

Strengthening Organic Enforcement (SOE) Final Rule

Webinar
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https://www.ams.usda.gov/sites/default/files/media/SOE-FR_RegTextSideBySide.pdf



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1- Introduction

This rulemaking amends the United States Department of Agriculture (USDA) organic regulations to strengthen oversight and enforcement of the production, handling, and sale of organic agricultural products. Strengthening of the rule became necessary due to a continuously growing market and increasing complexity of the supply chain.

The SOE final rule:

- ❖ Protects organic integrity and bolsters consumer confidence in the USDA organic seal. The SOE final rule:
- ❖ Reduces the number of uncertified entities in the organic supply chain that operate without USDA oversight
- ❖ Requires the use of NOP Import Certificates for all organic products entering the United States
- ❖ Strengthens recordkeeping and supply chain traceability
- ❖ Clarifies the Agricultural Marketing Service(AMS) NOP authority to oversee and enforce organic trade
- ❖ Strengthens oversight of accredited certifying agents

All companies must comply with the SOE Final Rule as of March 19, 2024.

2- Applicability and Exemptions from Certification

➤ Overview of Amendments

Section	Final regulatory text
205.2	Terms Defined. Definitions for <i>Handle, Handler, Handling operation, and Retail establishment.</i>
205.100	What has to be certified. Paragraph (a).
205.101	Exemptions from certification. Entire section.
205.310	Agricultural products produced or processed by an exempt operation. Paragraphs (a) and (b).

2- Applicability and Exemptions from Certification

► Who needs to be certified?

Section 205.100(a) of the organic regulations states that any operation that produces or handles organic agricultural products must be certified organic. This means that operations conducting activities described in the definition of handle must be certified organic

In general, handle means to “sell, process, or package” organic agricultural products.

Key Takeaway: The SOE Final Rule adds trade, facilitating sale, import, and export to this definition of handle, indicating that some businesses which do not physically handle products may still need to be certified if they conduct one of these activities

2- Applicability and Exemptions from Certification

► Applicability 205.100(a)

Who needs to be certified?

- The regulation now states that anyone that produces or handles organic products must be certified. According to §205.2, handle means:

“To sell, process, or package agricultural products, including but not limited to trading, facilitating sale or trade on behalf of a seller or oneself, importing to the United States, exporting for sale in the United States, combining, aggregating, culling, conditioning, treating, packing, containerizing, repackaging, labeling, storing, receiving, or loading.”

- The SOE Final Rule adds trade, facilitating sale, import, and export to this definition of handle, indicating that some businesses which do not physically handle products may still need to be certified if they conduct one of these activities.

Key Takeaway: The biggest change in the SOE Final Rule is that more operations in the organic supply chain will need to be certified organic.

2- Applicability and Exemptions from Certification

➤ Exemptions

Not every operation must be certified. Exemptions to certification are allowed for operations with low-risk activities. Exempt operations must still follow the rules for producing and handling organic products.

The following operations in paragraphs (a) through (h) of this section are exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part, the applicable labeling requirements of subpart D of this part, and any requirements described in paragraphs (a) through (i) of this section.

See Ceres homepage <https://www.ceres-cert.de/en/documents>

4-3-20_EN_Exempt Handler Affidavit-ACA

3-2-10-5_EN_Brief Info NOP Handler Certification Self-Assessment
Flowchart_ACA.pptx

2-Applicability and Exemptions from Certification

➤ Exemptions

- ❖ A production or handling operation that sells agricultural products as 'organic' but whose gross agricultural income from organic sales totals \$5,000 or less annually".
Key Takeaway: Very small farms and businesses are exempt from certification. There is no change in policy.
- ❖ "A retail establishment that does not process organically produced agricultural products."
Key Takeaway: Most retailers (like grocery stores) that sell organic products are exempt from certification. There is no change in policy.
- ❖ "A retail establishment that processes, at the point of final sale, [organic] agricultural products..."
Key Takeaway: A broader range of retailers is exempt from certification (including restaurants and stores that cook or prepare food). Online retailers that process but do not have a physical location where they sell products must be certified.
- ❖ "A handling operation that only handles agricultural products that contain less than 70 percent organic ingredients...or that only identifies organic ingredients on the information panel."
Key Takeaway: Processors that make products with lower amounts of organic ingredients (e.g., "made with organic...") are exempted from certification. There is no change in policy.
- ❖ "An operation that only receives [or] stores organic...products that [are] enclosed in sealed, tamper-evident packages or containers...[and] remain in the same...packages..."
Key Takeaway: Warehouses and storage operations that only store packaged organic products are exempted from certification, including both retail and nonretail packaging. **Operations that store bulk or unpackaged products must be certified.**

