



USDA-NOP Strengthening Organic Enforcement Proposed Rule SUMMARY OF PROVISIONS

Prepared by the Organic Trade Association, August 2020

Title: Strengthening Organic Enforcement (SOE) Proposed Rule

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Comment Deadline: October 5, 2020

OTA webpage: <https://ota.com/advocacy/critical-issues/organic-oversight-enforcement>

NOP webpage: <https://www.ams.usda.gov/rules-regulations/strengthening-organic-enforcement-proposed-rule>

Introduction

The United States Department of Agriculture's (USDA's) Agricultural Marketing Service (AMS) is updating its regulations to support continued growth of the organic market and improve oversight at critical links in the supply chain. This action is the largest single piece of rulemaking since the implementation of the National Organic Program (NOP) regulations. If implemented, this proposed rule will improve organic integrity across the organic supply chain, and transform the oversight and enforcement of organic production worldwide. The proposed amendments will close gaps in the current regulations to build consistent certification practices to deter and detect organic fraud, and improve transparency and product traceability. In addition, the proposed amendments will assure consumers that organic products meet a robust, consistent standard and reinforce the value of the organic label.

List of Topics Covered and Page Numbers in the Proposed Rule:

1. Applicability and Exemptions from Certification. Pg. 13
2. Imports to the United States. Pg. 22
3. Labeling of Non-retail Containers. Pg. 28
4. On-Site (Unannounced) Inspections. Pg. 30
5. Certificates of Organic Operation (required standardized certificates generated by INTEGRITY). Pg. 33
6. Continuation of Certification. Pg. 37
7. Paperwork Submissions to the Administrator (includes required **data reporting**). Pg. 39
8. Personnel Training and Qualifications. Pg. 40
9. Oversight of Certification Activities (includes a revision to the intro on **accreditation fees**). Pg. 48
10. Accepting Foreign Conformity Assessment Systems. Pg. 50
11. Compliance—General. Pg. 54
12. Non-compliance Procedure for Certified Operations. Pg. 55
13. Mediation. Pg. 56
14. Adverse Action Appeal Process—General. Pg. 59
15. Adverse Action Appeal Process—Appeals. Pg. 61
16. Grower Group Operations. Pg. 63
17. Calculating the Percentage of Organically Produced Ingredients. Pg. 72
18. Supply Chain Traceability and Organic Fraud Prevention. Pg. 74
19. Technical Corrections. Pg. 81
20. Additional amendments considered but not included in this Proposed Rule. Pg.81

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.

Supporting Documents:

- [Proposed Rule \(official publication\) \(pdf\)](#)
- [Proposed Rule \(draft copy\) \(pdf\)](#) – page numbers on previous page are based on this copy
- [Side-by-Side Comparison \(current regulations to proposed rule\) \(pdf\)](#)
- [Fact sheets: Safeguarding Organic Supply Chains \(pdf\)](#)
- [Infographic: Retail Exemption Flowchart \(pdf\)](#)

Summary of Provisions: What will the rule do?

The Organic Trade Association, on behalf of its members, has been in the driver's seat with Congress in the 2018 Farm Bill debate leading up to this historic rulemaking. Several proposed requirements are the outcome of the Organic Trade Association's priorities and successful legislative work in the 2018 Farm Bill. As a result, this proposed rule will strengthen enforcement of the USDA organic regulations through several actions mandated by Congress:

Exemptions from Organic Certification

Reduce the types of uncertified entities in the organic supply chain that operate without USDA -NOP certification and oversight—including importers, brokers, and traders of organic products. This will safeguard organic product integrity and improve traceability.

- The proposal requires organic certification of businesses that buy or sell organic products and/or *negotiation sales* of organic products between buyers and sellers.
- Businesses that may need certification include brokers, traders, importers, grain elevators, ports and storage facilities that are processing or altering products (including repack or packaging).
- Businesses that may continue to be exempt include retail operations and transporters, depending on the type of activity they are engaged in.
- The proposal also clarifies organic compliance requirements for exempt operations.

Import Certificates

Require the use of NOP Import Certificates, or equivalent data, for all organic products entering the United States. This proposed change will expand the use of NOP Import Certificates to all organic products imported into the United States, improving the oversight and traceability of imported organic products.

- Requires the creation and review of NOP Import Certificates for each shipment. An exporter must request an import certificate from their certifier and the certifier must review the request and issue the import certificate.
- The importer must verify that the shipment matches the associated import certificate.
- Data from the import certificate must be uploaded into the U.S. Customs and Border Protection's Automated Commercial Environment (ACE).

