

Strengthening Organic Enforcement (SOE)

Final Rule Primers

Final Rule available at: www.ams.usda.gov/rules-regulations/strengthening-organic-enforcement

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Strengthening Organic Enforcement: Who Needs to Be Certified?

SOE’s biggest change is that **more operations in the organic supply chain will need to be certified organic**. These changes are described in [SOE section A](#).—Applicability and Exemptions from Certification. This document pairs a condensed version of the relevant regulatory text with a plain-language description of what the change means. **Bolded text** in the table below indicates a **key concept**.

General Comments from the National Organic Program: We strongly encourage certification of all businesses engaged in organic. It benefits the organic sector to have as many businesses certified as possible along a supply chain. There are many business benefits for being certified, and more and more buyers expect it to do business in organic. As a program, we need to protect the integrity of the entire supply chain – this is facilitated by having a certifier overseeing each business along that chain. Having everyone certified helps us oversee the sector from farm to market.

A. Applicability and Exemptions from Certification		
Section	Condensed Regulatory Text	Key Takeaways
205.100 (a)	WHAT HAS TO BE CERTIFIED. Except for...exempt operations...each operation...that produces or handles [organic] agricultural products must be certified.	Who needs to be certified? Anyone that produces or handles organic products . To produce means to grow or raise...but what does <u>handle</u> mean?



Section	Condensed Regulatory Text	Key Takeaways
205.2	<i>Handle.</i> 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.	Handle means many things! In general, operations that do these things must be certified. SOE adds more specific activities to “handle,” including trade, facilitate sale (broker), import, and export. Even businesses that don’t physically handle products may still need to be certified if they conduct one of these activities.
205.101	EXEMPTIONS FROM CERTIFICATION [Operations listed in] this section are exempt from certification ...and from submitting an organic system plan...but must comply with the applicable organic production and handling requirements...[and]...applicable labeling requirements.	<i>NOTE: SOE thoroughly revises and reorganizes § 205.101. Former references to specific paragraphs may no longer be valid!</i> Not every operation that does these things must be certified. Reasonable exemptions to certification are allowed for operations with low-risk activities. These operations don’t need to be certified, but they must still follow the rules for producing and handling organic products. SOE = narrower exemptions = more certified operations
205.101 (a)	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.	This exempts very small farms and businesses from certification. <i>No change in policy.</i>



Section	Condensed Regulatory Text	Key Takeaways
205.101 (b)	EXEMPTIONS FROM CERTIFICATION, cont. A retail establishment that does not process organically produced agricultural products.	This exempts most retailers (like grocery stores) that sell organic products. <i>No change in policy.</i>
205.101 (c)	A retail establishment that processes, at the point of final sale , [organic] agricultural products...	This exempts a broader range of retailers from certification (including restaurants and stores that cook or prepare food). <i>Online retailers that process but don't have a physical location where they sell products must be certified.</i>
205.101 (d)	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.	This exempts processors that make products with lower amounts of organic ingredients (e.g., “made with organic...”). <i>No change in policy.</i>
205.101 (e)	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...	This exempts warehouses and storage operations that only store packaged organic products. This includes both retail and nonretail packaging. <i>Operations that store bulk or unpackaged products must be certified.</i>
205.101 (f)	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...	This exempts wholesalers that only sell retail-packaged products. Wholesalers that sell bulk products or nonretail-packaged products must be certified.



Section	Condensed Regulatory Text	Key Takeaways
205.101 (g)	A Customs broker (per 19 CFR 111.1) that only conducts customs business...	This exempts CBP-licensed Customs brokers . These operations file import paperwork, but don't touch or handle products.
205.101 (h)	An operation that only arranges for the shipping, storing, transport, or movement of organic agricultural products...	This exempts logistics brokers —businesses that connect operations with carriers and storage facilities for a fee.
N/A	TRANSPORT	Businesses that strictly transport organic products do not require organic certification. Transport is not included in the regulatory or statutory definition of handle . SOE requires that certified operations use audit trails and traceability to verify that uncertified transporters don't compromise integrity.

Strengthening Organic Enforcement: Improving Traceability and Preventing Organic Fraud

One of SOE’s primary goals 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—makes several important changes that protect against both. It ensures organic products can be traced all the way back from retail to production. This document pairs condensed regulatory text with a plain-language description of what the change means. **Bolded text** in the table below indicates a **key concept**.

General Comments from the National Organic Program: The provisions on traceability and fraud prevention work together to protect the organic integrity of the entire supply chain. Along with the Applicability and Exceptions from Certification section, these provisions outline actions required by both certifiers and operations to enable full supply chain traceability. The rule encourages risk-based approaches to these processes to be sound and sensible, while also effectively protecting the market.

P. Supply Chain Traceability and Organic Fraud Prevention

Section	Condensed Regulatory Text	Key Takeaways
205.2	DEFINITIONS <i>Organic fraud.</i> Deceptive representation , sale, or labeling of nonorganic agricultural products or ingredients as ... organic.	<i>Organic fraud</i> was not previously defined in regulatory text. Defining it helps the industry understand what the rule is intended to prevent.
205.103 (b)(2)	RECORDKEEPING 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;	This section describes additional recordkeeping responsibilities of certified operations . SOE adds the bolded clause to ensure that traceability is maintained within an operation and back to the last certified operation . These key elements are required to conduct full supply chain traceability audits.



Section	Condensed Regulatory Text	Key Takeaways
		<p>When using a noncertified intermediary (e.g., an exempt wholesaler or shipping company), certified operations will need records showing both the last certified operation to possess or handle the product, and that organic integrity was maintained by the noncertified intermediary.</p> <p>This provision further highlights the importance of having entities certified across the supply chain.</p>
205.103 (b)(3)	[Such records must] Include audit trail documentation ... and identify agricultural products on these records as “100% organic,” “organic,” or “made with organic...”	<p>This specifies that certified operations must keep <i>audit trail</i> records—i.e., transactional or external records, and that these records must identify products as organic.</p> <p>This is a new paragraph. Former paragraphs (3) and (4) move down to (4) and (5), respectively.</p>
205.201 (a)(3)	ORGANIC PRODUCTION AND HANDLING SYSTEM PLAN ... must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of agricultural products received, and to prevent organic fraud ... as appropriate to the certified operation’s activities, scope, and complexity;	This requires certified operations to add a “ fraud prevention plan ” (FPP) to their OSP. The rule allows for flexibility with respect to how the FPP is modified for different supply chain environments in a sound and sensible way. For example, a granola producer combining many organic ingredients will need a FPP that is more complex than a vegetable farm selling to local vendors. FPPs are an industry best practice.
205.501 (a)(10)	REQUIREMENTS FOR ACCREDITATION [Certifying agents must] Maintain strict confidentiality with respect to its clients ... except:	SOE requires that <i>certifying agents</i> share information with each other to assist with compliance and enforcement. This is



