

## Compliance -- Preamble

This portion of subpart G sets forth the enforcement procedures for the National Organic Program (NOP). These procedures describe the compliance responsibilities of the NOP Program Manager, State organic programs' (SOP) governing State officials, and State and private certifying agents. These provisions also address the rights of certified production and handling operations and accredited certifying agents operating under the NOP. The granting and denial of certification and accreditation are addressed under subparts E and F.

### Description of Regulations

The Secretary is required under the Act to review the operations of SOP's, accredited certifying agents, and certified production or handling operations for compliance with the Act and these regulations. The Program Manager of the NOP may carry out compliance proceedings and provide oversight of compliance proceedings on behalf of the Secretary and the Administrator. The Program Manager will initiate proceedings to suspend or revoke a certified operation's certification if a certifying agent or SOP's governing State official fails to take appropriate enforcement action. The Program Manager may also initiate proceedings to suspend or revoke a certified operation's certification if the operation is found to have been erroneously certified by a certifying agent whose accreditation has been suspended or revoked. We anticipate, however, that most investigations, reviews, and analyses of certification noncompliance and initiation of suspension or revocation will be conducted by the certified operation's certifying agent. With regard to certifying agents, the Program Manager will, when appropriate, initiate proceedings to suspend or revoke the accreditation of a certifying agent for noncompliance with the Act and these regulations.

In States with an approved SOP, the SOP's governing State official is responsible for administering a compliance program for enforcement of the NOP/SOP. SOP's governing State officials may review and investigate complaints of noncompliance involving organic production or handling operations operating within their State and, when appropriate, initiate suspension or revocation of certification. SOP's governing State officials may also review and investigate complaints of noncompliance involving accredited certifying agents operating within their State. They must report the findings of any review and investigation of a certifying agent to the Program Manager along with any recommendations for appropriate action.

The compliance provisions of the NOP are consistent with the requirements of the Administrative Procedure Act (APA) (5 U.S.C. 553-559) in that this program provides for due process including an opportunity for hearing, appeal procedures, written notifications of noncompliance, and opportunities to demonstrate or achieve compliance before any suspension or revocation of organic certification or accreditation is invoked. A compliance action regarding certification carried out under an approved SOP's compliance procedures will have the same force and effect as a certification compliance action carried out under these NOP compliance procedures. The notification process for denying certification and accreditation is laid out in subparts E and F, respectively.

Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued under these regulations must be sent to the recipient's place of business via a delivery service which provides return receipts. Certified operations and certifying agents must respond to all compliance notifications via a delivery service which provides return receipts.

### Noncompliance Procedure for Certified Operations

The Act provides for the enforcement of certification requirements. Statutory oversight of production and handling operations by certifying agents includes review of organic plans, on-site inspections, residue and tissue testing, authority to conduct investigations and initiate suspension or revocation actions, and responsibility to report violations.

### **Notification of Noncompliance**

A written notification of noncompliance will be sent to the certified operation when an inspection, review, or investigation reveals any noncompliance with the Act or these regulations. A noncompliance notification may encompass the entire operation or a portion of the operation. For instance, a violation at one farm may not warrant loss of certification at other farms of the certified operation not affected by the violation. The notification of noncompliance will provide: (1) a description of each condition, action, or item of noncompliance; (2) the facts upon which the notification is based; and (3) the date by which the certified operation must rebut the notification or correct the noncompliance and submit supporting documentation of the correction. A certified operation may continue to sell its product as organic upon receiving a notification of noncompliance and throughout the compliance proceeding and any appeal procedure which might follow the compliance proceeding unless otherwise notified by a State or Federal government agency.

If a certified operation believes the notification of noncompliance is incorrect or not well-founded, the certified operation may submit a rebuttal to the certifying agent or SOP's governing State official, as applicable, providing supporting data to refute the facts stated in the notification. The opportunity for rebuttal is provided to allow certifying agents and certified operations to informally resolve noncompliance issues. The rebuttal process should be helpful in resolving differences which may be the result of misinterpretation of requirements, misunderstandings, or incomplete information. Alternatively, the certified operation may correct the identified noncompliances and submit proof of such corrections. When the certified operation demonstrates that each noncompliance has been corrected or otherwise resolved, the certifying agent or SOP's governing State official, as applicable, will send the certified operation a written notification of noncompliance resolution.

