

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 it 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. 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	



Section	Regulatory Text	Key Takeaways
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>
205.403 (d)(4)	<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)).
205.406 (b)	<p>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>	<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>