Section	Condensed Regulatory Text	Key Takeaways
	<p>(ii) For enforcement purposes, certifying agents must exchange any compliance-related information that is credibly needed to certify, decertify, or investigate an operation, including for the purpose of verifying supply chain traceability and audit trail documentation; and</p> <p>(iii) ... all of the certifying agents that are involved in the exchange still have a duty to preserve the confidentiality of [proprietary] information.</p>	<p>necessary to conduct supply chain traceability audits and verify integrity of products traveling across supply chains.</p> <p>If shared information is sensitive or proprietary, the certifying agent must maintain its confidentiality, even after sharing it.</p>
205.501 (a)(13)	<p>Accept the certification decisions made by another certifying agent... provide information to other certifying agents to ensure organic integrity or to enforce organic regulations, including to verify supply chain integrity, authenticate the organic status of certified products, and conduct investigations;</p>	
205.501 (a)(21)	<p>Conduct risk-based supply chain traceability audits ... and share audit findings with other certifying agents as needed to determine compliance.</p>	<p>SOE requires certifying agents to conduct risk-based supply chain traceability audits to trace products across multiple links in a supply chain. Traceability between operations is a key element of modern supply chain and product verification.</p> <p>This is a new paragraph. Former paragraph (a)(21) is now (a)(23).</p>
205.2	<p><i>Supply chain traceability audit.</i> The process of identifying and tracking the movement, sale, custody, handling, and organic status of an agricultural product along a supply chain to verify</p>	<p>SOE adds <i>supply chain traceability audit</i> to clarify the scope and objective of this certifier requirement. The requirements in 501(a)(21) give certifiers flexibility to choose how they conduct audits to verify compliance.</p>



Section	Condensed Regulatory Text	Key Takeaways
	the agricultural product's compliance with [the organic regulations]	
205.504 (b)(4)	A copy of the procedures to be used for sharing information with other certifying agents and for maintaining the confidentiality of any business-related information...	Certifying agents must have written procedures and criteria for conducting risk-based supply chain audits. This will allow NOP to audit certifiers and assess how certifiers are implementing this supply chain traceability requirements. This is a new paragraph.
205.504 (b)(7)	A copy of the criteria to identify high-risk operations and agricultural products for supply chain traceability audits; and procedures to conduct risk-based supply chain traceability audits.	

Strengthening Organic Enforcement: Import Certificates

NOP Import Certificates are a key part of Strengthening Organic Enforcement’s (SOE) integrated strategy. By providing an auditable record trail of the import process, Import Certificates support traceability and verification of organic integrity. The data collected in Import Certificates will also allow NOP to monitor market trends, surveil imports, and detect and prevent fraud. This document pairs condensed regulatory text from [section B—Imports to the United States](#)—with a plain-language description of what the change means. **Bolded text** in the table below indicates a **key concept**.

General Comments from the National Organic Program: Organic import certificates provide critical data allowing USDA to see what organic products are coming into the country and from where. This will help guide future surveillance work. Further, invalid certificate numbers will be flagged, allowing us to follow-up quickly with importers. It is critical that certifiers overseeing exporters sending product to the U.S. have effective organic control system for verifying the integrity of organic products and claims.

B. Imports to the United States

Section	Condensed Regulatory Text	Key Takeaways
205.2	DEFINITION <i>Organic exporter.</i> The final certified exporter of the organic agricultural product, who facilitates the trade of, consigns , or arranges for the transport/shipping of the organic agricultural product from a foreign country to the United States.	Organic exporters to the U.S. must be certified. They export the product and therefore must have their certifier approve and generate an Import Certificate.
205.2	DEFINITION <i>Organic importer.</i> The operation responsible for accepting imported organic agricultural products within the United States and ensuring NOP Import Certificate data are entered into the U.S. Customs and Border Protection import system of record.	Organic importers must be certified. They import the product and must verify its integrity. They also check that the import matches the Import Certificate.



Section	Condensed Regulatory Text	Key Takeaways
205.273	Imports to the United States.	This section is entirely <i>new</i> .
205.273	Each shipment of organic agricultural products imported into the United States must be certified pursuant to subpart E of this part, labeled pursuant to subpart D of this part, be declared as organic to U.S. Customs and Border Protection, and be associated with valid NOP Import Certificate data .	SCOPE of the NOP Import Certificate: <ul style="list-style-type: none"> • What can be imported? Products certified to the USDA organic standard or equivalent under a trade arrangement. • When is an Import Certificate needed? For any organic agricultural product <u>imported into the U.S., regardless of country of origin</u>. • What needs an Import Certificate? Each <u>shipment</u> of organic agricultural product needs to be associated with an NOP Import Certificate.
205.273 (a)	Persons exporting organic agricultural products to the United States must request an NOP Import Certificate from a certifying agent prior to their export . Only certifying agents accredited by the USDA or foreign certifying agents authorized under an organic trade arrangement may issue an NOP Import Certificate.	NOP Import Certificate PROCESS : <ul style="list-style-type: none"> • 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.
205.273 (b)	The certifying agent must review an NOP Import Certificate request and determine whether the export complies with the USDA organic regulations. The certifying agent must have and implement a documented organic control system for intaking and approving or rejecting the validity of an NOP Import Certificate request. The certifying agent shall issue the NOP	PROCESS continued... <ul style="list-style-type: none"> • 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.



Section	Condensed Regulatory Text	Key Takeaways
	<p>Import Certificate through the Organic Integrity Database only if the export complies with the USDA organic regulations.</p>	<ul style="list-style-type: none"> • 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 in a given timeframe or volume of product.
205.273 (c)	<p>Each compliant organic import must be declared as organic to U.S. Customs and Border Protection by entering NOP Import Certificate data into the U.S. Customs and Border Protection’s Automated Commercial Environment system. Organic imports must be clearly identified and marked as organic on all import documents including but not limited to invoices, packing lists, bills of lading, and U.S. Customs and Border Protection entry data. Only NOP Import Certificate data generated by the Organic Integrity Database are valid.</p>	<p>PROCESS continued...</p> <ul style="list-style-type: none"> • A Customs broker uploads the Import Certificate data into ACE. 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.
205.273 (d)	<p>Upon receiving a shipment...the organic importer must ensure the import is accompanied by accurate NOP Import Certificate data and must verify that the shipment has had no contact with prohibited substances...or exposure to ionizing radiation... since export. The organic importer must have a documented organic control system to conduct this verification.</p>	<p>PROCESS continued...</p> <ul style="list-style-type: none"> • 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.

