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Attention: Strengthening Organic Enforcement Final Rule

Implementation Date: March 19, 2024

February 2023

Dear PCO Certified Operators, Members, and Inspectors,

The United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) published a final rule to amend the USDA organic regulations to strengthen oversight and enforcement of the production, handling and sale of organic agricultural products.

- Full text of the **Strengthening Organic Enforcement (SOE)** final rule can be found at <https://www.federalregister.gov/documents/2023/01/19/2023-00702/national-organic-program-nop-strengthening-organic-enforcement> or contact the PCO office for a hard copy.
- Visit the NOP's Strengthening Organic Enforcement webpage at <https://www.ams.usda.gov/rules-regulations/strengthening-organic-enforcement> for additional resources, such as a side-by-side comparison of the current regulations and the final rule.
- **The SOE final rule was published on January 19, 2023 with an implementation date of March 19, 2024. This means all operations in the supply chain must be in compliance by March 19, 2024 at the latest.**

List of Topics Covered in the SOE Final Rule (outlined in more detail below):

1. Applicability and Exemptions from Certification.
2. Imports to the United States.
3. Labeling of Nonretail Containers.
4. On-Site Inspections.
5. Certificates of Organic Operation.
6. Continuation of Certification.
7. Paperwork Submissions to the Administrator.
8. Personnel Training and Qualifications.
9. Oversight of Certification Activities.
10. Accepting Foreign Conformity Assessment Systems.
11. Compliance and Noncompliance Procedures.
12. Mediation.
13. Adverse Action Appeal Process.
14. Producer Group Operations.
15. Calculating the Percentage of Organically Produced Ingredients.
16. Supply Chain Traceability and Organic Fraud Prevention.
17. Technical Corrections. (not outlined in this summary)

Who will be impacted by this Final Rule?

If you are engaged in the organic industry, you will likely be affected by this final rule. Affected entities may include but are not limited to:

- Organic supply chain participants that are not currently certified under the USDA organic regulations, including but not limited to brokers, traders, exporters and importers of organic products
 - All producers, processors and handlers of organic products that are currently certified organic under the USDA organic regulations;
 - USDA-accredited certifying agents, inspectors, and reviewers
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SOE is the largest regulatory change to the organic regulations since the final rule was first published in 2002. Throughout the remainder of this year PCO will be digging into the details, revising forms and policies. PCO will inform clients along the way what steps they need to take to come into compliance. PCO is here to assist you in ensuring operations implement the applicable parts of the new rule by the implementation due date.

In the meantime, it is recommended to start with the following:

- Review your supply chains
 - Who do you purchase organic ingredients, livestock feed, etc from? Are they certified? Does the physical product flow through any uncertified operations from the last certified operation until it gets to you? *If there are uncertified entities in your supply chain, review the Section 1 below to determine if those uncertified entities will need to become certified or will remain exempt based on their activities.*
 - If certification is required PCO is here to help. Inform these entities to contact the PCO Client Service Team at cst@paorganic.org or 814-422-0251.
- Start thinking about your fraud prevention plan
 - The inclusion of how an operation prevents and monitors potential fraud will be required to be added to your OSP.
 - The new rule specifically states that it is the responsibility of the certified operation to ensure ingredients, livestock feed, livestock for slaughter, etc. are indeed organic.
- Review your Nonretail labels
 - If you use nonretail containers (e.g. containers used to ship or store organic products), the new rule requires the organic identification on the label.
- Contact your Certification Specialist
 - PCO staff are a wealth of information. Reach out to your Certification Specialist early to discuss if there are other parts of the rule besides those listed above that will impact your operation.

Please contact me if you have any questions or feedback on what PCO can do to aid your operation in a successful implementation of these new regulations (e.g. webinar, specific resource documents, etc.).

Best,



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Summary of Topics Covered:

1. Applicability and Exemptions from Certification

The USDA organic regulations were amended at § 205.2, 205.100-101 and 205.310 to clarify the applicability of the regulations and limit the types of operations excluded from organic certification.

