

Certification -- Preamble

Subpart E - Certification

This subpart sets forth the requirements for a national program to certify production and handling operations as certified organic production or handling operations. This certification process will be carried out by accredited certifying agents.

Description of Regulations

General Requirements

Production and handling operations seeking to receive or maintain organic certification must comply with the Act and applicable organic production and handling regulations. Such operations must establish, implement, and annually update an organic production or handling system plan that is submitted to an accredited certifying agent. They must permit on-site inspections by the certifying agent with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices.

As discussed in subpart B, certified operations must maintain records concerning the production and handling of agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" sufficient to demonstrate compliance with the Act and regulations. Records applicable to the organic operation must be maintained for not less than 5 years beyond their creation. Authorized representatives of the Secretary, the applicable State organic program's (SOP) governing State official, and the certifying agent must be allowed access to the operation's records during normal business hours. Access to the operation's records will be for the purpose of reviewing and copying the records to determine compliance with the Act and regulations.

Certified operations are required to immediately notify the certifying agent concerning any application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of the organic operation. They must also immediately notify the certifying agent concerning any change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and regulations.

Certification Process

To obtain certification, a producer or handler must submit an application for certification to an accredited certifying agent. The application must contain descriptive information about the applicant's business, an organic production and handling system plan, information concerning any previous business applications for certification, and any other information necessary to determine compliance with the Act.

Applicants for certification and certified operations must submit the applicable fees charged by the certifying agent. An applicant may withdraw its application at anytime. An applicant who withdraws its application will be liable for the costs of services provided up to the time of withdrawal of the application.

The certifying agent will decide whether to accept the applicant's application for certification. A certifying agent must accept all production and handling applications that fall within its area(s) of accreditation and certify all qualified applicants to the extent of its administrative capacity to do so. In other words, a certifying agent may decline to accept an application for certification when the certifying agent is not accredited for the area to be certified or when the certifying agent lacks

the resources to perform the certification. However, the certifying agent may not decline to accept an application on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

Upon acceptance of an application for certification, a certifying agent will review the application to ensure completeness and to determine whether the applicant appears to comply or may be able to comply with the applicable production or handling regulations. As part of its review, the certifying agent will verify that an applicant has submitted documentation to support the correction of any noncompliances identified in a previously received notification of noncompliance or denial of certification. We anticipate that at a future date the certifying agent will also review any available U.S. Department of Agriculture (USDA) data on production and handling operations for information concerning the applicant.

We anticipate using data collected from certifying agents to establish and maintain a password-protected Internet database only available to accredited certifying agents and USDA. This database would include data on production and handling operations issued a notification of noncompliance, noncompliance correction, denial of certification, certification, proposed suspension or revocation of certification, and suspension or revocation of certification. Certifying agents would use this Internet database during their review of an application for certification. This data will not be available to the general public because much of the data would involve ongoing compliance issues inappropriate for release prior to a final determination.

After a complete review of the application, which shall be conducted within a reasonable time, the certifying agent will communicate its findings to the applicant. If the review of the application reveals that the applicant may be in compliance with the applicable production or handling regulations, the certifying agent will schedule an on-site inspection of the applicant's operation to determine whether the applicant qualifies for certification. 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 for certification. 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.

The certifying agent will conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in the applicant's operation. As a benchmark, certifying agents should follow auditing guidelines prescribed by the International Organization for Standardization Guide 10011-1, "Guidelines for auditing quality systems - Part 1: Auditing" (ISO Guide 10011-1).⁽¹⁾ The certifying agent will use the on-site inspection in determining whether to approve the request for certification and to verify the operation's compliance or capability to comply with the Act and regulations. Certifying agents will conduct on-site inspections when an authorized representative of the operation who is knowledgeable about the operation is present. An on-site inspection must also be conducted when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable production or handling regulations can be observed.

The on-site inspection must verify that the information provided to the certifying agent accurately reflects the practices used or to be used by the applicant or certified operation and that prohibited substances have not been and are not being applied to the operation. Certifying agents may use the collection and testing of soil; water; waste; plant tissue; and plant, animal, and processed products samples as tools in accomplishing this verification.

The inspector will 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 main purpose of this exit interview is to present the inspection observations to those in charge of the

firm in such a manner so as to ensure they clearly understand the results of the inspection. The firm is not required to volunteer any information during the exit interview but would be required to respond to questions or requests for additional information. The inspector will raise and discuss during the exit interview any known issues of concern, taking into account their perceived significance. As a general rule, the inspector will not make recommendations for improvements to the operation during the exit interview. However, the certifying agent will have the discretion to decide the extent to which an inspector may discuss any compliance issue. 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.

The certifying agent shall, within a reasonable time, provide the inspected operation with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed and provide the operation with a copy of the test results for any samples taken by an inspector.

Notification of Approval

A certifying agent will review the on-site inspection report, the results of any analyses for substances, and any additional information provided by the applicant within a reasonable time after completion of the initial on-site inspection. The certifying agent will grant certification upon making two determinations: (1) that the applicant's operation, including its organic system plan and all procedures and activities, is in compliance with the Act and regulations and (2) that the applicant is able to conduct operations in accordance with its organic systems plan.

Upon determining the applicant's compliance and ability to comply, the agent will grant certification and issue a "certificate of organic operation." The certification may include requirements for the correction of minor noncompliances within a specified time period as a condition of continued certification. A certificate of organic operation will specify the name and address of the certified operation; the effective date of certification; the categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and the name, address, and telephone number of the certifying agent. Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the SOP's governing State official, or the Administrator.