2-Applicability and Exemptions from Certification

➤ Exemptions

- ❖ "An operation that only buys, sells...[or] stores...organic... products...labeled for retail sale that [are] enclosed in sealed, tamper-evident packages or containers [and] remain in the same sealed, tamper-evident packages or containers..."
Key Takeaway: Wholesalers that sell only retail-packaged products are exempt from certification. Wholesalers that sell bulk products or nonretail-packaged products must be certified.
- ❖ "A Customs broker (per 19 CFR 111.1) that only conducts customs business..."
Key Takeaway: U.S. Customs and Border Protection (CBP)-licensed Customs brokers are exempt from certification. These operations file import paperwork, but they do not touch or handle products.
- ❖ "An operation that only arranges for the shipping, storing, transport, or movement of organic agricultural products..."
Key Takeaway: Logistics brokers—businesses that connect operations with carriers and storage facilities for a fee—are exempt from certification.
- ❖ "Businesses that strictly transport organic products do not require organic certification."
Key Takeaway: Businesses that transport strictly organic products do not require organic certification

3- Supply Chain Traceability and Organic Fraud Prevention (Section P)

- One of the primary goals of the Strengthening Organic Enforcement (SOE) Final Rule is to continuously improve the **oversight of organic integrity within** increasingly complex **supply chains**. Organic integrity can be lost due to both fraud and accidental mishandling.
- Section P—Supply Chain Traceability and Organic Fraud Prevention—in the Final Rule makes several important changes that protect against both threats to organic integrity preservation. **It ensures that organic products can be traced all the way back from retail to production.**
- Having entities certified across the supply chain is easier for operations (located both ahead of you and behind you in the supply chain). Otherwise, an operation would need to ask them **for records that would be sent to the previous certified operation.**

Key Takeaway: The SOE Final Rule incentivizes certification for the full supply chain

3- Supply Chain Traceability and Organic Fraud Prevention

- What actions does the SOE Final Rule require of certified operations and certifiers to enable full supply chain traceability and Organic Fraud Prevention?

Certified organic operations must:

- ❖ Maintain **records** of their activities that span the time of purchase or acquisition, through production, to sale or transport;
- ❖ Maintain records that trace back to the last certified operations in their supply chain;
- ❖ When using a noncertified intermediary (e.g., an exempt wholesaler or shipping company), **certified operations will need records showing that organic integrity was maintained by the noncertified intermediary.**
- ❖ Maintain **audit trail documentation** to facilitate supply chain traceability, including identification of agricultural products as organic on audit trail documents; and
- ❖ Describe in their organic system plan the monitoring practices and procedures used to prevent organic fraud and verify suppliers and organic product status.

Terminology (Section E)

Audit trail: Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as "100 percent organic," the organic ingredients of any agricultural product labeled as "organic" or "made with organic (specified ingredients)" or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement ([7 CFR 205.2](#))

3- Supply Chain Traceability and Organic Fraud Prevention

- ▶ What actions does the SOE Final Rule require of certified operations and certifiers to enable full supply chain traceability and Organic Fraud Prevention?

Certifying agents must:

- ❖ Conduct risk-based **supply chain traceability audits** of products they certify to verify compliance;
- ❖ Maintain procedures for identifying high-risk operations and agricultural products, conducting risk-based supply chain audits, and reporting credible evidence of organic fraud to the USDA; and
- ❖ Share information with other certifying agents to conduct investigations, conduct supply chain traceability audits, and verify compliance of organic products.