- Revises the definitions of Handle, Handler, Handling operation, and Retail establishment and who must be certified.
 - The examples provided for in the definition of “Handle” is not an exhaustive list.
 - These revisions will require organic certification for operations that sell, process or package agricultural products, including but not limited to trading, facilitating trade, importing, exporting, combining, aggregating, culling, conditioning, treating, packing, containerizing, repackaging, labeling, storing, receiving or loading.
- Reduces the number of uncertified entities in the organic supply chain.
- Clarifies that most operations in the middle of the supply chain must be certified.
- Describes the “low-risk” activities that do not require organic certification and are therefore exempt:
 - Operations grossing less than \$5000 annually;
 - Retail establishments that do not process organic products;
 - Retail establishments that process at the point of final sale (e.g. at the same location);
 - operations handling products containing less than 70% organic ingredients;
 - Handling operations that only receive, store and/or prepare for shipment but do not otherwise handle organic products (e.g. storage facilities or warehouses);
 - Handling operations that only buy, sell, receive, store and/or prepare for shipment but do not otherwise handle, organic products already labeled for retail sale (e.g. distributors)
 - Customs brokers the only conduct customs business
 - Operations that only arrange for the shipping, storing, transport or movement of organic products (e.g. logistics brokers)
- Streamlines and clarifies the regulatory requirements exempt operations must follow.

2. Imports to the United States

The USDA organic regulations were amended to add a new section, § 205.273, requiring the use of the NOP Import Certificate for all imported products.

- Adds definitions for Organic exporter and Organic importer.
- Adds new section § 205.273 Imports to the United States.
- Includes new requirement for NOP Import Certificates for ALL imports. Currently, NOP Import Certificates are only required for certain equivalency arrangements.
- NOP Import Certificate must be generated in the Organic Integrity Database (OID) by the certifier of the organic exporter.
- Certifiers may issue NOP Import Certificates for an individual shipment or for multiple shipments across a defined timeframe and volume. Certifiers must have a documented organic control system for intaking and reviewing the validity of an NOP Import Certificate request.
- Data from the NOP Import Certificate must be entered into the US Customs and Border Protection’s (CBP) Automated Commercial Environment system (ACE) by the organic importer or customs broker.
- NOP will access CBP-ACE’s data on quantity and origin of imported organic products and validate against certifier-approved data in the Organic Integrity Database to monitor and identify indicators of potential fraud.

- Clarifies that the organic exporter and organic importer are fully accountable for the compliance of the imported product(s), including the importer having a documented organic control system to ensure that imported products correspond with the amount of product listed on the NOP Import Certificate and that the products didn't have contact with prohibited substances or ionizing radiation.

3. Labeling of Nonretail Containers

The USDA organic regulations were amended at § 205.307 to add new requirements for the labeling of nonretail containers.

- Requires that nonretail container (e.g. containers used to ship or store organic products) labels include organic identification and information that links the container to the audit trail documentation.
- Audit trail documentation associated with a nonretail container must identify the last certified operation that handled the product, and be sufficient to determine the source, transfer of ownership, and transportation of the product.
 - There is a limited exception to organic identification for non-retail containers of retail-labeled products when the organic identification of the retail label is visible.

4. On-site Inspections (Unannounced and Audit Requirements)

The USDA organic regulations were amended at § 205.403(b) to address the requirements for unannounced on-site inspections. Additionally, clarification was provided regarding requirements for audits conducted during the on-site inspection.

- Requires that ACAs must, on an annual basis, conduct unannounced inspections of a minimum of 5% of the operations it certifies, rounded up to the nearest whole number, without advanced notice (no more than 4 hours prior to inspector arriving on-site).
- Requests that an ACA must be able to conduct unannounced inspection of any operation it certifies.
- Requires that ACAs must not accept applications or continue certification with operations located in areas where are unable to conduct unannounced inspections.
- Requires that ACAs must verify, at on-site inspections, that:
 - The quantity of organic product sold does not exceed the quantity of organic product that is produced or purchased (aka Mass-Balance).
 - Organic products and organic ingredients are traceable from the time of production or purchase to the time of sale or movement of product from the operation and vice versa (aka Trace-Back). Verification is required back to the last certified operation.

