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NOP Proposed Rule: Strengthening Organic Enforcement

Comment deadline is October 5, 2020

August 11, 2020

Dear PCO Certified Operators, Members, and Inspectors,

The United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) proposes 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)** proposed rule can be found at www.govinfo.gov/content/pkg/FR-2020-08-05/pdf/2020-14581.pdf, or contact the PCO office for a hard copy. Visit the Strengthening Organic Enforcement webpage at www.ams.usda.gov/rules-regulations/strengthening-organic-enforcement-proposed-rule for additional resources, such as a side-by-side comparison of the current regulations and the proposed rule. The SOE proposed rule was published on August 5, 2020, with a 60-day comment period. The comment deadline is October 5, 2020, at 11:59pm ET. See below for instructions to submit comments. AMS will consider all comments submitted when deciding if this proposed rule should be finalized or not, or if it should be changed in any way.

List of Topics Covered in the SOE Proposed 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—General.
 12. Noncompliance Procedure for Certified Operations.
 13. Mediation.
 14. Adverse Action Appeal Process—General.
 15. Adverse Action Appeal Process—Appeals.
 16. Grower Group Operations.
 17. Calculating the Percentage of Organically Produced Ingredients.
 18. Supply Chain Traceability and Organic Fraud Prevention.
 19. Technical Corrections.
 20. Additional amendments considered but not included in this Proposed Rule
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Who will be impacted by this Proposed Rule?

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

- Brokers, traders, and importers of organic products that are not currently certified under the USDA organic regulations (AMS estimates that 961 domestic, and an equal number of foreign-based, operations would need to become certified as a result of this rule);
- Individuals or business entities that are considering organic certification;
- Existing production and handling operations that are currently certified organic under the USDA organic regulations;
- Operations that use non-retail containers for shipping or storing organic products;
- Retailers that sell organic products;
- Storage facilities, grain elevators or ports that process or alter organic products in anyway;
- Operations that receive or review organic certificates to verify compliance with USDA organic regulations;
- USDA-accredited certifying agents, inspectors, and reviewers;
- Operations that import organic products into the United States; and/or
- Operations that export organic products to the United States.

Summary of Topics Covered:

1. Applicability and Exemptions from Certification

AMS proposes amending §§ 205.5 and 205.100-101 of the USDA organic regulations to clarify the applicability of the regulations and limit the types of operations excluded from organic certification.

- Revises definitions on Handle, Handler, Handling Operation
 - These revisions will require organic certification for operations that sell, process or package agricultural products, including but not limited to trading, facilitating trade, brokering, etc.
- Renames and revises definition from Retail Food Establishment to Retail Operation, which now includes current modes of direct to consumer sales that commonly occur in the modern marketplace (e.g. online sales)
- Continues the exemption from certification for operations grossing less than \$5000 annually, certain retail operations (must not process) and operations handling products containing less than 70% organic ingredients
- Includes exemption from certification for operations that only store, receive, load and/or transport provided that they do not process or alter the product(s)
- Clarifies organic compliance and recordkeeping requirements of exemption operations

2. Imports to the United States

AMS proposes amending the USDA organic regulations by adding a new section (205.273) discussing the use of the National Organic Program Import Certificate.

- Adds definitions for Organic Exporter and Organic Importer of Record
- 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:
 - Electronic

- Requested by organic exporter prior to shipment to ACA
- Issued by ACA within 30 calendar days of receipt of shipment
- Uploaded into the US Customs and Border Protection's (CBP) Automated Commercial Environment system (ACE)
- Clarifies that the organic exporter and organic importer of record are fully accountable for the compliance of the imported product(s)

3. Labeling of Nonretail Containers

AMS proposes amending §§ 205.307 to add new requirements for the labeling of nonretail containers.

- Requires that non-retail containers used to ship or store organic products are labeled with two NEW pieces of information in addition to the currently required lot #:
 - a statement identifying the product as organic; and
 - the name of the certifier that certified either the producer of the product, or, if the product is processed, the last handler that processed the product
- Expanded the lot number requirement
- Clarifies that the use of the USDA seal must comply with §205.311
- Note: This would not apply to large non-retail containers. However, information must be evident in documentation associated with and traceable to the container, to ensure that organic integrity is maintained during transport, storage, and handling.

4. On-site Inspections (Unannounced)

AMS proposes adding §205.403(b) to address the requirements for unannounced on-site inspections.

- 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
- 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 inspection, 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)

5. Certificates of Organic Operation

AMS proposes revising §205.404 to require certifying agents to issue standardized certificates of organic operation generated from USDA's Organic Integrity Database (INTEGRITY), and to keep accurate and current certified operation data in INTEGRITY.

- Adds definitions for INTEGRITY
- Requires that ACA generate organic certificate from INTEGRITY
- Adds section that allows ACAs to issue their own product addendum and specifies what must be included

6. Continuation of Certification

AMS proposes amending § 205.406 to clarify the annual update requirements for certified operations and to clarify that certifying agents must conduct annual inspections of certified operations.