### **Proposed Suspension or Revocation of Certification**

If the noncompliance is not resolved or is not in the process of being resolved by the date specified in the notification of noncompliance, the certifying agent or SOP's governing State official will send the certified operation a written notification of proposed suspension or revocation of certification for the entire operation or a portion of the operation affected by the noncompliance. The notification will state: (1) the reasons for the proposed suspension or revocation; (2) the proposed effective date of the suspension or revocation; (3) the impact of the suspension or revocation on the certified operation's future eligibility for certification; and (4) that the certified operation has a right to request mediation or to file an appeal. The impact of a proposed suspension or revocation may include the suspension or revocation period or whether the suspension or revocation applies to the entire operation or to a portion or portions of the operation.

If a certifying agent or SOP's governing State official determines that correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification of proposed suspension or revocation. The certified operation will have an opportunity to appeal the proposed suspension or revocation.

If a certifying agent or SOP's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations, a notification of proposed suspension or

revocation will be sent to the certified operation. The proposed suspension or revocation will be for the entire operation or a portion of the operation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

## **Mediation**

A production or handling operation may request mediation of any dispute regarding denial of certification or proposed suspension or revocation of certification. Mediation is not required prior to filing an appeal but is offered as an option which may resolve the dispute more quickly than the next step, which is filing an appeal. When mediation is requested, it must be requested in writing to the applicable certifying agent. The certifying agent will have the option of accepting or rejecting the request for mediation. If the certifying agent rejects the request for mediation, the certifying agent must provide written notification to the applicant for certification or certified operation. The written notification must advise the applicant for certification or certified operation of the right to request an appeal in accordance with section 205.681. Any such appeal must be requested within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation must be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If an SOP is in effect, the mediation procedures established in the SOP, as approved by the Secretary, must be followed. The parties to the mediation will have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the production or handling operation will have 30 days from termination of mediation to appeal the denial of certification or proposed suspension or revocation in accordance with the appeal procedures in section 205.681.

Any agreement reached during or as a result of the mediation process must be in compliance with the Act and these regulations. The Secretary reserves the right to review any mediated agreement for conformity to the Act and these regulations and to reject any agreement or provision not in conformance with the Act or these regulations

## **Suspension or Revocation**

The certifying agent or SOP's governing State official will suspend or revoke the certified operation's certification when the operation fails to resolve the issue through rebuttal or mediation, fails to complete needed corrections, or does not file an appeal. The operation will be notified of the suspension or revocation by written notification. The certifying agent or SOP's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation or filed an appeal while final resolution of either is pending.

The decision to suspend or revoke certification will be based on the seriousness of the noncompliance. Such decisions must be made on a case-by-case basis. Section 6519 of the Act establishes that willful violations include making a false statement, knowingly affixing a false label, or otherwise violating the purposes of the Act.

In addition to suspension or revocation, a certified operation that knowingly sells or labels a product as organic, except in accordance with the Act, will be subject to a civil penalty of not more than \$10,000 per violation. Further, a certified operation that makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent will be subject to the provisions of section 1001 of title 18, United States Code.

A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating

correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the NOP.

A certified operation or a person responsibly connected with an operation that has had its certification revoked will be ineligible to receive certification for an operation in which such operation or person has an interest for 5 years following the date of revocation. Accordingly, an operation will be ineligible for organic certification if one of its responsibly connected parties, was a responsibly connected party of an operation that had its certification revoked. The Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

### **Noncompliance Procedure for Certifying Agents**

The Program Manager, on behalf of the Secretary, may initiate a compliance action against an accredited certifying agent who violates the Act or these regulations. Compliance proceedings may be initiated as a result of annual reviews for continuation of accreditation, site evaluations, or investigations initiated in response to complaints of noncompliant activities. Compliance proceedings also may be initiated on recommendation of an SOP's governing State official.

