# MASSACHUSETTS INDEPENDENT CERTIFICATION



## BAYSTATE ORGANIC CERTIFIERS

PROGRAM MANUAL

Version 3.3

#### **Massachusetts Independent Certification**

#### **Baystate Organic Certifiers Certification Program**

Massachusetts Independent Certification, Inc. (MIC) operates the Baystate Organic Certifiers organic certification program. From our inception until the end of 2003, our program name was NOFA/Mass Organic Certification. It officially changed to Baystate Organic Certifiers on January 1, 2004. Baystate Organic Certifiers is operated by Massachusetts Independent Certification, Inc. (MIC). MIC is a non-profit business incorporated in the state of Massachusetts as a 501(c)3 corporation. MIC's focus is sustainable agriculture and food certification. MIC provides affordable certification services to farms using sustainable agricultural practices and to food processing and handling operations that purchase sustainable agricultural products. Through its Baystate Organic Certifiers program, MIC provides affordable and timely organic certifications to farmers, processors and handlers in the continental United States. Baystate Organic Certifiers certifies farms using organic agricultural practices, as well as food processing and handling operations and personal care processing and handling operations that purchase organic agricultural products.

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## THE BAYSTATE ORGANIC CERTIFIERS PROGRAM MANUAL

#### INTRODUCTION

"An organic farm, properly speaking, is not one that uses certain methods and substances and avoids others; it is a farm whose structure is formed in imitation of the structure of a natural system that has the integrity, the independence and the benign dependence of an organism."

Wendell Berry
The Gift of Good Land

Massachusetts Independent Certification was formed by the former certification committee of the Northeast Organic Farming Association – Massachusetts Chapter (NOFA/Mass). Massachusetts Independent Certification is dedicated to developing local, sustainable agriculture; to promoting organic farming practices; and to enhancing the economic and ecological viability of organic farms and organic processing operations. Our organic certification program is accredited to certify crops, wild crops, livestock, and handling operations anywhere in the continental United States.

Local organic farmers initially researched and wrote the NOFA/Mass standards in 1984-85. Those standards were for crop and livestock farms. Certification of organic processing (handlers) operations was added in 2001. In 2002 the NOFA/Mass Organic Certification Program was accredited by the USDA National Organic Program to certify operations to the following scopes – Crops, Livestock, Wild Crops, and Handling. As of October 21, 2002, the NOFA/Mass standards were replaced by a program manual that combined the procedures and policies of the NOFA/Mass Organic Certification Program with the organic standards of the National Organic Program (NOP). As of January 1, 2004, the NOFA/Mass Organic Certification Program name was retired and the organic certification program name was changed to – Baystate Organic Certifiers.

In order to ensure that agricultural and processed organic products produced and sold under the Baystate Organic Certifiers label are grown in accordance with these standards, Baystate Organic Certifiers has developed strict certification procedures. We recognize, however, that any standards are far from definitive, and that each farm and processing operation is unique; situations may arise which have not foreseen or which are too complex to define in a document for general use. In such cases, we deal with each operation in an individual and personal manner using all the tools available to us as accredited certifying agents.

We welcome your comments and look forward to working with you.

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The key to organic farming is the treatment of the soil. In evaluating agricultural practices, Baystate Organic Certifiers has made their effect on soil health its touchstone. A living, healthy soil produces healthy, life-sustaining plants (and food), and agricultural methods which short-cut this natural order by feeding plants directly, without regard for their effect on the soil, lead in the long run to disease, pest problems and infertility, and to the destruction of soil structure until it can no longer sustain continuing life.

Sir Albert Howard has written that a good farm, like a forest, manures itself. This image is particularly appropriate for New England, where mixed forest is the natural vegetation.

#### **GUIDING PRINCIPLES**

The National Organic Program standards cover a wide range of products. Farmers are encouraged to produce all their crops according to these standards.

The certification program is intended to cover production that will remain in organic management. It is expected that under most circumstances farmers or producers will not remove from certification organic enterprises that have previously been certified.

The Baystate Organic Certifiers Certification Program is not based on formulas, but rather on individuals and the system plan they produce for their farm or handler operation. Our confidence in farm or producer management's ability to implement their Organic System Plan is the central pillar upon which the certification program relies. Our judgment about the manager's competence and dedication to organic principles, as well as the quality of the Organic System Plan and records submitted as part of the application process, will shape the level of detail with which we exercise oversight of a farm or processing operation.

Baystate Organic Certifiers would like to encourage more farms and processing operations to use organic practices. We also encourage growers and producers to educate themselves about crops, methods, tools, and other aspects of organic management in either formal or informal learning situations.

#### CERTIFICATION REQUIREMENTS

#### **General Requirements**

The General Requirements for certification are spelled out in section 205.400 and 205.401 of the National Organic Standards which are included in this Program Manual.

As specified by the standards, new applicants for certification by Baystate Organic Certifiers are required to:

- 1. Comply with the Organic Food Productions Act and all applicable regulations specified in the National Organic Standards and with all Baystate Organic Certifiers certification requirements as outlined in this Program Manual.
- 2. Establish, implement, and update annually an organic production or handling system plan that is submitted to Baystate Organic Certifiers.
- 3. Permit on-site inspections by Baystate Organic Certifiers with complete access to the production or handling operation, including noncertified production and handling areas, structures, and offices.
- 4. Maintain all records applicable to the organic operation for not less than 5 years beyond their creation and allow authorized representatives of the Secretary of Agriculture, and Baystate Organic Certifiers access to such records during normal business hours for review and copying to determine compliance with the Organic Food Productions Act and all applicable regulations specified in the National Organic Standards. Records must comply with section 205.103 of the standards and 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, and be sufficient to demonstrate compliance with the Organic Food Productions Act and all applicable regulations specified in the National Organic Standards. See *Recordkeeping for Certified Operations* for additional guidance on the recordkeeping requirements of the National Organic Standards.
- 5. Submit applicable fees according to the Baystate Organic Certifiers' Fee Schedule.
- 6. Immediately notify Baystate Organic Certifiers concerning any:
  Application, including drift, of a prohibited substance to any field, production unit, site, facility, livestock, or product that is part of an operation; and Notify Baystate of any change in a certified operation or any portion of a certified operation that may affect its compliance with the Act and the regulations in this part.
- 7. All labels used to market organic produce, meat, or products must be submitted to Baystate Organic Certifiers for review and approval prior to using these labels to market the produce, meat, or products. See sections 205.300 205.311 for information on labeling requirements.

#### **Application for Certification**

As specified by Section 205.401 of the standards, applicants for certification by Baystate Organic Certifiers must submit an application for certification that includes the following:

1. A complete organic production or handling system plan, as required by section 205.200 of the standards. See *Application Procedures* for additional information on System Plan requirements.

- 2. 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.
- 3. The name(s) of any organic certifying agent(s) to which an organic certification application has previously been made; the year(s) of application; the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliances noted in the notification of noncompliance, including evidence of such correction; and
- 4. Other information necessary to determine compliance with the Organic Food Productions Act and all applicable regulations specified in the National Organic Standards.