Denial of Certification

Should the certifying agent determine that the applicant is not able to comply or is not in compliance with the Act, the certifying agent will issue a written notification of noncompliance to the applicant. The notification of noncompliance will describe each noncompliance, the facts on which the notification is based, and the date by which rebuttal or correction of each noncompliance must be made. Applicants who receive a notification of noncompliance may correct the noncompliances and submit, by the date specified, a description of correction and supporting documentation to the certifying agent. As an alternative, the applicant may submit a new application to another certifying agent, along with the notification of noncompliance and a description of correction of the noncompliances and supporting documentation. Applicants may also submit, by the date specified, written information to the issuing certifying agent to rebut the noncompliance described in the notification of noncompliance. When a noncompliance cannot be corrected, a notification of noncompliance and a "notification of denial of certification" may be combined in one notification.

The certifying agent will evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal. If necessary, the certifying agent will conduct a

followup on-site inspection of the applicant's operation. When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, the certifying agent will approve certification. When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, the certifying agent will issue the applicant a written notice of denial of certification. The certifying agent will also issue a written notice of denial of certification when an applicant fails to respond to the notification of noncompliance. The notice of denial of certification will state the reasons for denial and the applicant's right to reapply for certification, request mediation, or file an appeal.

An applicant who has received a notification of noncompliance or notice of denial of certification may apply for certification again at any time with any certifying agent. When the applicant submits a new application to a different certifying agent, the application must include, when available, a copy of the notification of noncompliance or notice of denial of certification. The application must also include a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance. When a certifying agent receives such an application, the certifying agent will treat the application as a new application and begin a new application process.

A certifying agent has limited authority to deny certification without first issuing a notification of noncompliance. This authority may be exercised when the certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented its operation or its compliance with the requirements for certification.

Continuation of Certification

Each year, the certified operation must update its organic production or handling system plan and submit the updated information to the certifying agent and pay the certification fees to continue certification. The updated organic system plan must include a summary statement, supported by documentation, detailing deviations from, changes to, modifications to, or other amendments to the previous year's organic system plan. The updated organic system plan must also include additions to or deletions from the previous year's organic system plan, intended to be undertaken in the coming year. The certified operation must update the descriptive information about its business and other information as deemed necessary by the certifying agent to determine compliance with the Act and regulations. The certified operation must also provide an update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification.

Following receipt of the certified operation's updated information, the certifying agent will, within a reasonable time, arrange and conduct an on-site inspection of the certified operation. When it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months. However, the annual on-site inspection must be conducted within the first 6 months following the certified operation's scheduled date of annual update. As a benchmark, certifying agents should follow auditing guidelines prescribed by ISO Guide 10011-1. Upon completion of the inspection and a review of updated information, the certifying agent will determine whether the operation continues to comply with the Act and regulations. If the certifying agent determines that the operation is in compliance, certification will continue. If any of the information specified on the certificate of organic operation has changed, the certifying agent will issue an updated certificate of organic operation. If the certifying agent finds that the operation is not complying with the Act and regulations, a written notification of noncompliance will be issued as described in section 205.662.

In addition to annual inspections, a certifying agent may conduct additional on-site inspections of certified operations that produce or handle organic products to determine compliance with the Act

and regulations. The Administrator or SOP's governing State official may also require that additional inspections be performed by the certifying agent to determine compliance with the Act and regulations. Additional inspections may be announced or unannounced and would be conducted, as necessary, to obtain information needed to determine compliance with identified requirements.

Such on-site inspections would likely be precipitated by reasons to believe that the certified operation was operating in violation of one or more requirements of the Act or these regulations. The policies and procedures regarding additional inspections, including how the costs of such inspections are handled, would be the responsibility of each certifying agent. Misuse of such authority would be subject to review by USDA during its evaluation of a certifying agent for reaccreditation and at other times in response to complaints. Certified production and handling operations can file complaints with USDA at any time should they believe a certifying agent abuses its authority to perform additional inspections.

Certification After Suspension or Revocation of Certifying Agent's Accreditation

When the Administrator revokes or suspends a certifying agent's accreditation, affected certified operations will need to make application for certification with another accredited certifying agent. The certification of the production or handling operation remains in effect during this transfer of the certification. The certified production or handling operation may seek certification by any qualified certifying agent accredited by the Administrator. To minimize the burden of obtaining the new certification, the Administrator will oversee transfer of the original certifying agent's file on the certified operation to the operation's new certifying agent.

Upon initiation of suspension or revocation of a certifying agent's accreditation or upon suspension or revocation of a certifying agent's accreditation, the Administrator may initiate proceedings to suspend or revoke the certification of operations certified by the certifying agent. The Administrator's decision to suspend or revoke a producer's or handler's certification in light of the loss of its certifying agent's accreditation would be made on a case-by-case basis. Actions such as fraud, bribery, or collusion by the certifying agent, which cause the Administrator to believe that the certifying agent's clients do not meet the standards of the Act or these regulations, might require the immediate initiation of procedures to suspend or revoke certification from some or all of its client base. Removal of accreditation, regardless of the reason, in no way affects the appeals rights of the certifying agent's clients. Further, a certified operation's certification will remain in effect pending the final resolution of any proceeding to suspend or revoke its certification.