Terminology (Section E)

A **supply chain traceability audit** (SCT audit) is the process of identifying and tracking the movement, sale, custody, handling, and organic status of a product along a supply chain. The objective of a supply chain audit is to verify a product's compliance with the organic regulations. SCT audits can be used to investigate evidence or suspicion of fraud, verify compliance of high-risk products, investigate patterns of activity, trace the source of products contaminated with prohibited substances, surveil high-risk supply chains, or for other compliance-related reasons.

3- Supply Chain Traceability and Organic Fraud Prevention

- ▶ The SOE Final Rule requires operations to include how they will prevent fraud in their Organic System Plan (OSP).

Definitions § 205.2

Organic fraud is defined as “ **Deceptive representation**, sale, or labeling of **nonorganic agricultural products** or ingredients as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).

- ▶ The SOE Final Rule established this definition to help all stakeholders to clearly align organic activities directly with fraud prevention practices.

Key Takeaway: The ability to trace a product from farm to sale is an important aspect of fraud prevention. The rule encourages the use of sound and sensible risk-based approaches to traceability processes, while effectively protecting the market.

4. Import Certificates



- ▶ A new section (B) was added specifically to address imports into the United States. All organic imports must be:
 - Certified under subparts E and D of this part (Part 205).
 - Declared as organic to the U.S. Customs and Border Protection Service.
 - Associated with valid NOP Import Certificate data.
- ▶ NOP Import Certificate PROCESS:
- ▶ The certified exporter to the U.S. sends export shipment data to their certifier and requests an Import Certificate. The certifier verifies the information and issues the Import Certificate from the USDA Organic Integrity Database (INTEGRITY).
- ▶ The certifier who issues the NOP Import Certificate must be accredited either by USDA or by another government under a trade arrangement.
- ▶ The exporter's certifier reviews the Import Certificate request and determines if the shipment is compliant.
 - Once the approved, the certifier generates an Import Certificate in INTEGRITY.
 - The certifier then gives the Import Certificate (or data) to the exporter, who gives it to the importer. A physical copy does not need to accompany a shipment. Electronic transfer of records is already common in the industry.
 - If the certifier's control system provides sufficient oversight to allow it, a certifier may issue one Import Certificate for multiple shipments.

