NOP 2601 Effective Date: March 20, 2024 Page 1 of 9

Instruction The Organic Certification Process

1. Purpose and Scope

This instruction outlines the steps in the organic certification process. The National Organic Program (NOP) seeks to establish consistency and best practices in the certification process. This instruction explains the NOP's expectations of accredited certifying agents (certifiers) for completing the certification process according to the U.S. Department of Agriculture (USDA) organic regulations at 7 CFR Part 205. This document serves as a guide for implementing certification procedures.

This instruction is directed at accredited certifiers. Producers and handlers seeking information and instructions on organic certification should refer to the NOP's fact sheets, training modules, and guides to certification on the NOP's website at www.ams.usda.gov/nop.

2. Background

The Organic Foods Production Act, the Preamble to the NOP Final Rule, and §§ 205.400 – 406 of the USDA organic regulations outline the required steps in the organic certification process. These steps require certifiers to thoroughly review all information submitted by applicants and collected during the inspection or post-inspection process. They also require that certifiers clearly communicate all certification decisions to producers and handlers in a timely fashion. While each certification process will differ slightly based on the unique circumstances of the operation, the basic steps should remain consistent in order to ensure a thorough verification of compliance.

3. Policy and Procedures

Qualified reviewers and inspectors are essential to the certification process. A certifier must have sufficient administrative capacity to accept an application for certification, and its staff and inspectors must have the appropriate training, experience, knowledge, skill, and ability to understand and apply the regulations. In addition to ensuring that an application falls within one of its accredited scopes, a certifier must have a sufficient number of personnel to verify the operation's compliance through application reviews and onsite inspections. For more detail on the general requirements for accreditation, see § 205.501.

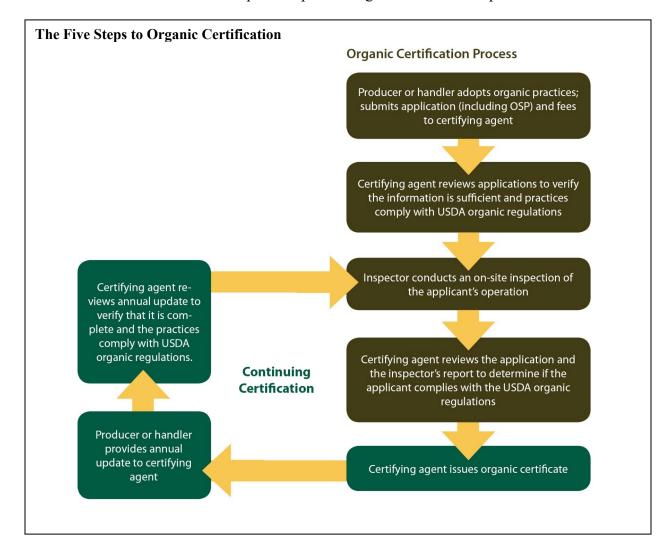
The NOP verifies certifier compliance during accreditation assessments.

3.1. The Organic Certification Process

The organic certification process includes five steps:

- NOP 2601 Effective Date: March 20, 2024 Page 2 of 9
- 1. The operation completes an application and develops an Organic System Plan (OSP);
- 2. The operation implements the OSP, and the certifier reviews the OSP;
- 3. The certifier's inspector completes an onsite inspection of the operation to evaluate the implementation of the OSP and the operation's compliance with the USDA organic regulations;
- 4. The certifier reviews the inspection report; and
- 5. The certifier decides whether to grant certification to the operation.

To continue certification, the operation submits an annual update to its OSP and certification fees to its certifier. The certifier then repeats steps 2 through 5 based on the updated information.



3.2. Step 1 – Application and Fees

An operation that wants to become certified first contacts a certifier. (A complete list of certifiers is available on the NOP Web site.) The certifier provides information about its application

NOP 2601 Effective Date: March 20, 2024 Page 3 of 9

process and certification fees, as outlined in its fee schedule. If the operation decides to proceed with that certifier, it completes an application, which includes the OSP.

The certifier should make its application forms, including any OSP forms and fee schedules, readily available. Posting this information online allows potential applicants to access it quickly and easily, but it should also be provided upon request to individuals without internet access. A published fee schedule may fulfill the certifier's responsibility to provide an estimate of fees to the operation, as long as a reasonable person could use the information to estimate the total cost of certification and inspection for its operation.

3.3. Step 2 – Review of the OSP

The certifier reviews the application for completeness and determines if the OSP appears to comply with the regulations. The certifier must clearly communicate to the applicant in a timely fashion whether the application appears complete and whether the OSP appears to comply with the regulations. If the initial review shows that the applicant appears to, or may be able to, comply with the regulations, then the certifier schedules an onsite inspection (see Step 3).