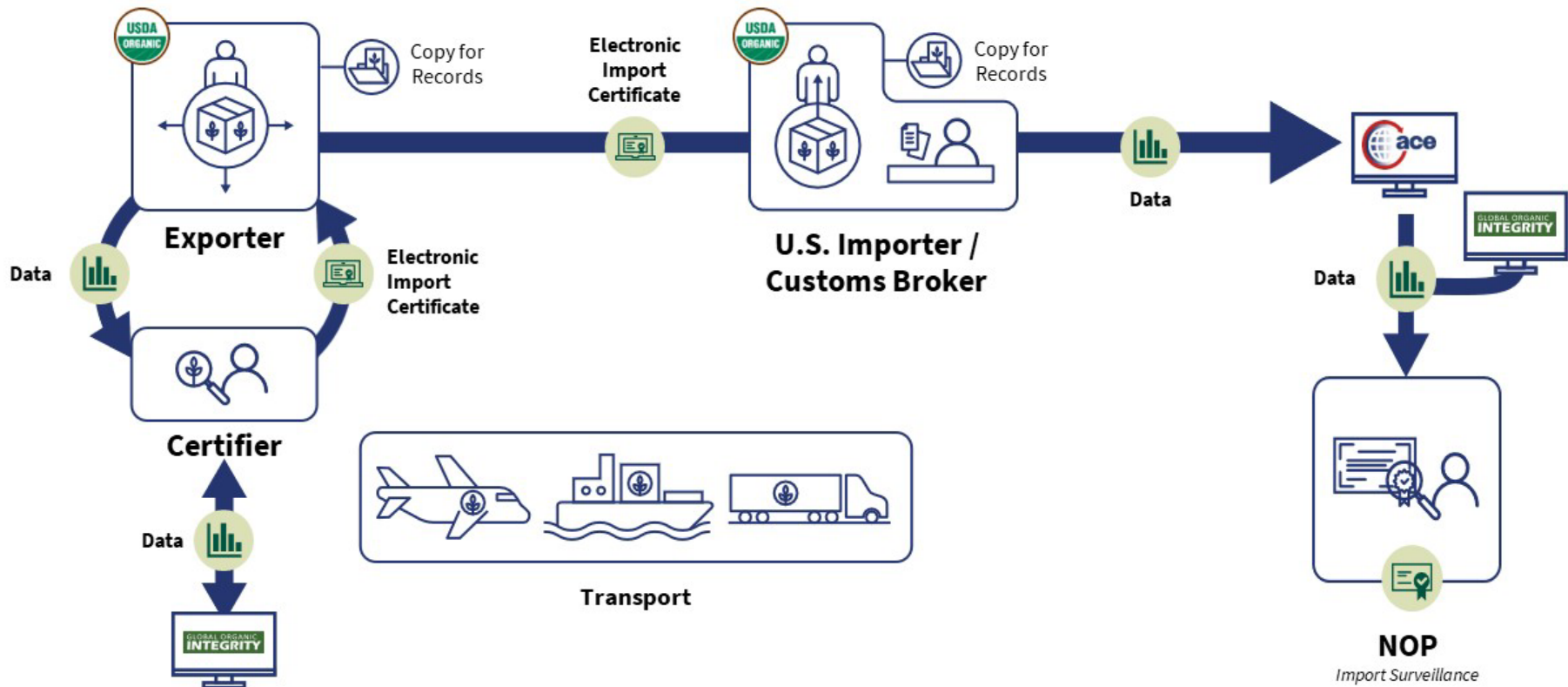


Agricultural Marketing Service

U.S. DEPARTMENT OF AGRICULTURE

Section	Condensed Regulatory Text	Key Takeaways
205.300 (c)	Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part, labeled pursuant to this subpart D, and must comply with the requirements in § 205.273.	This general labeling requirement in subpart D (Labels, Labeling, and Market Information) now includes a cross-reference to NOP Import Certificates.

NOP Import Certificate Data Flow

Strengthening Organic Enforcement: Certificates of Organic Operation and the Organic Integrity Database

The Strengthening Organic Enforcement (SOE) final rule updates how information about organic operations is generated and shared. The rule requires that certifiers:

- Generate standardized certificates of organic operation using USDA’s Organic Integrity Database (INTEGRITY); and
- Maintain up-to-date operation profiles in INTEGRITY.

These updates support organic integrity by giving certifiers and operations access to consistent and high-quality information that they use to validate organic products, ingredients, and supply chain operations. Uniform certificates of operation will also reduce confusion across the organic industry and deter fraud.

This document combines regulatory text from three sections ([E. Certificates of Organic Operation](#), [G. Paperwork Submissions to the Administrator](#), and [K. Compliance and Noncompliance Procedures](#)) with a plain-language description of what the changes mean. **Bolded text** in the table below indicates a **key concept**.

General Comments from the National Organic Program: The Organic Integrity Database (INTEGRITY) is a globally respected database that plays a central role in organic market development and oversight. These provisions maximize the use of INTEGRITY as a definitive source of data and certificates for organic trade. The provisions also remove some reporting requirements for certifiers, to balance the added update requirements to INTEGRITY. We expect that standardizing the operation-level certificate through INTEGRITY will both deter fraud and increase the regularity of reporting. Certifiers can still issue addenda to the standard operation certificate if they wish to.

E. Certificates of Organic Operation		
Section	Regulatory Text	Key Takeaways
205.2	Terms defined.	



Section	Regulatory Text	Key Takeaways
205.2	<i>Organic Integrity Database.</i> The National Organic Program's electronic, web-based reporting tool for the submission of data, completion of certificates of organic operation , and other information, or the tool's successors.	This is a newly defined term that explains the core functions of INTEGRITY—including that certificates of organic operation must be generated in INTEGRITY.
205.404	Granting certification.	
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.	Certifiers can no longer create certificates of organic operation using their own formats. Generating certificates in INTEGRITY will ensure consistent formatting and information , making it easier for certifiers and operations to verify suppliers, products, and ingredients. Certifiers can provide either electronic or paper copies to operations.
205.404 (c)	<i>[Redesignate former § 205.404(c) as (d) and add new paragraph (c) on certificate addenda.]</i> 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	Paragraph (c) on certificate addenda is new. Former paragraph (c) is moved down to (d). Issuing an addendum is optional . Addenda can provide additional useful information about the operation that is not included in the certificate of operation. If an addendum is issued, certain mandatory information must be included on the addendum to make it clear how someone can verify the operation's status. Specifically, the addendum must connect back to the operation profile in INTEGRITY and must have a clear statement that the operation's status can be verified in INTEGRITY . A certifier may generate addenda in INTEGRITY, or they may generate addenda using their own system.



Section	Regulatory Text	Key Takeaways
	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.”	This is a new paragraph .

G. Paperwork Submissions to the Administrator

Section	Regulatory Text	Key Takeaways
205.405	Denial of certification.	
205.405 (c)(3)	<i>[Remove paragraph (c)(3)]</i>	SOE removes former paragraph (c)(3) , which required a certifier to notify NOP when they took corrective actions on a notice of noncompliance issued to an operation. The INTEGRITY data requirements below make these notifications redundant.
205.501	General requirements for accreditation.	
205.501 (a)(15)	Maintain current and accurate data in the Organic Integrity Database for each operation which it certifies;	This replaces the former requirement to send NOP copies of denials of certification and notifications of noncompliance, noncompliance correction, proposed suspension or revocation, and suspension or revocation. It also removes the requirement to provide NOP a list of certified operations each year. Instead, operations must keep current and accurate operation data in INTEGRITY, including information about the certification status of the operation .

Section	Regulatory Text	Key Takeaways
		INTEGRITY will specify what types of information is required. Some of this information will be public (such as certification status and areas of operation) and other types of information will only be available to NOP and certifiers (such as acreage).

K. Compliance and Noncompliance Procedures

Section	Regulatory Text	Key Takeaways
205.662	Noncompliance procedure for certified operations.	
205.662 (e)(3)	<p>Within 3 business days of issuing a notification of suspension or revocation, or the effective date of an operation’s surrender, the certifying agent must update the operation’s status in the Organic Integrity Database.</p> <p><i>Note: This primer only covers <u>part</u> of section K; this section makes additional changes to compliance/noncompliance procedure!</i></p>	<p>Certifiers must update INTEGRITY with changes in an operation’s certification status within 3 business days. This will ensure that other operations and certifiers are promptly made aware of the change.</p> <p>This is a new paragraph.</p>

Strengthening Organic Enforcement: On-Site Inspections and Continuation of Certification

SOE requires that all certifiers conduct a minimum number of unannounced inspections per year; this was previously required through a certifier Instruction in the NOP Handbook, but is now codified in the regulations. Additionally, the rule requires that certifiers complete annual on-site inspections at least once per calendar year, during which certifiers must perform mass-balance audits and verify product traceability.

This document combines regulatory text from two sections ([D. On-Site Inspections](#) and [F. Continuation of Certification](#)) with a plain-language description of what the changes mean. **The bolded text** in the table below indicates a **key concept**.