5. Certificates of Organic Operation

The USDA organic regulations were amended at § 205.404 to require certifying agents to issue standardized certificates of organic operation generated from USDA's Organic Integrity Database (OID), and to keep accurate and current certified operation data in OID.

- Adds definition for Organic Integrity Database (OID).
- Requires that ACA generate organic certificate from OID.
- Adds section that allows ACAs to issue their own product addendum and specifies what must be included, such as a link to the operations profile in OID and the operation's unique OID identification number.

6. Continuation of Certification

The USDA organic regulations were amended at § 205.406 to clarify the annual update requirements for certified operations and to clarify that certifying agents must conduct annual inspections of operations it certifies once per calendar year.

- Requires that operations submit revisions to their Organic System Plans (OSP) annually, rather than submitting the OSP in its entirety every year.
- Requires that operations be inspected at least once per calendar year.
- Removes requirement for operations to provide an update on the correction of minor noncompliances with their annual update.

7. Paperwork Submissions to the Administrator

The USDA organic regulations were amended at §§ 205.405 and 205.501 to reduce the paperwork burden of accredited certifying agents as well as require certifying agents to maintain current and accurate data in OID on all operations which they certify.

- Eliminates the need to provide notices of approval or denial of certification to the Administrator following the issuance of a notice of non-compliance to an applicant for certification.
- Removes annual requirement for ACA to submit by Jan 2 an annual list of operations certified during the preceding year.
- Requires that ACAs maintain current and accurate data in OID for each operation it certifies, including acreage data (although acreage data will not be publicly available).
- Requires certifiers to update OID within 72 hours of an operation's suspension, revocation or surrender of certification.

8. Personnel Training and Qualifications

The USDA organic regulations were amended at § 205.501 to specify minimum requirements for knowledge, skills, training, and experience that inspectors and certification reviewers are required to have in order to work for a certifier.

- Adds definition for Certification review.
- Clarifies that ACAs must continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and reviewers.
- Specifies minimum qualifications and training requirements for inspectors and certification review staff:
 - Certification review staff and inspectors must demonstrate successful completion of 10 hours plus 5 hours per additional scope of training annually.
 - Certifying agents must demonstrate that Certification review staff and inspectors have a minimum of 1 year relevant qualifying experience; if less than 1 year experience then must have at least 50 hours of training.
- Certifiers must conduct a witness inspection of every 3 years. Inspectors with less than 3 years' experience must have witness inspection every year.

9. Oversight of Certification Activities

The USDA organic regulations were amended at §§ 205.2, 205.501, and 205.665 of the USDA organic regulations to strengthen oversight and enforcement of certifying agents and their activities.

- Adds definitions for Certification activity and Certification office.
- Clarifies that NOP oversight extends to the activities of any person performing work on behalf of a certifier, including subcontractors and satellite offices.
- Allows NOP to send notices of noncompliance to a certifier, based upon the certification activities at a specific office and in specific countries.
- Requires that certifiers notify NOP within 90 days of the opening of any office performing certification activities.

10. Accepting Foreign Conformity Assessment Systems

The USDA organic regulations were amended to add a new section, § 205.511, on accepting foreign conformity assessment systems that oversee organic production in foreign countries.

- Adds definitions of Conformity assessment system and Technical requirements.
- Describes AMS's authority under OFPA to make equivalence determinations.
- Describes the process of initiating a request for equivalence used by AMS and other foreign governments.
- Clarifies that AMS will determine the scope of each equivalence determination.
- Lays out the current process that AMS and other foreign governments use to monitor equivalence determinations that have been made.
- Describes the conditions under which AMS may terminate equivalence determinations.

11. Compliance and Noncompliance Procedure

The USDA organic regulations were amended at § 205.660 to add a new paragraph (c), which clarifies the scope of NOP Program Manager's enforcement authority. Additionally, §§ 205.100 and 205.662 were amended to clarify that a person who is responsibly connected to an operation that violates OFPA or the USDA organic regulations may be subject to a suspension of certification (if the responsibly connected person is certified), or civil penalties or criminal charges and/or may be ineligible to receive certification.