#### **Requirements for Continuing Certification**

As specified by section 205.406 of the standards, in order to continue certification a certified operation must do the following:

- 1. Comply with the Organic Food Productions Act and all applicable regulations specified in the National Organic Standards and with all Baystate Organic Certifiers certification requirements as outlined in this Program Manual.
- 2. Pay the applicable fees according to the Baystate Organic Certifiers' Fee Worksheet.
- 3. Submit an updated Organic System Plan by the annual renewal date established by Baystate Organic Certifiers by completing a Baystate Organic Certifiers renewal grower or processor application packet. The application packet must note any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, and note any additions to or deletions from the information submitted previously concerning 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.
- 4. Submit an update on the correction of minor noncompliances or continuous improvement points previously identified by Baystate Organic Certifiers as requiring corrective action. Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.
- 5. Submit other information necessary to determine compliance with the Organic Food Productions Act and all applicable regulations specified in the National Organic Standards.

#### Requirements for Operations that are certified by another Accredited Certification Agency

Operations that are currently certified by another certifying agency and want to be certified by Baystate Organic Certifiers are considered new applicants and must comply with all the certification requirements noted above, submit a new grower or processor application packet to Baystate Organic Certifiers, and submit the following additional information:

- 1. A copy of the most recent organic certification inspection report for their operation.
- 2. A copy of the most recent determination letter from their current certifying agent that shows that the farm or processing operation is in good standing and has no open compliance issues.

3. A copy of any notice of noncompliance, notice of proposed suspension, or notice of proposed revocation issued to the certified farm or processing operation, and documented evidence showing that the noncompliances contained in any of these documents have been corrected.

Please note that if you are certified by another agency, and apply for certification to Baystate Organic Certifiers you are responsible for disclosing all notices of noncompliance, notices of proposed suspension, or notices of proposed revocation to Baystate Organic Certifiers and resolving any of these notices before you may be certified by Baystate Organic Certifiers.

Certified operations that are changing certifying agents are responsible for either maintaining their prior certification according to the National Organic Program standards or surrendering their prior certification in writing. Certified operations who are changing certifying agents must maintain their current certification until they have been granted certification by Baystate Organic Certifiers if they intend to continue to produce or sell products as organic. If certification is maintained, it must be maintained until Baystate Organic Certifiers issues a new certification certificate.

Certified operations that apply for certification to Baystate Organic Certifiers and do not maintain or surrender their organic certification in writing, and are issued a notice of noncompliance or proposed adverse action are still bound by the notice of noncompliance or adverse action and must respond and correct the noncompliances before they can be certified organic by Baystate.

Certified operations that are issued a Notice of Suspension or Revocation by their prior certifying agent must immediately cease the sale, labeling, and representation of products as organic until all noncompliances are resolved and eligibility for reinstatement is granted by the NOP.

Certified operations that voluntarily change certifying agents may not use up existing supplies of labels which identify their prior certifying agent on products they produce or handle.

## Non Certified Operations that have Applied in the past to another Accredited Certification Agency or to Baystate Organic Certifiers

Operations that have applied for organic certification in the past or withdrawn their application for certification after receiving a notice of noncompliance are responsible for disclosing the fact that they applied for certification, and any denial of certification or notice of noncompliance to Baystate Organic Certifiers at the time they apply for certification. Additionally, operations that have applied for organic certification in the past or withdrawn their application for certification after receiving a notice of noncompliance are considered new applicants and must comply with all the certification requirements noted above, submit a new grower or processor application packet to Baystate Organic Certifiers, and submit the following additional information:

- 1. A copy of the Denial of Certification or the Notice of Noncompliance. *Note: this requirement is waived if Baystate Organic Certifiers issued the Denial or Notice.*
- 2. Documented evidence showing that the noncompliances contained in any of these documents have been corrected.

#### **Land Requirements**

The National Organic Standards require that any field or farm parcel from which harvested crops are to be sold, must not have had any prohibited substance applied to it for a period of 3 years immediately preceding harvest. Also, growers must maintain distinct, defined buffer zones to prevent the unintended application of a prohibited substance to crops from adjacent land not under organic management (See *Guidance Document: Buffer Zones and Environmental Contaminants*), and producers must prevent contamination and commingling of organic and non-organic production.

During the application process, the three-year history of a piece of land requested for certification must be documented by the grower/manager present during each of those three years by signing the Field/Greenhouse History Affidavit which is included as part of the application packet. If more than one person managed a particular piece of land over the three year period, then each person needs to sign the Field/Greenhouse History Affidavit in the appropriate place. If a piece of land remains in the certification program, but is used by different certified growers, the Field/Greenhouse History Affidavit should indicate who managed the land in each of the past three years, but only the previous one year's history needs to be reported.

As specified in the standards, we may, at our discretion, test soil and crops when necessary to verify the absence of toxic residues, and to verify that prohibited substances have not been used on farm.

#### **Partial Operation Certification**

Growers or producers may apply for certification on that portion of their operation which meets all the organic standards as set forth in the program. However, because we wish to verify that agricultural products being sold as Baystate Organic certified are indeed grown or produced according to organic management practices, there are strict production and certification guidelines for these operations.

#### Farms

- 1. To qualify for certification on a farm that follows both organic and non-organic practices, the land under consideration must be separated either by distance or physical barrier from the rest of the farm, and be free of prohibited materials for 3 years immediately preceding harvest of an organic crop. The grower or producer must complete the full application packet for certification, providing information on the enterprises managed organically as well as those managed non-organically or in transition.
- 2. The grower must detail what buffer areas or physical barriers exist between certified production areas and the rest of the farm to prevent the organic crop from coming into contact with a prohibited substance applied to the non-organic land. The producer must detail the physical barriers put in place to prevent contamination and commingling of organic ingredients and products with non-organic ingredients and products.
- 3. The grower must detail what plan he/she will put into place to prevent prohibited substances from coming into contact with organic crops throughout production, harvest, storage, and marketing. This plan must be comprehensive and include information on storage and handling locations on farm, the cleaning of shared equipment, and segregation of harvested product. Precautions taken to prevent contamination may include distinct boxes or bags, segregation of

- production by geographic location, employee training, and harvesting organic and non-organic products on different days. The detail of the required plan will depend on the complexity of the farming operation and the actual crop distinctions (e.g. non-organic chicken eggs on an otherwise all organic vegetable farm operated by one person, vs. organic and non-organic sweet corn on a farm with 15 employees).
- 4. The grower must maintain adequate written records for all crops (non-organic and organic) produced on the farm, including quantities grown, sales records, and harvest yield by field. The producer must maintain records of all aspects of production from receipt and origin of organic ingredients to shipment of final organic product. These records will be made available to Baystate Organic Certifiers and its inspector.

Note: Easily contaminated equipment such as sprayers may not be shared between organic and non-organic enterprises unless adequate measures are put in place to clean the equipment so that there is no contamination of organic crops or production with prohibited substances. Baystate reserves the right to review all plans for the sharing of equipment between organic and non-organic production sites.

#### Handlers and Processors

- Handling and processing operations must implement measures necessary to prevent the
  commingling of organic and non-organic ingredients, products, and finished goods, and protect
  organic ingredients, products, and finished goods from contact with prohibited substances. As
  part of their application for certification, handling and processing operations must detail the
  measures put in place for preventing commingling and contamination during all phases of the
  organic production process.
- 2. Handling and processing operations must implement, document and record cleaning and sanitation procedures that take place between organic and non-organic production runs that guarantee that organic ingredients, products, and finished goods are not contaminated by non-organic ingredients, products, and finished goods or prohibited substances used for cleaning and sanitizing purposes.

