perspective. For example, certification fees can be distributed across multiple stakeholders, lowering costs for all. Additionally, market access is achievable for small growers (due to a grower group's ability to meet high profile buyers' minimum volume requirements). Lastly, groups can develop more sophisticated quality assurance systems and teams.
- There is too much variability in grower groups to establish limits on member numbers effectively. Most often, the basis for creating and maintaining a grower group is to allow many small growers access to markets that they would not be able to access otherwise. OTCO believes this benefit should be extended to as many growers as possible.



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Question 3: Should there be a limit to the geographical distribution of members? This includes limits to the maximum geographical proximity or distance between grower group members, grower group production or gathering areas, or grower group production units within a single grower group operation. If yes, please describe these limits.

No. There should not be a limit to the geographical distribution of members.

- Geographic proximity or distance and the perceived risk it presents should be assessed in relation to ICS effectiveness and parcel accessibility. Limits imposed on distance, depending on a geographic zone's topographical characteristics, could result in very different considerations across territories. Operators located at a greater distance from ICS headquarters are not automatically at greater risk for poor oversight or deviation from its OSP. If the ICS demonstrates a robust quality assurance system, risk due to distance should only be relative to the ICS's functionality. Geographic proximity assessments should focus on ICS efficacy criteria, such as frequency and type of monitoring, available communication tools, ICS personnel capacity, experience levels, and parcel accessibility (identifying barriers like rivers or seasonal, temporal weather events), not a prescriptive maximum distance.
- OTCO suggests each operation's ICS describe how they define geographical proximity and/or its "serviceable area." This would then require certifiers to decide as to whether that definition is executable by the ICS and capable of enforcing compliance or not.
- OTCO believes that keeping certifier focus on evaluating the ICS's effectiveness is the most efficient way to allow a grower group organization's benefits. Meanwhile, certifiers are then well-positioned to concentrate on assessing compliance. For OTCO, grower groups represent a significant investment of resources (staff time), and the proposed changes will not require additional support.

OTCO's additional concerns, considerations and recommendations

- **205.2 — "Grower group operation" definition**
Update the "grower group operation" definition to show the changes highlighted below. The distinction clarifies that geographic proximity criteria applies to individual members and/or grower group members congregated within a production unit. The clarification is relevant for grower group operations with multiple production units distributed over a considerable distance. Geographic proximity to ICS central offices is not possible for all individual members, but geographic proximity to the established production unit (the



unit of ICS control) is possible. The new definition aligns with the grower group production unit definition and what is set forth by 205.201(c).

- *Grower group operation.* A single producer consisting of individual grower group members and grower group production units composed of members within geographical proximity governed by an internal control system under an organic system plan certified as a single crop and/or wild crop production or handling operation.
- **205.2 — “Internal control system” definition**

Update the "internal control system" definition to show the changes highlighted below. The distinction clarifies that input procurement and distribution can either be performed by the ICS or, in the case of geographical distant production units, the ICS may perform an oversight function, rather than an operative function regarding this activity. This is relevant for grower group operations with multiple production units distributed over a large distance, where input procurement and distribution via a centralized facility is not always feasible or efficient.

 - *Internal control system.* An internal quality management system that establishes and governs the review, monitoring, training, and inspection of the grower group operation and oversight of the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations as a single producer.
- **205.400(g)(5) — Crop from grower members**

Consider clarifying that not just crops and/or wild crops are from their grower members, but from their grower members' certified parcels.
- **205.400(g)(7) — Annual data reporting requirements**

Reporting requirements, particularly for estimated yield by crop/parcel/member, create an excessive administrative burden for large scale grower group ICS systems and their certifiers.
- **205.201(c)(7) — Reporting noncompliances to the certifying agent**

Clarify the noncompliance type (major or minor) that needs to be reported to the certifier. Generally, minor noncompliances are addressed by the ICS and verified by the inspector on-site. Major noncompliances are reported to the certifier for joint corrective action determination and monitoring.
- **205.403(a)(2)(iii) — Inspection of all high risk members per 205.201(c)(4)**

The proposed rule does not indicate minimum criteria for high-risk member designation. Some of the criteria provided through the preamble (but not outlined in the regulatory language) for on-site inspections by the certifying agent (listed below) could be