A private-entity certifying agent must furnish reasonable security for the purpose of protecting the rights of operations certified by such certifying agent. This security is to ensure the performance of the certifying agent's contractual obligations. As noted elsewhere in this rule, the specific amount and type of security that must be furnished by a private certifying agent will be the subject of future rulemaking by USDA. We anticipate that the amount of the security will be tied to the number of clients served by the certifying agent and the anticipated costs of certification that may be incurred by its clients in the event that the certifying agent's accreditation is suspended or revoked. We anticipate that the security may be in the form of cash, surety bonds, or other financial instrument (such as a letter of credit) administered in a manner comparable to cash or surety bonds held under the Perishable Agricultural Commodities Act.

Certification - Changes Based on Comments

This subpart differs from the proposal in several respects as follows:

(1) Access to Production and Handling Operation. We have amended section 205.400(c) by changing "noncertified areas and structures" to "noncertified production and handling areas, structures, and offices." A commenter requested that section 205.400(c) be amended to allow for access to farm-related structures only. The commenter believes that the requirements of section 205.400(c) could be interpreted as giving inspectors access to residential property. We agree with the commenter that residential privacy should be maintained. However, if a certified operation conducts business from or stores records at a residential property, the certified operation will be considered to be maintaining an office at the residential property. The records in such office shall be made accessible for review and copying. Accordingly, we have amended section 205.400(c) to further clarify which areas and structures are to be made accessible during an on-site inspection.

(2) Application for Certification. We have amended the first paragraph of section 205.401 by replacing the word, "request," each time it occurred with the word, "application." A commenter recommended that we amend the first paragraph of section 205.401 by replacing the word, "request," with "application." We have accepted the commenter's recommendation because the amendment makes the language in the first paragraph consistent with the title and the requirements of the section.

(3) Verification of Correction of Noncompliances. To make section 205.402(a)(3) consistent with section 205.401(c) we have amended the language in section 205.402(a)(3) to require that the certifying agent verify that an applicant who previously applied to another certifying agent and received a notification of denial of certification has submitted documentation to support the correction of any noncompliances identified in the notification of denial of certification. A commenter recommended that section 205.402(a)(3) be amended by inserting "or denial of certification" after the phrase, "notification of noncompliance." We have accepted the commenter's recommended amendment because it is consistent with the requirements of section 205.401(c). Section 205.401(c) requires an applicant for certification to include the name(s) of any organic certifying agent(s) to which application has previously been made, the year(s) of application, and the outcome of the application(s) submission. The applicant is also required to include, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification. The words, "when available," have been added to this requirement in this final rule to satisfy concerns regarding the status of applicants who cannot find or no longer have a copy of any notification of noncompliance or denial of certification previously received. We see no down side to relaxing this requirement since the applicant must still comply with each of the other provisions in section 205.401(c), including the requirement that the applicant include a description of the actions taken to correct the noncompliances noted in any notification of noncompliance or denial of certification, including evidence of such correction. Further, the certifying agent will be using USDA's database of certification actions during its review of an application for certification.

(4) Timely Communication to the Applicant. We have amended section 205.402(b), by requiring at paragraph (b)(1) that the certifying agent, within a reasonable time, review the application materials received and communicate its findings to the applicant. A commenter requested that we amend section 205.402(b) which required a certifying agent to communicate to the applicant its findings on the review of application materials submitted by the applicant. Specifically, the commenter requested that section 205.402(b) be amended by adding to the end thereof, "in a timely manner so as to prevent the avoidable tillage of native habitat that had been identified in the application as lands for organic production."

We concur that certification decisions should be timely. There are many reasons (e.g., financial and contractual) for why certification must be timely. It would be impractical, however, to attempt to address all of the reasons for timely certification in these regulations. We have, therefore, amended section 205.402(b) as noted above. This amendment is consistent with the requirement in section 205.402(a) that the certifying agent, upon acceptance of an application for certification, review the application for completeness, determine by a review of the application materials

whether the applicant appears to comply or may be able to comply with the requirements for certification, and schedule an on-site inspection. The "upon acceptance" requirement necessitates that the certifying agent review the application for certification and provide feedback to the applicant in a timely manner.

(5) On-site Inspections. We have amended section 205.403(a)(1) by specifying that the initial and annual on-site inspections of each production unit, facility, and site in an operation applies to those units, facilities, and sites that produce or handle organic products. A commenter recommended that section 205.403(a)(1) be amended to specify that on-site inspections of each production unit, facility, and site will include just those that produce or handle organic products. The commenter stated that this change was necessary because some retail corporations choose to certify all store locations regardless of whether the location sells organic products. The commenter went on to say that, if a location does not stock any organic products, the certifying agent should have the discretion to modify the inspection requirement.

We have excluded all retail food establishments from certification. The exclusion is found in section 205.101(b)(2). Accordingly, the commenter's recommendation is not applicable to retail food establishments. We have, however, made the recommended amendment to section 205.403(a)(1) because of its potential applicability to other operations which may apply for certification.

