

Date: October 5, 2020

Docket: AMS-NOP-17-0065

Re: Strengthening Organic Enforcement Proposed Rule – On-Site (Unannounced) Inspections

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

This comment addresses Section #4: On-site Inspections

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

- OTA supports mandatory unannounced inspections of a minimum of 5 percent of the operations it certifies.
- OTA recommends that certifiers have procedures for identifying high-risk operations and products to conduct risk-based unannounced inspections beyond the 5% minimum, as needed, and in response to complaints and investigations.
- OTA supports the requirement to only certify operations in areas where the certifier is able to conduct unannounced inspections.
- OTA recommends updating Guidance 2609 to further explain expectations around unannounced inspections.
- OTA supports the proposed requirement for certifying agents to conduct “trace-back” and “mass-balance” audits during inspections.
- OTA recommends including reference, in the regulation, to the common terms “trace-back audits” and “mass-balance audits.”
- OTA recommends that the meaning of the term ‘*source*’ as used in the requirement for supply chain traceability audits be clarified.
- OTA recommends adding as a new term and defining ‘*supply chain traceability*’ in the organic regulations.
- OTA supports the proposal that all requirements in this section be implemented within one year after the publication of the final rule.

OTA's Positions and Recommendations

Unannounced Inspections

- **§ 205.403(b): OTA supports mandatory unannounced inspections.** Although unannounced inspections are standard practice, we strongly support the proposal that will codify the practice and require a minimum number of unannounced inspections be conducted annually. Unannounced inspections are a critical enforcement tool. The cost of unannounced inspections should be factored into the certifier's fee structure.
- **§ 205.403(b)(1): OTA supports unannounced inspections of a minimum of 5 percent of the operations it certifies.** However, in addition, certifiers must have criteria for identifying high-risk operations and agricultural products to conduct risk-based unannounced inspections beyond the 5% minimum, as needed, and in response to complaints and investigations. Such a requirement would incorporate a risk-based approach to deciding when it is appropriate to conduct unannounced inspections above and beyond the 5% minimum and it would be consistent with the proposed requirement for Supply Chain Traceability, under § 205.504(b)(7), whereas certifiers must have a copy of the criteria to identify high-risk operations and products. We expect the criteria would be similar and could serve both aspects of the rule. *(See also our comments on Grower Group Operations)*
 - ➔ **Recommendation:** OTA recommends that certifiers be required to have criteria for identifying high-risk operations and agricultural products to conduct risk-based unannounced inspections beyond the 5% minimum, as needed, and in response to complaints and investigations. *See OTA's requested revision in Table 4*

§ 205.403(b)(2): OTA supports the requirement to only certify operations in areas where the certifier is able to conduct unannounced inspections. OTA strongly agrees. Unannounced inspections are a critical enforcement tool and being able to utilize this tool on any certified operation, regardless of where the operation is located, should be a basic and fundamental requirement of the organic regulations. In the preamble, NOP explains that certifying agents would be expected to “describe the areas where they operate in written materials they provide to both applicants and certified operations, and review the locations of all operations during the application review or annual review.” OTA agrees. However, it will be important that this expectation is communicated either in the Rule itself or in Guidance. In this case, OTA supports the use of Guidance.

- ➔ **Recommendation for Updated Guidance:** OTA recommends that NOP 2609 (Unannounced Inspections) be updated concurrently with this final rule to include the following expectation as expressed in the preamble:

- “To ensure consistency, transparency, and accountability, certifying agents would be expected to describe the areas where they operate in the written materials they provide to both applicants and certified operations, and review the locations of all operations during their application review or annual review.”
See OTA’s requested revision in Table 4

Supply chain traceability and mass balance audits

- **§§ 205.403(d)(4) and 205.403(d)(5): OTA strongly supports the proposed requirement for certifying agents to conduct “trace-back” and “mass-balance” audits during inspections.** NOP is proposing that the on-site inspection of an operation must verify that: 1) sufficient quantities of organic products and ingredients are produced or purchased to account for organic product sold or transported; and that 2) organic products and ingredients are traceable by the operation from the time of production or purchase to sale or transport; and that certifying agents can verify traceability back to the source per §205.501(a)(21). OTA strongly agrees. It would be helpful, however, if the regulatory text specifically referenced “trace-back audits” and “mass-balance audits” as they are referred to in the preamble. It will be easier for both certified operations and certifying agents to quickly and easily identify and understand these new requirements if the common terminology is used. OTA notes that the proposed regulations for Grower Groups, at §205.400(g), specifically reference “mass-balance audits.”