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incorporated as high-risk criteria "that the certifying agent may consider." Highlighted items are not included in the explanatory text but appear in OTCO's current risk analysis for grower groups:

- Noncompliance history
 - The criteria used to designate a collection of grower group members as a single grower group production unit
 - Application of prohibited materials adjacent to member fields
 - Split or parallel operations (i.e., they are also producing nonorganic crops and/or wild crops)
 - Integrated crop-livestock systems
 - Geographic proximity of grower group members and grower group production units
 - Large parcels of land
 - Significant expansion of grower member's production area
 - Members identified for a conflict of interest
 - Members identified to produce a crop that is dissimilar from the group
 - Members identified in a complaint
- **205.403(a)(2) — Initial and annual on-site inspections**
Consider integrating the highlighted comments (below), provided via *Preamble - On-site inspections by the certifying agent*, into this section. The regulatory text does not clearly outline these expectations.
 - Selection of members should include all high-risk members; however, the certifying agent should also select members from across the risk spectrum— including lower-risk members. This may require a sample size larger than the minimum required by the proposed regulation (i.e., more than 1.4 times the square root of the number of grower group members).
 - **205.400(g)(8) — Internal Inspections of each grower member**, it would be helpful to Consider integrating the highlighted comments (below), provided via *Preamble - the internal control system*, into this section. The regulatory text does not clearly outline these expectations.
 - ICS personnel conducting inspections should focus on critical organic control points such as buffer areas, condition of crops and/or wild crops, soil quality indicators, input and equipment use and storage areas, and level of understanding of organic requirements by the grower group members AMS expects that qualified ICS personnel would be familiar with the local production practices, general organic production and handling practices, the USDA organic



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regulations, ICS procedures and regulations, and be fluent in the language(s) of the grower group members and the ICS.

- **205.400(g)(8) — Internal Inspections of each grower member and 205.403(a)(2)(ii) — Initial and annual on-site inspections**

These two proposed sections use the terms "inspector" and "inspections" when referring to internal surveillance audits. Both terms are included under 205.2 definitions, and while "inspections" appears to be appropriately used, the term "inspector" is misused. The definition of "inspector," per 205.2 is "any person retained or used by a certifying agent to conduct inspections of certification applicants or certified production or handling operations." In the proposed regulations, this person is hired and overseen by the certified entity, not the certifying agent. OTCO recommends that the term be changed to "internal auditor" to keep the distinction clear.

Recommendations for timeline and implementation: Two year minimum

17. Calculating the Percentage of Organically Produced Ingredients

After discussing the proposed revisions to §205.302(a)(1) with other certifiers, we found that there is not 100 percent consistency in interpretation.

OTCO Concerns, Considerations and Recommendations

- We recommend revising the language at §205.302(a)(1) to state:
 - “Dividing the total net weight (~~excluding water and salt~~) of combined organic ingredients at formulation by the total weight (~~excluding water and salt~~) of all ingredients (**excluding water and salt added as ingredients in the formulation**).”
- Additionally, there is room for further clarification regarding the calculation of water in formulations to reconstitute concentrates and dehydrates per NOP Policy Memo 11-9.
- It would be helpful to include a definition of concentrate and dehydrate to clarify this section.
- In 205.302(a)(2), it should be specified that water in the formula can be calculated towards the organic weight *if* it is being used to reconstitute a concentrate up to single strength. This would allow operations using aloe vera powder concentrate to use water necessary for reconstitution to be calculated towards the organic percentage of the finished product.



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Recommendations for timeline and implementation: One year provided our comments are considered and suggestions are implemented to reflect the intent of the NOP, we see this to be feasible; if the NOP intends to implement a different interpretation, then we would support a two-year implementation timeline.

18. Supply Chain Traceability and Organic Fraud Prevention

OTCO is supportive of the intent of the proposed regulatory requirements for certified operations and certifiers to improve supply chain traceability and fraud prevention. However, there are areas where the intent of the proposed rule (as outlined in the explanatory text) is not reflected in the proposed regulatory language. We offer suggested revisions to match the regulation with intent using irrefutable language.

OTCO responses to NOP questions

Question 1: Does the proposed definition of organic fraud encompass the types of fraudulent activities you witness in the organic supply chain?