A written notification of noncompliance will be sent by the Program Manager to an accredited certifying agent when an inspection, review, or investigation of such person reveals any noncompliance with the Act or these regulations. A notification of noncompliance will provide a description of each noncompliance found and the facts upon which the notification is based. Additionally, the notification will provide the date by which the certifying agent must rebut or correct each noncompliance described and submit supporting documentation of each correction.

When documentation received by the Program Manager demonstrates that each noncompliance has been resolved, the Program Manager will send the certifying agent a written notification of noncompliance resolution.

If a noncompliance is not resolved by rebuttal or correction, the Program Manager will issue a notification of proposed suspension or revocation of accreditation. The notification will state whether the suspension or revocation will be for the certifying agent's entire accreditation, that portion of the accreditation applicable to a particular field office, or a specific area of accreditation. For instance, if a certifying agent with field offices in different geographic areas is cited for a compliance violation at one field office, the Program Manager could determine that only that portion of the accreditation applicable to the noncompliant field office should be suspended or revoked.

If the Program Manager determines that the noncompliance cannot be immediately or easily corrected, the Program Manager may combine the notification of noncompliance and the proposed suspension or revocation in one notification.

The notification of proposed suspension or revocation of accreditation will state the reasons and effective date for the proposed suspension or revocation. Such notification will also state the impact of a suspension or revocation on future eligibility for accreditation and the certifying agent's right to file an appeal.

If the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations, the Program Manager will issue a notification of proposed suspension or revocation of accreditation. The proposed suspension or revocation may be for the certifying agent's entire accreditation, that portion of the accreditation applicable to a particular field office, or a specified area of accreditation. This notification, because it involves a willful violation, will be sent without first issuing a notification of noncompliance.

The certifying agent may file an appeal of the Program Manager's determination pursuant to section 205.681. If the certifying agent fails to file an appeal of the proposed suspension or revocation, the Program Manager will suspend or revoke the certifying agent's accreditation. The certifying agent will be notified of the suspension or revocation by written notification.

A certifying agent whose accreditation is suspended or revoked must cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked. Any certifying agent whose accreditation has been suspended or revoked must transfer to the Secretary all records concerning its certification activities that were suspended or revoked. The certifying agent must also make such records available to any applicable SOP's governing State official. The records will be used to determine whether operations certified by the certifying agent may retain their organic certification.

A certifying agent whose accreditation is suspended by the Secretary may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. Such request must be accompanied by evidence demonstrating correction of each noncompliance and actions taken to comply with and remain in compliance with the Act and regulations. A certifying agent whose accreditation is revoked by the Secretary will be ineligible to be accredited as a certifying agent under the Act and regulations for a period of not less than 3 years following the date of revocation.

### **State Organic Programs' Compliance Procedures**

An SOP's governing State official may initiate noncompliance proceedings against certified organic operations operating in the State. Such proceedings may be initiated for failure of a certified operation to meet the production or handling requirements of this part or the State's more restrictive requirements, as approved by the Secretary.

The SOP's governing State official must promptly notify the Program Manager of commencement of noncompliance proceedings initiated against certified operations and forward to the Program Manager a copy of each notice issued. A noncompliance proceeding, brought by an SOP's governing State official against a certified operation may be appealed in accordance with the appeal procedures of the SOP. There will be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located.

An SOP's governing State official may review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the SOP's governing State official must send a written report of noncompliance to the Program Manager. The SOP's governing State official's report must provide a description of each noncompliance and the facts upon which the noncompliance is based.

### **Compliance - Changes Based On Comments**

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

(1) Written Notifications. We have added a new paragraph (d) to section 205.660. The preamble to the proposed rule stated that all written notifications sent by certifying agents and SOP's governing State officials, as well as rebuttals, requests for mediation, and notices of correction of noncompliances sent by certified operations, will be sent to the addressee's place of business by a delivery service which provides dated return receipts. The assurance of completed communications and timely compliance procedures was given as the reason for delivery by a service which provides dated return receipts. The addition of paragraph (d) at section 205.660 is

one of the actions that we have taken in response to requests from commenters that we further clarify the compliance process. Paragraph (d) requires that each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued in accordance with sections 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 return receipts. This action will facilitate the effective administration of the compliance process by assuring a verifiable time line on the issuance and receipt of compliance documents and the response given to each such document.