➔ **Recommendation:** OTA recommends revising §§ 205.403(d)(4) and (d)(5) to include reference to “trace-back audits” and “mass-balance audits,” respectively. *See OTA’s requested revision in Table 4*

Supply chain audits, both “trace-back” audits and “mass-balance” audits, are effective verification tools and they are fundamental to organic fraud prevention. A regulatory requirement to conduct such audits is important and it is needed to ensure that NOP can take appropriate action against certifying agents that are not conducting adequate audits during inspections. To ensure effective implementation of an entire supply chain traceability audit, as proposed at § 205.501(a)(21), there must be full participation from all NOP accredited certifying agents around the globe. Everyone must commit to working together and to sharing information in a timely manner. OTA believes that additional NOP support will be needed, including mandatory training and Guidance for all NOP accredited certifiers, domestic and international.

- **§ 205.403(d)(5): OTA recommends that the meaning of the term “source” in reference to traceability audits be clarified.** This proposal requires certifying agents to verify traceability back to the “source.” OTA agrees with this requirement. However, it is unclear in the proposed rule itself what is meant by the term “source.” The preamble clarifies this term to mean “farm,” or the source at “any step in the supply chain.” To improve the clarity of the proposed requirement, we recommend a minor revision that will capture this explanation.

➔ **Recommendation:** OTA recommends a revision at § 205.403(d)(5) to clarify meaning of the term “source” as it is explained in the preamble of this proposed rule. We recommend inserting the clause “at any step in the supply chain” to clarify that

certifying agents may verify traceability back to the source, at any step in the supply chain. We also recommend defining the term ‘*supply chain traceability*’ in the organic regulations. **See OTA’s requested revision in Table 4**

- **OTA recommends adding the term and definition for “supply chain traceability” to the organic regulations.** In the preamble, NOP explains the terminology and objectives of this proposed rule. In addressing terminology, NOP explains that four concepts are used throughout this proposed rule and they are integral to the purpose of this proposed rule. Those concepts are: 1) organic integrity; 2) organic fraud; 3) audit trails; and 4) supply chain traceability. NOP explains each concept upfront to assist reader understanding. Given the importance of these terms and concepts and to improve the clarity of this proposed rule, OTA strongly believes that all four terms should be defined in the organic regulations. Currently, the organic regulations define *audit trail* and NOP is proposing the term ‘*organic fraud*’ be added and defined. OTA requests that ‘*organic integrity*’ and ‘*supply chain traceability*’ be added and defined as well.

➔ **Recommendation:** To further clarify the term ‘source’ as well as the proposed requirement that certifying agents conduct trace-back or supply chain traceability audits, OTA recommends that the term ‘*supply chain traceability*’ be added as a new term to the organic regulations. We recommend using the definition provided in the preamble:

- *Supply Chain Traceability.* The ability to identify and track a product (including its location, history, and organic nature) along its entire supply chain, from source to consumption, and/or “backwards” from consumption to source. A supply chain audit assesses supply chain traceability for specific products, verifying whether records show all movement, transactions, custody, and activities involving the products.

See OTA’s requested revision in Table 4

Table 4: OTA’s Requested Revisions to the Proposed Rule and Recommendations for Guidance