#### **Transitional Production**

The National Organic Program does not have provisions for identifying crops as transitioning to organic. According to the organic standards, transitional growers must follow all the requirements of a certified grower, but are not required to submit an organic system plan until they qualify for organic certification. Baystate Organic Certifiers will work with transitional crop producers who are preparing their farms for organic certification. We encourage transitioning growers to work with us as early as possible in their transition process so that organic certification can proceed as smoothly as possible. Transitional growers may contact Baystate to get their questions answered, and for help in determining whether inputs to certified fields are compliant with the organic standards. If a transitional grower wants to have their farm evaluated for compliance with the organic standards they may submit a completed Organic System Plan to Baystate, pay the minimum fee, and go through the standard review and inspection process. Upon completion of this process Baystate will issue a determination letter stating whether the operation is or is not in compliance with the standards, and detailing any noncompliances noted by Baystate. Certification certificates are not issued to transitional growers, and the determination letter does not constitute certification.

#### APPLICATION PROCEDURES

#### **Equal Employment Opportunity and Civil Rights**

Massachusetts Independent Certification (Baystate Organic Certifiers) prohibits discrimination in its programs on the basis of race, color, national origin, sex, religion, age, disability, political beliefs, sexual orientation, or marital and family status.

#### Who may apply? (See National Organic Standards Sections 205.100-205.102)

The Baystate Organic Certification Program encourages all qualified producers of organic foods or processed products to apply for organic certification. We are accredited to certify crops, livestock, handlers (processors), and wild crops to the requirements of the National Organic Program. Baystate Organic Certifiers provides services to all applicants whose activities fall within Baystate's scope of operations. Access to the certification services of Baystate Organic Certifiers is not dependent upon the size of the applicant's operation, the number of certificates already issued, or membership in any group.

#### How to Apply

#### Organic System Plan

As required by the National Organic Standards, an operation applying for organic certification to the Baystate Organic Certification Program must submit an Organic System Plan. This Organic System Plan consists of a completed application packet that describes the farm or processing operation in its entirety. Application packets may be obtained from our website (www.baystateorganic.org) or from the Certification Program office by writing:

Baystate Organic Certifiers c/o Don Franczyk 1220 Cedarwood Circle North Dighton, MA 02764

Interested parties may also call (774)872-5544 or email baystateorganic@earthlink.net to request application packets.

When ordering application packets please specify whether you are a grower or a processor. If you are a grower please specify which of the following crops or livestock you are looking to certify: vegetables or other field crops, greenhouse crops, poultry, hogs, beef, dairy cows or goats, lambs or meat goats, cranberries, maple syrup, mushrooms, sprouts, or wild crops. Application forms and program manuals may be downloaded from our website www.baystateorganic.org for free. There is no charge for hardcopies of our application packets. Hardcopies of our Program Manual may be ordered from our office and cost \$25 per copy.

## Please make all checks payable to Massachusetts Independent Certification or Baystate Organic certifiers

Growers and processors already certified by Baystate Organic Certifiers will be sent an application packet approximately two months before their renewal application is due. Certified clients of

Baystate may download the Program Manual from our website or order a copy of the Program Manual for \$25 a copy.

#### Application Procedure

Complete the application packet in its entirety and make two copies. Retain one copy for your records. You must return one copy plus the original to the Program office. Copies must be dark enough to read and be collated. Applications that are illegible, or not collated may be returned, facsimiles (faxes) of certification applications will not be accepted. Operations that only submit the original hardcopy of an application will be charged a \$30 copying fee. Applicants that submit their application by file transfer or by email will not be charged a copying fee. Applications must be complete, and contain copies of all relevant supporting documentation. Incomplete applications will be placed on hold.

#### **Application Deadlines**

#### Farm or Livestock

Baystate Organic Certification will accept new operation applications at any time throughout the year. However, we encourage new Farm and Livestock operations to apply for the application deadlines listed below so that their operations can be inspected and their application processed when their operation is in peak production. For operations renewing their certification, you are assigned an annual renewal date when you first apply for certification. This date is usually the date you first applied for certification. The renewal date does not match and is not meant to match the date of certification or date of last annual update on your certification certificate.

Application Deadline
Before February 15<sup>th</sup>
Before March 15<sup>th</sup>
Before June 15th

Effective Date of Certification
May 1st
June 1st
September 1st

Applications must be postmarked by the application deadline in order for the operation to be certified for the appropriate period. Applications that are more than 7 days late will be considered in the next application period. Applications received outside of these deadlines will usually be notified of a certification decision 6-12 weeks after a complete application is received in the Program Office.

#### Processors or Handlers

Processing or handling operations can apply at any time during the year. First time applicants will usually be notified of a certification decision within 4-8 weeks of submitting a complete application packet. Our program office will send a renewal application packet and a reminder notice to certified processors approximately two months before their renewal application is due.

#### **Expedited Applications**

In special cases, for operations that are prepared to undergo inspection to the organic standards, Baystate Organic Certifiers can expedite the certification process so that an operation is certified two or three weeks after submitting an Organic System Plan. If you are interested in expediting your application for certification, please contact our office.

#### **Separate Businesses**

Farms on which different pieces of land or enterprises are managed by different people, or processing businesses managed by different people who share packing facilities, are regarded as separate businesses and must apply separately if they wish to be certified. Records, names, and labels used in marketing, storage, handling, and transportation must be separate and distinct for each business.

#### FEE SCHEDULE

#### In General

Unlike many other certifying agents, for operations in our core certification area, Baystate Organic Certifiers charges one all-inclusive application fee that combines the certification fee and the cost of the annual certification inspection. For operations based outside of our core area, Baystate Organic Certifiers does charge additional inspection costs. See below for an explanation of those charges.

Our core certification area consists of the following states: CT, DE, IN, MA, MD, ME, NC, NH, NY, NJ, OH, PA, RI, VA, VT, WV.