(2) Determination of Willful. The preamble statement that "only the Program Manager or governing State official may make the final determination that a violation is willful" was incorrect and inconsistent with the regulatory language in section 205.662(d). Section 205.662(d) provides that, "if a certifying agent or State organic program's governing State official has reason to believe that a certified operation has willfully violated the Act or regulations in this part, the certifying agent or State organic program's governing State official shall send the certified operation a notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance." Accordingly, as recommended by a commenter, the incorrect statement has been deleted from the preamble to this final rule.

(3) Proposed Suspension or Revocation. We have amended sections 205.662(c) and 205.665(c) by removing the redundant phrase "or is not adequate to demonstrate that each noncompliance has been corrected" from the first sentence of each section.

(4) Suspension or Revocation. We have amended section 205.662(e)(2) by adding "while final resolution of either is pending" to the end thereof. The language of section 205.662(e)(2) now reads: "A certifying agent or State organic program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to section 205.663 or filed an appeal pursuant to section 205.681 while final resolution of either is pending." We have made this change because we agree with those commenters who expressed the belief that section 205.662(e)(2) needed to be amended to clarify the duration of the stay on the issuance of a notification of suspension or revocation when mediation is requested or an appeal is filed. Several commenters stated that section 205.662(e)(2) needed to be amended to clarify that requesting mediation or filing an appeal does not indefinitely stop the suspension or revocation process.

(5) Eligibility After Suspension or Revocation of Certification. We have amended section 205.662(f) such that it now parallels section 205.665(g) which addresses suspension and revocation of certifying agents. We have also changed the title of section 205.662(f) from "Ineligibility" to "Eligibility" to parallel section 205.665(g). A few commenters referred to the provisions in section 205.665(g), which addresses eligibility after suspension or revocation of accreditation, and requested clarification of the difference between suspension and revocation of certification. Upon reviewing section 205.662(f), we decided that amendment was needed to clarify the difference between suspension and revocation of certification relative to eligibility for certification. Accordingly, we added a new paragraph (1) which provides that a certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The paragraph also provides that the request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. We also amended what is now paragraph (2) of section 205.662(f) to clarify that the period of ineligibility following revocation of certification is 5 years unless reduced or eliminated by the Secretary.

Further, we have amended section 205.665(g)(1) to clarify that a certifying agent that has had its accreditation suspended may request reinstatement of its accreditation rather than submit a new request for accreditation. The amendment also clarifies that the reinstatement may be requested

at any time unless otherwise stated in the notification of suspension. This amendment makes section 205.665(g)(1) similar to new paragraph (1) of section 205.662(f). This amendment is also consistent with commenter desires that the noncompliance procedures for certified operations and accredited certifying agents be similar.

(6) Penalties for Violations of the Act. We have amended section 205.662 by adding a new paragraph (g) which incorporates therein the provisions of paragraphs (a) and (b) of section 2120, 7 U.S.C. 6519, Violations of Title, of the Act. Specifically, paragraph (g) provides that, in addition to suspension or revocation, any certified operation that knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 per violation. This paragraph also provides that any certified operation that makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code. Commenters requested regulatory language citing section 2120, 7 USC 6519, Violations of Title, of the Act. Commenters also requested a clearer description of enforcement. Specifically, they want provisions describing how USDA will deal with operations that make false claims or do not meet the NOP requirements. Further, numerous commenters expressed concern that there are no penalties in the regulations other than suspension and revocation. The European Community stated that it did not find, in the proposal, requirements for penalties to be applied by certifying agents when irregularities or infringements are found. The European Community went on to say that the European Union requires such penalties.

The Act provides for suspension and revocation of certification and the civil and criminal penalties addressed in 7 U.S.C. 6519. Certified operations are also required through the compliance program set forth in these regulations, to correct all noncompliances with the Act or regulations as a condition of retaining their certification. Furthermore, to get a suspended certification reinstated, an operation must submit a request to the Secretary. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. An operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of not more than 5 years.

We believe adding paragraph (g) will help clarify that there are penalties which may be imposed on certified operations that violate the Act and these regulations in addition to suspension or revocation.