General Comments from the National Organic Program: Every certified organic farm and business is inspected at least once a year by a qualified organic inspector. These inspections assess the operation’s compliance and determines if they are following their approved Organic System Plan. These SOE provisions clarify how these inspections are done. The rules also mandate that certifiers cannot certify operations that they cannot access for unannounced inspections.

D. On-Site Inspections		
Section	Regulatory Text	Key Takeaways
205.2	Terms defined.	
205.2	<i>Unannounced inspection.</i> 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.	An unannounced inspection can include a full operation or be limited to a portion of an operation or an operation’s activities , allowing certifiers to use unannounced inspections as a risk-based tool to target specific areas, activities, or times of the year.



Section	Regulatory Text	Key Takeaways
		Unannounced inspections aren't scheduled like full annual inspections. However, certifiers may give up to four hours prior notice to ensure the operation is accessible and safe to visit.
205.403	On-site inspections	
205.403 (b)	<p><i>[SOE adds this new paragraph on unannounced inspections. Former paragraphs (b) – (e) shift down one each to (c) – (f).]</i></p> <p><i>Unannounced inspections.</i></p> <p>(1) A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number.</p> <p>(2) Certifying agents must be able to conduct unannounced inspections of any operation they certify and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections.</p>	<p>Certifiers must complete a minimum number of unannounced inspections per year. Operations may be randomly selected or selected in response to high risk, investigations, or other criteria.</p> <p>The ability to conduct an unannounced inspection is considered part of a certifier's administrative capacity: if a certifier cannot conduct an unannounced inspection due to geography, logistics, staffing, security, or other reasons, then they cannot certify that operation.</p>
205.403 (d)(4)	<p><i>[Add mass-balance requirements to "Verification of Information," formerly § 205.403(c).]</i></p> <p><i>An on-site inspection of an operation must verify:</i></p> <p>Mass-balances, in that quantities of organic product and ingredients produced or purchased account for organic product and ingredients used, stored, sold, or transported.</p>	<p>During full annual on-site inspections, certifiers must perform mass-balance or "in-out" audits to confirm that inputs match outputs. This is an effective way to detect and discourage fraud. For example, if a manufacturer's records show they are producing more organic product than the volume of organic ingredients they purchase would suggest, this is a flag that they might be fraudulently using nonorganic ingredients.</p>



Section	Regulatory Text	Key Takeaways
205.403 (d)(5)	<p><i>[Add traceability requirements to “Verification of Information,” formerly § 205.403(c).]</i></p> <p><i>An on-site inspection of an operation must verify:</i></p> <p>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.</p>	<p>Certifiers must verify traceability within an operation and traceability to their certified supplier(s).</p> <p>This pairs with an operation’s traceability and audit trail documentation requirements in § 205.103(b)(2) and (3) (<i>see the primer on Supply Chain Traceability and Organic Fraud Prevention</i>). Certifiers must evaluate how operations maintain traceability.</p>

F. Continuation of Certification

Section	Regulatory Text	Key Takeaways
205.406	Continuation of certification	
205.406 (b)	<p>To continue certification, a certified operation must annually ... submit the following information to the certifying agent:</p> <p>(1) A summary statement, supported by documentation, detailing any ... changes to... the organic system plan...</p> <p>(2) Any additions or deletions to the previous year's organic system plan...</p> <p>(3) Any additions to or deletions from the information required pursuant to § 205.401(b); and</p> <p>(4) Other information as deemed necessary ... to determine compliance with the Act and the regulations...</p>	<p>Reduces paperwork by eliminating the need to annually submit:</p> <ul style="list-style-type: none"> • A full, updated copy of the OSP • Updates on the correction of minor noncompliances (operations must already do this as part of noncompliance procedure at § 205.662(a)(3) and certification procedure at § 205.404(a)).



Section	Regulatory Text	Key Takeaways
205.406 (b)	The certifying agent must arrange and conduct an on-site inspection , pursuant to § 205.403, of the certified operation at least once per calendar year .	<p>Ensures that all operations are inspected annually. The previous requirement was sometimes interpreted to allow up to an additional 6 months (18 months total) between inspections.</p> <p>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).</p> <p>If a certifier cannot complete a full annual inspection due to an emergency or other condition, they are to conduct follow-up inspections to determine the operation's compliance.</p>

Strengthening Organic Enforcement: Nonretail Labeling and Calculating Percent Organic

SOE requires that operations label nonretail containers with critical information that will help prevent contamination and comingling and support traceability and verification. SOE also clarifies how to calculate the percentage of organic ingredients in multi-ingredient products.

This document combines sections C. Labeling of Nonretail Containers and O. Calculating the Percentage of Organically Produced Ingredients with a plain-language description of what the change means. **The bolded text** in the table below indicates a **key concept**.

General Comments from the National Organic Program: The emergence of longer and more complex supply chains has highlighted the need for more tools as organic goods travel from farm to market. This section of the rule outlines risk-based requirements that protect organic integrity, decrease the risk of comingling, and facilitate organic verification traceability in real time. The section on calculating organic ingredients completed our work on a long-standing Draft Guidance document that has been of interest to the organic community.

C. Labeling of Nonretail Containers

Section	Regulatory Text	Key Takeaways
205.2	<p><i>[For context only; SOE does not change this term]</i></p> <p>Nonretail container. Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.</p>	<p>Nonretail containers are defined in § 205.2 and may include:</p> <ul style="list-style-type: none"> • 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.
205.307	Labeling of nonretail containers	



Section	Regulatory Text	Key Takeaways
205.307 (a)	Nonretail containers used to ship or store certified organic agricultural products must display:	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.
205.307 (a)(1)	Identification of the product as organic; and	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.
205.307 (a)(2)	The production lot number, shipping identification, or other unique information that links the container to audit trail documentation.	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. Operations may include additional information on labels such as special handling instructions, operation or certifier names, and contact information.
205.307 (b)	Audit trail documentation for nonretail containers must identify the last certified operation that handled the agricultural product.	This reinforces an SOE recordkeeping requirement to trace back to the last certified operation in a supply chain. <i>(See § 205.103(b)(2) and the primer on “Supply Chain Traceability and Organic Fraud Prevention”)</i>
205.307 (c)	Paragraph (a)(1) of this section does not apply to nonretail containers used to ship or store agricultural	This avoids duplicative labeling . Master cases, pallets, or other containers don’t need additional organic identification if the retail



Section	Regulatory Text	Key Takeaways
	products packaged for retail sale with organic identification visible on the retail label.	packages they hold indicate the products are organic (for example, if the USDA organic seal is visible). These types of containers must still include information linking back to audit trail documentation.

O. Calculating the Percentage of Organically Produced Ingredients

Section	Regulatory Text	Key Takeaways
205.302	Calculating the percentage of organically produced ingredients.	
205.302 (a)(1)	Dividing the total net weight of the combined organic ingredients at formulation by the total weight of all ingredients of the product at formulation . Water and salt added as ingredients at formulation are excluded from the calculation.	The regulation previously used “weight of the <i>finished product</i> .” This did not account for water loss from ingredients such as fruit during baking or other processing. 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.
205.302 (a)(2)	Dividing the total fluid volume of the combined organic ingredients at formulation by the total fluid volume of all ingredients of the product at formulation if the product and ingredients are liquid. Water and salt added as ingredients at formulation are excluded from the calculation. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made based on single-strength concentrations of all ingredients.	For consistency, calculating based on the weight of all ingredients at formulation carries through to liquid products .