- The proposed definition for organic fraud includes “intentional deception for illicit economic gain....” However, we believe that this may be too limiting to effectively capture all of the fraudulent activities that can occur in the organic supply chain.
 - By removing the words, “for illicit economic gain,” the rule will ensure that even when economic gain is *not* realized, *any* intentional deception can still be considered fraud.
- Additionally, amending the definition language by replacing “intentional” with “willful” is consistent with its use to describe/modify fraud across the NOP. We suggest the following revision to the definition of “organic fraud”:
 - Intentional, **willful** deception ~~for illicit economic gain~~ where nonorganic products are labeled, sold, or represented as “100 percent organic,” “organic,” or “made with organic” (specified ingredients or food group(s)).
- By incorporating these revisions, any willful violation of organic regulations or misrepresentation would qualify as fraudulent activity *regardless of whether economic gain was a result*.

Question 2: Should certifying agents be required to perform a minimum number of traceback audits each year?



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- OTCO is highly supportive of requiring traceback and mass balance audits as part of the annual inspection process. They should be encouraged as part of unannounced inspections when they are useful and appropriate. The audits should also be encouraged for compliance exercises involving supply chains certified across multiple certifying agents.
- We caution against mandating a minimum number of traceback audits to be performed each year. It would establish an arbitrary baseline and veer away from focusing on a risk-based approach.
- We would encourage the NOP to provide clear guidance for certifiers to establish their risk-assessment procedures, including when to conduct additional mass balance and traceback audits at an operation. The efficacy of each certifier's approach should be a key component of their accreditation audits. Certifiers must be able to demonstrate that their risk assessment procedures are effective.

Question 3: Should more specific fraud prevention criteria be included in the regulation?

- OTCO supports general fraud prevention criteria to be included in the regulation to ensure a consistent certifier approach. Yet, we caution against becoming overly prescriptive in the regulatory language when outlining criteria. There are many types of organic operations, each with unique circumstances in maintaining organic integrity. It would be tough to adequately capture a list of criteria applicable to all types of operations in the regulation.
- Instead, we encourage the NOP to provide clear guidance to certifiers via an NOP Handbook document. The handbook would outline the different types of fraud prevention criteria that should be considered for different operation types. This should be the starting point for certifiers to develop their own set of criteria explicitly tailored to the types of operations they certify. The NOP will review and verify to ensure they are sufficient during accreditation audits.

OTCO's additional concerns, considerations and recommendations

- The proposed revision to 205.103(b)(2) does not fully reflect the intent as described in the explanation of the proposed rule.
 - The proposed revision states "...including identification in records of products as 100% organic, organic, or made with, as applicable."
 - However, the explanatory text states that it is "not intended to limit an operation's flexibility to use alternative abbreviations or indicators of a product's



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organic status on non-retail labels or other recordkeeping. This may include use of abbreviations such as “MWO” (i.e., “made with organic”), ORG (i.e., “organic”), color designations, or other tracking systems that are used internally within a certified organic operation to denote a product’s organic status.”

- To align the regulatory text with the explanation, OTCO suggests the following revision:
 - “...including identification in transaction records of products as “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as applicable; *internal recordkeeping systems which use other designations or identification methods for organic ingredients and products may be used, provided these systems are clearly described in an operation’s organic system plan.*”
- OTCO is supportive of the proposed revisions to 205.501(a)(10) and 205.501(a)(13). These should lead to additional clarity and cooperation between certifiers.
- For conducting risk-based supply chain audits, the proposed revision to 205.201(a)(3) adds requirements for "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." The proposed rule provides several points for creating robust oversight for a supply chain and an organic fraud prevention plan. Additional points to consider include:
 - Some of the proposed requirements would be excessive and not apply to crop/wild or crop/livestock producers who do not purchase many (if any) external organic inputs.
 - It's unclear if certifiers will be expected to require these points in every organic system plan. If this is the case, it should be captured in either the regulation text or in a separate guidance/instruction document. An accompanying guidance document for the NOP handbook should be developed to include these points.
- Consider clarifying the proposed rule language by amending to:
 - “...This must include a description of the monitoring practices and procedures used to assess risk to organic integrity within the operation, to verify suppliers in the supply chain and organic status of products received, and to prevent organic fraud, as appropriate applicable to the certified operation’s activities;”
- The proposed revision to 205.501(a)(2) uses vague language, leading to the potential for confusion and inconsistent interpretation. It is unclear what is meant by “annually,” “conduct risk-based supply chain audits,” or “back to the source(s).” OTCO requests consideration and clarification to the following questions:



