



## Strengthening Organic Enforcement (SOE)

**SUMMARY:** The [SOE Rule](#) amends the National Organic Standards to strengthen oversight and enforcement of the production, handling, and sale of organic agricultural products.

Topics addressed in this rulemaking include:

- Applicability of the regulations and exemptions from organic certification
- Recordkeeping, product traceability, and fraud prevention
- National Organic Program Import Certificates
- Labeling of nonretail containers
- Standardized certificates of organic operation and data requirements
- On-site and unannounced inspections of certified operations
- Calculating organic content of multi-ingredient products.
- Compliance and appeals processes
- Certification of producer group operations
- Certifying agent personnel qualifications and training
- Foreign conformity assessment systems

Details and additional resources for the rule can be found on the NOP website here:

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

**We encourage all clients to review the final rule and prepare to make necessary updates to your operation. New and updated regulations will be included within the National Organic Standards available at:**

<https://www.ecfr.gov/current/title-7/subtitle-B/chapter-I/subchapter-M/part-205> soon after the effective date of **March 20, 2023**. Contact MOSA with any questions.

**DATES:** This rule is effective on March 20, 2023 with a full implementation date of March 19, 2024. **This means that all entities affected by this rule, including certified operations and certifying agents, must comply with the provisions of this final rule by March 19, 2024.**

**AFFECTED OPERATIONS:** You may be affected by this action if you are engaged in the organic industry. Potentially affected entities may include, *but are not limited to*, the following:

- Individuals or business entities that are considering organic certification
- Existing production and handling operations that are currently certified organic under the USDA organic regulations
- Brokers, traders, exporters, and importers of organic products that are not currently certified under the USDA organic regulations
- Operations that use nonretail containers for shipping or storing organic products
- Retailers that sell organic products
- Operations that receive or review certificates of organic operations to verify compliance with USDA organic regulations
- USDA-accredited certifying agents, inspectors, and certification review personnel

- Operations that import organic products into the United States
- Operations that export organic products to the United States and the corresponding certifying agents

This list is not exhaustive but identifies key entities likely to be affected by this action. Other types of entities may also be affected. **To determine whether you or your business may be affected by this action, you should carefully read MOSA's summary below and [read the rule](#).**

#### KEY PROVISIONS:

1. Who Must be Certified: This action reduces the types of uncertified entities in the organic supply chain that operate without USDA oversight—including importers, brokers, distributors, and traders of organic products—to safeguard organic product integrity and improve traceability. This rulemaking clarifies that most operations that operate in the middle of organic supply chains must be certified organic. Specifically,
  - All operations that handle organic products must be certified, unless they are exempt from certification. The definition of handle has been updated.  
*Handle. 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.*

**Handlers that you work with in your supply chain may now need to be certified. Proactive communication will enable certification by March 19, 2024. MOSA has a new streamlined process for certification of previously exempted non-processing operations.**

2. Exemptions from Certification: There are still a few limited low-risk exemptions from certification described in §205.101(a)-(h). Exempt operations must still follow the applicable production and handling National Organic Standards, including labeling, and, as applicable, keep required records for three years. Exempt products must not be represented as organic in products processed by other operations. **Exempt operations are encouraged to opt into certification.** MOSA's Non-Processing Handler OSP provides a streamlined process for certifying such operations.

Specific exempt operations are:

- *Operations with less than \$5000 gross income.* There is no change to this exemption. §205.101(a)
- *Retail establishments that do not process and sell directly to the consumer.* Examples include retailers who remove produce from shipping boxes, wash and transfer product to display cases or open bags of oats and transfer contents to bulk food dispensers. While virtual sales are permitted, operations must have a physical location where products are sold to consumers. §205.101(b)
- *Retail establishments that process at the point of final sale to the consumer.* This means that the products must be processed and sold in the same physical location. This could include repackaging bulk containers of organic product into individual units for retail sale within an individual grocery store or a retail

establishment that prepares ready-to-eat meals and sells them online to consumers from the processing location. §205.101(c)

- *Operations that only handle products containing less than 70% organic ingredients or that only identify organic ingredients in the information panel.* There is no change to this exemption. Products must be certified organic if used in or on a product that is represented as “organic” by another operation. §205.101(d)
- *An operation that only receives, stores, and/or prepares for shipment, but does not otherwise handle, organic agricultural products.* Products must be enclosed in a sealed, tamper-evident package or container prior to receipt and remain in the same enclosure the entire time under the control of the operation. Tamper-evident packaging or container means that the contents are sealed in a manner where an attempt to break the seal, access the contents, or reclose the package would be obvious. §205.101(e)

- Examples include produce boxes with “DO NOT TAMPER WITH” tape across the box flaps or a sealed drum of olive oil. This exemption does not, for example, cover buying, selling, receiving, storing, or loading of unpackaged products; those activities require certification. This exemption is intended primarily for storage and warehouse facilities.

Preparing for shipment is an activity that is covered under both this exemption and the next and may include various tasks that must be performed with the sealed, tamper-evident packaging remaining intact and without altering product contents or any retail labeling.