Oversight of Certification Activities

Clarify NOP's authority to oversee certification activities, including the authority to act against an agent or office of a certifying agent. Additionally, certifying agents must notify NOP upon opening a new office, which will allow NOP to provide more effective and consistent oversight of certifying agents and their activities.

- Adds the new term *certification activities* to the organic regulations that defines the general activities that are considered essential and subject to oversight;
- Clarifies that NOP oversight extends to the activities of any person performing work on behalf of the certifying agent;
- Adds the new term *certification office* defined as any site or facility where certification activities take place (except for activities that take place at certified operations or other specialized facilities, such as inspection, sampling, and testing);
- Allows NOP to send notices of non-compliance to a certifying agent, based upon the certification activities at a specific certification office and in specific countries;
- Revises the introductory paragraph of §205.640 (fees and other charges for accreditation) by eliminating "for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation." This change is not addressed or explained.
- Requires that certifying agents notify NOP within 90 calendar days of the opening of any office performing certification activities.

Additionally, this proposed rule includes several discretionary actions that work in alignment with the provisions above to further strengthen enforcement of the USDA organic regulations:

Supply Chain Traceability and Organic Fraud Prevention Procedures

Require certified operations and certifying agents to develop improved recordkeeping, organic fraud prevention, and trace-back audit processes. Information sharing between certifying agents and documented organic fraud prevention procedures are also required.

Under the proposal, certified operators would be required to:

- Maintain records that document a product's source and chain of custody across the supply chain;
- Clearly identify products as organic on all records and labels;

- Document the monitoring practices used to prevent fraud and verify suppliers and product. Such procedures and practices are often referred to as “fraud prevention plans.”
 - See OTA’s private sector initiative [“Organic Fraud Prevention Solutions”](#) to receive training on “Developing an Organic Fraud Prevention Plan.”

USDA-accredited certifiers would be required to:

- Describe the procedures they use to identify operations and products at high risk of organic fraud;
- Conduct supply chain audits to verify the origin and chain of custody of high-risk products;
- Share compliance-related information about certified operations with other certifiers.

Labeling of Non-retail Containers

Clarify the labeling of non-retail containers used to ship or store organic products. Requiring additional information on non-retail containers will clearly identify organic products, reduce the mishandling of organic products, and support traceability. This is needed to maximize the linkage between operation certificates and import certificates and the organic product.

- Requires that non-retail containers used to ship or store organic products are labeled with two additional pieces of information (in addition to the currently required lot #): (1) a statement identifying the product as organic; and (2) the name of the certifying agent that certified either the producer of the product, or, if the product is processed, the last handler that processed the product.
- Does 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.

Data Reporting (Paperwork Submissions to the Administrator)

Reduces paperwork burden and specifies that certifying agents must maintain current data in INTEGRITY (USDA-NOP Integrity Database) on all operations that they certify. The availability of accurate and current information about certified operations is an essential tool for certifying agents and operations in the organic supply chain to support the verification of specific organic products.

- 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;
- Certifying agents must maintain current and accurate data in INTEGRITY for each operation that it certifies;
- Mandatory data requirements will include listings of items and certified acreage, among other data fields.

Grower Group Operations

Specify certification requirements for grower group operations to provide consistent, enforceable standards and ensure compliance with the USDA organic regulations. Grower group certification would be restricted to crop production and handling only, and would require the use of an internal control system to monitor compliance.

- Adds the following new terms: 1) *Grower group member*; 2) *Grower group operation*; 3) *Grower group production unit*; and 4) *Internal control system*.

- Specifies that a grower group operation may sell, label, or represent only crops or wild crops as organic; any non-crop agricultural products (e.g., livestock or livestock products) would not be eligible for certification under the grower group operation.
- Specifies that a grower group operation's organic system plan must describe its internal control system; the required details of the plan are specified.
- Grower group operations must use centralized processing, distribution, and marketing facilities and systems, and all crops and/or wild crops sold, labeled, or represented as organic by a grower group operation must be grown or gathered by grower group members only.
- Grower group operations may not buy crops and/or wild crops from non-member growers and sell, label, or represent them as organic using the grower group certification, and grower group members must not market crops and/or wild crops as organic outside of the grower group operation unless they are individually certified.
- Grower group operations must provide their certifying agent with the name and location of all grower group members, grower group production units, and the crops, wild crops, estimated yield, and growing/gathering areas (acreage) of each grower group member and grower group production unit. This information must be submitted at least annually as part of the organic system plan.
- The organic system plan must include a description of the Internal Control System (ICS) and how it verifies compliance with the organic regulations. The ICS is central to Grower Group certification and compliance; extensive details are provided.
- Establishes requirements for how certifying agents must conduct annual on-site inspections of grower group operations.

