1400 Independence Avenue SW. Room 2648-South Building Washington, DC 20250 NOP 2609 Effective Date: March 20, 2024 Page 1 of 5

Instruction Unannounced Inspections

1 Purpose

This instruction is provided to promote consistent application of the United States Department of Agriculture (USDA) regulations by certifying agents. This instruction is based upon recommendations from the National Organic Standards Board (NOSB) and updates made to the USDA organic regulations as part of the Strengthening Organic Enforcement (SOE) final rule. Certifying agents must conduct unannounced inspections of a minimum number of operations they certify. This instruction describes this requirement and best practices for certifying agents conducting unannounced inspections of certified operations.

2 Background

The USDA organic regulations at 7 CFR 205.403 describe the on-site inspections that certifying agents conduct.

On June 23, 2011, the Deputy Administrator of the National Organic Program (NOP) issued a memorandum to the chair of the NOSB requesting a proposal on best practices for unannounced inspection. The NOSB Certification, Accreditation and Compliance Subcommittee (CACS) reviewed the request and, in consultation with representatives from the organic community, developed a proposal. On December 2, 2011, the NOSB approved the CACS's proposal, and submitted it as a recommendation to the NOP.

On February 27, 2012, the Office of Inspector General recommended that the NOP develop guidance on the frequency with which certifying agents should conduct unannounced inspections of NOP-certified milk operations, and to select milk operations based on the risk inherent in each operation. AMS concurred with this recommendation and agreed to issue guidance to certifying agents regarding conducting unannounced inspections. This instruction (NOP 2609), effective September 12, 2012, provided the requested information.

On January 19th, 2023, USDA published the Strengthening Organic Enforcement (SOE) final rule. The rule added a requirement that certifying agents must conduct unannounced inspections of a minimum of five percent of the operations that they certify. This instruction was updated to reflect the requirements SOE added to 7 CFR 205.403.

3 Scope

This instruction applies to all certifying agents accredited under the USDA organic regulations, 7 CFR 205, and certifying agents operating under the foreign recognition agreements.

4 Authority

The NOP accredits certifying agents under the authority of the Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 et seq.), as described in 7 CFR Part 205. Section 205.403(b) describes that certifying agents must conduct unannounced inspections of a minimum of five

Room 2648-South Building Washington, DC 20250

NOP 2609 Effective Date: March 20, 2024 Page 2 of 5

percent of the operations that they certify. Certifying agents also have a responsibility, under 7 CFR 205.501(a)(23), to comply with, implement, and carry out any terms and conditions determined by the Agricultural Marketing Service (AMS) Administrator to be necessary as a general accreditation requirement. In addition, the Administrator or State organic program's governing State official may require that additional inspections are conducted by certifying agents for the purpose of determining compliance with the USDA organic regulations (§ 205.403(a)(3)(ii)).

Policy

Unannounced inspections are one of the most effective and useful tools in the USDA organic regulations to ensure compliance across certified operations, and give consumers additional reasons to trust the organic label. Unannounced inspections serve the dual purpose of giving the certifying agent the opportunity to observe the activities of a specific operation without the advance notice, as provided in the annual monitoring inspections, and acting as a deterrent to other operations who may consider violating USDA regulations.

4.1 General

- Certifying agents **must** conduct unannounced inspections of a minimum of five percent of their total certified operations per year as a tool in ensuring compliance with the regulations. When calculating five percent of the total operations, a certifying agent must round up to the next highest number. This will ensure that certifying agents with less than 20 certified operations conduct at least one (1) unannounced inspection per year. (7 CFR 205.403(b)(1))
- 4.1.2 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. (7 CFR) 205.403(b)(2))

Because certifying agents must be able to conduct unannounced inspections of any operation they certify, they must only accept applications for certification or continue certification from operations for which the certifying agent is able to conduct unannounced inspections. To ensure consistency, transparency, and accountability, certifying agents are expected to describe the areas where they operate in the written materials they provide to both applicants and certified operations, and review the locations of all operations during their application review or annual review.

A certifying agent that cannot conduct unannounced inspections in an applicant's or certified operation's location due to logistical challenges, staffing, security, or other reasons, is considered to not have the administrative capacity for certification activities in that area, consistent with § 205.501(a)(19). In this case, the certifying agent must document the specific reasons it does not have the administrative capacity to certify in that area, and must inform the applicant or certified operation to seek certification from another certifying agent. If new certification is not obtained, the operation's certification

Room 2648-South Building Washington, DC 20250

NOP 2609 Effective Date: March 20, 2024 Page 3 of 5

would be suspended/revoked. This process is similar to the current procedures used when a certifying agent surrenders its accreditation or is suspended/revoked.