- Clarifies that the NOP may take an enforcement action against any violator of OFPA, regardless of certification status.
- Clarifies that a person responsibly connected to a violator of OFPA may be complicit in the OFPA violation(s) because of that association, and may be ineligible to receive certification.
- Clarifies that a person responsibly connected to a person who knowingly sells non-organic product as organic or makes a false statement to authorities about compliance with OFPA, may be subject to fines and/or imprisonment (18 U.S.C. 1001).
- Requires certifiers to update the status of an operation that has been suspended or revoked, or that has surrendered its certification in OID within 3 business days.

12. Mediation

The USDA organic regulations were amended at § 205.663 to improve the general readability of this section and to more clearly explain how mediation may be used in noncompliance procedures.

- Requires certifiers to submit their decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions with its administrative policies and procedures.
- Permits certifiers and certified operations or applicants to engage in mediation without a third-party mediator, provided that all parties agree upon the person who will serve as the mediator.

- Clarifies that the Secretary does not require, manage, or otherwise participate in mediation between operations and certifiers or State organic programs, and is not involved in determining the outcome of a mediation, notwithstanding his or her authority to review dispute resolution terms for conformity with OFPA and the USDA organic regulations.

13. Adverse Action Appeal Process

The USDA organic regulations were amended at §§ 205.680 and 205.681 to clarify parts of the adverse action appeals process.

- Adds definitions of Adverse action.
- Clarifies that any person who believes they are adversely affected by an adverse action of the NOP's Program Manager, of a state organic program, or of a certifying program, may appeal such decision.
- Clarifies that any person who believes they are adversely affected by an adverse action of a state organic program or of a certifying program, may request mediation.
- Clarifies that if the Administrator or State organic program denies an appeal of a denial of certification or proposed suspension or revocation, a formal administrative proceeding *may* be initiated to deny, suspend, or revoke the certification.
- Stipulates that all appeals must comply with the procedural requirements in §205.681(c) and (d), including filing timelines and how to submit the appeal.

14. Producer Group Operations (previously referred to as "Grower Groups")

The USDA organic regulations were amended at §§ 205.201, 205.400, and 205.403 to clarify regulatory requirements for crop and/or wild crop production and handling operations with multiple member growers that are certified as a single producer.

- Adds definitions for Producer group member, Producer group operation, Producer group production unit, and Internal control system.
- Adds specific eligibility criteria to qualify for certification as a group such as members are organized into production units, use common production practices and inputs, and use centralized collection, processing, distribution, marketing systems and facilities.
- Requires that groups have an Internal Control System (ICS) to oversee and ensure compliance of group members with organic regulations, conduct internal inspections of group members, maintain traceability records, and other activities related to the review, monitoring, surveillance, training, inspection, auditing, and sanctions of group members and the producer group operation.
- Adds specific requirements for the inspection of producer groups.

15. Calculating the Percentage of Organically Produced Ingredients

The USDA organic regulations were amended at § 205.302, which describes how to calculate the organic content of multi-ingredient products.

- Clarifies that when calculating organic content in multi-ingredient products, the weight or volume of the organic ingredients (excluding water and salt) should be divided by the total weight (excluding water and salt) of all ingredients rather than dividing by the total weight or volume of the product.
- Clarifies that the percentage of organic ingredients calculation must be calculated from the ingredients at formulation (i.e. before processing such as baking or cooking).

16. Supply Chain Traceability and Organic Fraud Prevention

The USDA organic regulations were amended at §§ 205.103, 205.201, 205.501, and 205.504 to require certified operations and certifying agents to develop improved recordkeeping, organic fraud prevention, and trace-back audit processes.

- Adds definitions of Organic fraud and Supply chain traceability audit.
- Requires organic operations to:
 - Maintain audit trail documentation to facilitate supply chain traceability from the time of purchase or acquisition through production to sale or transport and be traceable back to the last certified operation, including identification of products as organic on documents.
 - Describe in their organic system plan the monitoring practices and procedures used to prevent organic fraud and verify suppliers and organic product status.
- Certifiers must share information with other certifiers to verify supply chains and conduct investigations and have procedures for (1) identifying high-risk operations and agricultural products to conduct risk-based supply chain audits and for (2) reporting credible evidence of organic fraud to the USDA.