#### **Application Fees**

All operations must pay an annual fee (listed as Certification Fee below) based on the actual and projected gross value of the certified products produced, handled, co-packed, repacked, or represented as organic by the operation. The gross value of a product is the value of the certified product to the farm or processor (either the wholesale or retail organic price whichever is applicable), even if sold to a non-organic market. Contact our office if you have questions about calculating the gross value of your products.

| Gross Value of Organic Products              | <b>Certification Fee</b> | Reimbursement |
|--|--------------------------|---------------|
| \$0 or more, but less than \$5,000           | \$330                    | \$82.50       |
| at least \$5,000, less than \$10,000         | \$390                    | \$97.50       |
| at least \$10,000, less than \$20,000        | \$440                    | \$110         |
| at least \$20,000, less than \$30,000        | \$580                    | \$145         |
| at least \$30,000, less than \$40,000        | \$700                    | \$175         |
| at least \$40,000, less than \$50,000        | \$800                    | \$200         |
| at least \$50,000, less than \$75,000        | \$900                    | \$225         |
| at least \$75,000, less than \$100,000       | \$1100                   | \$350         |
| at least \$100,000, less than \$200,000      | \$1500                   | \$750         |
| at least \$200,000, less than \$300,000      | \$1750                   | \$1000        |
| at least \$300,000, less than \$500,000      | \$2000                   | \$1250        |
| at least \$500,000, less than \$750,000      | \$2300                   | \$1550        |
| at least \$750,000, less than \$1,000,000    | \$2800                   | \$2050        |
| at least \$1,000,000, less than \$1,500,000  | \$3300                   | \$2550        |
| at least \$1,500,000, less than \$2,000,000  | \$3800                   | \$3050        |
| at least \$2,000,000, less than \$2,500,000  | \$4300                   | \$3550        |
| at least \$2,500,000, less than \$3,000,000  | \$4800                   | \$4050        |
| at least \$3,000,000, less than \$3,500,000  | \$5700                   | \$4950        |
| at least \$3,500,000, less than \$4,000,000  | \$6800                   | \$6050        |
| at least \$4,000,000, less than \$5,000,000  | \$8000                   | \$7250        |
| at least \$5,000,000, less than \$10,000,000 | \$11000                  | \$10250       |
| at least \$7,500,00, less than \$10,000,000  | \$13000                  | \$12250       |
| over \$10,000,000                            | \$15000                  | \$14250       |

**Fee after Cost Share** 

No matter what the level of the gross value of organic product, organic certification fees are capped at no more than \$15,000 per year (note that the inspection fee and new operation fee, if applicable, are additional fees and not certification fees.)

Income documentation must satisfy our staff or inspector and all such information will be kept confidential. Operations that cannot provide adequate documentation to support their claimed gross value figure will be assessed an annual fee based on a gross value figure determined by Baystate Organic Certifiers. Operations that increase organic production during the certification year are responsible for notifying Baystate Organic Certifiers and paying any incremental certification fees due for the increased production.

All checks must be made payable to Baystate Organic Certifiers or Massachusetts Independent Certification.

#### **New Operation Fee**

Operations that were not certified the previous year must pay a \$150 initial fee in addition to the certification fee. This is a one-time fee.

#### **Late Fees**

Renewal operations are charged a late fee according to the following schedule if the renewing operation's application or fee payment is submitted more than 14 days after its due date. These fees are non-negotiable.

Applications or fee payments that are postmarked 1-14 days after their due date – no late fee. Applications or fee payments that are postmarked 15-30 days after their due date - \$150 Applications or fee payments that are postmarked 31 days or more after their due date – \$300

#### **Copying Fee**

Baystate is required to have two copies of every application. If an applicant does not submit the original and a copy of the application, Baystate must make one. In order to recover the cost of making copies of applications, Baystate has instituted a charge for copying applications according to the following schedule.

Application packets that are submitted by email – no charge Two hardcopies of the application packet submitted – no charge One hardcopy of the application packet submitted - \$30

#### **Schedule of Additional Fees**

#### Inspections:

Baystate Organic Certifiers reserves the right to charge any operation for additional inspection costs caused by an applicant's failure to appear at the time agreed upon for inspection, or for additional inspection costs caused by an operation submitting an incomplete Organic System Plan. Charges will be limited to 100% of the inspection costs including labor, mileage, and travel expenses.

Applicants are not charged if a responsible party is not available at the time of an unannounced inspection.

As stated above, farms, and processing and handler applicants located in our core certification area do not pay an inspection fee for the annual inspection in addition to their normal certification fee. Our core certificate area consists of the states of CT, DE, IN, MA, MD, ME, NC, NH, NY, NJ, OH, PA, RI, VA, VT, WV.

Operations in all other states will be charged an inspection fee based upon the certification fee they pay as follows:

Operations that pay a certification fee of \$2000 or greater, cost of inspection is included in fee. Operations that pay a certification fee between \$700-\$1750 will be charged 50% of the costs of the inspection.

Operations that pay a certification fee less than \$700 will be charged 100% of the cost of the inspection.

The inspection fee will be charged after the inspection takes place. Inspection costs include charges for travel, lodging, meals, rental car, and time spent inspecting the operation and preparing the inspection report.

Applicants headquartered in our core certification area with facilities in other states, will be charged a separate inspection fee for each facility located outside of our core certification area. This fee will be limited to 100% of the inspection costs. Please call us for a quote on the cost of inspecting a second facility outside of our core certification area. The inspection fee will be charged after the inspection takes place. Valid inspection costs include charges for travel, lodging, meals, rental car, and time spent inspecting the operation and preparing the inspection report. Operations that pay a certification fee greater than \$5000 will not be charged an inspection fee for the first 2 facilities inspected. The inspection fee will begin with the third facility inspected.

If any operation certified by Baystate needs an additional inspection during the certification year because the operation expanded the scope of their certification, changed locations, added new fields, failed to have documentation or recordkeeping available at their annual scheduled inspection, or made significant changes to their System Plan after the renewal application for the year was submitted and the annual inspection was performed, then the operation is responsible for the cost of that additional inspection. This policy is only for additional inspections for the reasons noted above and is applicable to all operations including those in our core certification area. The cost of the inspection will be \$150 for field only inspections, \$250 for other crop and livestock farm inspections or for handling operation inspections. Baystate does not charge for unannounced inspections, follow-up compliance inspections except as noted above, or pesticide residue sampling inspections.

#### Reinstatement Fees:

Operations that are applying for reinstatement of their organic certification because their certification has been suspended or revoked must pay a reinstatement fee of \$500 in addition to any other certification fees they may owe.

#### Bank Fees:

Operations are responsible for any bank charges caused by checks that are returned for insufficient funds.

#### **Export Document Fees:**

Baystate charges a \$50 fee for completing TM-11 certificates for shipments to Taiwan and Japan, and for creating Import Certificates for shipments to Korea, Switzerland, and any country in the EU.

Baystate charges \$30 for transaction certificates that are not TM-11s or Import Certificates.

#### **Non-refundable Fees**

For new operations, only, applications may be withdrawn, and fees partially refunded only if the application is withdrawn less than 90 days after submission and before the inspection is performed. No fee will be refunded more than 90 days after submission, or after the inspection is performed, or after certification is granted or denied. Fees are not refunded for renewal operations.

- 1. Application withdrawn after submission, up to 90 days after submission, but before the inspection has been performed. If an applicant has paid the total annual fee, 50% of the total annual fee will be refunded. If the applicant has paid 50% of the annual fee, 25% of the annual fee will be refunded. The new operation certification fee will not be refunded.
- 2. Application withdrawn more than 90 days after submission, or after the inspection has been performed, no refund will be issued.

#### **Partial Payment of Certification Fees**

Baystate Organic Certifiers realizes that farming operations may not be able to afford the entire certification fee in the offseason. Therefore, growers have the option to defer paying up to 50% of their new or renewal certification fee until later in the year if they submit their applications for one of the 4 spring application deadlines.

For applications submitted for the February  $1^{st}$  or  $15^{th}$  deadline, the deferred balance is due on August  $1^{st}$ .

For applications submitted for the March 15<sup>th</sup> or May 1<sup>st</sup> deadlines, the deferred balance is due on September 1<sup>st</sup>.