(6) Scheduling Initial On-site Inspection. We have amended section 205.403(b) to provide 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 with the organic production and handling requirements can be observed. We received a comment stating that if an application is received in January for a crop that will be planted in May, it would be necessary to delay the inspection until late May or June to observe the crop in the field. The commenter went on to say that the alternative would be to conduct the initial inspection before the crop is planted, in order to meet the "within a reasonable time" requirement, and then conduct a reinspection during the growing season. The commenter recommended amending section 205.403(b) to allow the certifying agent to delay the initial on-site inspection until the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

We have accepted the recommendation because there may be situations where a later on-site inspection will prove mutually beneficial to the certifying agent and the operation to be inspected. However, certifying agents are reminded that the operation may be certified following a demonstration that the operation is able to comply with the organic production and handling requirements found in subpart C of these regulations. Accordingly, certifying agents should not unnecessarily delay the certification of an organic production or handling operation by insisting that the inspection only be performed when the operation can demonstrate its actual compliance with the organic production and handling requirements. Applicants who believe that the certifying agent is abusing its authority to delay the on-site inspection may file a complaint with the Administrator.

We have also amended the second sentence in section 205.403(b) by inserting the word, "all," and removing both references to "applicant" to clarify that the provision applies to all on-site inspections.

(7) Exit Interview. We have amended section 205.403(d) by requiring that the inspector conduct an exit interview with "an authorized representative of the operation who is knowledgeable about the inspected operation" rather than "an authorized representative of the inspected operation" as required in the proposed rule. This amendment is consistent with the requirement in section 205.403(b) that an on-site inspection be conducted when an authorized representative of the operation who is knowledgeable about the operation is present.

A commenter requested that we define "authorized representative." Another commenter recommended changing the term, "authorized representative," to "responsible executive." Our amendment of section 205.403(d) responds to both of these comments by clarifying the qualifications of an authorized representative.

A third commenter stated that an exit interview is not a practical requirement and that an initial interview is often preferred. The commenter stressed that verification that the inspector has correctly understood what is presented is ongoing. This commenter also expressed the belief that there may be times when it may not be appropriate for the inspector to address issues of concern and that such issues may be best left to the certifying agent. The commenter recommended that the requirement for an exit interview be deleted or presented as an option. Another commenter suggested that issues of concern are often identified and discussed with the operation's representative during the course of the inspection. This commenter believes that it is unnecessarily confrontational to require an exit interview during which these issues of concern are repeated. This commenter recommended replacing the required exit interview with a communications provision that would require the inspector to discuss the need for any additional information as well as any issues of concern. The recommended provision would also authorize the certifying agent to provide the applicant with a summary of the inspector's areas of concern.

While we agree that the language in section 205.403(d) needed clarification, we do not agree that the exit interview is impractical or unnecessarily confrontational. The exit interview is intended to give the inspector an opportunity to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection, to request any additional information necessary to establish eligibility for certification, and to raise and discuss any known issues of concern. Issues of concern that may involve compliance issues will be handled as authorized by the certifying agent. The exit interview is also intended to give the inspected operation's authorized representative general information concerning the inspector's observations. Such exit interviews are required under ISO Guide 10011-1. Accordingly, requiring exit interviews is consistent with ISO standards and our expectation, as stated earlier in this preamble, that certifying agents benchmark their on-site inspection procedures to ISO Guide 10011-1.

(8) On-site Inspection Documentation. We have amended section 205.402(b) by adding the requirements that the certifying agent: (1) provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed and (2) provide the applicant with a copy of the test results for any samples taken by an inspector. We have also amended section 205.403 by adding a new paragraph (e) that requires the inspector, at the time of the inspection, to provide the operation's authorized representative with a receipt for any samples taken by the inspector. This new paragraph also addresses the requirement that the certifying agent provide the operation inspected with a copy of the inspection report and any test results. Having the certifying agent issue the on-site inspection report to the operation inspected is consistent with ISO Guide 65, section 11(b).

Several commenters recommended that section 205.403 be amended to require that the inspector issue a copy of the on-site inspection report to the operation at the exit interview. They also recommended that the inspector be required to provide the operation with a receipt for samples collected for testing. The commenters, further, recommended that the certifying agent be required to provide the operation with a written report on the results of the testing performed on the samples taken. A commenter also recommended that the operation be paid for any samples taken. One of the commenters recommended that section 205.403 be amended by adding protocol for an exit interview.

We concur that the applicant for certification and certified operations should be provided with a copy of the on-site inspection report, a receipt for samples taken, and a copy of the test results for samples taken. Accordingly, we have amended sections 205.402(b) and 205.403 as noted above.

The protocol for an exit interview will be set forth in the certifying agent's procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates. The NOP is available to respond to questions and to assist certifying agents in the development of these procedures which are required under section 205.504(b)(1). Accordingly, AMS is not amending the section to include a protocol for exit interviews. AMS is also not including a requirement that the certifying agent pay the applicant for samples taken, since such charges would just be charged back to the applicant as a cost for processing the applicant's application for certification.

(9) Granting Certification. We have amended the last sentence of section 205.404(a) by removing the word, "restrictions," and replacing it with "requirements for the correction of minor noncompliances within a specified time period." A commenter suggested that the last sentence of section 205.404(a) be amended to read: "The approval may include restrictions or requirements as a condition of continued certification, which includes a time line for fulfilling the requirement." Another commenter requested that we define "restrictions." This commenter also recommended amending section 205.404(a) to clarify the meaning of "restrictions" and to require corrective action by the operator within a specific time period. We agree with the commenters that the last sentence of section 205.404(a) was in need of further clarification. We also agree that it is appropriate for the regulations to require that the requirements for correction include a specified time period within which the corrections must be made. Accordingly, we amended section 205.404(a) as noted above. The certifying agent will make the determination of whether a violation of the Act and regulations is minor. Minor noncompliances are those infractions that, by themselves, do not preclude the certification or continued certification of an otherwise qualified organic producer or handler. The certifying agent would be free to modify the time period for correction should it believe it to be appropriate.