The provisions of the Act and these regulations apply to all persons who sell, label, or represent their agricultural product as organic. Accordingly, persons who falsely sell, label, or represent their product as organic, are subject to the provisions of paragraphs (a) and (b) of section 2120, 7 USC 6519, of the Act. To clarify this, we have added a new paragraph (c) to section 205.100 of the Applicability subpart.

Certifying agents, SOP's governing State officials, and USDA will receive complaints alleging violations of the Act or these regulations. Certifying agents will review all complaints that they receive to determine if the complaint involves one of their clients. If the complaint involves a client of the certifying agent, the agent will handle the complaint in accordance with its procedures for reviewing and investigating certified operation compliance. If the complaint involves a person who is not a client of the certifying agent, the certifying agent will refer the complaint to the SOP's governing State official, when applicable, or, in the absence of an applicable SOP's governing State official, the Administrator. SOP's governing State officials will review all complaints that they receive in accordance with their procedures for reviewing and investigating alleged violations of the NOP and SOP. The SOP's governing State official's review of the complaint could result in referral of the complaint to a certifying agent when the complaint involves a client of the certifying agent, dismissal, or investigation by the SOP's governing State official. SOP's governing State officials will, as appropriate, investigate allegations of violations of the Act by noncertified

operations operating within their State. USDA will review all complaints that it receives in accordance with its procedures for reviewing and investigating alleged violations of the NOP. USDA will refer complaints alleging violations of the NOP/SOP to the applicable SOP's governing State official, who may, in turn, refer the complaint to the applicable certifying agent. In States without an approved SOP, USDA will refer complaints to the applicable certifying agent. USDA will, as appropriate, investigate allegations of violations of the Act by noncertified operations operating in States where there is no approved SOP.

(7) Mediation. We have amended section 205.663 by providing that a dispute with respect to proposed suspension or revocation of certification may, rather than shall, be mediated. We have also provided that mediation must be requested in writing to the applicable certifying agent. The certifying agent will have the option of accepting or rejecting the request for mediation. If the certifying agent rejects the request for mediation, the certifying agent must provide written notification to the applicant for certification or certified operation. The written notification must advise the applicant for certification or certified operation of the right to request an appeal within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation must be conducted by a qualified mediator mutually agreed upon by the parties to the mediation.

Several commenters wanted section 205.663 amended to provide that disputes "may," rather than "shall," be mediated. The commenters advocated allowing the certifying agent to determine when mediation is a productive option. Several State commenters wanted to amend the second sentence to read as follows: "If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed for cases involving the State organic program and its applicants or certified parties." Another commenter wanted to retain the requirement that disputes "shall" be mediated but wanted disputes mediated in accordance with 7 CFR Part 11 and section 205.681 of these regulations.

We concur that certifying agents should be authorized to reject a request for mediation, especially when they believe that the noncompliance issue is not conducive to mediation. Accordingly, we amended section 205.663 as noted above. We disagree, however, with the State commenters who want to amend the second sentence. We believe that the recommended change would exclude the clients of private-sector certifying agents operating within the State. USDA approval of an SOP will require that all certified operations operating within the State have the same opportunities for mediation, regardless of whether they are certified by a private or State certifying agent. If an approved SOP provides for mediation, such mediation must be available to all certified operations operating within the State. We also disagree with the commenter who requested that disputes be mediated in accordance with 7 CFR Part 11 and section 205.681 of these regulations. First, we believe that States with an approved SOP must be allowed to establish their own mediation program and procedures. Second, the Act and its implementing regulations are subject to the APA for adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR Part 11, National Appeals Division Rules of Procedure. Even if 7 CFR Part 11 were applicable, it does not address mediation procedures. Mediation is merely addressed in 7 CFR Part 11 as an available dispute resolution method along with its impact on the filing of an appeal.

(8) Noncompliance Procedure for Certifying Agents. We have amended section 205.665(a)(3) to clarify that, like certified operations, certifying agents must submit supporting documentation of each correction of a noncompliance identified in a notification of noncompliance. This amendment to section 205.665(a)(3) was made in response to commenter concerns that the noncompliance procedures for certified operations and certifying agents be similar. It had been our intent that certifying agents would have to document their correction of noncompliances and that the noncompliance procedures for certified operations and certifying agents would be similar.