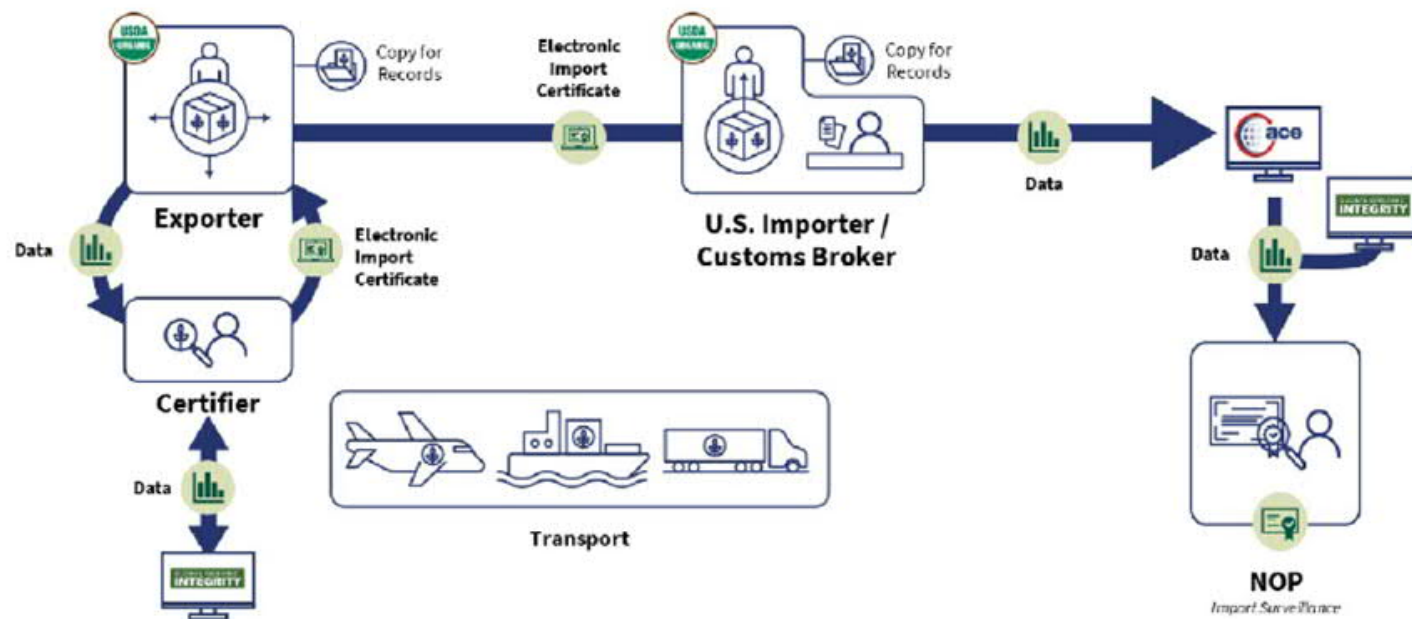
4. Import Certificates



- ▶ A Customs broker uploads the Import Certificate data into ACE (Automated Commercial Environment) . If the importer is a licensed Customs broker, they may upload the data themselves.
 - “Clearly identified and marked as organic” is a reference to SOE’s updated labeling and recordkeeping requirements. This reinforces that clear organic identification in records is necessary for traceability and product verification.
- ▶ The importer verifies compliance of the import. This includes verifying that the shipment has a valid Import Certificate and has not been fumigated or irradiated.
 - Other types of verification may be necessary depending on the product and country of origin.

4. Import Certificates

NOP Import Certificate Data Flow



4. Import Certificates

- Important Take Aways:
- -Operators exporting organic agricultural products to the U.S. must apply for an Import Certificate from their certifier.
- -If the export meets organic standards, the NOP Import Certificate is issued by a certifier through the INTEGRITY Organic Database.
- -Each import must be declared organic, and the certificate data must be entered into U.S. Customs and Border Protection's Automated Commercial Environment (ACE) system by the importer.
- -The import must be linked to the import certificate data to verify that organic integrity has been maintained (ensuring no contact with prohibited substances or ionizing radiation).

5. Certificates of Organic Operation

- ▶ **The Strengthening Organic Enforcement (SOE) Final Rule requires that certifiers:**
 - ❖ Generate standardized certificates of organic operation using USDA's Organic Integrity Database (INTEGRITY).
 - ❖ Maintain up-to-date operation profiles in INTEGRITY.
- ▶ The SOE Final Rule introduces a new definition of the Organic INTEGRITY Database (**INTEGRITY**) functions and new details for when a certifier issues a certificate of organic operation.

Per 7 CFR §205.404 (b):

"The certifying agent must issue a certificate of organic operation. The certificate of organic operation must be generated from the Organic Integrity Database and may be provided to certified operations electronically."

Key Takeaway: Certifiers must generate certificates of organic operation in INTEGRITY. They cannot use their own formats.

Key Takeaway: Certifiers now must keep **current and accurate data** on their operations in INTEGRITY, including information about their certification status.

Key Takeaway: NOP will publish a new certificate for all operations in OID on March twentieth, therefore, for certificates to be accurate, certifiers need to make sure their operation data is accurate by March.

5. Certificates of Organic Operation

■ Addenda to the certificate of organic operation

- ❖ In addition to the certificate of organic operation provided for in paragraph(b) of this section, a certifying agent may issue its own addenda to the certificate of organic operation. If issued, any addenda must include: .

- (1) Name, address, and contact information for the certified operation;
- (2) The certified operation's unique ID number/code that corresponds to the certified operation's ID number/code in the Organic Integrity Database;
- (3) A link to the Organic Integrity Database or a link to the certified operation's profile in the Organic Integrity Database, along with a statement, "You may verify the certification of this operation at the Organic Integrity Database," or a similar statement;
- (4) Name, address, and contact information of the certifying agent; and
- (5) "Addendum issue date."

Key Takeaway: Certifiers must generate certificates of organic operation in INTEGRITY. They cannot use their own formats.

Key Takeaway: Certifiers may issue its own addenda to the certificate of organic operation

Key Takeaway: Certifiers now must keep **current and accurate data** on their operations in INTEGRITY, including information about their certification status.