Section	Regulatory Text	Key Takeaways
205.302 (a)(3)	For products containing organically produced ingredients in both solid and liquid form, dividing the combined net weight of the solid organic ingredients and the net weight of the liquid organic ingredients at formulation by the total weight of all ingredients of the product at formulation. Water and salt added as ingredients at formulation are excluded from the calculation.	For consistency, calculating based on the weight of all ingredients at formulation carries through to products that contain both liquid and solid ingredients.
205.302 (b) – (c)	<i>Paragraphs (b) and (c) are unchanged.</i>	

Strengthening Organic Enforcement: Personnel Training and Qualifications

This section of SOE more clearly lists qualifications for organic inspectors and certification reviewers, including specific knowledge, skills, expertise, training, and experience requirements. It also requires that certifiers evaluate the performance of inspectors in the field (witness audits). Because inspectors and certifiers are the first lines of defense against fraud, these requirements will protect the integrity of the organic label across entire supply chains.

This document combines regulatory text from section [H. Personnel Training and Qualifications](#) with a plain-language description of what the change means. **The bolded text** in the table below indicates a **key concept**.

General Comments from the National Organic Program: Organic is a process standard, and process standards are ultimately people standards – we need qualified professionals in a range of organic certification jobs. These rule provisions boost confidence for certified operations that well-trained and experienced professionals are visiting their farms and businesses and reviewing their plans and records.

H. Personnel Training and Qualifications

Section	Regulatory Text	Key Takeaways
205.2	Terms defined.	
205.2	<i>Certification review.</i> The act of reviewing and evaluating a certified operation or applicant for certification and determining compliance or ability to comply with the USDA organic regulations . This does not include performing an inspection.	Along with the existing definition of <i>inspection</i> , this term describes who these requirements apply to . Anyone who performs an inspection or certification review must meet the criteria.
205.501	General requirements for accreditation.	
205.501 (a)(4)	Continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and	Paragraphs under (a)(4) cover training and qualifications for both inspectors and certification reviewers . SOE adds



Section	Regulatory Text	Key Takeaways
	certification review personnel, to comply with and implement the USDA organic standards.	<i>“continuously”</i> and <i>“qualified”</i> to communicate the requirements for certifier personnel more clearly.
(a)(4)(i)	Certifying agents must demonstrate that all inspectors , including staff, volunteers, and contractors , have the relevant knowledge, skills, and experience required to inspect operations of the scope and complexity assigned and to evaluate compliance with the applicable [USDA regulations].	Paragraphs under (a)(4)(i) cover inspectors . An inspector’s knowledge, skills, and experience must fit the scope and complexity of the operations they will inspect . For example, crop operations may require different knowledge, skills, and experience than a dairy operation or food manufacturer.
	(A) Certifying agents must demonstrate that inspectors continuously maintain adequate knowledge and skills about the current USDA organic standards, production and handling practices, certification and inspection, import and/or export requirements, traceability audits, mass-balance audits, written and oral communication skills, sample collection, investigation techniques, and preparation of technically accurate inspection documents.	This paragraph describes the knowledge and skills that all inspectors must have. To reinforce other parts of SOE, this includes specific skills related to importing and exporting, traceability audits, and mass-balance audits.
	(B) All inspectors must demonstrate successful completion of training that is relevant to inspection. Inspectors with less than one year of inspection experience must complete at least 50 hours of training within their first year and prior to performing inspections independently. Inspectors with one or more years of inspection experience must annually complete at least 10 hours of training if inspecting one area of operation (as defined at § 205.2) and an additional 5 hours of training for each additional area of operation inspected.	This paragraph focuses on training relevant to inspection. SOE requires annual training that scales to experience and the types of operations an inspector inspects. For example, an inspector who inspects crop, livestock, and wild crop operations (i.e., three “scopes” or areas of operation) must complete at least 20 hours of training annually.



Section	Regulatory Text	Key Takeaways
	<p>(C) Certifying agents must demonstrate that inspectors have a minimum of 2,000 hours of experience relevant to the scope and complexity of operations they will inspect before assigning initial inspection responsibilities.</p>	<p>All inspectors must have an equivalent of one year of relevant experience before inspecting operations independently. This can include education, training, work on a farm or ranch, internships, apprenticeships, volunteer work, and more.</p>
(a)(4)(ii)	<p>Certifying agents must demonstrate that all certification review personnel, including staff, volunteers, or contractors, have the knowledge, skills, and experience required to perform certification review of operations of the scope and complexity assigned and to evaluate compliance with the applicable regulations of this part.</p>	<p>Paragraphs under (a)(4)(ii) cover certification reviewers. Like inspectors, certification reviewers must have knowledge, skills, and experience appropriate for the scope and complexity of operations they review.</p>
	<p>(A) Certifying agents must demonstrate that all certification review personnel continuously maintain adequate knowledge and skills in the current USDA organic standards, certification and compliance processes, traceability audits, mass-balance audits, and practices applicable to the type, volume, and range of review activities assigned.</p>	<p>Like certifiers, certification reviewers must also have the knowledge and skills required to review an operation's compliance. The specific skills are a little different than inspectors because they perform different duties (e.g., certification reviewers typically don't need to know how to collect samples).</p>
	<p>(B) All certification review personnel must demonstrate successful completion of training that is relevant to certification review. Certification review personnel with less than one year of certification review experience must complete at least 50 hours of training within their first year performing certification review. Certification review personnel with one or more years of certification review experience must annually complete at least 10 hours of training if conducting certification review related to one area of operation and an</p>	<p>Certification reviewers must complete the same amount of annual training as inspectors.</p>



Section	Regulatory Text	Key Takeaways
	additional 5 hours of training for each additional area of operation.	
(a)(4)(iii)	Certifying agents must maintain current training requirements , training procedures , and training records for all inspectors and certification review personnel.	Keeping records and other information allows NOP to evaluate a certifier’s compliance during audits.
(a)(5)	Demonstrate that all persons with inspection or certification review responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned. Sufficient expertise must include knowledge of certification to USDA organic standards and evidence of education, training, or professional experience in the fields of agriculture, science, or organic production and handling that relates to assigned duties.	In addition to general knowledge and skill, inspectors and certification reviewers must also demonstrate expertise specific to organic production and handling This can be gained through education, professional experience in agriculture or science, or direct experience working on a farm or in a handling facility.
(a)(6)	Conduct an annual performance evaluation of all persons who conduct inspections, certification review, or implement measures to correct any deficiencies in certification services.	Certifiers must annually review the performance of all inspectors and certification reviewers.
	(i) Witness inspections—certifying agents must ensure that each inspector is evaluated while performing an inspection at least once every three years, or more frequently if warranted. Inspectors with less than three years of inspection experience must undergo a witness inspection annually. Witness inspections must be performed by certifying agent personnel who are qualified to evaluate inspectors.	Certifiers must evaluate inspectors during inspections . The frequency of these witness audits is scaled to the inspector’s experience and performance.



Section	Regulatory Text	Key Takeaways
	(ii) Certifying agents must maintain documented policies, procedures, and records for annual performance evaluations and witness inspections.	Keeping records and documenting policies allows NOP to evaluate a certifier's compliance during audits.

Strengthening Organic Enforcement: Compliance, Mediation, and Appeals

SOE includes many mechanisms that prevent organic fraud and mishandling *before* it happens (e.g., certification of more businesses in supply chains, NOP Import Certificates, improved recordkeeping and traceability). The rule also updates the processes and procedures for handling noncompliance *after* it occurs. Key changes include clearer authority to strengthen enforcement against uncertified operations, updates to promote the use of mediation as an alternate dispute resolution method, and revisions to the appeals process.