#### **Compliance - Changes Requested But Not Made**



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

(1) Funding for Enforcement. Several commenters stated that USDA should provide funding to the States for the cost of performing enforcement activities. Others asked who should fund investigations and enforcement actions if certifying agents (State and private) are enforcing compliance with a Federal law. Numerous commenters requested information on how enforcement will be funded. The National Organic Standards Board (NOSB) recommended that the NOP examine existing models for capturing enforcement fees such as the State of California's registration program for all growers, handlers, and processors who use the word, "organic," in marketing their products.

We disagree with the commenters who stated that USDA should fund enforcement activities (State and private). Costs for compliance under the NOP will be borne by USDA, States with approved SOP's, and accredited certifying agents. Each of the entities will bear the cost of their own enforcement activities under the NOP. AMS anticipates that States will consider the cost of enforcing their SOP's prior to seeking USDA approval of such programs. We also anticipate that certifying agents will factor the cost of compliance into their certification fee schedules.

We agree that there may be alternatives, such as the State of California's registration program, available to raise funds for enforcing the NOP. We will help identify existing models and potential options that may be available in the future at the Federal, State, or certifying agent level. In the interim, we believe that SOP's should explore funding options at their level and that certifying agents should factor the cost of enforcement into their certification fees structure.

(2) Stop Sale. A number of commenters requested that the regulations include the ability to stop sales or recall misbranded or fraudulently produced products. The Act does not authorize the NOP to stop sales or recall misbranded or fraudulently produced product. Accordingly, USDA cannot authorize stop sales or the recall of product. We also believe that the certified operation's right to due process precludes a stop sale or recall prior to full adjudication of the alleged noncompliance. However, the Food and Drug Administration (FDA) and the USDA's Food Safety Inspection Service (FSIS) have stop sale authority that may be used in certain organic noncompliance cases. Further, States may, at their discretion, be able to provide for stop sale or recall of misbranded or fraudulently produced products produced within their State. While the Act does not provide for stop sale or recall, it does provide at 7 U.S.C. 6519 that any person who: (1) knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 and (2) makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

(3) Notification of Proposed Suspension or Revocation. A commenter recommended replacing "notification of proposed suspension or revocation" in section 205.662(d) with "notification of suspension or revocation." Certification cannot be suspended or revoked without due process. Accordingly, the issuance of a written notification of proposed suspension or revocation is necessary to provide the certified operation with information regarding the alleged noncompliance(s) and its right to answer the allegations. For this reason we have not accepted the commenter's recommendation.

(4) Mediation for Certifying Agents. Several commenters recommended amending section 205.665(c)(4) to provide for mediation between a certifying agent and the Program Manager when a proposed suspension or revocation is disputed by the certifying agent. We have not accepted the recommendation. USDA uses 7 CFR Part 1, Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary Under Various Statutes, for adjudicatory proceedings involving the denial, suspension, and revocation of accreditation.

(5) Revocation of Accreditation. A commenter stated that revocation of accreditation for 3 years is excessive. The commenter stated that a period of 6 to 12 months might be reasonable. We have not amended section 205.665(g)(2) because the Act requires that the period of revocation for certifying agents, who violate the Act and these regulations, be for not less than 3 years. Suspension is available to the Secretary to address less egregious noncompliances. A certifying agent whose accreditation is suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and these regulations.

(6) Appeals Under SOP's. Several commenters recommended amending 205.668(b) by adding at the end thereof: "unless the State program's appeals procedures include judicial review through the State District Court." Another commenter wanted 205.668(b) amended by removing "of the State organic certification program. There shall be no subsequent rights of appeal to the Secretary. Final decisions of a State may be appealed to the United States District Court for the district in which such certified operation is located," and inserting in its place "at 7 CFR part 11 and 205.681 of this chapter." We have not accepted the recommendations because the Act at 7 U.S.C. 6520 provides that a final decision of the Secretary may be appealed to the United States District Court for the district in which the person is located. We consider an approved SOP to be the NOP for that State. As such, we consider the SOP's governing State official of such approved SOP to be the equivalent of a representative of the Secretary for the purposes of the appeals procedures under the NOP. Accordingly, the final decision of the SOP's governing State official of an approved SOP is considered the final decision of the Secretary and, as such, is appealable to the United States District Court for the district in which the person is located, not a State's District Court.