We have also made editorial changes to section 205.404(a) consistent with suggestions we received on section 205.506. In the title to section 205.404 we have replaced "Approval of" with "Granting." In section 205.404(a) we have replaced "approve" with "grant" and "approval" with "certification." This change makes the language in section 205.404 consistent with ISO Guide 65, section 4.6, which addresses the granting of certification.

(10) Payment of Fees. We have amended the introductory statement within section 205.406(a) by adding the requirement that, to continue certification, a certified operation annually pay the certifying agent's certification fees. A commenter recommended amending section 205.404(c) by adding a sentence providing that a certified operation's failure to pay the certifying agent's certification fees may be a cause for suspension or revocation of certification. We agree that the issue of payment of fees should be addressed but not in section 205.404(c), which deals with the duration of a certified operation's certification. We believe the issue of payment of certification fees is more appropriately addressed in section 205.406, which deals with continuation of certification. Accordingly, we have amended section 205.406(a) to require payment of the certifying agent's fees as a condition of continued certification. This addition would allow a certifying agent to initiate suspension or revocation proceedings against any operation that fails to pay the required fees. The certifying agent is not required to initiate suspension or revocation proceedings for failure to pay the fees. In fact, the certifying agent is encouraged to use one or more of the legal debt collection alternatives available to it.

(11) Denial of Certification. We have amended section 205.405 to include noncompliance and resolution provisions originally included by cross-reference to section 205.662(a). We have made this amendment in response to a comment that these regulations do not provide an opportunity for a hearing upon denial of certification. We disagree with the commenter's assessment but have amended section 205.405(a) to eliminate confusion that may result from the cross-reference to section 205.662(a). We have determined that section 205.662(a) may cause confusion for certification applicants because the section does not specifically address applicants.

As amended, section 205.405(a) required a written notification of noncompliance that describes each noncompliance, the facts on which the noncompliance is based, and the date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. Section 205.405(b) lists the options available to the applicant, including the options of correcting the noncompliance or submitting written information to rebut the noncompliance. Successful correction or rebuttal will result in an approval of certification. When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, the certifying agent will issue a written notice of denial of certification. This notice will state the reason(s) for denial and the applicant's right to request mediation in accordance with section 205.663 or to file an appeal in accordance with section 205.681.

(12) Rebuttal of a Noncompliance. We have amended section 205.405(b)(3) to clarify that rebuttal of a noncompliance shall be submitted to the certifying agent that issued the notification of noncompliance. We made this amendment in response to a commenter's question about who has authority to evaluate a written rebuttal.

(13) Correction of Minor Noncompliances. We have amended section 205.406(a) by adding a new paragraph (3) which requires the certified operation to include with its annual reporting an update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification. A commenter recommended adding at 205.406(a) a requirement that the certified operation address any restrictions that have been applied to its certification under 205.404(a). We agree with the commenter that the annual reporting by the certified operation should include an update addressing the certified operation's compliance with the certifying agent's requirements for the correction of minor noncompliances. Accordingly, we amended section 205.406(a) as noted above and redesignated paragraph (3) as paragraph (4). The certifying agent will make the determination of whether a violation of the Act and regulations is minor. Minor noncompliances are those infractions that, by themselves, do not preclude the certification or continued certification of an otherwise qualified organic producer or handler.

(14) Scheduling Annual On-site Inspections. We have amended section 205.406(b) to provide that, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months. The annual on-site inspection, required by section 205.403, must, however, be conducted within the first 6 months following the certified operation's scheduled date of annual update.

A commenter expressed the belief that the requirement for an on-site inspection after receipt of the certified operation's annual update of information would have required that all annual on-site inspections be performed at the same time of the year. The commenter went on to express the belief that, to avoid inspecting certified operations twice a year, certifying agents would have to schedule the annual update to occur during the growing season in order to comply with the requirement for timing inspections when normal production activities can be observed. The commenter stated that certifying agents should be given more flexibility for scheduling inspections and conducting their certification programs according to management procedures best suited to their agency. The commenter recommended amending section 205.406(b) by adding to the end thereof: "or base the decision regarding eligibility for renewal on an on-site inspection conducted during the previous 12 months."

We agree with the commenter that certifying agents should be given more flexibility for scheduling on-site inspections so as to best meet the management needs of the certifying agent. Accordingly, we have amended section 205.406(b) to allow continuation of certification and issuance of an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months. This option will

be available to the certifying agent when renewal is scheduled for a time when it is impossible to conduct the annual on-site inspection following receipt of the annual update and at a time when land, facilities, and activities that demonstrate the operation's compliance or capability to comply can be observed. This change does not affect the requirement in section 205.403(a)(1) that the certifying agent conduct an annual on-site inspection of each certified operation. Further, the annual on-site inspection must be conducted within the first 6 months following the certified operation's scheduled date of annual update.

Certification - Changes Requested But Not Made

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) Number of On-site Inspections. A commenter recommended that section 205.403(a)(1) be amended by adding a requirement that production operations be under active organic management for the last year of the 3-year land conversion period and that two on-site inspections be performed prior to organic certification.