- The certifying agent should strive to conduct unannounced inspections broadly across all 4.1.3 certified operations, including a broad spectrum of production types, products, and locations. The inspections should not be limited to nearby operations or certain production types. Certifying agents should have a long-term plan for conducting unannounced inspections across their client base, including geographic location and certification scope.
- **4.1.4** Operations chosen for unannounced inspections may be random, risk based, or the result of a complaint or investigation. The certifying agent should disclose to the operation the reason that the operation was chosen for the unannounced inspection.
 - a. Criteria for conducting an unannounced inspection of an operation may include, but are not limited to:
 - i. Previous noncompliance issues.
 - ii. Complaints.
 - iii. Organic and non-organic production or handling, especially of visually indistinguishable varieties.
 - iv. Risk of contamination from adjoining land use or commingling, or contamination during handling.
 - v. Complexity of operation.
- Unannounced inspections may fulfill the requirements for annual on-site monitoring inspections, required by section § 205.403, only if the inspector is able to conduct a full inspection of the operation as required by this section.
- **4.1.6** Unannounced inspections may be limited in scope, depth, and breadth, and may cover only certain aspects of the operation, such as parcels, facilities, products, etc. Certifying agents should direct the inspector to a portion of the operation to review during an unannounced inspection.
- An inspection report must be written by the inspector, sent to the client, reviewed by the 4.1.7 certifying agent, and the results communicated to the clients pursuant to § 205.403(f), § 205.404(a), and the certifying agent's internal protocols.
- Inspectors may conduct sampling during an unannounced inspection. Such an inspection would count toward a certifying agent's number of samples and the number of unannounced inspections. However, if a visit of the operation is to be considered as both an instance of sample collection and an unannounced inspection, the inspector must review some aspects of the operation besides collecting a sample.

1400 Independence Avenue SW. Room 2648-South Building Washington, DC 20250 NOP 2609 Effective Date: March 20, 2024 Page 4 of 5

- **4.1.9** An unannounced inspection should not include prior notification of the inspector's arrival. However, there may be special cases where extenuating circumstances make it impossible to conduct an unannounced inspection of the operation without prior notification (e.g., biosecurity issues). In such cases, the certifying agent may notify the operation up to four (4) hours prior to the inspector arriving on-site to ensure that appropriate representatives are present.
- 4.1.10 Certifying agents are responsible for providing adequate training for their inspectors to ensure that inspectors do not trespass or break any laws during unannounced inspections. Inspectors should not enter private property without explicit permission of the operation. Inspectors are advised to have adequate identification, such as a business card, and/or explanatory letter from the certifying agents, to demonstrate they are acting on behalf of the certifying agent. Certifying agents are encouraged to have a written policy on unannounced inspections and inspector access to certified facilities. This policy should be provided to all certified operations and inspectors.
- **4.1.11** If an operation refuses to allow an inspector access to any part of an operation, during normal business hours, including the non-organic portions of the operation, the operation would be in violation of 7 CFR 205.403, and the certifying agents should promptly issue a Notice of Noncompliance to the operation.
- **4.1.12** A certifying agent should clearly disclose the protocols for unannounced inspections to certified operations. Certifying agents may charge an operation for unannounced inspections as long as the fees are clearly disclosed to all certified operations. Fees charged must be filed with the Administrator in accordance with 7 CFR 205.642.

5.0 Records

- 5.1 Certifying agents will maintain records according to § 205.510(b).
- 5.2 Certified operations will maintain records according to § 205.400(d).

6.0 References

USDA Organic Regulations (as amended to date)

7 CFR 205.400 General requirements for certification.

7 CFR 205.403 On-site inspections.

7 CFR 205.501 General requirements for accreditation.

7 CFR 205.510 Annual report, recordkeeping, and renewal of accreditation

(b) Recordkeeping.

1400 Independence Avenue SW. Room 2648-South Building Washington, DC 20250 NOP 2609 Effective Date: March 20, 2024 Page 5 of 5

7 CFR 205.642 Fees and other charges for certification.

7 CFR 205.670 Inspection and testing of agricultural product to be sold or labeled "organic."

Original Issue Date: September 6, 2012