We also disagree with the commenter who wanted all appeals to be made to the National Appeals Division under the provisions at 7 CFR Part 11 and section 205.681 of these regulations. First, we believe that States with an approved SOP must be allowed to establish their own appeal procedures. Such procedures would have to comply with the Act, be equivalent to the procedures of USDA, and be approved by the Secretary. Second, as noted elsewhere in this preamble, the Act and its implementing regulations are subject to the APA for adjudication. The provisions of the APA generally applicable to agency adjudication are not applicable to proceedings under 7 CFR Part 11.

### **Compliance - Clarifications**

Clarification is given on the following issues raised by commenters:

(1) Complaints, Investigations, Stop Sales, and Penalties. Many commenters wanted USDA to spell out the responsibilities and authorities of States, State and private certifying agents, Federal agencies, and citizens to make complaints, investigate violations, halt the sale of products, and impose penalties. Anyone may file a complaint, with USDA, an SOP's governing State official, or certifying agent, alleging violation of the Act or these regulations. Certifying agents, SOP's governing State officials, and USDA will receive, review, and investigate complaints alleging violations of the Act or these regulations as described in item 6 above under Changes Based on Comments. Citizens have no authority under the NOP to investigate complaints alleging violation of the Act or these regulations.

As noted elsewhere in this preamble, the Act does not authorize USDA to stop the sale of product. Accordingly, USDA cannot authorize stop sales by accredited certifying agents. We also believe that the certified operation's right to due process precludes a stop sale prior to full adjudication of the alleged noncompliance. However, FDA and FSIS have stop sale authority that may be used in the event of food safety concerns. Further, States may, at their discretion, be able

to provide for stop sale of product produced within their State. Citizens have no authority under the NOP to stop the sale of a product.

The Act and these regulations provide for suspension or revocation of certification by certifying agents, SOP's governing State officials, and the Secretary. Only USDA may suspend or revoke a certifying agent's accreditation. All proposals to suspend or revoke a certification or accreditation are subject to appeal as provided in section 205.681. The Act provides at 7 U.S.C. 6519 that any person who: (1) knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than \$10,000 and (2) makes a false statement under the Act to the Secretary, an SOP's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code. Only USDA may bring an action under 7 U.S.C. 6519.

(2) Certifying Agent's Identifying Mark. The NOSB reaffirmed its recommendation which would allow private certifying agents to prevent the use of their service mark (seal) upon written notification that: (1) certification by the private certifying agent has been terminated, and (2) the certifying agent has 30 days to appeal the certifying agent's decision to the Secretary of Agriculture. We will neither prohibit nor approve a certifying agent's actions to withdraw a certified operation's authority to use the certifying agent's identifying mark for alleged violations of the Act or regulations. We stand fast in our position that all certified operations are to be given due process prior to the suspension or revocation of their certification. The reader is also reminded that the certifying agent cannot terminate, suspend, or revoke a certification if the certified operation files an appeal with an SOP's governing State official, when applicable, or the Administrator as provided for in the notification of proposed suspension or revocation. The certifying agent accepts full liability for any action brought as a result of the withdrawal of a certified operation's authority to use the certifying agent's identifying mark.

(3) Loss of Certification. A commenter posed several questions regarding the loss of certification. The commenter's questions and our responses are as follows.

How will consumers and affected regulatory agencies know if a grower or handler loses its certification? We will provide public notification of suspensions and revocations of certified operations through means such as the NOP website.

What will the effect of a lost certification be? Suspension or revocation of a producer's or handler's certification will require that the producer or handler immediately cease its sale, labeling, and representation of agricultural products as organically produced or handled as provided in the suspension or revocation order. A production or handling operation or a person responsibly connected with an operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a new request for certification in accordance with section 205.401. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. An operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of not more than 5 years following the date of such revocation, as determined by the Secretary. Any producer or handler who sells, labels, or represents its product as organic contrary to the provisions of the suspension or revocation order would be subject to prosecution under 7 U.S.C. 6519 of the Act.