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- What is a “supply chain audit?” Is it a traceability audit like a mass balance or traceback exercise?
- Does the use of “annual” mean that certifiers need to conduct these audits at every operation every year?
- What does “back to the source(s)” mean? Do certifiers need to go back to the original producer of a raw ingredient or back to the last certified supplier? What are the expectations for operations around documentation to track back to the origin of an ingredient? Such tracing goes beyond and in contradiction to current regulatory requirements.
- How should certifiers be assessing risk to conduct “risk-based” audits?
- If the intent of the regulation is to require certifiers to conduct mass balance and traceback exercises at each certified operation each year (which OTCO fully supports), then to clarify that intent, we suggest the following revision:
 - “Annually, conduct risk-based ~~supply chain audits~~ traceability audits, including mass balance and trace-back exercises, to verify organic status of a one or more products at each certified operation it certifies, back to the ~~source(s)~~ last certified entity in the supply chain.”
- The proposed revision to §205.504(b)(4) is a step in the right direction to ensure clear and consistent practices for certifiers sharing information. We recommend that the NOP consider referencing the [ACA Best Practice on Cross-Agency Collaboration](#). We also suggest one small revision:
 - “A copy of the procedures to be used for sharing information with other certifying agents to ensure compliance across the organic supply chain...”
- The proposed addition at §205.504(b)(7) is well-intended, but the vague language regarding the use of “supply chain audits” presents issues. Additionally, it would be helpful to have a definition of “credible evidence.”
- The proposed rule requires certifiers to develop risk-assessment criteria to determine which operations, products, and supply chains are vulnerable to fraud or mishandling. OTCO is supportive of this approach, which would allow individual certifiers to identify criteria that are specific to the types of operations they certify, as opposed to a more restrictive and less effective “one size fits all” method. However, the proposed rule language does not define the term “high risk” or guide certifiers on what criteria to use to identify high-risk operations and products. Additional suggestions include:



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- “High risk” should be defined to ensure universal interpretation of this term, and to facilitate the development of criteria to guide certifiers in fulfilling requirements to perform both supply chain audits (proposed addition at §205.501(a)(21)), as well as unannounced inspections (proposed addition at §205.403(b)(1)).
- OTCO encourages the NOP to develop an accompanying guidance document for the NOP Handbook to address these points and suggests referring to the ACA best practices on [verifying traceability in the supply chain](#) and [risk assessment](#).
- Additionally, we suggest the following revision to the proposed language at §205.504(b)(7):
 - “...A copy of the criteria to identify high-risk operations and products; and procedures to conduct ~~risk-based supply chain~~ traceability audits, as required in §205.501(a)(21); and procedures to report credible evidence of organic fraud to the Administrator.”

Recommendations for timeline and implementation: Considering the current lack of clarity in this section regarding practical implementation, certifiers and operations will need at least two years to implement these requirements if they are published as written.

20. Additional Amendments

OTCO Responses to Questions on Packaged Product Labeling

Question 1: For private-label packaged products, which certified operation(s) should be listed on the retail label (brand name/distributor, contract manufacturer, or both)?

- The certified brand owner should be the entity listed on the label; they're responsible for the product. It would also be acceptable to have both the brand owner and the manufacturer/co-packer listed, although listing the manufacturer/co-packer should not be mandatory.
 - Note that it is unclear in the proposed regulatory text that brand owners are required to be certified. On page 81 of the proposed rule, it states the NOP expects brand owners to be certified. We request that the NOP explicitly call this out if this is the intent.
 - If brand owners are required to be certified, then it should not be necessary to list the manufacturer or co-packer information or their certifier on the label.



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- Brand owners will be able to protect confidential business information on the label by not listing co-packer information. Additionally, they will not need multiple versions of the same label if they work with several co-packers (who may have different certifiers). Of course, while some brand owners may have reasons to feature this information, it should not be a requirement to verify organic compliance.
- The brand owner's certifier should have sufficient information from the brand owner's organic system plan to track a product back to the manufacturer or co-packer to address concerns.
- The NOP should also look to FDA labeling requirements for the identification of product manufacturing location(s). NOP requirements should align and not exceed the FDA.