If an operation does not pay their certification in full by the end of the calendar year, then they lose the right to defer 50% of their fee payment for the next two calendar years. The Executive Director may waive the penalty in the case of economic hardship.

#### **Fee Reimbursement**

Each state government has Federal money available to refund organic certification fees. Contact your Department of Agriculture for information on applying for this cost share reimbursement program. Under this program, applicants may recover 75% of certification fees up to \$750 total per scope of certification in any one year. You may also apply for this reimbursement through your local Farm Service Agency office. The reimbursement year follows a Federal calendar year, so it runs from October 1 until September 30 the following year.

#### **CERTIFICATION PROCEDURES**

#### Introduction

Baystate Organic Certifiers is responsible for making decisions relating to the granting, maintaining, extending, suspending, and withdrawing of organic certification. Authority to perform these actions is not subcontracted to other parties. Baystate Organic Certifiers staff, reviewers, inspectors, board members, and decision makers are always willing to provide additional information about the certification standards; however, Baystate Organic Certifiers does not provide advice or consultation to operators on how to meet the certification standards or address nonconformances that may arise during the certification process.

#### **The Certification Process**

The Baystate Organic Certification Program has put in place a process of evaluating an operation to verify that it complies with all organic certification regulations in these standards. For additional information on the certification process see the relevant sections of the National Organic Standards.

#### New Farms and Handling Operations

- 1. After a new farm or handling operation applies for certification, it is reviewed for completeness by the program office to make sure that all the proper forms and documentation have been submitted. If not, the grower is notified that the application is incomplete and is sent a request for additional information.
- 2. Once the application is complete it is forwarded to a staff member for review. The staff member evaluates the application against the technical requirements of the standards, verifies that all inputs and ingredients listed in the Organic System Plan comply with the NOP regulations, and verifies that any non-compliances cited by other certification organizations, if applicable, have been corrected. After the review is completed, the staff member submits a copy of their review and the file is prepared for inspection.
- 3. The same or different staff member prepares the file for inspection. If there are any noncompliances with the requirements of the standards, the applicant is notified and corrective actions requested. If additional information is required to complete the review, then it is requested. If there are no non-compliances, and if the application is complete, then a Certification Profile is prepared, a letter is sent to the applicant, and the staff member notifies the inspector that has been assigned the file that it is ready for inspection.
- 4. An inspection is scheduled. An authorized representative of the operation must be present for the inspection. The Inspector verifies that the operation is in compliance with the standards or has the ability to comply with the National Organic Standards, that the Organic System Plan accurately reflects the activities of the operation, and ensures that prohibited substances have not been applied. Verification may include, at the discretion of Baystate Organic Certifiers, collection and testing of soil, water, waste, seeds, plant tissue, and plant, animal, or processed products samples. The certified operation and the inspector are not charged for any samples collected. A receipt for any samples will be given to the applicant at the time of inspection.
- 5. At our discretion, Baystate Organic Certifiers may conduct additional inspections to determine compliance with the NOP regulations; these may be announced or unannounced inspections.
- 6. After the inspection is complete, the inspector conducts an Exit Interview with the applicant for certification and leaves a copy of the Exit Interview form with the applicant.

- 7. The inspector files a report with Baystate.
- 8. A qualified staff member reviews the inspection report and all other documentation regarding the operation and makes a decision regarding the compliance of the operation with the National Organic Standards. The staff member determines if the applicant is in compliance with its organic system plan and all procedures, if the applicant's operation is in compliance with the regulations, and if the applicant is able to conduct operations in accordance with its plan. The possible outcomes of this determination include:

<u>Certification</u> – a certification certificate, letter, copy of the inspection report, and results of any sampling or residue testing are sent to the applicant.

<u>Certification with conditions</u> – a certification certificate, a letter spelling out the conditions placed on certification, a copy of the inspection report, and results of any sampling or residue testing are sent to the applicant.

<u>Noncompliance</u> – a notice of noncompliance, a copy of the inspection report, along with any results of any residue testing are sent to the applicant.

- <u>Denial of certification</u> a notice of denial of certification, a copy of the inspection report, and results of any sampling or residue testing are sent to the applicant.
- 9. If necessary, a second inspection is scheduled after the new operation has begun to grow or harvest product. The inspector verifies that the organic system plan is being adhered to and records are up to date and complete. The second inspection may be delayed as much as 6 months so that the inspector can see the operation when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.
- 10. After the qualified staff member reviews the inspection report, a copy of the inspection report and any test results from samples taken as part of the inspection process will be sent to the inspected operation along with any additional requirements for continued compliance with the standards.

#### New Farms or Handling Operations Withdrawing an Application for Certification

New farm, or new handling operation applicants may withdraw their application for certification at any time. An applicant that voluntarily withdraws its application prior to the issuance of a Notice of Noncompliance will not be issued a Notice of Noncompliance. Similarly, an applicant that voluntarily withdraws its application prior to the issuance of Notice of Denial of Certification will not be issued a Notice of Denial of Certification. Notices of Noncompliance that have been issued to a new applicant for certification that has withdrawn its application for certification remain open, and must be corrected before the applicant can apply to Baystate Organic Certifiers or any other certifying agent. The Notice of Noncompliance and the corrective actions must be disclosed as part of any new application for organic certification. Applicants must notify Baystate Organic Certifiers by email or in writing that they want their application withdrawn. Baystate will confirm that the application has been withdrawn in writing, and refund any fees owed to the applicant as specified in the Fee Schedule.

#### Farms or Processors that are Renewing their Certification

1. After a processor or handler or farm or livestock operation submits an updated and complete application for renewal certification, it is reviewed by the program office to make sure that all the proper forms and documentation have been submitted, and that all noncompliances cited by

- Baystate Organic Certifiers the previous year have been corrected. If not, the applicant is notified that the application is incomplete and is sent a request for additional information.
- 2. Once the application is complete it is forwarded to a staff member for review. The staff member evaluates the revised system plan against the technical requirements of the standards, verifies that all inputs and ingredients listed in the Organic System Plan comply with the NOP regulations. After the review is completed, the staff member submits a copy of the review and the file is prepared for inspection.
- 3. The same or different staff member prepares the file for inspection. If there are any noncompliances with the requirements of the standards, the applicant is notified and corrective actions requested. If additional information is required to complete the review, then it is requested. If there are no non-compliances, and if the application is complete, then a Certification Profile is prepared, a letter is sent to the applicant, and the staff member notifies the inspector that has been assigned the file that it is ready for inspection
- 4. The annual inspection is scheduled. An authorized representative of the operation must be present for the inspection. The Inspector verifies that the operation is in compliance with the standards or has the ability to comply with the National Organic Standards, that the Organic System Plan accurately reflects the activities of the operation, and ensures that prohibited substances have not been applied. Verification may include, at the discretion of Baystate Organic Certifiers, collection and testing of soil, water, waste, seeds, plant tissue, and plant, animal, or processed products samples. The certified operation and the inspector are not charged for any samples collected. A receipt for any samples will be given to the applicant at the time of inspection.
- 5. At our discretion, Baystate Organic Certifiers may conduct additional inspections to determine compliance with the NOP regulations; these may be announced or unannounced inspections. If possible, unannounced inspections may replace annual inspections.
- 6. After the inspection is complete, the inspector conducts an Exit Interview with the applicant for certification and leaves a copy of the Exit Interview form with the applicant.
- 7. The inspector files a report with Baystate.
- 8. A qualified staff member reviews the inspection report and all other documentation regarding the operation and makes a decision regarding the continued compliance of the operation with the National Organic Standards. The staff member determines if the applicant is in compliance with its organic system plan and all procedures, if the applicant's operation is in compliance with the regulations, and if the applicant is able to conduct operations in accordance with its plan. The possible outcomes of this determination include:
  - Renew Certification an updated certification certificate, letter, copy of the inspection report, and results of any sampling or residue testing are sent to the applicant.
  - Renew Certification with conditions an updated certification certificate, a letter spelling out the conditions placed on certification, a copy of the inspection report, and results of any sampling or residue testing are sent to the applicant.