Will the certifying agent give a future effective date for loss of certification, or could the loss of certification be immediate or even retroactive? Suspension or revocation will become effective as specified in the suspension or revocation order once it becomes final and effective. The operation, upon suspension or revocation, will be prohibited from selling, labeling, and representing its product as organic per the provisions of the suspension or revocation order.

If organic products already on the market were grown or handled by someone whose certification is revoked or suspended, would USDA require that the products be recalled and relabeled?

USDA will not, unless the noncompliance involves a food safety issue under FSIS, require the recall or relabeling of product in the channels of commerce prior to the issuance of a suspension or revocation order. First, at the time the product was produced, it may have been produced in compliance with the Act and these regulations. Second, USDA does not have the authority, under the Act, to issue a stop sale order for product sold, labeled, or represented as organic and placed in the channels of commerce prior to suspension or revocation of a certified operation's certification. The Act, however, provides at 7 U.S.C. 6519(a) for the prosecution of any person who knowingly sells or labels a product as organic, except in accordance with the Act. Such persons shall be subject to a civil penalty of not more than \$10,000 per violation.

(4) Investigations. A commenter suggested that we amend section 205.661(a) to require that all complaints must be investigated in accordance with the certifying agent's complaints policy. The commenter also stated that the Administrator should know which complaints were not investigated. We disagree that all complaints must be investigated since, upon review of the alleged noncompliance, some complaints may lack grounds for investigation. For example, a concerned citizen could allege that an organic producer was seen applying a pesticide to a specific field. Upon review of the allegation, the certifying agent could determine that the producer in question was a split operation and that the field in question was part of the conventional side of the production operation. Accordingly, there would be no need for an investigation. However, the certifying agent will be expected to: (1) take each allegation seriously, (2) review each complaint received, (3) make a determination as to whether there may be a basis for conducting an investigation, (4) investigate all allegations when it is believed that there may be a basis for conducting the investigation, and (5) maintain a detailed log of all complaints received and their disposition. The actions taken by the certifying agent must be in conformance with the certifying agent's procedures for reviewing and investigating certified operation compliance.

(5) Deadline for the Correction of a Noncompliance. Several commenters requested that 205.662(a)(3) be amended by adding: "The deadline for correction of the noncompliance may be extended at the discretion of the certifier if substantial progress has been made to correct the noncompliance." We believe that the requested amendment is unnecessary. Section 205.662(a)(3) requires that the notification of noncompliance include a date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible. There is no prohibition preventing the certifying agent from extending the deadline specified when the certifying agent believes that the certified operation has made a good faith effort at correcting each noncompliance.

(6) Compliance with SOP. Several States requested that section 205.665 be amended to clarify how States may handle a private certifying agent found to be in noncompliance with SOP's approved by the Secretary. A majority of these commenters also asked if NOP intends to suspend or revoke the accreditation of certifying agents on a State-by-State basis. Section 205.668(c) authorizes an SOP's governing State official to review and investigate complaints of noncompliance with the Act or regulations concerning accreditation of certifying agents operating in the State. When such review or investigation reveals any noncompliance, the SOP's governing State official shall send a written report of noncompliance to the NOP Program Manager. The report shall provide a description of each noncompliance and the facts upon which the noncompliance is based. The NOP Program Manager will then employ the noncompliance procedures for certifying agents as found in section 205.665. This may include additional investigative work by AMS. Only USDA may suspend or revoke a certifying agent's accreditation.

SOP's must meet the general requirements for organic programs specified in the Act and be at least equivalent to these regulations. Accordingly, noncompliances worthy of suspension or revocation would in all probability be worthy of national suspension or revocation of accreditation for one or more areas of accreditation. Therefore, USDA does not anticipate suspending or

revoking accreditations, or areas of accreditation, on a State-by-State basis. It is possible, however, that the Secretary may decide to only suspend or revoke a certifying agent's accreditation or an area of accreditation to certify producers or handlers within a given State. Such a decision would in all probability be tied to a State's more restrictive requirements.