This document discusses sections [K. Compliance and Noncompliance Procedures](#), [L. Mediation](#), and [M. Adverse Action Appeal Process](#). Regulatory text is paired with a plain-language description of what the change means. **The bolded text** indicates a **key concept**.

General Comments from the National Organic Program: Over the past several years, AMS has introduced new appeals processes and enforcement procedures that stress alternative dispute resolution solutions that bring operations into compliance more quickly than the traditional noncompliance escalation steps. SOE integrates many of these processes into the regulations. The updates also clarify NOP’s ability to enforce against uncertified operations through formal administrative law processes.

K. Compliance and Noncompliance Procedures

Section	Regulatory Text	Key Takeaways
205.660	Compliance—General.	
205.660 (c)	Note: <i>This is a new paragraph! Former paragraphs (c) and (d) are now (d) and (e), respectively.</i> The Program Manager may initiate enforcement action against any person who sells, labels, or...implies...[a] product is...organic, if the product was produced or handled in violation of the OFPA or the regulations in this part.	The change clearly states NOP’s authority to take enforcement action against uncertified operations or individuals that falsely represent conventional products as organic.



Section	Regulatory Text	Key Takeaways
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.
205.100	What has to be certified.	
(c)	Any person or responsibly connected person that... [knowingly sells fraudulent organic products or makes false claims is subject to civil penalties, fines, or imprisonment]	SOE clarifies that the penalties for organic fraud apply to responsibly connected persons who created or perpetuated the fraud.
205.662	Noncompliance procedure for certified operations.	
(e)(3)	Within 3 business days of issuing a notification of suspension or revocation , or the effective date of an operation's surrender , the certifying agent must update the operation's status in the Organic Integrity Database.	Certifiers provide a specific timeframe by which certifiers must report critical changes in operation status (i.e., status changes that could affect the integrity of products that another operation buys or receives) by updating INTEGRITY.
(f)(1)	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...	A person responsibly connected to a suspended operation may lose eligibility to be certified . Just like an operation, this responsibly connected person must apply though NOP to review their eligibility for certification.
(g)(1)	[In addition to suspension or revocation, any certified operation that] knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than the amount specified in 7 CFR 3.91(b)(1)(xxxvi) per violation .	Civil penalties have generally been used mostly with uncertified operations. This clarifies that certified operations may also be fined in addition to losing their certification. This change explicitly notes that certified more precisely cites the maximum civil penalty for violations.

L. Mediation

Section	Regulatory Text	Key Takeaways
205.663	Mediation.	§ 205.663 has been divided into subparagraphs for clarity.
(a)	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).	Certifying agents must include mediation criteria and procedures in their administrative policies and procedures. This is needed to fulfill due process requirements under the Administrative Procedures Act (APA) when cases proceed through an administrative law process.
(b)	A certified operation or applicant for certification may request mediation to resolve a denial of certification or proposed suspension or proposed revocation of certification issued by a certifying agent or State organic program.	This codifies that mediation is an available method of alternative dispute resolution to resolve noncompliances before an operation or certifying agent appeals to AMS.
(b)(1)	A certified operation or applicant for certification must submit any request for mediation in writing... within 30 calendar days of receipt of the notice of proposed suspension or proposed revocation of certification or denial of certification.	Clarifies the timeline to submit a request for mediation. 30 days aligns with the timeframe provided to submit an appeal of a proposed adverse action.
(b)(2)	A certifying agent or State organic program may accept or reject a request for mediation based on the decision criteria required in paragraph (a) of this section. Certifying agents must document these criteria. and how the certifying agent applied the criteria to the request.	Decision criteria for accepting or rejecting mediation must be fair and not arbitrary . The agent must be able to document how standard criteria were used to make a specific acceptance or rejection decision.
(b)(3)	If a certifying agent rejects a mediation request, it must provide this rejection, and the justification for the rejection, in writing to the applicant for certification or certified operation. The rejection must include the right to request an appeal, pursuant	SOE adds a reference to the updated appeals process in § 205.681 to clarify what steps the certifier and operation should take following rejection of a mediation request.



Section	Regulatory Text	Key Takeaways
	to § 205.681 , within 30 calendar days of the date of receipt of the written notification of rejection of the request for mediation.	
(b)(4)	(4) When an operation appeals a rejection of mediation, the adverse action which is contested must not be finalized during the appeal proceeding.	The rule clarifies that the adverse action being contested cannot be finalized during the appeal proceeding. This clarification supports the right to due process .
(c)	Both parties must agree on the person conducting the mediation.	This is required for both formal and informal mediation.
(d)	If a State organic program is in effect, the parties must follow the mediation procedures established in the State organic program and approved by the Secretary.	All parties must follow any additional mediation requirements of a State organic program.
(e)	The parties to the mediation have a maximum of 30 calendar days to reach an agreement from the start of mediation . Successful mediation results in a settlement agreement agreed to in writing by both the certifying agent and the certified operation. If mediation is unsuccessful, the applicant for certification or certified operation has 30 calendar days from receipt of a written notice of termination of mediation to appeal the denial of certification or proposed suspension or revocation pursuant to §205.681 .	Clarifies that the 30 days starts when mediation starts. This paragraph also clarifies what the successful outcome of mediation looks like: the goal of mediation is to reach a settlement agreement that leads to compliance (either by exiting the market or coming into compliance).
205.663 (f)	Any settlement agreement reached through mediation must comply with the Act and the regulations in this part. The Program Manager may review any mediated settlement agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.	Clarifies that NOP , not the Secretary, may review mediated settlement agreements.



Section	Regulatory Text	Key Takeaways
205.663 (g)	The Program Manager may propose mediation and enter into a settlement agreement at any time to resolve any adverse action notice.	Clarifies that NOP may use mediation as part of its oversight, compliance, and enforcement activities.
205.504	Evidence of expertise and ability. [certifying agents]	
	A private or governmental entity seeking accreditation...must submit...documents and information to demonstrate its expertise in organic production or handling techniques [and] its ability to fully comply with and implement...205.661 through 205.663...	Certifiers must include mediation criteria and procedures in the information that they provide to demonstrate their ability to comply with the organic regulations.
(b)(8)	<i>Administrative policies and procedures.</i> (8) A copy of reasonable decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation.	

M. Adverse Action Appeals Process

Section	Regulatory Text	Key Takeaways
205.2	Terms defined.	
205.2	<i>Adverse action.</i> A noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease and desist notice; or a civil penalty.	<i>Adverse action</i> is a newly defined term that replaces <i>noncompliance decision</i> throughout the appeals sections of the regulation. It clarifies what specific types of notices are appealable.
205.680	Adverse Action Appeal Process—General.	