6. On-Site Inspections and Continuation of Certification (Section D)

- ▶ The SOE Final Rule requires that a certifier completes the following activities annually:
 - ❖ Conduct annual inspections of all operations once **per calendar year**.
 - ❖ Conduct **unannounced inspections** equaling at least five percent of the operations that it certifies—rounded up to the nearest whole number—each year.
 - ❖ Conduct **mass balance audits** during on-site inspections.
 - ❖ **Verify traceability of product and ingredients** within an operation during on-site inspections.
 - ❖ **Verify traceability of product** in an operation's supply chain back to the last certified operation during an on-site inspection.

Key Takeaway: Although most of this information is not new to certifiers and operations, **requirements for mass balance and traceability have been updated in the Final Rule to clearly define how inspections are conducted.**

6. On-Site Inspections and Continuation of Certification (Section D and F)

According to §205.2, *unannounced inspection* is defined as:
"The act of **examining and evaluating all or a portion of** the production or handling activities of a certified operation **without advance notice** to determine compliance with the Act and the regulations in this part."

➤ Unannounced inspections.

Background

- ❖ Unannounced inspections are an effective and useful tool to ensure compliance across certified operations and bolster consumer trust in the organic label. Therefore, the SOE Final Rule codified the requirement for certifiers to conduct a minimum number of unannounced inspections annually of certified operations.

Use

- ❖ Unannounced inspections differ from full annual inspections because they can include a **include a full operation** or be **limited to a portion of an operation or an operation's activities without advanced notice**.

Scope

- ❖ Unannounced inspections can be used as a **risk-based tool** to target specific areas, activities, or times of the year to determine an operation's compliance with the regulations. Examples of these inspection targets include parcels, facilities, products, or a review of records. Inspectors may also conduct sampling during an unannounced inspection.

Planning and Scheduling

- ❖ The SOE Final Rule states that certifiers must conduct unannounced inspections of a **minimum of five (5) percent** of the operations that they certify **annually**. This number of inspections is rounded to the next whole number so that certifying agents with very few certified operations (e.g., less than 20 operations) would still be required to conduct at least one unannounced inspection per year. Operations may be selected randomly or in response to high risk, investigations, or other criteria.
- ❖ In addition, the ability to conduct an unannounced inspection is considered part of a certifier's administrative capacity. So, **if a certifier cannot conduct an unannounced inspection** due to geography, logistics, staffing, security, or other reasons, then **they cannot certify that operation**.

6. On-Site Inspections and Continuation of Certification (Section D and F)

► Mass-Balance Requirements

For mass balance audits, the following requirement is outlined in §205.403 of the regulations:

- ❖ *"An on-site inspection of an operation must verify: Mass-balances, in that **quantities** of organic product and ingredients **produced or purchased account for** organic product and ingredients **used, stored, sold, or transported.**"*
- ❖ Therefore, certifiers must perform mass balance or "in-out" audits during full annual on-site inspections to confirm that inputs match outputs. This approach is effective for detecting and discouraging fraud

6. On-Site Inspections and Continuation of Certification (Section D and F)

Traceability Requirements

For traceability audits, the following requirement is outlined according to §205.403 of the regulations:

- ❖ *"An on-site inspection of an operation must verify: That organic products and ingredients are traceable by the operation from the **time of purchase or acquisition through production** to sale or transport; and that the certifying agent can **verify compliance back to the last certified operation.**"*
- ❖ Therefore, certifiers must verify traceability **within an operation and traceability to their certified supplier(s)**. This requirement pairs with an operation's traceability and audit trail documentation requirements specified in §205.103(b)(2) and (3). For more information, read the primer on [Supply Chain Traceability and Organic Fraud Prevention](#). It is important that **certifiers must evaluate how operations maintain traceability.**

6. On-Site Inspections and Continuation of Certification (Section D and F)

► Continuation of Certification

- ❖ The regulation in §205.406 states:

"To continue certification, a certified operation must annually ... submit the following information to the certifying agent:

(1) A summary statement, supported by documentation, detailing any ... changes to... the organic system plan...