Foreign Conformity Assessment Systems (Equivalency Agreements)

Clarify conditions for establishing, evaluating, and terminating equivalence determinations with foreign government organic programs, based on an evaluation of their organic foreign conformity systems. This will ensure the compliance of organic products imported from countries that have organic equivalence determinations with the United States.

- Describes AMS' authority under OFPA to make equivalence determinations;
- Adds two new terms: *conformity assessment systems* and *technical requirements*. These terms are defined to clarify the requirements in this section;
- Describes the process for initiating the request for equivalence used by AMS and other foreign governments;
- 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 and are based upon the core concepts underlying equivalence.

Unannounced On-site Inspections

Require and specify the minimum number of unannounced inspections of certified operations that must be conducted annually by accredited certifying agents, and require that supply chain audits be completed during on-site inspections.

- Must conduct unannounced inspections of at least 5% of the operations they certify annually;
- Must not certify operations located where they are unable to conduct unannounced inspections;

- Must verify that the quantity of organic product sold does not exceed the quantity of organic product that is produced or purchased (aka Mass-Balance);
- Must verify that 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).

Standardized Certificates of Organic Operations

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. Standardization will simplify the verification of valid organic certificates and import certificates. It will also reduce reporting, by eliminating the need to provide notices of approval or denial of certification and annual lists of certified operations to USDA.

- Certificates must be generated from INTEGRITY and may be provided electronically;
- Certificate expiration date generated via INTEGRITY-- remains valid for 12 months;
- Certifying agents could continue to provide their own certification addenda provided it can be connected to the certificate generated by INTEGRITY.

Annual Update Requirements for Certified Operations

Clarify that certified operations only need to submit changes to their organic system plan (OSP) during annual updates, and clarify that certifying agents must conduct annual inspections of certified operations. This will reduce paperwork burden for organic operations, and ensure that all organic operations are inspected at least once a year.

- Require that operations annually submit revisions to the OSP rather than annually submitting the OSP in its entirety;
- All certified operations must be inspected at least annually, regardless of when the certified operation was last inspected and when, or if, the certified operation provided its annual updates;
- The on-site inspection must verify that the entire OSP is implemented as described.

Certifying Agent Personnel Qualifications and Training

Establish specific qualification and training requirements for certifying agent personnel, including inspectors and certification reviewers. Requiring that personnel meet minimum education and experience qualifications and requiring continuing education will ensure quality and consistency of certification activities performed by certifying agents.

- Continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and persons who conduct certification review;
- Certifying agents must ensure all inspectors have the level of knowledge, skills, and experience needed to conduct the specific inspections assigned, based on the scope and scale of the operations to be inspected;
- 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;

- Certifying agents must maintain current documented training requirements, procedures, and records for all inspectors and certification review personnel;
- Certifying agents must observe each inspector performing on-site inspections at least once every three years, or more frequently if warranted.

Compliance and Appeals Processes

Clarify requirements to strengthen and streamline enforcement processes, specifically noting that the NOP may initiate enforcement action against any violator of the Organic Foods Production Act (OFPA), including responsible parties; defining the term adverse action to clarify what actions may be appealed and by whom; and clarifying NOP's appeal procedures and options for alternative dispute resolution.

- The Program Manager may initiate enforcement action against any person who sells, labels, or provides other market information concerning an agricultural product if such label or information implies, directly or indirectly, that such product is produced or handled using organic methods, if the product was produced or handled in violation of the Organic Foods Production Act or the regulations in this part.

Non-compliance Procedure for Certified Operations

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. This will bolster the enforcement capacity of AMS by ensuring that penalties for violations of OFPA extend to all accountable parties.

- 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;
- Updates the citation which specifies the maximum civil penalty amount for violations of OFPA. This aligns with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015.

Mediation

Revising the existing requirements for mediation to support a process that is efficient and accessible to producers and handlers who want to resolve a denial of certification, proposed suspension, or revocation of certification. The proposed changes would clarify the process for engaging in mediation, and would clarify that a settlement agreement is the outcome of successful mediation.