Section	Regulatory Text	Key Takeaways
(d)	Persons subject to the Act who believe they are adversely affected by an adverse action ... may request mediation as provided in § 205.663.	<i>New paragraph! Former (d) is redesignated as (f).</i> Cross-reference to mediation as an appropriate course of action to resolve an adverse action before a party appeals.
(e)	All appeals must comply with the procedural requirements in § 205.681(c) and (d).	<i>New paragraph! Former (e) is redesignated as (g).</i> Cross-reference to appeals filing requirements.
205.681	Adverse Action Appeals Process—Appeals.	
(a)	Adverse actions by certifying agents. An applicant for certification may appeal...	SOE changes the title of this paragraph from “Certification appeals” to “Adverse actions by certifying agents” to better distinguish it from adverse actions by the NOP.
(a)(2)	If the Administrator or State organic program denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification unless the parties resolve the issues through settlement, or the appellant waives or does not timely request a hearing ...	SOE clarifies that denial of an operation’s appeal does not always result in a formal administrative hearing. The affected parties may choose to accept a settlement or waive or decline a hearing . If a hearing is waived or not requested, the certifier issues the adverse action without a formal proceeding. This is an important change in the default from “Hearing” to “no Hearing unless requested.”
(b)	<i>Adverse actions by the NOP Program Manager.</i> A person affected by an adverse action, as defined by § 205.2, issued by the NOP Program Manager, may appeal to the Administrator.	This section updates the outcomes that may follow an appeal. The regulations formerly only addressed the continuance or denial of accreditation. SOE adds that if an appeal is sustained :
(b)(1)	(1) If the Administrator sustains an appeal, an applicant will be issued accreditation, a certifying agent will continue its accreditation, or an operation will continue its certification, a civil penalty will be withdrawn and a cease-and-desist notice will be withdrawn , as applicable to the operation.	<ul style="list-style-type: none"> • An operation may continue certification, and • Civil penalties and cease-and-desist notices are withdrawn. If an appeal is denied :



Section	Regulatory Text	Key Takeaways
(b)(2)	If the Administrator denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the accreditation or certification and/or levy civil penalties unless the parties resolve the issues through settlement , the appellant waives a hearing , or the appellant does not timely request a hearing...	<ul style="list-style-type: none">• 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
(c)	<i>Filing period.</i> An appeal must be filed in writing within the time period provided in the letter of notification or within 30 days... An adverse action will become final and nonappealable unless an appeal is timely filed.	SOE updates this paragraph to remove “noncompliance decision” and use “adverse action,” It also clarifies that an adverse action becomes final unless an appeal is timely filed.
(d)(1)	Appeals to the Administrator and Requests for Hearing must be filed in writing and addressed to: 1400 Independence Ave., [etc.] ... or electronic transmission , NOPAppeals@usda.gov	SOE adds an email address where appeals may be sent electronically.
(d)(3)	All appeals must include a copy of the adverse action and a statement of the appellant's reasons for believing that the action was not proper...	The regulation now uses the new term <i>adverse action</i> to encompass the decisions an appellant may appeal.

Strengthening Organic Enforcement: Producer Groups, Satellite Offices, and Equivalency

Sensible oversight of the global organic supply protects organic integrity. In addition to the NOP Import Certificate, SOE introduces several mechanisms that safeguard the integrity of imported products. The rule codifies standards for producer groups, a type of certification commonly used in other countries to produce favorites like coffee and bananas. SOE clarifies the USDA’s authority to enforce the activities of individual certification offices in other countries. Finally, SOE also codifies how the USDA determines if another country’s organic standard is equivalent to the USDA organic standard, allowing that country’s organic products to be sold in America.

This document discusses sections [N. Producer Group Operations](#), [I. Oversight of Certification Activities](#), and [J. Accepting Foreign Conformity Assessment Systems](#). Condensed regulatory text is paired with a plain-language description. **Bolded text** indicates a **key concept**.

General Comments from the National Organic Program: The Strengthening Organic Enforcement (SOE) rule includes many provisions that address different topics, but that work together to create an inter-connected, systematic network of organic control systems at different oversight levels. These control systems protect the organic market from the level of a two-acre farm, to a country-specific certifier office, to another government’s organic program.

N. Producer Group Operations		
Section	Regulatory Text	Key Takeaways
205.2	Terms defined.	
	<i>Producer group operation.</i> A producer, organized as a person, consisting of producer group members and production units in geographic proximity governed by an internal control system under one organic system plan and certification.	A group of individual farmers that are collectively certified under one organic certificate .



Section	Regulatory Text	Key Takeaways
	<i>Producer group member.</i> An individual engaged in the activity of producing or harvesting agricultural products as a member of a producer group operation.	A member is a single farmer within a producer group.
	<i>Producer group production unit.</i> A defined subgroup of producer group members in geographic proximity within a single producer group operation that use shared practices and resources to produce similar agricultural products .	A production unit is a collection of members in the same area that produce the same commodity . A producer group can have several production units, or just one.
	<i>Internal control system (ICS).</i> An internal 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.	The ICS is directly responsible for the compliance of the producer group. The ICS trains members but also inspects, monitors, and enforces members. In contrast, the certifier reviews the ICS and determines the ICS’s ability to ensure compliance with the regulations.
205.400	General requirements for certification.	
(g)	In addition to paragraphs (a) through (f) of this section, a producer group operation must:	This section describes what it takes to be eligible for producer group certification under a single organic certificate.
(1)	Be organized as a person;	
(2)	Use centralized processing, distribution, and marketing facilities and systems;	
(3)	Be organized into producer group production units;	
(4)	Maintain an internal control system...	
(5)	Ensure that all agricultural products sold, labeled, or represented as organic are produced only by producer group members using land and facilities within the certified operation;	



Section	Regulatory Text	Key Takeaways
(6)	Ensure that producer group members do not sell, label, or represent their agricultural products as organic outside of the producer group operation unless they are individually certified;	To be eligible for producer group certification, the group must follow specific organizational and procedural criteria , such as having an ICS, selling only through the producer group, providing certain data to certifying agents, conducting annual inspections of every member, and ensuring traceability.
(7)	Report to the certifying agent... [data about each member]	
(8)	Conduct internal inspections of each producer group member...	
(9)	Implement recordkeeping requirements to ensure traceability...	
(10)	Implement procedures to ensure... complian[ce] with the USDA organic regulations and the Act; and	
(11)	Address any other terms or conditions determined by the Administrator to be necessary...	
205.201	Organic production and handling system plan	Because the ICS is the cornerstone of producer group certification, the OSP must thoroughly describe how the ICS will maintain compliance with the organic regulations. Like other parts of an OSP, this information helps the ICS function well and helps certifiers assess compliance . Key areas of focus include the structure and function of both the ICS and the producer group, risk management, training, recordkeeping, traceability, monitoring, and inspection.
(c)	... [A] producer group operation's organic system plan must describe its internal control system...	
(1)	Define the organizational structure, roles, qualifications, and responsibilities of all personnel;	
(2)	Identify producer group production units and locations;	
(3)	Describe measures to protect against potential conflicts of interest...	
(4)	Define geographic proximity criteria...	
(5)	Describe procedures for accepting new members...	
(6)	Describe characteristics of high-risk producer group members...	
(7)	Describe [use and distribution of] shared resources...	
(8)	Describe...training, education, and technical assistance...	
(9)	Describe the system of records used to demonstrate compliance...	

Section	Regulatory Text	Key Takeaways
(10)	Describe how internal monitoring, surveillance, inspection, sanctions, and auditing are used to assess compliance...	
205.403	On-site inspections.	
(a)(2)	Inspections of producer group operation must:	This section covers what certifiers must do when inspecting a producer group. Certifiers must: <ul style="list-style-type: none"> • Assess the ICS’s inspection of members • Observe the ICS inspecting members • Inspect a minimum number of members • Inspect handling facilities
(i)	Assess the internal control system’s compliance, [including] review of the internal inspections...	
(ii)	Conduct witness audits of internal control system inspectors...	
(iii)	Individually inspect at least 1.4 times the square root or 2% of the total number of producer group members...	
(iv)	Inspect each handling facility.	