(2) Any additions or deletions to the previous year's organic system plan...

(3) Any additions to or deletions from the information required pursuant to § 205.401(b); and

(4) Other information as deemed necessary ... to determine compliance with the Act and the regulations..."

- ❖ Certifiers can **schedule annual on-site inspections at a time when they are best able to observe and evaluate the operation's activities** (e.g., the growing season). If a certifier cannot complete a full annual inspection due to an emergency or other condition, they must **conduct follow-up inspections** to determine the operation's compliance.

Key Takeaways:

Essentially, this regulation **reduces paperwork** for the certifiers and certifying operations by eliminating the need to annually submit a full, updated copy of the OSP and updates on correction of any minor noncompliances.

The revised section also states that **certifiers must arrange and conduct an on-site inspection of the certified operation at least once per calendar year**

7. Labeling Containers and Calculating Percent Organic



LABEL

- ▶ The SOE final rule requires nonretail containers to be labelled with critical information.
- ▶ Nonretail containers are defined in § 205.2 and may include:
 - Produce boxes, totes, bulk containers, bulk bags, flexible bulk, containers, harvest crates and bins;
 - Boxes, crates, cartons, and master cases of wholesale packaged products; and
 - Trailers, tanks, railcars, shipping containers, vessels, cargo holds, freighters, barges, grain elevators, silos, grain bins, or other methods of bulk transport or storage.

7. Labeling Containers and Calculating Percent Organic



- ▶ AMS adopts a risk-based approach by only requiring the most critical information on nonretail container labels: organic identification and information that links the container to audit trail documentation. This reduces administrative burden and cost to operations while still protecting organic integrity.
- ▶ Clear identification reduces the likelihood of accidental contamination or commingling. "Organic identification" can be anything that allows someone to clearly and immediately identify the contents as organic, such as a short statement, "organic," an abbreviation, an acronym, or a USDA seal. Operations may use temporary signs or labels for containers that are difficult to label due to size, shape, material, etc.
- ▶ Linking a container to audit trail documentation reduces information on labels without sacrificing the ability to trace or verify products. Audit trail documentation allows someone to determine the source, transfer of ownership, and transport of a product.
- ▶ SOE requires record keeping that allows trace back to the last certified operation in a supply chain

7. Labeling Containers and Calculating Percent Organic



- ▶ INGREDIENT CALCULATION § 205.301 Product composition
- ▶ Clear instruction now: Operations must now calculate the percentage of organic content based on the weight of all ingredients before processing. Consistent with current policy, salt and water are not included in calculations.
- ▶ This applies to formulations with liquid ingredients, as well to products which contain both liquid and solid ingredients
- ▶ The net weight of all organic ingredients before processing in relation to the total weight before processing (without Water and Salt)
- ▶ Extracts need to be calculated on single-strength concentrations

7. Labeling Containers and Calculating Percent Organic



- ▶ This applies to formulations with liquid ingredients, as well to products which contain both liquid and solid ingredients
- ▶ The net weight of all organic ingredients before processing in relation to the total weight before processing (without Water and Salt)
- ▶ Extracts need to be calculated on single-strength concentrations

8. Compliance and Noncompliance Procedures, Mediation, and Appeals



NONCOMPLIANCES

- NOP's authority to take enforcement action against uncertified operations or individuals that falsely represent conventional products as organic.
- 205.661 Investigation. Changing the title of § 206.661 more clearly states that NOP has authority to investigate uncertified operations (not just certified operations) for violations of OFPA and the regulations.
- SOE clarifies that the penalties for organic fraud apply to responsibly connected persons who created or perpetuated the fraud.
- - civil penalties (in the US)

8. Compliance and Noncompliance Procedures, Mediation, and Appeals



NONCOMPLIANCES

- Update of the OID about suspension, revocation or surrender within 3 business days
- A certified operation or a person responsibly connected with an operation whose certification has been suspended may... submit a request...for reinstatement of its certification, or submit a request for eligibility to be certified...
- In addition to suspension or revocation of certified operations they may receive civil penalties (in the US)

8. Compliance and Noncompliance Procedures, Mediation, and Appeals



Mediation

- A certifying agent must submit with its administrative policies and procedures: decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions per § 205.504(b)(8)
- Intention of a mediation request as an alternative way to resolve noncompliances stays the same, some details have been changed
- the goal of mediation is to reach a settlement agreement that leads to compliance (either by exiting the market or coming into compliance).
- The Program Manager/NOP may propose mediation and enter into a settlement agreement at any time to resolve any adverse action notice.