Noncompliance – a notice of noncompliance, a copy of the inspection report, along with any results of any sampling or residue testing are sent to the applicant. When correction of a noncompliance is not possible, the notice of noncompliance may be combined with a notice of proposed suspension or revocation of certification.

#### Renewal Operations Surrendering Certification

Certified Operations that no longer require certification may surrender their certification at any time. Operations surrendering their certification must notify Baystate by email or in writing, and if possible, may return their current organic certification certificate. Upon notification that an operation is surrendering its organic certification, Baystate Organic Certifiers will issue a Notice of Surrender of Certification that states the effective date of surrender, and any open compliance issues the operation must correct before they reapply for certification.

#### <u>Unannounced Inspections</u>

As part of the organic certification program all operations certified by Baystate are eligible for unannounced inspections. Baystate staff members determine what operations will be subject to unannounced inspection in a given year. It is the goal of Baystate to annually do unannounced inspections at 5% of its certified operations. Some annual inspections will be scheduled as unannounced inspections, but unannounced inspections do not have to be a complete inspection of an operation, they may be limited in scope, depth, or breadth to cover only a portion of the operation. Except for random unannounced inspections, most unannounced inspections will have a particular focus or purpose that will be revealed to the certified party during the inspection.

Inspectors assigned to do unannounced inspections for Baystate will be provided an Unannounced Inspection Letter that that details the Baystate's regulatory authority for conducting unannounced inspections. A copy of this letter will be given to the representative of the certified operation at the beginning of the inspection. After completing an unannounced inspection, the inspection will leave an Exit Interview form with the client, and file a report. This report will be reviewed and a copy of the report along with a determination letter will be provided to the client.

If an operation refuses to allow an inspector access to any part of the operation, during normal business hours, including the non-organic portions of the operation, the operation will be in violation of section 205.400 of the standards. Failure to allow an inspector access to an operation will result in the issuance of a Notice of Noncompliance by Baystate.

#### Periodic Residue Testing

Section 205.670 of the organic standards requires that Baystate do annual periodic residue testing of certified organic agricultural products to determine that they are not contaminated by prohibited substances. Baystate must test samples from 5% of its operations every year. Samples are taken by inspectors and sent to accredited labs chosen by Baystate for testing. If a sample is taken during an inspection, the inspector gives a receipt for the sample to the representative of the certified operation. The sample is then sealed and sent by expedited delivery to the lab. Once Baystate receives the test results from the sample, it reviews the results, and sends a copy of the results to the certified party along with a determination letter. If the test result indicates that pesticide residues or environmental contaminants are in the sample, then Baystate takes appropriate action as required by section 205.670 of the standards.

Certified operations are not charged for periodic testing. All testing under this program is done at Baystate's expense.

#### **Adverse Action Process**

#### Notices of Noncompliance

For new operations, Notices of Noncompliance issued by Baystate Organic Certifiers are subject to the requirements of section 205.405 of the standards. When Baystate Organic Certifiers finds that a new applicant for certification is noncompliant with the requirements of the National Organic Standards, Baystate will issue a Notice of Noncompliance that includes the following information:

- 1. The facts on which the determination of noncompliance is based.
- 2. The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation showing that the noncompliance has been corrected.

Upon receipt of a notice of noncompliance, the applicant may do one of the following:

- 1. Correct the noncompliances and submit a description of the corrective actions taken with supporting documentation to Baystate Organic Certifiers or submit written information to Baystate rebutting the noncompliances.
- 2. Correct the noncompliances and submit a new application to another certifying agent.

Once corrective actions are received, Baystate Organic Certifiers will review them and if they are sufficient Baystate will grant the applicant certification and issue a Notice of Noncompliance Correction. The NOP is copied on all Notices of Noncompliance Correction. If corrective actions are not adequate, Baystate will issue the operation a Notice of Denial of Certification.

For renewal operations, Notices of Noncompliance issued by Baystate Organic Certifiers are subject to the requirements of section 205.662 of the standards. When Baystate Organic Certifiers finds that a certified operation is noncompliant with the requirements of the National Organic Standards, Baystate will issue a Notice of Noncompliance that includes the following information:

- 1. The facts on which the determination of noncompliance is based.
- 2. The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation showing that the noncompliance has been corrected.

Once appropriate corrective actions for a Notice of Noncompliance are received, a Notice of Noncompliance Correction is issued, and if the Notice of Noncompliance was issued after an annual inspection, an updated certification certificate will be issued. The NOP is copied on all Notices of Noncompliance Correction.

All Notices of Noncompliance are sent by certified mail. If they are returned unopened they are sent back out by standard mail service. A copy may be sent out by standard mail service at the same time that a certified copy is sent. Copies may also be emailed to clients. The NOP is copied on all Notices of Noncompliance.

#### Denial of Certification

Notices of Denial of Certification are subject to the requirements of section 205.405 of the standards. When Baystate finds that a new applicant is unable to comply with the requirements for certification, certification is denied and a Notice of Denial of Certification is issued to the applicant that contains the following information:

The reasons for the denial.

The applicant's right to reapply for certification pursuant to sections 205.401 and 205.405(e) of the standards.

The right to request mediation.

The right to appeal.

All Denials of Certification are sent by certified mail. If they are returned unopened they are sent back out by standard mail service. A copy may be sent out by standard mail service at the same time that a certified copy is sent. Copies may also be emailed to clients.

#### Suspension or Revocation of Certification

When certified operations fail to correct or rebut noncompliances noted in a notice of noncompliance, Baystate Organic Certifiers will send the certified operation a Notice of Proposed Suspension or Revocation of Certification that includes the following information.

The reason for the proposed suspension or revocation.

The proposed effective date of such suspension or revocation.

For suspension, the length of the suspension, usually one year. For revocation, the fact that the certified operation will be ineligible to receive certification for 5 years.

The right to request mediation.

The right to appeal.

All Notices of Proposed Suspension or Revocation of Certification, and all Notices of Suspension or Revocation of Certification are sent by certified mail. If they are returned unopened they are sent back out by standard mail service. A copy may be sent out by standard mail service at the same time that a certified copy is sent. Copies may also be emailed to clients.

Notice of Proposed Suspension or Revocation of Certification may only be resolved through mediation or appeal. If a Notice of Proposed Suspension or Revocation of Certification is not adequately addressed through mediation or appeal, then the operation will be sent a written Notice of Suspension or Revocation of Certification.

