



Instruction Who Needs to be Certified?

1. Purpose and Scope

This instruction clarifies the certification requirements for operations that produce or handle agricultural products to be sold, labeled or represented as organic. This instruction affects accredited certifying agents that certify operations to the U.S. Department of Agriculture (USDA) organic regulations.

2. Background

Certification is the process by which certifying agents and the USDA National Organic Program (NOP) ensure that agricultural products sold, labeled or represented as organic are produced and handled in compliance with the Organic Foods Production Act (OFPA)(7 USC § 6501 *et seq.*) and the USDA organic regulations (7 CFR part 205). The NOP has recently noted that certifying agents are inconsistently interpreting and applying the regulations in determining who needs to be certified.

3. Policy

The OFPA requires that agricultural products sold or labeled as organically produced must be produced only on certified farms and handled only through certified handling operations (see 7 USC § 6506(a)(1)). The USDA organic regulations reiterate these requirements (see 7 CFR [205.100.](#))¹ Although these requirements are clear regarding the necessity for organic agricultural products to be produced and handled exclusively at certified organic farms and handling operations, their consistent application has sometimes proven difficult because of the great variety of business arrangements found in organic agriculture.

Certified operations commonly contract with other businesses for goods and services. Such contracts may be permissible, as long as they do not involve the production or handling of organic agricultural products not explicitly subject to inspection by a certifying agent or the NOP. (See 7 CFR [205.400](#), [205.403](#) and [205.660](#).) In other words, an uncertified operation may not produce or process, on its own land or premises, agricultural products to be sold, labeled, or represented as organic on behalf of a certified operation.

¹ The USDA organic regulations also provide for several exemptions from the certification requirements, e.g. for small businesses, retail food establishments and certain handlers. However, operations eligible for such exemptions are not within the scope of this instruction.



Specifically, a certified operation may:

- Organically produce agricultural products on leased land that meets all the organic requirements;
- Organically process agricultural products using leased facilities or equipment. Leased facilities must be available for inspection while organic handling is ongoing;
- Purchase or contract for services (e.g., planting seeds, harvesting crops, providing pest control, cleaning processing lines), provided the services are conducted at the certified operation's production unit, facility, or site, which may be leased or rented, and are described in the certified operation's approved Organic System Plan (OSP); and
- Contract with an uncertified operation to transport its agricultural products, provided the transportation is described under the certified operation's approved OSP (see "[NOP 5031 Certification Requirements for Handling Unpackaged Organic Products](#)").

When organically producing or handling agricultural products, a certified operation may not:

- Allow an uncertified operation to produce or handle agricultural products, under contract or other arrangement, on the uncertified operation's land or premises (i.e., at units, facilities, or sites not explicitly subject to inspection or compliance action by the NOP or a certifying agent).



4. References

Organic Foods Production Act of 1990 (7 U.S.C. § 6501 et seq.)

§ 6506. General requirements

- (a) IN GENERAL. —A program established under this title shall—
 - (1) provide that an agricultural product to be sold or labeled as organically produced must—
 - (A) be produced only on certified organic farms and handled only through certified organic handling operations in accordance with this title; and
 - (B) be produced and handled in accordance with such program.

USDA Organic Regulations (7 CFR part 205)

7 CFR 205.100 What has to be certified.

- (a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

7 CFR 205.101 Exemptions and exclusions from certification.

- (a) Exemptions.
 - (1) 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 is exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part and the labeling requirements of § 205.310. The products from such operations shall not be used as ingredients identified as organic in processed products produced by another handling operation.
 - (2) A handling operation that is a retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from the requirements in this part.
 - (3) A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in this part, except:
 - (i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;
 - (ii) The labeling provisions of §§ 205.305 and 205.310; and



- (iii) The recordkeeping provisions in paragraph (c) of this section.
- (4) A handling operation or portion of a handling operation that only identifies organic ingredients on the information panel is exempt from the requirements in this part, except:
 - (i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;
 - (ii) The labeling provisions of §§ 205.305 and 205.310; and
 - (iii) The recordkeeping provisions in paragraph (c) of this section.
- (b) Exclusions.
 - (1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in § 205.272 with respect to any organically produced products, if such operation or portion of the operation only sells organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” that:
 - (i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and
 - (ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation.
 - (2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” is excluded from the requirements in this part, except:
 - (i) The requirements for the prevention of contact with prohibited substances as set forth in § 205.272; and
 - (ii) The labeling provisions of § 205.310.
- (c) Records to be maintained by exempt operations.
 - (1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:
 - (i) Prove that ingredients identified as organic were organically produced and handled; and
 - (ii) Verify quantities produced from such ingredients.
 - (2) Records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State organic programs’ governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

7 CFR 205.400 General requirements for certification.

A person seeking to receive or maintain organic certification under the regulations in this part must:



- (a) Comply with the Act and applicable organic production and handling regulations of this part;
- (b) Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in § 205.200;
- (c) Permit on-site inspections with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices by the certifying agent as provided for in § 205.403;
- (d) Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary, the applicable State organic program's governing State official, and the certifying agent access to such records during normal business hours for review and copying to determine compliance with the Act and the regulations in this part, as provided for in § 205.104.
- (e) Submit the applicable fees charged by the certifying agent; and
- (f) Immediately notify the certifying agent concerning any:
 - (1) Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and
 - (2) Change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.

7 CFR 205.403 On-site inspections.

(a) On-site inspections.

- (1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.
- (2)(i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.
- (ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.
- (iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.
- (b) Scheduling. (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: Except, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.



(2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.

(c) Verification of information. The on-site inspection of an operation must verify:

- (1) The operation's compliance or capability to comply with the Act and the regulations in this part;
- (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;
- (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

(d) Exit interview. The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.

(e) Documents to the inspected operation. (1) At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.

(2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.

7 CFR 205.660 General.

- (a) The National Organic Program's Program Manager, on behalf of the Secretary, may inspect and review certified production and handling operations and accredited certifying agents for compliance with the Act or regulations in this part.
- (b) The Program Manager may initiate suspension or revocation proceedings against a certified operation:
 - (1) When the Program Manager has reason to believe that a certified operation has violated or is not in compliance with the Act or regulations in this part; or
 - (2) When a certifying agent or a State organic program's governing State official fails to take appropriate action to enforce the Act or regulations in this part.
- (c) The Program Manager may initiate suspension or revocation of a certifying agent's accreditation if the certifying agent fails to meet, conduct, or maintain accreditation requirements pursuant to the Act or this part.



- (d) Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.

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

NOP 5031 Certification Requirements for Handling Unpackaged Organic Products

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