If the application does not include enough information for the certifier to determine whether the operation may be able to comply with the regulations, then the certifier is to request more information from the operation before scheduling the onsite inspection. If the applicant fails to submit all of the required information or minor items prior to the inspection, then the certifier may instruct the inspector to collect this information onsite. If the operation fails to provide or willfully withholds significant information, then the certifier shall take appropriate compliance actions.

The certifier verifies that all inputs and ingredients listed in the OSP comply with the regulations. Certifiers must review all multi-ingredient products before they are sold, labeled, or represented as organic to ensure that the product composition meets the requirements for the proposed labeling category. Certifiers must be able to verify that all ingredients listed as organic are certified. Certifiers should also verify the use of any nonorganic ingredients or processing aids to determine that they are allowed. This may require consideration of commercial availability and any restrictions on substances as indicated on the National List of Allowed and Prohibited Substances (§§ 205.601 – 205.606). During the onsite inspection, inspectors should review a sample of these products to determine compliance.

The certifier should also review all retail product labels for compliance with the labeling requirements outlined in $\S\S 205.300 - 205.311$. Certifiers are to record and file labels they have approved; the NOP will review a sample of approved labels during accreditation audits. (The inspector will review a sample of these labels at the onsite inspection to ensure compliance.)

Additionally, the certifier should review the monitoring practices and procedures that the operation uses to verify effective implementation of their OSP. This should include the operation's procedures to verify their suppliers and prevent organic fraud (§ 205.201(a)(3)). For more information about monitoring practices and procedures, please see the Strengthening

NOP 2601 Effective Date: March 20, 2024 Page 4 of 9

Organic Enforcement final rule's discussion on "Supply Chain Traceability and Organic Fraud Prevention," starting at <u>88 FR 3601</u>.

If an applicant is a producer group operation, the certifier should also review the operation's internal control system, pursuant to § 205.201(c). For more information about internal control systems, please see the Strengthening Organic Enforcement final rule's discussion on "Producer Group Operations," starting at 88 FR 3592.

If an applicant was previously certified by another certifier, then the applicant must provide their previous certification history, including documentation to support the correction of any preexisting noncompliances, and report any adverse actions (e.g., Notices of Proposed or Final Suspension or Revocation). Certifiers should inform such applicants of their responsibility to maintain or surrender their existing organic certification with their previous certifier, as described in NOP 2604 Responsibilities of Certified Operations Changing Certifying Agents. The certifier is responsible for verifying any information provided regarding previous certifications thoroughly, both during reviews and inspections. The NOP expects that the new certifier will contact the previous certifier to ensure that all noncompliances and any subsequent adverse actions were correctly reported and successfully corrected. If a certified operation was previously suspended for regulatory violations, the NOP must approve reinstatement before a certifier can approve the continuation of certification.

If the certifier knows that a certified operation has appealed a proposed adverse action from its previous certifier, the new certifier should notify the NOP appeals team if the certifier grants certification.

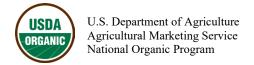
3.4. Step 3 – Inspection

Once the certifier's initial review determines that the operation may be able to comply with the regulations, the certifier schedules an onsite inspection. The inspection must be scheduled within a reasonable time, although it may be delayed for up to six months so that the inspector can observe the relevant land, facility, or activities. For example, if the certifier receives a crop production application during the winter, the inspection may be delayed until the spring or summer when the production season is underway.

The purpose of the onsite inspection is to:

- 1. Assess whether the operation complies or has the ability to comply with the regulations;
- 2. Verify that the OSP accurately reflects the operation's activities; and
- 3. Ensure that prohibited substances have not been applied.

The inspector should conduct an opening meeting to discuss the inspection plan. This meeting defines the role of the inspector, communicates the confidentiality of all information, and outlines the planned inspection activities. This is the inspector's opportunity to set expectations and answer the applicant's questions. The NOP considers opening meetings to be a best practice for all inspections.



NOP 2601 Effective Date: March 20, 2024 Page 5 of 9

The inspector will review <u>each</u> production unit, facility, and site where the operation produces or handles organic products. The inspection includes, but is not limited to:

- 1. Evaluation of the OSP that the operator maintains onsite to ensure that the operator has an updated OSP, is implementing the OSP, and that the OSP complies with the regulations;
- 2. For crop producers: evaluation of soil and nutrient management, adjoining land use, buffer zones, land use history, production capacity of the land, seeds and planting stock used, crop rotation practices, pest control practices, harvest, labeling, and shipping;
- 3. For wild crop producers: evaluation of designated harvest areas, sustainable harvest practices, and re-seeding or pruning activities;
- 4. For livestock producers: evaluation of soil and nutrient management, adjoining land use, buffers, land history, seeds and planting stock used, health care practices, origin of livestock, livestock living conditions, access to the outdoors, temporary confinement, feed and feed rations, and pasture management practices;
- 5. For handlers: evaluation of product composition, receiving, processing, pest control, storage, labeling and shipping, as well as practices to prevent commingling and contact with prohibited substances;
- 6. For producer group operations: evaluation under the specific inspection requirements listed at § 205.403(a)(2);
- 7. Verification of the operation's production or handling capacity;
- 8. Evaluation of the recordkeeping system and verification of activities through appropriate records;
- Reconciliation of the volume of organic products produced or received with the amount
 of organic products shipped, handled and/or sold, also known as trace-back audits or inout balances; and
- 10. Sampling of organic agricultural products for residue testing, if applicable. The inspector will provide a receipt for any samples taken.

At the end of the inspection, the inspector conducts an exit interview with an authorized representative of the operation. During the exit interview, the inspector communicates any potential noncompliances observed, and requests any additional information that may be missing from the OSP. If significant information is missing, the inspector should note this in the inspection report and discuss this as a concern during the exit interview.

Inspectors often discover new information or documentation during onsite inspections. The inspector may accept additional OSP updates during the inspection, up until the start of the exit interview, and should provide any new information received onsite to the certifier. If the inspector and the operator update the OSP during the inspection, then the inspector should provide a copy of the update to both the operator and the certifier. Once the inspector finishes the inspection report, he or she sends the report to the certifier for review. The certifier will evaluate the inspector's findings when making a final certification decision.

Inspections are <u>not</u> consulting visits. Inspectors may ask questions, collect and provide information, and explain the regulations or the certifier's requirements. Inspectors are prohibited, however, from advising the operator on how to overcome barriers to certification.

NOP 2601 Effective Date: March 20, 2024 Page 6 of 9

Organic inspectors play a vital role in ensuring organic integrity. Their visits to organic farms and processing facilities are often the most direct contact that certifiers have with organic operations. It is important for certifiers to appropriately assess the inspector's level of expertise and ability, both during the hiring process and as part of regular performance evaluations.

3.5. Step 4 – Review of Inspection Report

Within a reasonable period of time, the certifier evaluates the inspection report, the OSP, the results of any analyses conducted, and any additional information provided. The review of the inspection report may lead to different paths, each of which may require additional evaluations or decisions. After assessing whether the operation appears to comply with the organic regulations, the certifier makes one of the following certification recommendations:

- 1. Certification, if the operation is fully compliant;
- 2. Certification with conditions, if there are minor, non-violative issues;
- 3. Notice of Noncompliance for correctable violations. A Notice of Noncompliance allows the operation to submit a response with proposed corrective actions, typically within 30 days of the date of issuance. The certifier must evaluate the corrective actions to determine whether the operation complies with the regulations. If the operation appears to comply, then the certifier should recommend certification or certification with conditions. If the operation does not appear to comply, then the certifier should proceed to denial of certification; or
- 4. Combined Notice of Noncompliance and Denial of Certification for non-correctable violations.

The final review of the inspection report and the certification decision steps may be performed by the same person, but that person may not be the inspector. (See NOP 2006 Separation of Duties in Certification Decisions.)

The certifier may conduct additional onsite inspections to verify continued compliance with the regulations. These inspections may be announced or unannounced, as deemed appropriate by the certifier.

3.6. Step 5 – Certification Decision

The final decision-maker determines which action is appropriate to the operation. If the operation complies or is capable of complying with the regulations, the certifier issues a certificate of organic operation according to the instructions in NOP 2603 Organic Certificates. If the operation does not comply with the regulations, then the certifier issues adverse actions in accordance with NOP 4002 Enforcement.

Once certified, the operation's certification remains in effect until it's surrendered, suspended, or revoked. The certifier, the State organic program, or the NOP may initiate adverse actions, up to and including suspensions and revocations.

NOP 2601 Effective Date: March 20, 2024 Page 7 of 9

3.7. Renewing Certification – the Annual Update

The annual update adds new information to the existing OSP. A certified operation must submit:

- A summary of any deviations, changes to, modifications to, or other amendments made to the OSP submitted during the previous year, pursuant to § 205.406(a)(1);
- Any additions or deletions to the previous year's OSP intended to be undertaken in the coming year, pursuant to § 205.406(a)(2)-(3); and
- Fees to its certifier at least once per year to continue its organic certification.

If the operation fails to submit its annual update and/or fees, the certifier issues a Notice of Noncompliance. The annual update must include a summary statement outlining any changes to the OSP that were made during the last year, as well as any changes planned for the coming year. If the certifier requires supporting documentation to verify these changes, then the operation will provide it.