Once an operation is suspended, it must be reinstated by the National Organic Program. See the National Organic Program Handbook available at the NOP website for information on applying for reinstatement.

Revoked operations or a person responsibly connected to a revoked operation are ineligible for certification for a period of 5 years. The Secretary of Agriculture, when in the best interest of the certification program, may reduce or eliminate the period of ineligibility.

#### Mediating a Notice of Proposed Suspension or Revocation or Denial of Certification

Mediation of disputes between Baystate Organic Certifiers and its certified parties or applicants is subject to the requirements of section 205.663 of the National Organic Standards. All certified parties that are issued a Notice of Proposed Suspension or a Notice of Proposed Revocation of certification, and all applicants that are subject to a Notice of Denial of Certification may request mediation of the noncompliances noted in the appropriate notice. Mediation requests must be made in writing and must be submitted to Baystate within the timeframe specified by the Notice of Proposed Suspension or Revocation or Notice of Denial of Certification. If the request for mediation is accepted, Baystate will either work with the certified party through informal mediation or work to find a mediator that is mutually acceptable to both parties. Mediation will then take place. After mediation, the parties will have 30 days to reach a settlement agreement. If no agreement is reached, then the certified party has 30 days from termination of mediation to appeal the certifying agent's decision to the National Organic Program.

If Baystate refuses a request for mediation, we will send a written notice of rejection of mediation to the certified party, and the certified party has 30 days to request an appeal of Baystate's certification decision to the National Organic Program.

#### Appealing a Notice of Proposed Suspension or Revocation or Denial of Certification

Appeals to Notices of Proposed Suspension or Revocation or Denials of Certification are subject to the requirements of section 205.681 of the National Organic Standards. Applicants may submit an appeal in writing to the National Organic Program. Appeals must be filed within the time period specified in the appropriate Notice or within 30 days whichever is later. All appeals must include a copy of the Notice issued by Baystate and a statement of the reasons why the appellant believes the decision was not proper according to the applicable regulations, policies, or procedures. See the National Organic Program website for information on filing an appeal.

If an appeal is sustained, the applicant will be issued organic certification or a certified operation will continue its certification.

If an appeal is denied, a formal administrative proceeding will be initiated to deny, suspend, or revoke certification of the applicant or the certified operation.

#### Willful Violations of the Standards

If Baystate Organic Certifiers believes that a certified operation has willfully violated the National Organic Standards we will issue a Notice of Proposed Suspension or Revocation of a portion of the operation or the entire operation as applicable to the noncompliance.

#### **Transferring Certification**

Certification and certificates issued to certified operations are not transferable to new owners in cases of mergers, acquisitions, or other transfers of ownership of the certified operation. When there is a change in ownership of a certified operation, the certified operation must apply for and receive new certification from Baystate Organic Certifiers or another certifying agency prior to selling, labeling or representing products as organic.

#### **Public Information and Confidentiality**

Information about certified operations submitted as part of the application process or uncovered during onsite inspections is kept strictly confidential, and confidentiality agreements are in force for all staff members of Baystate Organic Certifiers, and board members of Massachusetts Independent Certification who have access to this information. Business related information is not revealed to third parties with the exception of the Secretary of the Department of Agriculture or his authorized representative unless permission is granted by the certified operation.

In addition, the National Organic Program requires the Baystate Organic Certification Program to make some information available to the public upon request (See National Standards Section 205.504 (b)(5)).

The fact that an operation is certified and what it is certified to produce is not confidential information and must be disclosed by Baystate Organic Certifiers upon request.

#### **Conflict of Interest**

As part of the agreement to provide Certification services as part of the National Organic Program, it is the responsibility of Baystate Organic Certifiers to prevent conflict of interest according to section 205.501 of the National Standards. The following policies are in place to prevent conflict of interest.

- 1. All certification personnel including Inspectors, Certification Specialists, the Executive Director, Certification Administrators, and all Directors and Officers of the Board must complete an annual Conflict of Interest Disclosure Form. This form must disclose all commercial interests in operations certified by Baystate Organic Certifiers, and all other commercial interests regardless of certified status. Disclosure must extend to interests held by immediate family members and any consulting services provided within the 12-month period prior to the application for certification.
- 2. All certification personnel are responsible for notifying the Executive Director immediately, if during the course of the year, there is a change in the list of operations that they have a conflict of interest in. If an additional Conflict of Interest develops, a new Conflict of Interest form must be completed and submitted to the Executive Director.
- 3. No Directors, Officers of the Board, the Executive Director, or Certification Administrators can have any commercial interest or family interest in operations certified by Baystate Organic Certifiers as of October 21, 2002 or thereafter.
- 4. All individuals holding any conflict of interest specified in (1), are excluded from all aspects of the certification process and all monitoring of the certification status for any operation that they possess an interest in.
- 5. All personnel including Inspectors and contractors are prohibited from accepting payments, gifts, or favors of any kind from certified operations.
- 6. Baystate Organic Certifiers, and the personnel who work for Baystate, are prohibited from giving advice or providing consultant services to applicants for certification, or to certified operations, for the purpose of overcoming identified barriers to certification.
- 7. Individuals who perform the technical review of documents and inspections of applicant operations or certified operations cannot make the decision to certify those operations.

Inspectors who are contractors, who also do consulting, must disclose all operations that they have consulted for on their conflict of interest forms. Inspectors that have consulted with applicant operations are prohibited from participating in any portion of the certification process for any operation that they have consulted for.

If it is determined within 12 months of certifying an operation, that any person participating in the certification process and covered under the conflict of interest provisions of the National Organic Program (NOP Section 205.501(12)(i), has or had a conflict of interest involving an applicant for certification, then Baystate Organic Certifiers must reconsider the certified operation's application for certification, and, if necessary, perform a new on-site inspection. All costs associated with a reconsideration of application, including onsite inspection costs, shall be borne by Baystate Organic Certifiers.

If it is determined that any person covered under the conflict of interest provisions of the National Organic Program (NOP Section 205.501(12)(ii), has or had a conflict of interest involving an applicant for certification at the time of certification, then Baystate Organic Certifiers must refer the certified operation to a different accredited certifying agent for recertification and reimburse the operation for the cost of the recertification.

#### The Baystate Organic Certifiers Seal and the Program Name

Operations which are in compliance with all requirements of these standards may use the Baystate Organic Certifiers seal on their products as per sections 205.303, 304, and 307 of the organic standards.

If an operation subsequently has its certification suspended or revoked, or voluntarily chooses to leave the program, then all rights to use this seal are immediately forfeited.

When displaying the Baystate Organic Certifiers Seal and the USDA seal according to the requirements in these standards, the Baystate Organic Certifiers seal cannot be displayed more prominently than the USDA seal.

The Baystate Organic Certifiers seal may be downloaded from www.baystateorganic.org. Use of the Baystate Organic Certifiers' seal is voluntary and not required of certified operations.

Operations certified by Baystate Organic Certification that are required to name their certifier must use the whole program name "Baystate Organic Certifiers". Any labeling that shortens this name will not be accepted, and the certified operation will have to change any and all incorrect labeling at its own expense.