Section 205.403(a)(1) provides that the 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. The requirement does not preclude a certifying agent from conducting additional on-site inspections, if necessary, to establish the applicant's eligibility for certification. The Act requires a 3-year period immediately preceding harvest, during which the production operation must be free from the application of prohibited substances. The Act does not, however, require that land be under active organic management during this period, and we do not believe such a requirement in these regulations is necessary. Such a requirement, for example, would necessitate some process for verifying that an operation is under active organic management, which would, in effect, require a certification-type decision a year before certification is granted and the operation can begin to label products as certified organic. Accordingly, we disagree with the commenter's recommendation that an operation be under active organic management for the last year of the 3-year land conversion and that two on-site inspections be required.

(2) Unannounced Inspections. A commenter recommended that section 205.403(a)(2)(iii) be amended to require additional unannounced inspections either by defining the circumstances under which the inspections should be undertaken or by setting a minimum percentage of unannounced inspections. The commenter claimed that 5 percent is a common percentage adopted by certifying agents around the world.

Section 205.403 requires an initial on-site inspection, annual on-site inspection, and additional on-site inspections to determine compliance with the Act and regulations, to verify that information provided reflects actual practices, and to verify, through testing if necessary, that prohibited substances are not used by the operation. Because of the widely disparate nature of certified operations, we believe the certifying agent is in the best position to determine the need for additional on-site inspections. Accordingly, we have rejected the commenter's request that the regulations require additional unannounced visits either by defining the circumstances under which these should be undertaken or by setting a minimum percentage.

(3) Timeliness of Certifying Agent Review Information. A commenter requested that section 205.404(a) be amended to specify a timeframe of 60 days rather than "Within a reasonable time" as the time by which the certifying agent must review the on-site inspection report, the results of any analyses for substances, and any additional information requested from or supplied by the applicant.

Section 205.404(a) requires the certifying agent, within a reasonable time after completion of the initial on-site inspection, to review the on-site inspection report, the results of any analyses for substances conducted, and any additional information requested from or supplied by the applicant. Section 205.504(b)(1) requires the certifying agent to submit a copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates. Such procedures and the certifying agent's performance in making timely certification decisions will be subject to review during accreditation and reaccreditation of the certifying agent. Certifying agents are expected to make timely decisions regarding whether to certify an applicant and whether a certified operation is in compliance with the Act and regulations. Applicants with complaints regarding timeliness of service could forward their complaints to the Administrator. Accordingly, timely service will be in the best interest of certifying agents since such complaints could have an impact on their reaccreditation or continued accreditation. Further, our original position is consistent with those commenters requesting flexibility in determining what constitutes reasonable time. Accordingly, we have not amended section 205.404(a) as requested.

(4) Categories of Organic Operation. We received a variety of comments regarding the requirement that the certifying agent issue a certificate of organic operation which specifies the categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation. One commenter recommended that section 205.404(b)(3) be amended, with regard to processing, to only require a processing category to be specified on the certificate, such as food processing or feed processing. The commenter stated that it should not be necessary to list every product on the certificate. Specifically, the commenter recommended amending section 205.404(b)(3) by inserting the words, "general categories of," immediately in front of the word, "processed." Another commenter recommended amending section 205.404(b)(3) to require the identity of specific crops and the specific processing operations certified. Still another commenter requested that section 205.404(b) be amended by adding a new paragraph requiring that the certificate include the number of livestock of each species produced on the certified operation. This same commenter also recommended the addition of a new paragraph requiring that the certificate identify the specific location of each certified organic field and handling operation. We also received support for section 205.404(b)(3) as written. This commenter does not support the addition of information regarding the number of livestock or the location of fields.

We disagree with the suggestion that the certificate list every crop, wild crop, livestock, or processed product produced by the certified operation. We believe that listing categories of organic operation is sufficient. This does not, however, prevent the certifying agent, in cooperation with the certified operation, from listing specific crops, livestock, or processed products on the certificate. Such information could always be listed on the certificate when requested by the certified operation. We also disagree with the commenter who requested that certifying agents display the number of livestock of each species produced by the certified operation and the specific location of each certified organic field and handling operation. We do not believe it is necessary to list the quantity of product to be produced or handled at a certified operation, nor do we believe it is necessary to list the location of a certified operation's fields or facilities. Such information may, however, be listed on the certificate upon the written request of the certified operation. By requiring the name, address, and telephone number of the certifying agent, the certificate would provide interested persons with a contact for obtaining releasable information concerning the certified operation. Further, the certifying agent is the first line of compliance under this program and, as such, is the person to whom all questions and concerns should be addressed about certified operations.

(5) Annual Renewal of Certification. Numerous commenters requested that section 205.404(b)(2) be amended to provide for the placement of an expiration date on the certificate of organic operation. The commenters want yearly expiration of certification and yearly expiration of the certificate of organic operation. Commenters also requested that section 205.404(c) be amended to provide that once certified, a production or handling operation's organic certification continues

in effect until the expiration date on the certificate, until surrendered by the organic operation, or until suspended or revoked by the certifying agent, the SOP's governing State official, or the Administrator. Some commenters recommended the addition of a new paragraph 205.406(e) that would provide for automatic suspension of a certification if the certified operation did not provide the information required in paragraph 205.406(a) by the expiration date to be placed on the certificate of organic operation.