8. Compliance and Noncompliance Procedures, Mediation, and Appeals



APPEALS

- Some details changed and more clear wording (i.e. adverse action as opposite to noncompliance before) in regard to operators appealing to a NOP Program manager Adverse Action (Denial, proposed Suspension, proposed revocation) basically sta
- A sustained appeal:
 - ❖ An operation may continue certification, and
 - ❖ Civil penalties and cease-and-desist notices are withdrawn
- Denied Appeal:
 - ❖ IF the appellant wants to further contest the notice, he/she must timely request a formal hearing.
 - ❖ Civil penalties may be levied during the Hearing process
 - ❖ The parties may resolve the matter through settlement before a Hearing

9. Producer Group Operations, Oversight of Certification Activities

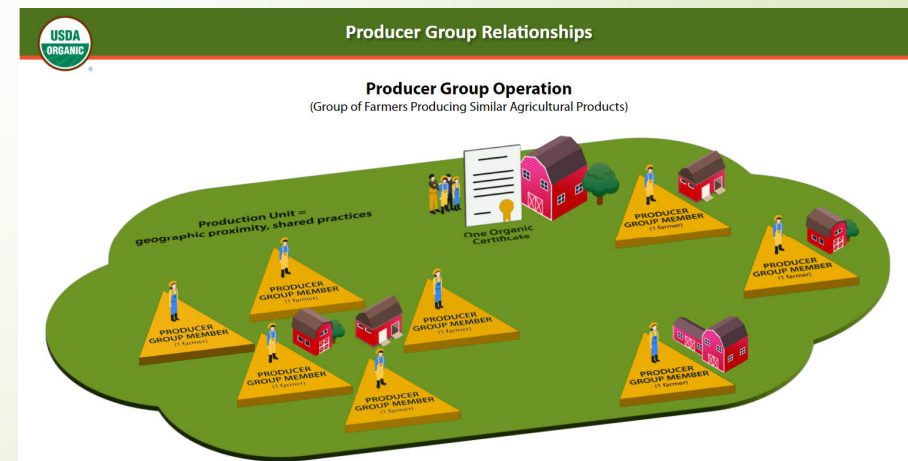
➤ Certification of Producer Groups

- ❖ Each producer group operation must be organized **as one person**. The Organic Foods Production Act (OFPA) refers to this requirement as the “regulatory requirement for certification.” **A person** is also defined as a **corporation, a partnership, or an association**
- ❖ If several farmers have shared geographic proximity, products, and practices, they can form a production unit.
- ❖ Each operation needs to have an organic system plan (OSP), and each production group has one OSP. The OSP describes the internal control system (ICS) and how it will work to help with overseeing the operation and maintaining compliance with the organic regulations.
- ❖ The ICS team is directly responsible for the producer group’s compliance with the organic regulations. The team trains, inspects and monitors the producer group’s members and enforces their compliance.

9. Producer Group Operations, Oversight of Certification Activities, and Assessing Foreign Conformity Assessment Systems

► Producer Group Relationships

- ❖ Each producer group member is one farmer and all the producer group members collectively operate in one producer group operation.
- ❖ If several farmers have shared geographic proximity, products, and practices, they can form a production unit.
- ❖ These units and the members form the producer group operation, which has one organic certificate and one OSP.
- ❖ They work within that producer group operation, and everyone's products must be sold through that group operation.
- ❖ They cannot individually sell their products because the certification applies to the producer group operation and not to individual farmers.



9. Producer Group Operations, Oversight of Certification Activities

- ▶ Certifiers must perform the following activities when inspecting a producer group:
 - ❖ Observe and assess the ICS inspection of members.
 - ❖ Inspect a minimum number of members.
 - ❖ Inspect handling facilities.
 - ❖ At least one producer group member from each producer group production unit must be inspected, and each handling facility, including all collection sites, must be inspected
 - ❖ USDA organic regulations do not set a minimum number or percentage of witness inspections that a certifying agent must conduct at each producer group operation inspection.