I. Oversight of Certification Activities

Section	Regulatory Text	Key Takeaways
205.2	Terms defined.	
	<i>Certification activity.</i> Any business conducted by a certifying agent , or by a person acting on behalf of a certifying agent, including but not limited to: certification management; administration; application review; inspection planning; inspections; sampling; inspection report review; material review; label review; records retention; compliance review; investigating complaints and taking adverse actions; certification decisions; and issuing transaction certificates.	This new term describes the scope of activities that certifiers perform and defines some of the activities that are subject to NOP oversight and enforcement.
205.2	<i>Certification office.</i> Any site or facility where certification activities are conducted , except for certification activities that	In combination with <i>certification activities</i> , this new term helps clarify that any office may be subject to NOP oversight and enforcement , whether it is a “central” or “satellite” office.



Section	Regulatory Text	Key Takeaways
	occur at certified operations or applicants for certification, such as inspections and sampling.	
205.501	General requirements for accreditation.	
(a)(22)	Notify AMS not later than 90 calendar days after certification activities begin in a new certification office. ...[I]nclude the countries... the nature of the certification activities, and the qualifications of the personnel...	Note: This paragraph is new and was a requirement in the 2018 Farm Bill to help support NOP oversight of certifiers. Certifiers must notify NOP when they open a new certification office —also known as a “satellite office”—and must report information about the location, activities, and personnel.
205.665	Noncompliance procedure for certifying agents.	
(a)	(1) A written notification of noncompliance will be sent to the certifying agent when... (ii) The Program Manager determines that the certification activities of the certifying agent, or any person performing certification activities on behalf of the certifying agent , are not compliant... (iii) The Program Manager determines that the certification activities at a certification office, and/in specific countries, are not compliant...	SOE reorganizes paragraph (a) and adds clearer language about when USDA may initiate enforcement action against a certifier . This means that USDA can take enforcement action based on the activity of subcontractors , an individual remote certification office or “ satellite office ,” or the activities within a specific country.

J. Assessing Foreign Conformity Assessment Systems

Section	Regulatory Text	Key Takeaways
205.2	Terms defined.	
	<i>Technical requirements.</i> A system of relevant laws, regulations, regulatory practices, standards, policies, and procedures that address... organic agricultural products.	This is a new term for the standards that another government uses to describe and regulate organic production and handling.
	<i>Conformity assessment system.</i> All activities ... undertaken by a government to ensure that the applicable technical requirements... are fully and consistently applied.	How another government ensures compliance with their organic standards.
205.511	Accepting foreign conformity assessment systems.	<i>New section!</i>
(a)	...Foreign product that is produced and handled under another country's organic certification program may be sold, labeled, or represented in the United States as organically produced if the U.S. Government determines that such country's organic certification program provides technical requirements and a conformity assessment system... that are at least equivalent to [U.S.] requirements.	Organic products produced overseas can be sold in the U.S. if they are certified USDA organic <u>OR</u> if the products are certified under another government's organic standard that is determined to be equivalent to USDA organic. Equivalent means that the other organic standard is similar enough to USDA organic that it's considered interchangeable. It does not mean the standards are identical.
(b)	Countries desiring to establish eligibility of product certified under that country's organic certification program...may request equivalence determinations from AMS ... the requesting country must submit documentation that describes its technical requirements and conformity assessment system...	A government can apply to request a determination of whether its organic standard is technically equivalent to the USDA organic standard. The government needs to provide all the information needed to assess technical equivalence.
(c)	AMS will describe the scope of an equivalence determination.	
(d)	AMS will conduct regular reviews ...to verify that the foreign [organic standard is] equivalent... and will determine if the	IF the U.S. government determines the systems to be equivalent, AMS will regularly reevaluate the other



Section	Regulatory Text	Key Takeaways
	equivalence determination should be continued, amended, or terminated. AMS will determine the timing and scope of reviews and re-assessments...	government’s organic standard—and their system and ability to enforce this standard—to see if it remains equivalent to USDA organic. The U.S. government may choose to continue, update, or end equivalence.
(e)	The U.S. Government may terminate equivalence... if AMS determines that the country’s technical requirements and/or conformity assessment program are no longer equivalent; if AMS determines that the foreign government’s organic control system is inadequate...; or for other good cause.	Equivalence may end if the other government’s: <ul style="list-style-type: none">• Organic standard is no longer similar to USDA’s organic standard;• System of oversight and enforcement is no longer similar to USDA organic; or• Ability to enforce the standard does not ensure integrity.

Quick Guide: SOE CFR Reference Changes

Purpose: The SOE rule significantly updated the USDA organic regulations. This document lists sections and/or paragraphs that the rule *redesignated*. For example, former paragraph 205.501(a)(21) is now paragraph (a)(23). It also lists new paragraphs and sections that SOE added. The table below lists these changes so that NOP can begin updating these references in NOP documents.

*Note: This table is a **guide only**. Please check the CFR when updating references in documents. If you are updating regulatory text, you must read the read [final rule](#) and the updated [CFR](#).*

Former Reference	New Reference	Description of Change
205.2	205.2	Several revised and new definitions. See the CFR.
205.101		Significantly revised and reorganized. All references to paragraphs in 101 may need and update.
205.103(b)(3)	205.103(b)(4)	(b)(3) redesignated as (b)(4)
205.103(b)(4)	205.103(b)(5)	(b)(4) redesignated as (b)(5)
N/A	205.201(c)	New paragraph on producer group OSPs.
N/A	205.273	New section on NOP Import Certificates.
205.307	205.307	Significantly revised and reorganized. Title of section and references to paragraphs in 307 will need an update.
N/A	205.400(g)	New paragraph on producer group criteria.
N/A	205.403(a)(2)	New paragraph on producer group inspections.
205.403(a)(2)	205.403(a)(3)	(a)(2) redesignated as (a)(3)
N/A	205.403(b)	New paragraph on unannounced inspections.
205.403(b)	205.403(c)	Former paragraphs move up one letter. Paragraph (d) now also has new subparagraphs (1) and (2) on mass-balance and traceability.
205.403(c)	205.403(d)	
205.403(d)	205.403(e)	
205.403(e)	205.403(f)	
N/A	205.404(c)	New paragraph on organic certificate addenda.
205.404(c)	205.404(d)	(c) redesignated as (d)
205.405(c)(3)	<i>Removed</i>	Remove paragraph about sending notices of approval or denial of certification to NOP.
205.500(c)	205.511	Replaced by new section on equivalency.
N/A	205.501(a)(21)	New paragraph on traceability audits.
N/A	205.501(a)(22)	New paragraph on new office notifications.
205.501(a)(21)	205.501(a)(23)	(a)(21) redesignated as (a)(23)
N/A	205.504(b)(7)	New paragraph on traceability audit procedures.
N/A	205.504(b)(8)	New paragraph on mediation criteria.
N/A	205.511	New section on equivalency.
N/A	205.660(c)	New paragraph on enforcement authority.
205.660(c)	205.660(d)	(c) redesignated as (d)

Former Reference	New Reference	Description of Change
205.660(d)	205.660(e)	(d) redesignated as (e)
205.661	205.661	Section title changed to "Investigation."
<i>N/A</i>	205.662(e)(3)	New paragraph on updating INTEGRITY.
205.663	205.663(a) – (g)	Section on mediation revised and broken into paragraphs
205.665(a)	205.665(a)	Paragraph revised and reorganized with additional subparagraphs.
<i>N/A</i>	205.680(d)	New paragraph on mediation requests.
<i>N/A</i>	205.680(e)	New paragraph on appeals procedure.
205.680(d)	205.680(f)	(d) redesignated as (f)
205.680(e)	205.680(g)	(e) redesignated as (g)