We disagree with the commenters who have requested annual renewal of certification and that the certified operation's certification and its certificate of organic operation expire annually. We prefer continuous certification due to the very real possibility that the renewal process might not always be completed before expiration of the certification period. Expiration of the certification period would result in termination of the operation's certification. Even a short period of interruption in an operation's organic status could have severe economic ramifications. Further, we believe that a regular schedule of expiration of certification is unnecessary inasmuch as all certified operations are required to annually update their organic system plan and submit any changes to their certifying agent. More importantly, unlike accreditation, where the Act provides for expiration and renewal, the Act does not provide for an expiration or renewal of certification. Therefore, it is also our position that once granted certification the production or handling operation retains that certification until voluntarily surrendered or removed, following due process, for violation of the Act or these regulations.

(6) Denial of Certification. A commenter recommended that section 205.405(e) be amended to place a time restriction on reapplication for certification after denial of certification. The commenter suggested a 3-year period. We disagree with this recommendation because the reasons for denial include a wide range of noncompliances. The ability to correct noncompliances will vary as will the time needed to correct the noncompliances.

(7) Production and Handling Operation Certification Following Suspension or Revocation of Certifying Agent Accreditation. A few commenters requested amendment of section 205.406 through the addition of a new paragraph (f). Specifically, the commenters requested provisions that would provide for USDA notification of certified operations regarding the suspension or revocation of their certifying agent's accreditation. Some of these commenters requested that the provisions also allow the affected certified operation to use current market labels for a maximum period of 12 months, provided the certified operation made application for certification with another USDA-accredited certifying agent within 3 months of being notified of their certifying agent's suspension or revocation of accreditation. Another commenter requested that the new paragraph provide that the affected certified operation will continue to operate as if certified by the USDA and will be allowed to use current market labels for a maximum period of 12 months. The commenter stated that this amendment would provide the certified operation with the time needed to obtain recertification by an accredited certifying agent and to prepare new labels.

We disagree with the recommendations. USDA does not perform organic certification activities under any circumstance, including upon surrender, suspension, or revocation of an accredited certifying agent's accreditation. Operations certified by a certifying agent that surrenders or loses its USDA accreditation will be notified by USDA and given an opportunity to immediately begin seeking certification by the USDA-accredited certifying agent of their choice. Certified operations shall not affix the seal or other representation of a certifying agent to any product that they produce after the certifying agent has surrendered or had its accreditation revoked. The certified operation may use the USDA organic seal. In the case of suspension of the certifying agent, the reasons for the suspension and the terms of the suspension will determine whether the certifying agent's certified operations will have to seek recertification or stop affixing the certifying agent's seal or other representation to their products. USDA will announce the suspension or revocation of a certifying agent's accreditation, and the announcement will address the status of operations certified by the certifying agent.

Certification - Clarifications

Clarification is given on the following issues raised by commenters as follows:

(1) Recordkeeping. A commenter stated that most computerized recordkeeping systems used at retail and wholesale are set up to save the data for a maximum of 2 years; adding 3 additional years to that requirement would be extremely costly as systems modifications and additional hardware and support would be required to meet the mandate. The commenter suggested that since food product is generally sold and consumed within a matter of months (if not weeks), shortening this requirement to 2 years should meet the goal for tracking of any product through the distribution system. This commenter was referring to the requirement in section 205.400(d) that records be maintained for not less than 5 years beyond their creation.

Section 205.103 requires that a certified operation maintain records; that the records be adapted to the particular business that the certified operation is conducting, fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited, be maintained for not less than 5 years beyond their creation, and be sufficient to demonstrate compliance with the Act and the regulations in this part; and that the certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable SOP's governing State official, and the certifying agent. The requirements do not state in what form (i.e., paper, electronic, film) that the records must be maintained. Therefore, in answer to the commenter's concern, database records more than 2 years old could be stored in any form, including on an electronic storage device, which would permit retrieval upon request.

(2) Application Fees. A commenter recommended that section 205.401 be amended by adding a new paragraph (e) which would require an applicant for certification to include, along with the other required application information, the application fees required by the certifying agent.

The requested language is unnecessary because section 205.400(e) requires submission of the applicable fees charged by the certifying agent as a general requirement for certification.

(3) Applicant Identification. In reference to section 205.401(c) a commenter stated that an applicant that is a corporation could easily change the name of the corporation in order to avoid having to report applications submitted and denied under the previous name. The commenter went on to state that there must be a database available to certifying agents that includes names and location addresses of operations that have received a notification of noncompliance, denial of certification, or a suspension or revocation of certification.

Section 205.401(b) requires the applicant to include in its application the name of the person completing the application; the applicant's business name, address, and telephone number; and, when the applicant is a corporation, the name, address, and telephone number of the person authorized to act on the applicant's behalf.

As we stated in the preamble to the proposed rule, we anticipate using the data collected under section 205.501(a)(15) to establish and maintain two Internet databases. The first Internet database would be accessible to the general public and would include the names and other appropriate data on certified organic production and handling operations. The second Internet database would be password protected and only available to accredited certifying agents and USDA. This second database would include data on production and handling operations issued a notification of noncompliance, noncompliance correction, denial of certification, certification, proposed suspension or revocation of certification, and suspension or revocation of certification. Certifying agents would use the second Internet database during their review of an application for certification.

