On January 18, 2023, the USDA National Organic Program (NOP) published a mammoth rule, titled Strengthening Organic Enforcement, which was touted as the most substantive change to the NOP regulations since they were first introduced in 2002. Congress mandated that the NOP enhance its oversight of the organic industry after several high profile fraud cases emerged in the last several years. The rule adds to many current sections, while also creating new definitions, reducing exemptions to certification, and codifying longstanding guidance to accredited certifiers. The following is a detailed breakdown of the new rule and its effect on certified organic producers and certifiers.

Summary
The SOE Rule amends the National Organic Standards to strengthen oversight and enforcement of the production, handling, and sale of organic agricultural products. One significant area is the removal of activities and producers that were previously considered exempt from certification.

Topics addressed in this rulemaking include:
- Applicability and exemptions from organic certification.
- Imports to the United States.
- Record-keeping, product traceability and fraud prevention requirements.
- Labeling of non-retail containers.
- Standardized certificates of organic operations and data reporting.
- On-site and unannounced inspections of certified operations.
- Calculating organic content of multi-ingredient products.
- Compliance and appeals.
- Certification of producer group operations in the United States.
- 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: ams.usda.gov/rules-regulations/strengthening-organic-enforcement. The NOP has also created a handy side-by-side comparison of changes to the regulation, which can be found here: ams.usda.gov/sites/default/files/media/SOE-FR-RegTextSideBySide.pdf.

MCS will make efforts to inform producers of the changes to the regulations, both in this article as well as other notices and publications ahead of the March 19, 2024, implementation date. You’ll see new questions in your 2024 Organic System Plan (OSP) materials and supplements, as well as new items that MCS will verify at on-site inspections.

Dates
This rule became 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

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organic under the USDA organic regulations, particularly those who utilize uncertified handlers in their supply chain.

- Brokers, traders, exporters and importers of organic products that are not currently certified under the USDA organic regulations.
- Operations that use non-retail containers for shipping or storing organic products.
- Retailers that sell organic products or handle organic products in facilities other than where final sales take place.
- 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, combining, aggregating, culling, conditioning, treating, packaging, containerizing, repackaging, labeling, storing, receiving, or loading.

The definition of “handle” has been updated per §205.2, and NOP has signaled that most all activity within the supply chain will now require certification oversight:

**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, packaging, containerizing, repackaging, labeling, storing, receiving, or loading.

Some handlers with more complex supply chains will need to identify uncertified handlers used and determine if the activity of the uncertified handler now requires certification. MCS will be contacting those processor/handlers that identify using uncertified handlers, asking that the certified operation makes the uncertified handler aware of the new provisions.

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 requirements, including appropriate labeling as well as keeping required records for three years. Exempt products used as ingredients must not be represented as organic in products processed and marketed by other operations.
An operation that only receives, stores and/or prepares for shipment but does not otherwise handle remains exempt; however, the scope of this is very limited. Exempt handlers in this regard must adhere to the following requirements for packaged 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, per the rule, that the contents are safely contained in a manner where an attempt to break the seal, access the contents or re-close the package would be obvious. This exemption is intended primarily for storage and warehouse facilities moving organic products within the supply chain.

An operation that only buys, receives, stores and/or prepares for shipment but does not otherwise handle organic agricultural products already labeled for retail sale may be exempt. 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. Private labeling operations that process organic products must be certified. In addition, an operation that only arranges for the shipping, storing, transport or movement of organic agricultural products but does not otherwise handle organic products continues to be exempt. There are specific nuances that need to be considered with the new rule, and operations that aren’t sure should contact MCS. NOP has signaled that those used for shipping or storage as the non-retail container carrying the organic product. Non-retail containers are those used for shipping or storage of a product that is not used in the retail display or sale of the product. In addition, a lot number, shipping identification, or other unique information that links the container to audit trail documentation must be present on the container.

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 record-keeping and organic fraud prevention processes and procedures as applicable, depending on risk. New definitions for “organic fraud” and “supply chain traceability audit” were added to the regulations. Certifying agents will conduct risk-based supply chain traceability audits between certifiers to fully verify organic integrity. The OSP must also include measures implemented to prevent fraud. MCS will be providing guidance for operations requiring fraud prevention plans and supply chain verifications.

4. NOP Import Certificates: The use of NOP Import Certificates for all organic products entering the United States is now required. Exporters will request import certificates to be issued by their certifier from the Organic Integrity Database (OID) for all imports to the United States. Import certificates may be issued for individual shipments or for multiple shipments of a product over a specific timeframe and with a designated quantity. Additionally, all import documents must identify products as organic, as well as the non-retail container carrying the organic product. Non-retail containers are now codified in the regulations (MCS has been doing this for several years). In addition, 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. Mass balance and traceability audits will continue to be conducted at all annual on-site inspections.

6. On-site and Unannounced Inspections: While certifiers have been required through NOP guidance to conduct unannounced inspections for at least 5% of clients per year, the SOE rule codifies this requirement in regulation. Mass-balance audits during annual on-site inspections are now codified in the regulations (MCS has been doing this for several years). In addition, 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. Mass balance and traceability audits will continue to be conducted at all annual on-site inspections.

7. Producer Group Operations: SOE adds definitions and options for producer group certification, which has previously taken place outside of the United States. Producer groups must meet certain criteria to qualify for certification and must use an internal control system to monitor compliance. Please review the specific criteria and contact MCS if you think you may qualify.

Certifying agents must also keep accurate and current certified operation data in OID, which will further support verification of operations’ certified status. Changes in certification status (i.e., newly certified, surrendered, suspended or revoked) must be made by the certifier within 72 hours of the change.

5. Organic Certificates and Data Reporting: Certifying agents will now be required to issue publicly available, standardized certificates generated from the USDA’s Organic Integrity Database (OID). While the certificate must be issued from the OID, the product list (MCS refers to this as the Product Verification list) or addendum listing specific products certified under a NOP scope can be issued from the certifier and not the OID.

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