Question 2: Which certifying agent(s) should be listed?

- The certifier of the brand owner should be listed. If the manufacturer or co-packer information is included on the label, their certifier should also be listed.

Question 3: Should the certifying agent listed on a label always be the certifying agent of the certified operation listed on the label (i.e., should the certifying agent match the operation)?

- Yes. Listing only the brand owner of a product and the certifier of their manufacturer or co-packer could be incredibly confusing.

Question 4: Should listing contract manufacturers on labels be mandatory? Should it be optional?

- Optional. See the comments above.

OTCO Responses to Questions on Expiration of Certification

Question 1: How might annual expiration of certification improve organic integrity?

- OTCO does not benefit from adding expiration dates to organic certificates and does not support their addition.



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- Likewise, annual expiration of certification would likely lead to a significant administrative burden for certifiers and operators. It would also raise questions about the certifiability of land, livestock, or products that undergo a lapse in certification due to administrative expiration.

OTCO Concerns, Considerations and Recommendations on Fees to AMS and Oversight of Certifying Agents' Fees

- While OTCO is in strong support for robust funding for the NOP to support the organic industry, particularly in compliance and enforcement activities, we disagree that accreditation fees should be a primary source for that funding.
 - The NOP is a federal program under USDA, and most funding should come from congressional appropriations for USDA.
 - Increasing accreditation fees as a mechanism to provide funding for NOP compliance and enforcement activities raises several key concerns.
 - Any additional increase in accreditation fees will be passed on to certified operations. Higher certification costs would result for the organic sector, an increase that would be difficult to absorb for many medium and small scale operations. Many would be forced out of certification. This creates inequitable access to a Federal program and likely harms the public image of organic agriculture.
 - Certifiers are on the front lines to perform investigation and sampling work. Yet this proposal would increase our accreditation costs without providing financial support for this work. If there was an increase in fees, would the NOP assume responsibility for more compliance and enforcement work? At a glance, this seems unlikely since, in many cases, certifiers are well-suited to perform investigations.
 - OTCO would like to see an increase in local testing and enforcement, supported by various state fees and funding sources. We believe it could be more effective and efficient and not require an increase in NOP federal accreditation fees.



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Conclusion

In summary, we believe that the Strengthening Organic Enforcement (SOE) Proposed Rule is a critical leap forward to address concerns of fraud, inconsistent oversight, and improving organic products' integrity.

We urge the USDA NOP to align its good intentions to the proposed regulatory text. Overall, our comments reflect issues with vague language or omission of text that justifies actionable authority. Additionally, we encourage dropping administrative burden wherever possible, in particular for operators and certifiers. Increases to paperwork don't directly translate to better traceability or transparency; our comments indicate opportunities to take sensible steps that prevent fraud while making the certification audit process easier to implement. Lastly, we've provided recommendations to consider the unintended consequences of the proposed changes, particularly around equity and accessibility. Safeguarding organic integrity can and should not disenfranchise existing or newcomers to the marketplace. Promoting and implementing a robust and enforceable oversight culture should demonstrate that investing in organic growth is worthwhile. Our goal is to grow the sector while cultivating an unshakeable trust among organic supply chain participants.

Without question, closing loopholes, creating consistency among certifiers, correcting vague language, and increasing fraud prevention collaboration are urgent and overdue for the organic sector. OTCO prioritizes oversight and enforcement as the foundation of our work, investing in developing systems, controls, and policies to ensure certified organic businesses and products' unquestionable integrity.

We're excited to see the USDA NOP consider our comments and perspective from our four decades of organic commitment. OTCO urges quick action to approve SOE, make it official, and put in place sensible timelines so implementation can begin.

OTCO looks forward to continuing its work as a part of the organic movement to build a brighter and more secure food future.

Respectfully submitted,
Oregon Tilth

Oregon Tilth is a leading certifier, educator and advocate for organic agriculture and products since 1974. Our mission to make our food system and agriculture biologically sound and socially equitable requires us to find practical ways to tackle big challenges. We advance this mission to balance the needs of people and planet through focus on core areas of certification, conservation, policy and the marketplace.