(4) Withdrawal of Application. Several commenters expressed the belief that allowing an applicant to voluntarily withdraw its application will be used as a tool to avoid denial of certification. They expressed concern that voluntary withdrawal before denial of certification will allow the applicant to make application with a different certifying agent with a clean record. These commenters were responding to the provision in section 205.402(e) which allows an applicant for certification to withdraw its application at any time.

We continue to believe that operations should not be unnecessarily stigmatized because they applied for certification before the operation was ready to meet all requirements for certification. While some operations may use voluntary withdrawal as a means to avoid the issuance of a notification of noncompliance or a notice of denial of certification, this should not adversely affect the National Organic Program (NOP) because all certifying agents are responsible for using qualified personnel in the certification process and for ensuring an applicant's eligibility for certification. Further, all applicants for certification are required under section 205.401(c) to include in their application the name(s) of any organic certifying agent(s) to which application has previously been made, the year(s) of application, and the outcome of the application(s) submission.

(5) On-site Inspections. Section 205.403(a)(2)(ii) provides that the Administrator or SOP'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. In commenting on this provision, a commenter asked, "Who is running this program: State or Federal officials?"

This is a national organic program administered by the Agricultural Marketing Service of the United States Department of Agriculture. States may administer their own organic program. However, all SOP's are subject to USDA approval. The National Organic Standards and a State's organic standards under a USDA-approved SOP are the National Organic Standards for that State. The State, under USDA's approval of the SOP, has enforcement responsibilities for the Federal and State components of the organic program within the State.

(6) Verification of Information. A commenter stated that section 205.403(c) is insufficiently comprehensive. The commenter stated that organic inspection is assessment of a process evaluated against comprehensive standards and, as such, it requires specific rules to provide confidence in the quality of the inspection. The commenter recommended amending section 205.403(c) by including requirements on minimum verification methods.

Section 205.403(c) identifies what must be verified during the on-site inspection. The details on how the verification will be accomplished will be set forth in the certifying agent's procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates and the certifying agent's procedures for reviewing and investigating certified operation compliance with the Act and regulations. The NOP is available to respond to questions and to assist certifying agents in complying with the on-site inspection requirements, including those for the verification of information.

(7) Notifying Customers of Change in Certification Status. A commenter stated that the regulations do not indicate when a certified organic producer must stop using the organic seal or whether they must notify customers of their denial of certification. The commenter recommended amending section 205.405 to include a provision for notifying customers of a certified operation's change in certification status.

Any producer or handler who plans to sell, label, or represent its product as "100 percent organic," "organic," or "made with..." must be certified unless exempted under the small operation exemption under section 205.101(a)(1) or not regulated under the NOP (i.e., a producer of dog

food). Only certified operations may represent themselves as certified. Operations denied certification may not represent their products as "100 percent organic," "organic," or "made with..." Operations that have had their certification suspended or revoked will be subject to the terms and conditions of their suspension or revocation relative to the labeling of product produced prior to the suspension or revocation. No product produced by an operation after suspension or revocation of certification may be sold, labeled, or represented as "100 percent organic," "organic," or "made with..."

Buyers of organic product can request to see the producer's or handler's certificate of organic operation. Operations that have lost their organic status will be unable to obtain an updated certificate. Buyers with questions regarding an operation's organic status may also contact the certifying agent identified on a certificate of organic operation. Further, as previously noted, we anticipate using the data collected under section 205.501(a)(15) to establish and maintain an Internet database accessible to the general public that will include the names and other appropriate data on certified organic production and handling operations.

(8) Continuation of Certification. A few commenters recommended amending section 205.406 to include a safety net for producers who are certified by a certifying agent that does not become accredited by USDA. They stated that the rule must clearly state that a certified organic producer will have the full 18-month implementation period starting from the effective date of the final rule to get recertified if their certifying agent is not accredited. One of the commenters stated that because the NOP anticipates that the accreditation process will require 12 months, producers will, in effect, have 6 months to be certified by a new certifying agent should the producer's certifying agent not be accredited.

Certification under the NOP will become mandatory 18 months after the effective date of the final rule. Applications for accreditation will be processed on a first-come, first-served basis. Accreditations will be announced approximately 12 months after the effective date of the final rule for those qualified certifying agents who apply within the first 6 months following the effective date and for any other applicants that AMS determines eligible. Certifying agents will begin the process of certifying organic production and handling operations to the national standards upon receipt of their USDA accreditation. All production and handling operations certified by an accredited certifying agent will be considered certified to the national standards until the certified operation's anniversary date of certification. This phase-in period will only be available to those certified operations certified by a certifying agent that receives its accreditation within 18 months from the effective date of the final rule. We anticipate that certifying agents and production and handling operations will move as quickly as possible to begin operating under the national organic standards. Operations certified by a certifying agent, which fails to apply for or fails to meet the requirements for USDA accreditation under the NOP, must seek and receive certification by a USDA-accredited certifying agent before they can sell, label, or represent their products as organic, effective 18 months after the effective date of the final rule.

1. ISO Guide 10011-1 is available for viewing at USDA-AMS, Transportation and Marketing Programs, Room 2945-South Building, 14th and Independence Ave., SW, Washington, DC, from 9:00 a.m. to 4:00 p.m., Monday through Friday (except official Federal holidays). A copy may be obtained from the American National Standards Institute, 11 West 42d Street, New York, NY 10036; Website: www.ansi.org; E-mail: ansionline@ansi.org; Telephone: 212-642-4900; Facsimile: 212-398-0023.