Action & Section	Proposed Rule Text	Revisions and/or Guidance needed to implement OTA’s Positions and improve the quality, clarity and utility of the Proposed Rule
<p>Redesignate 205.403(b) as 205.403(c) and</p> <p>Add new paragraph 205.403(b)</p>	<p>Unannounced inspections. (1) A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number. (2) Certifying agents must be able to conduct unannounced inspections of any operation it certifies and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections.</p>	<p>Support with a revision: OTA supports 5% as a minimum. However, in addition, certifiers must have criteria for identifying high-risk operations and agricultural products to conduct risk-based unannounced inspections beyond the 5% minimum as needed and in response to complaints and investigations.</p> <p>Updated Guidance (NOP 2609) Requested: The preamble explains that certifiers are expected to describe the areas where they operate in written materials they provide to both applicants and certified operations, and review the locations of all operations during the application review or annual review. OTA agrees; however, it will be important that this expectation is communicated either in the Rule or in Guidance. In this case, OTA supports the use of Guidance and recommends that NOP 2609 (Unannounced Inspections) be updated concurrently with this final rule and revised to include the following:</p> <p>“To ensure consistency, transparency, and accountability, certifying agents would be expected to describe the areas where they operate in the written materials they provide to both applicants and certified operations, and review the locations of all operations during their application review or annual review.”</p>
<p>OTA Requested Revision: 205.403(b - Unannounced inspections. (1) A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number. <u>(2) A certifying agent must have criteria for identifying high-risk operations and agricultural products to conduct risk-based unannounced inspections beyond the 5% minimum as needed and in response to complaints and investigations.</u> (2) (3) Certifying agents must be able to conduct unannounced inspections of any operation it certifies and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections.</p>		
<p>Redesignate 204.403(d)(1)</p>	<p>Verification of information. The on-site inspection of an operation must verify:</p>	<p>Technical correction; no concerns.</p>

<p>– (3); correct 205.200 to 205.201</p>	<p>(1) The operation’s compliance or capability to comply with the Act and the regulations in this part; That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200 205.201, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.</p>	
<p>OTA Requested Revision: None</p>		
<p>Add 205.403(d)(4)</p>	<p>That sufficient quantities of organic product and ingredients are produced or purchased to account for organic product sold or transported; and</p>	<p>Revision needed: OTA recommends revising §§ 205.403(d)(4) to include reference to “mass-balance audits.” It will be easier for both certified operations and certifying agents to quickly and easily identify and understand this new requirement if the common terminology is used.</p>
<p>OTA Requested Revision: That sufficient quantities of organic product and ingredients are produced or purchased to account for organic product sold or transported (“mass-balance audits”); and</p>		
<p>Add 205.403(d)(5)</p>	<p>That organic products and ingredients are traceable by the operation from the time of production or purchase to sale or transport; and that certifying agents can verify traceability back to the source per §205.501(a)(21) (“trace-back audits”).</p>	<p>Revision needed: OTA recommends revising §§ 205.403(d)(5) to include reference to “trace-back audits.” It will be easier for both certified operations and certifying agents to quickly and easily identify and understand this new requirement if the common terminology is used.</p> <p>Revision needed: OTA recommends that the meaning of the term “source” in reference to traceability audits be clarified. The preamble clarifies this term to mean “farm,” or the source at “any step in the supply chain.” To improve the clarity of the proposed requirement, we recommend a minor revision that will capture the explanation provided in the preamble.</p>

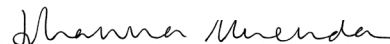
		<p>Request to add a NEW term and definition to the organic regulations: To further clarify the term ‘source’ and the requirement that certifying agents conduct supply chain traceability audits, OTA recommends that the term, ‘<i>supply chain traceability</i>’ be added as a new term to the organic regulations. We recommend using the definition provided in the preamble. See below.</p> <p>Guidance, Training and Support Requested: For full supply chain audits to be feasible, there must be complete participation from all NOP accredited certifying agents around the globe. Everyone must commit to working together and sharing information in a timely manner. OTA believes that strong NOP support and monitoring will be needed, including training and Guidance.</p>
<p>OTA Requested Revision: § 205.403(d) 5) That organic products and ingredients are traceable by the operation from the time of production or purchase to sale or transport; and that certifying agents can verify traceability back to the source <u>at any step in the supply chain</u> per §205.501(a)(21).</p> <p>OTA Requested Revision (NEW term – supply chain traceability): Add a new term to §205.2 - <i>Supply Chain Traceability</i>. The ability to identify and track a product (including its location, history, and organic nature) along its entire supply chain, from source to consumption, and/or “backwards “from consumption to source. A supply chain audit assesses supply chain traceability for specific products, verifying whether records show all movement, transactions, custody, and activities involving the products.</p>		

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

Respectfully submitted,



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