- Examples of preparing for shipment include putting packaged products into shipping containers, applying internal tracking numbers, shrink-wrapping shipping cartons to a pallet, breaking down pallets of fully packaged products, adding protective packaging to nonretail containers or retail displays of organic products, packing individual packaged products onto a shipping pallet, loading/unloading packaged products onto or from transport vehicles.
- *An operation that only buys, sells, receives, stores, and/or prepares for shipment, but does not otherwise handle, organic agricultural products already labeled for retail sale.* Products must be enclosed in a sealed, tamper-evident package or container labeled for retail sale prior to receipt and remain in the same retail package or container while under control of the operation. This allowance may cover, for example, some distributors, brand name owners, and sales brokers that purchase and/or receive products in their finished retail packaging. §205.101(f)
  - Private labeling operations that process organic products must be certified.
- *A Customs broker (per [19 CFR 111.1](#)) that only conducts customs business but does not otherwise handle organic agricultural products.* Customs brokers must only conduct customs business. If a Customs broker conducts any additional activity within the definition of handle—such as selling, importing, or trading—the Customs broker must be certified. Customs brokers facilitate the entry of products into the United States by helping meet import documentation and filing requirements and by acting as intermediaries between importers and the U.S. government. Customs brokers do not take ownership or physical possession of organic products and their actions present minimal risk to organic integrity. They are often distinct from sales or commodity brokers, who sell or facilitate the sale of organic products—those operations must be certified if they handle organic products. Customs brokers also play a critical role by filing NOP Import Certificate data in the U.S. Custom and Border Protection’s (CBP) Automated Commercial

- Environment (ACE) import entry system. §205.101(g)
- *An operation that only arranges for the shipping, storing, transport, or movement of organic agricultural products but does not otherwise handle organic products.* Sometimes known as “logistics brokers,” these operations facilitate the movement and storage of agricultural products by connecting a consigner (or consignee) with a carrier who can transport/store the products. Logistics brokers do not take ownership or physical possession of organic products. The activities they conduct present minimal risk to organic integrity because they only secure transport/storage to meet the needs of a third party who owns or is responsible for the organic product. If an operation conducts other handling activities, such as selling, importing, or trading, the operation must be certified. §205.101(h)

Transportation remains an activity exempt from certification, though not specified under NOS operation exemptions. Any activities other than the movement of product on a transportation vehicle or moving products between transportation vehicles (transloading) are handling and require certification. Handling activities which are adjacent to transport require certification unless they are covered by exemptions for packaged products. Examples of adjacent activities which do not qualify as transport include combining, splitting, containerizing, packing/repacking, treating, sorting, opening, enclosing, or labeling/relabeling. In addition, loading or unloading of unpackaged products into or from a storage facility is not a form of transportation; this activity must be certified.

Certified operations are responsible for verifying that products handled by uncertified entities in their supply chain remain in compliance with the organic regulations including verifying organic products transported by an uncertified transporter. Organic system plans will need to be updated with a full description of how the certified operation verifies any uncertified operations in the supply chain. Records back to the last certified operation are required and must demonstrate prevention of commingling and contamination during transportation.

3. Supply Chain Traceability and Fraud Prevention: Requires **all** certified operations to develop and implement improved recordkeeping and organic fraud prevention processes and procedures as applicable. New terms “organic fraud” and “supply chain traceability audit” were added to the regulations. Records must fully disclose all activities and transactions of the certified operation, in sufficient detail as to be readily understood and audited; records must span the time of purchase or acquisition, through production, to sale or transport and be traceable back to the last certified operation. External audit trail documentation must identify organic products as “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as appropriate. Operations may use abbreviations or acronyms to identify products, provided that the abbreviations or acronyms are easily understood. This information will clearly identify organic products, reduce the mishandling of organic products, and support traceability. **Certifying agents will conduct risk-based supply chain traceability audits between certifiers.**

Organic system plans must include verification practices for organic ingredients and all suppliers in the supply chain and describe how product is traced back clearly and completely to the last certified operation.

The OSP must also include measures implemented to prevent fraud (i.e. fraud prevention plan). Such plans should include:

- A map or inventory of the operation's supply chain that identifies suppliers;
- Identification of critical control points in the supply chain where organic fraud or loss of organic status are most likely to occur;
- A vulnerability assessment to identify weaknesses in the operation's practices and supply chain;
- Practices for verifying the organic status of any product they acquire and/or use;
- A process to verify suppliers and minimize supplier risk to organic integrity;
- Mitigation measures to correct vulnerabilities and minimize risks;
- Monitoring practices and verification tools to assess the effectiveness of mitigation measures; and
- A process for reporting suspected organic fraud to certifying agents and the NOP.