9. Producer Group Operations, Oversight of Certification Activities

- ▶ During on-site inspections, certifying agents must inspect:
 - ❖ At least 1.4 times the square root or 2% of the total number of producer group members, whichever is higher
 - ❖ All numbers must be rounded up to the next whole number (e.g., using square root method, 50 members = 10 inspections, 100 members = 14 inspections, 500 members = 31 inspections, and 1,000 members = 44 inspections)
 - ❖ Two sampling rates are provided because the power of the square root sampling power begins to decline when operations exceed 5,000 members so that a smaller proportion of members are inspected relative to the total number of members.
 - ❖ USDA organic regulations do not set a minimum number or percentage of witness inspections that a certifying agent must conduct at each producer group operation inspection.

9. Producer Group Operations, Oversight of Certification Activities

- During on-site inspections, certifying agents must inspect:
 - ❖ The addition of the 2% rate more evenly distributes the number of external inspections across producer groups regardless of the number of members as shown in [table 1](#):
 - ❖ The number of producer group members inspected by the certifying agent must include all high-risk members.
 - ❖ Certifying agents must inspect at least one producer group member in each production unit to ensure all producer group production units are inspected, as well as each handling facility.
 - ❖ The certifying agent should apply the risk assessment procedures to determine and instruct the inspector on which producer group members to inspect during the annual inspection. After all risk-based and other inspection selection criteria are satisfied, certifying agents should randomly select the remaining member inspections so that different lower-risk producer group members are inspected each year.

9. Producer Group Operations, Oversight of Certification Activities

Table 1—Certifying Agent ICS Inspection Sampling Rates

Producer group members (N)	Square root method	Flat 2%	Final rule
N	$1.4 * \sqrt{N}$	2%	Greater of $1.4 * \sqrt{N}$ or 2%
50	10	1	10
100	14	2	14
250	23	5	23
500	32	10	32
1000	45	20	45
5000	99	100	100
7500	122	150	150
10000	140	200	200

9. Producer Group Operations, Oversight of Certification Activities

- ❖ The ICS must identify the criteria for the members of the high-risk producer group and the production unit.
- ❖ Certifiers must also determine which producer members are high risk. Listed below are examples of risk factors that can be used by both the ICS and the certifier:
 - ❖ History of non-compliance of the group as a whole and of each of its members;
 - ❖ Criteria used to designate a set of members of a producer group as a single producer group production unit;
 - ❖ High risk members identified in the SCI and member producer groups with non-compliance;
 - ❖ Application of prohibited materials next to members' fields;
 - ❖ Split or parallel operations (i.e. operations that also produce non-organic agricultural products);

9. Producer Group Operations, Oversight of Certification Activities

- ❖ Members of the producer group with income greater than 5,000 USD annually;
- ❖ The acquisition, availability and distribution of inputs and resources to members;
- ❖ The prevalence of non-organic production of similar products and crops in the region;
- ❖ Post-harvest handling practices designed to avoid mixing and contact with prohibited substances;
- ❖ New members of the producer group;
- ❖ Size of the production or collection areas of the members of the producer group; and
- ❖ Significant expansion of the production area of a member of the producer group.

9. Producer Group Operations, Oversight of Certification Activities

Key Takeaways:

The ICS must identify criteria for high-risk producer group members and production unit

Certifying agents must also determine which producer members are high risk.

Producer group operation

A group of individual farmers who are collectively certified under one organic certificate.

Producer group member

A single farmer within a producer group.

Producer group production units

A collection of members in the same area who produce the same commodity. A producer group can have several production units, or just one.

Internal control system (ICS)

A quality management system that establishes and governs the review, monitoring, training, and inspection of the producer group operation—and the procurement and distribution of shared production and handling inputs and resources—to maintain compliance with the USDA organic regulations.

Muchas gracias

Vă mulțumesc foarte mult

Herzlichen Dank.

Благодаря ви много

Muchas gracias