- Clarifies the annual update requirements for certified operations
- 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

AMS proposes amending § 205.405 and § 205.501 to reduce the paperwork burden of accredited certifying agents. In addition, AMS is proposing that certifying agents must maintain current data in INTEGRITY 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 INTEGRITY for each operation it certifies, including acreage data

8. Personnel Training and Qualifications

AMS proposes amending § 205.501 to specify minimum qualifications and training requirements for inspectors and persons who perform certification review activities

- 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 persons who perform certification review activities:
 - Certifiers and inspectors must demonstrate successful completion of a minimum of 20 hours of training in topics relevant to inspection
 - Certifying agents must demonstrate that inspectors have a minimum of 1 year of field-based experience related to both the scope and scale of operations they will inspect before assigning inspection responsibilities

9. Oversight of Certification Activities

AMS proposes amending §§ 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 the ACA
- Allows NOP to send notices of noncompliance to an ACA, based upon the certification activities at a specific office and in specific countries
- Requires that ACAs notify NOP within 90 days of the opening of any office performing certification activities

10. Accepting Foreign Conformity Assessment Systems

AMS proposes adding a new section to the USDA organic regulations, § 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 – General

AMS proposes adding new paragraph (c) to § 205.660, to clarify the scope of NOP Program Manager's enforcement authority.

- Clarifies that the NOP may take an enforcement action against any violator of the OFPA, regardless of certification status.

12. Noncompliance Procedure for Certified Operations

AMS proposes amending §§ 205.100 and 205.662 to clarify that a person who is responsibly connected to an operation that violates the 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 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 certifying agents to update (within 3 business days) the status of an operation that has been suspended or revoked, or that has surrendered its certification;

13. Mediation

AMS proposes revising § 205.663 to improve the general readability of this section and to more clearly explain how mediation may be used in noncompliance procedures.

- Requires certifying agents 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 provided in 205.50(b) of the regulations.
- Permits certifying agents 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 certifying agents 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.

14. Adverse Action Appeal Process – General

AMS proposes to revise and clarify parts of the adverse action appeals process in §§ 205.680 and 205.681.

- 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

15. Adverse Action Appeal Process – Appeals

AMS is proposing several changes to § 205.681 to revise and clarify appeal procedures.

- 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

16. Grower Group Operations

AMS proposes amending §§ 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 Grower Group Member, Grower Group Operation, Grower Group Production Unit, and Internal Control System
- Adds new requirements for grower group's OSP, general requirements for grower groups, and requirements for the inspection of grower groups

17. Calculating the Percentage of Organically Produced Ingredients

AMS proposes revising § 205.302, which describes how to calculate the organic content of multi-ingredient products.

- Clarifies that when calculating organic content, 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.

18. Supply Chain Traceability and Organic Fraud Prevention

AMS proposes amending §§ 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 definition of Organic Fraud
- Requires organic operations to:
 - maintain audit trail documentation to facilitate supply chain traceability, 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
- Certifying agents must share information with other certifying agents 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

19. Additional amendments considered but not included in this Proposed Rule

AMS considered, but did not include in the proposed rule, the following topics:

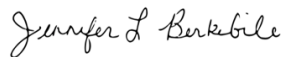
- **Packaged Product Labeling:** Considers terminology that should be used to describe private-labeled organic products as well as a revision to the labeling regulations to specify the certified operation and certifying agent that should be listed on the retail label for private-label packaged products.
- **Expiration of Certification:** Considers an annual expiration of certification (vs. expiration of the certificate) if the operation does not submit fees and update its certificate of operation.
- **Fees to AMS and Oversight of Certifying Agent's Fees:** Considers OFPA and its allowance for NOP to include fees from producers, certifying agents and handlers, and points to the role of AMS to periodically review the fees for accreditation and accreditation services and oversee the NOP fees that certifying agents and others charge for their service. AMS is seeking public comment on how fees in NOP could strengthen testing and enforcement across all stakeholders to ensure that NOP keeps pace with the rapid growth and better serves the industry.

Instructions for Submitting Comments: Comments must be received by 11:59PM ET October 5, 2020, and must reference the docket number AMS-NOP-17-0065. Submit written comments online via www.regulations.gov/document?D=AMS_FRDOC_0001-2099, or by mail to Jennifer Tucker, Deputy Administrator, National Organic Program, USDA-AMS-NOP, 1400 Independence Ave. SW, Room 2642-So., Ag Stop 0268, Washington, DC 20250-0268; (202) 260-9151 (fax).

Alternatively, PCO can submit comments on your behalf. Contact Jen at the PCO office, 814-422-0251, with any comments that you would like us to submit for you, such as your support for the proposed rule or your suggested changes.

Please contact me if you have any questions.

Best,



Jen Berkebile

Materials Program Manager