- 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.

Calculating Organic Content of Multi-Ingredient Products

Clarify the method of calculating the percentage of organic ingredients in a multi-ingredient product to promote consistent interpretation and application of the regulation. The proposed changes are consistent with the NOSB recommendation of December 2016.

- 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.

Technical Corrections

- Revise the regulation under product composition (§ 205.301) to specify that organic products must not be “processed” (vs. “produced”) using ionizing radiation and must not be “processed” (vs. “produced”) using sewage sludge.
- Correct the reference to organic system plans (§205.201), which is incorrectly cited in the current organic regulation at 205.400 (b) and 205.401(a).

Additional amendments considered but not included in this Proposed Rule

- **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.*

NOP REQUEST FOR COMMENT

In addition to the questions on each topic listed below, AMS is requesting comments on the following general topics:

1. The clarity of the proposed requirements. Can certified operations, handlers, and certifying agents readily determine how to comply with the proposed regulations?
2. The implementation timeframe. AMS is proposing that all requirements in this proposed rule be implemented within ten months of the effective date of the final rule (this is also one year after publication of the final rule).
3. The accuracy of the estimates in the Regulatory Impact Analysis and Regulatory Flexibility Analysis, which describe the expected costs of this proposed rule on all affected entities and on small businesses, respectively.

4. Are there alternatives to regulations, or less stringent requirements, that could achieve the same objectives as this proposed rule?
5. How will certifying agents cover the costs of additional actions required under this rule, such as the required unannounced inspections and the issuing of NOP Import Certificates? Will certifying agents charge fees that are consistent for expanded handlers, brokers, importers and exporters?

AMS is also requesting comments on each of the following topics:

Exemptions from Organic Certification

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?
2. Are there specific activities not included in the proposed rule that you believe should be exempt from organic certification?
3. Are there additional requirements that exempt handlers described in this proposed rule should follow?
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?

Import Certificates

1. Is the 30-day timeframe for certifying agents to review and issue an NOP Import Certificate appropriate? Why or why not?
2. How could the mode of transportation and frequency of shipments affect the use of the NOP Import Certificate?

Record Keeping and Organic Fraud Prevention Procedures

1. Does the proposed definition of *organic fraud* encompass the types of fraudulent activities you witness in the organic supply chain?
2. Should certifying agents be required to perform a minimum number of trace-back audits each year?
3. Should more specific fraud prevention criteria be included in the regulation?

Labeling of Non-retail Containers

1. 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.

Grower Group Operations

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

Foreign Conformity Assessment Systems

1. AMS seeks comment regarding whether the public sees a differential risk to enforcement associated with certain organic trade relationships. Specifically, compared with organic equivalence determinations, are

there increased risks associated with recognition agreements where other countries' governments oversee the implementation of NOP certification?

Standardized Certificates of Organic Operations

1. How frequently should accredited certifying agents update the information in an operation's organic certificate?
2. Should a minimum reporting frequency (e.g., monthly, quarterly, etc.) be added to the regulations?
3. Should an expiration date be included on all certificates of organic operation? Would this make them more useful?

Certifying Agent Personnel Qualifications and Training

1. Is 20 training hours a year an appropriate amount of continuing education for organic inspectors and certification review personnel?
2. Should organic inspectors be evaluated on-site more frequently than once every three years?
3. Should any other types of knowledge, skills, and experience be specified?

Packaging Product Labeling (amendment considered but not in this PR)

1. For private-label packaged products, which certified operation(s) should be listed on the retail label (brand name/distributor, contract manufacturer, or both)? Which certifying agent(s) should be listed?
2. 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)?
3. Should listing contract manufacturers on labels be mandatory? Should it be optional?
4. What terminology should be used to describe private-labeled organic products?
5. What terminology should be used to describe the operations involved in packaged product

Expiration of Certification (amendment considered but not in this PR)

1. How might annual expiration of certification improve organic integrity?
2. What are the limitations of requiring expiration of certification?
3. What minimum requirements must be met before renewing certification?
4. Could an operation with unresolved adverse actions renew certification?
5. Would a grace period be appropriate for operations that failed to renew by the expiration date? If so, what length grace period would be appropriate?
6. What process should exist for an operation to regain organic certification should it allow its certification to expire?
7. Should certifying agents notify certified operations of their upcoming expiration of certification?