The annual update only needs to describe changes to the operation; it does not need to reiterate information that was previously submitted. If the certifier requires the operation to resubmit all information, including that which has not changed, then it is putting an unnecessary burden on the operation, and the NOP may issue a Notice of Noncompliance as a result.

Operations must also notify its certifier of any ongoing changes that may affect its compliance with the regulations. If an operation plans to add new products, fields, operations, or labels to its OSP, then the certifier must first approve these changes and issue an updated certificate. A request to add new fields, animal species, or facilities would require an additional onsite inspection.

The certifier shall inspect the operation at least once per calendar year to determine whether its certification should continue. If an operation fails to submit an annual update prior to the onsite inspection, the certifier should issue a Notice of Noncompliance. However, the failure of an operation to submit an annual update does not relieve the certifier of its obligation to conduct an annual inspection. (See § 205.403(a)(1).)

After the inspection is complete, and the certifier has reviewed both the annual update and the inspection report, the certifier chooses one of the four certification decisions below and communicates this decision in writing to the operation. The NOP expects that certifiers will follow the procedures outlined in NOP 2006 Separation of Duties in Certification Decisions when making these decisions. As with the initial certification decision, the decision to continue certification may include new conditions for minor, non-violative issues. However, if an operation shows evidence of a repeated minor issue, the certifier should elevate the violation to a Notice of Noncompliance.

The four certification decisions are:

1. Continuation of certification, if the operation is fully compliant, including the issuance of a new certificate pursuant to § 205.406(d);

NOP 2601 Effective Date: March 20, 2024 Page 8 of 9

- 2. Certification with conditions, if there are minor, non-repetitive, non-violative issues;
- 3. Notice of Noncompliance for correctable violations. A Notice of Noncompliance allows the operation to submit a response with proposed corrective actions, typically within 30 days of the date of issuance. The certifier must evaluate the corrective actions to determine whether the operation complies with the regulations. If the operation appears to comply, then the certifier should recommend certification or certification with conditions. If the operation does not appear to comply, then the certifier should proceed to a Notice of Proposed Suspension or revocation of certification; and
- 4. Combined Notice of Noncompliance and Proposed Suspension or Revocation for non-correctable violations, including willful or fraudulent violations.

3.8. Certification Resources

To maintain consistency in certifiers' interpretations of production and handling practice standards, the NOP encourages certifiers and operations seeking certification to consult the NOP Program Handbook. The Program Handbook provides instructions, guidance, and policy on a variety of topics, from wild crop harvesting to compliance with the pasture rule to OSPs. The Handbook is available on the NOP Web site at https://www.ams.usda.gov/rules-regulations/organic/handbook.

4. References

USDA Organic Regulations (7 CFR Part 205)

7 CFR 205.2 Terms Defined

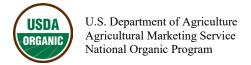
<u>Certified operation.</u> A crop or livestock production, wild-crop harvesting or handling operation, or portion of such operation that is certified by an accredited certifying agent as utilizing a system of organic production or handling as described by the Act and the regulations in this part.

<u>Certifying agent.</u> Any entity accredited by the Secretary as a certifying agent for the purpose of certifying a production or handling operation as a certified production or handling operation.

<u>Inspection.</u> The act of examining and evaluating the production or handling operation of an applicant for certification or certified operation to determine compliance with the Act and the regulations in this part.

<u>Organic system plan.</u> A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent and that includes written plans concerning all aspects of agricultural production or handling described in the Act and the regulations in subpart C of this part.

7 CFR 205.201 Organic production and handling system plan.



Effective Date: March 20, 2024 Page 9 of 9

NOP 2601

7 CFR 205.400 General requirements for certification.

7 CFR 205.401 Application for certification.

7 CFR 205.402 Review of application.

7 CFR 205.403 On-site inspections.

7 CFR 205.404 Granting certification.

7 CFR 205.406 Continuation of certification.

NOP Program Handbook: Guidance and Instructions for Accredited Certifying agents and Certified Operations

NOP 2006 Separation of Duties in Certification Decisions

NOP 2603 Organic Certificates

NOP 2604 Responsibilities of Certified Operations Changing Certifying agents

NOP 2605 Reinstating Suspended Organic Operations

NOP 2609 Unannounced Inspections

NOP 2610 Sampling Procedures for Residue Testing

NOP 2614 Technical Assistance

NOP 2615 Organic System Plans, Organic System Plan Updates, and Notification of Changes

NOP 4002 Enforcement

Document Control: This instruction replaces NOP 2601 Five Steps to Organic Certification Rev01.

Original Issue Date: August 24, 2010