**We are updating our organic system plans accordingly and operations will be required to provide additional information.**

4. NOP Import Certificates: The use of NOP Import Certificates for **all** organic products entering the United States is required. This change expands the use of NOP Import Certificates to all organic products imported into the United States, improving the oversight and traceability of imported organic products. Exporters will request import certificates to be issued by their certifier from the Organic Integrity Database (OID) for all imports to the US planned. **This system in OID is being developed and by the time the rule is fully implemented, certifiers will have the ability to generate import certificates.** Import certificates may be issued for individual shipments or for multiple shipments of a product over a specific timeframe and with a designated quantity. **Importers must have a documented control system and verify that shipments have no contact with prohibited substances or exposure to ionizing radiation since export.** Additionally, all import documents (i.e. invoices, packing lists, and BOLs) must identify products as organic.
5. Labeling of Nonretail Containers: Requires that nonretail containers used by **all** organic operations to ship or store organic products are labeled with organic identity and are traceable to audit trail documentation. Audit trail documents must identify the last certified operation that handled the product. Nonretail containers are those used for shipping or storage of a product that is not used in the retail display or sale of the product. Examples 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.Nonretail containers, regardless of shape or size, must display:
  - Identification of the product as organic. Operations may use abbreviations or acronyms to identify products as organic, provided that they are clear and easily understood; and

- The production lot number, shipping identification, or other unique information that links the container to audit trail documentation.

Other optional information may be included. Operations may use temporary labels or signage to meet the requirements. This provides additional flexibility for containers that may be difficult to label due to size, shape, material, or use. **Updated nonretail labels must be approved by MOSA and in use by March 19, 2024.**

The only nonretail containers that do not have to display required information are containers of retail products where the organic information on the retail product is clearly visible. Examples include master cases and pallets where the organic identification (*e.g.*, the USDA organic seal) of individual retail units is visible.

6. Organic Certificates and Data Reporting: Certifying agents will issue publicly available standardized certificates of organic operation generated from the USDA's Organic Integrity Database (OID) (<https://organic.ams.usda.gov/Integrity>).
  - Examples of mandatory, public data fields include certification status, scope(s) of certification ( *e.g.*, crops, livestock, handling, wild-crop), and the organic commodities produced or handled by the operation. This will simplify the verification of valid certificates of organic operation.
  - Certifying agents must also keep accurate and current certified operation data in OID, which will further support verification of operations' certified status. Organic acreage is an example of mandatory data that will not be publicly available.
  - MOSA will continue to issue a separate Certified Organic Products Sheet with additional details about certified operations. This information will not be publicly available.
  - Updates will be made to this system within 72 hours for operations that are suspended, revoked, or surrender.

**MOSA will begin using the OID for generating certificates later this year.**

7. On-site and Unannounced Inspections: Clarifies timing and details of annual and unannounced inspections
  - Certifying agents must conduct on-site inspections at least once per calendar year.
  - At least 5% of the operations we certify will continue to receive an unannounced inspection which will be random, risk-based, in response to complaints, or other criteria; and typically be limited in scope. These will continue to be conducted without advance notice; and, **as a new clarification**, can be performed without an authorized representative of the operation present when the inspector is not trespassing. Any operation MOSA certifies may be the subject of an unannounced inspection. Refusal to allow for an unannounced inspection will result in a notification of noncompliance. Results of all inspections will be communicated to the organic operation.
  - Mass-balance audits during annual on-site inspections. Mass-balances must account for quantities of organic product and ingredients produced or purchased account for organic product and ingredients used, stored, sold, or transported. That is, inputs account for outputs.

- Inspections must verify traceability back to the previous certified operation in the supply chain during annual on-site inspections. Traceability audits must show that organic products and ingredients are traceable by the operation from the time of purchase or acquisition through production to sale or transport.

**Both types of audits will continue to be conducted at all annual on-site inspections and may be part of an unannounced inspection.**

8. Calculating Percent Organic Ingredients: Clarifies the method of calculating the percentage of organic ingredients in a multi-ingredient product to promote consistent interpretation and application of the regulation. Ingredients are to be calculated at formulation and salt and water added as ingredients must be excluded from the calculation.
9. Noncompliance, Mediation, and Appeals: Clarifies that the NOP may initiate enforcement action against any violator of the Organic Foods Production Act, including uncertified operations and responsibly connected parties; clarifies what actions may be appealed and by whom; and clarifies NOP's appeal procedures and options for mediation (alternative dispute resolution). A settlement agreement is the result of successful mediation and can be between the certifier and the operation or the National Organic Program and the operation. The new term "adverse action" has been added to the regulations.
10. Producer Group Operations: This action adds terms "producer group operation, producer group member, producer group production unit, and internal control system" and specifies requirements for producer group operations (previously referred to as grower groups), to provide consistent, enforceable standards and ensure compliance with the organic regulations. Producer groups must meet certain criteria to qualify for certification, and must use an internal control system to monitor compliance. MOSA does not currently certify any producer group operations as defined.
11. Personnel Training and Qualifications: New regulations establish specific qualification and training requirements for certifying agent personnel (inspectors and certification reviewers) and require that personnel meet minimum education and experience qualifications and include continuing education requirements. **MOSA is confident that our staff and inspectors meet the new requirements.**
12. Foreign Conformity Assessments: The regulations define NOP oversight over foreign conformity assessment systems that oversee organic certification in foreign countries. This will ensure the compliance of organic products imported from countries that have organic trade arrangements or agreements with the United States.

Read the Rule:

<https://www.federalregister.gov/documents/2023/01/19/2023-00702/national-organic-program-nop-strengthening-organic-enforcement>