#### RECORDKEEPING FOR CERTIFIED OPERATIONS

#### **Background**

Section 205.103 of the NOP regulations requires that certified operations maintain records. Such records must fully disclose all activities in sufficient detail and in a format that can be readily understood, audited, and available for inspection. Certified operations must make records available for review by the NOP, the applicable State program's governing State official, and the certifying agent during normal business hours (205.103(c)).

Section 205.201 requires certified operations to describe the recordkeeping system that will be implemented in accordance with Section 205.103 as part of the Organic System Plan for their operation. The Organic System Plan serves as a management and verification tool specific to the unique characteristics of each operation and should reflect the practices, procedures, inputs, and recordkeeping approach that will be used by an operation.

Maintenance of records enables certified operations to meet the requirements for continuing their organic certification. On an annual basis, certified operations must submit to their certifying agent an updated Organic System Plan, which includes documentation of any deviations in the practices, procedures, and inputs from what was specified in the previous year's Organic System Plan and any changes to the previous year's Organic System Plan that will be undertaken in the coming year (205.406(a)(1)(i-ii)). Documenting such changes allows certifying agents to verify an operator's compliance with the NOP.

#### **Policy**

Certified operations can demonstrate compliance with the recordkeeping requirements under the NOP regulations by ensuring that the records maintained are up to date and sufficiently document the practices, procedures, and inputs used by the operation. Many certifying agents provide recordkeeping forms and sample Organic System Plans specific to crops, livestock, handling, and retail operations that may be suitable for documenting the activities and transactions of a certified operation. Certified operations and certifying agents can also consider the records listed when establishing their recordkeeping approach.

The records listed below are examples of records that can be used to demonstrate compliance with the recordkeeping requirements in the NOP regulations. All records maintained by the certified farm, handler or processor to demonstrate compliance with the NOP regulations need to be listed in the organic system plan. Other records not listed below may also be useful to verify compliance with the NOP regulations.

#### **Organic Crop Producer Records**

#### Seeds and Transplants – including cover crop and pasture seeds

- Receipts of seeds and transplants delivered to farm
- Invoices of seeds and transplants purchased
- Seed packages and labels
- Phone logs of attempts to obtain organic seeds and transplants
- Seed catalogs
- Letters from seed suppliers concerning the availability of organic seeds
- Organic certificates for organic seeds purchased

- For seed savers harvest records showing production of organic seed
- Seed treatment records
- Verification from supplier that non-organic seed is not genetically modified. This is only necessary for seeds that have commercially available GMO seeds (e.g. corn, soybeans, sugar beets, etc.)

#### **Material Application Records**

- Invoices or receipts for all materials purchased including custom applicator invoices
- Documentation that purchased manure is free of prohibited additives
- Fertilizer and soil amendments application records for fertilizers, manure, compost, soil amendments, and synthetic micronutrients
- Pest control products application records for pesticides, acidifiers, spreader/stickers and other spray adjuvants
- Crop production aids application records for foliar sprays, gibberellic acid, kelp or other approved products

#### **Production Records**

- Farm activity log
- Invoices for contracted services (e.g. seeding, mowing, spreading manure, etc.)
- Recommendations from pest consultants or other field persons
- Soil, water and tissue analysis reports
- Records of cultivation practices, weeding and planting dates
- Compost production records

#### **Field History Records**

- Cropping history or land use for the previous three years
- Material application records for the previous three years
- A copy of the organic certificate if the land was previously certified under another producer's certificate
- Lease agreements
- Maps

#### **Harvest and Storage Records**

- Yield records (e.g. pounds harvested, weigh tickets, boxes harvested)
- Receipts from processor or warehouse for delivery of organic product
- Custom harvest records
- Clean truck affidavits
- Crop Storage locations and inventories

#### **Sales Records**

• Deposit records, ledgers, receipts

- Purchase orders
- Invoices
- Sales summaries from wholesalers or processors
- Delivery and/or pick up records and farmer's market/farmstand sales records

#### **Organic Livestock Producer Records**

#### **Origin of Livestock Records**

- Breeding, birthing, and weaning records (e.g. calendar, chart, notebook, veterinary documents)
- Invoices, receiving records, and organic certification verification for all purchased animals

#### **Feed Records**

- Organic verification for all purchased feed, including grain, hay or silage (e.g. copy of organic certificates)
- Grain invoices with weights from your grain company
- Records of purchased feed supplements, and animal health care products
- Feed supplements and additive ingredient labels and purchase records
- Feeding records (i.e.: Dry Matter Demand and Dry Matter Intake Records)
- Harvest and storage records for feed grown on farm, feed labels, and organic certificates

#### **Animal Health Care Records**

- Loss/cull records
- Medication records
- Vaccinations
- Somatic cell counts

#### **Livestock Living Conditions and Pasture Records**

- Animal Identification records
- Grazing records
- Records of inclement weather
- Records of when animals were temporarily confined with description of the rational for confinement
- Pasture rotation records

#### **Production Records**

- Date and weight at slaughter
- Milk or value added product production records
- Egg production records

#### **Organic Handler & Processor Records**

## Receiving Records – records that verify that product received was organic and records that verify the amount of organic product received

- Organic certificate for each organic product or organic ingredient received
- Clean truck affidavit for bulk product verifies that truck was cleaned prior to hauling organic products
- Invoices, purchase orders, bills of lading, scale tickets
- Handler organic certificates and contracts
- Certificates of Analyses or Product Specification Sheets
- Raw product inventory reports and records
- Weigh tickets, receipts and tags

#### Storage and Production Records – records that describe handling and processing activities

- Non-organic ingredient records
- Equipment clean-out logs
- Product specification sheets and ingredient inspection forms
- Recipes and product formulations
- Ingredient usage reports and production logs
- Quality Control reports
- Records as to reconditioning, shrinkage, and dumping, container, storage and processing area clean-out and reuse
- Purchased inputs, including ingredients, sanitizers, food contact substances, packaging, pest management materials
- Inventory reports for ingredients and finished products
- Packaging reports
- Pest control and sanitation logs

#### Shipping Records – records that verify type and amount of organic product shipped

- Pallet/tote tickets and scale tickets
- Certificates of analyses
- Purchase orders and sales journals
- Finished product inventory reports and records
- Shipping logs and bills of lading
- Export records and transaction certificates
- Sales, accounts payable, accounts receivable, and cash disbursement journals
- Broker's contracts and statements
- Phytosanitary certificates

Sample recordkeeping forms for organic operations may be downloaded from www.attra.org.

#### **EXPORTING CERTIFIED ORGANIC PRODUCTS**

#### **Canadian Equivalency**

In June of 2009 the US-Canada Equivalence Agreement was signed. This agreement specifies the conditions under which organic products certified to the National Organic Program requirements may be shipped into Canada. If you are applying for certification to Baystate Organic Certifiers or are already certified by Baystate Organic Certifiers, then you must disclose that you are shipping products into Canada. In addition, you must comply with the following requirements of the Equivalence Agreement. All Baystate's application forms ask for information about shipments to Canada and compliance with the requirements specified below.

For Farmers selling crops in Canada:

- 1. Proof that agricultural products were produced without the use of sodium nitrate.
- 2. Proof that the agricultural products were not produced using hydroponic and aeroponic methods.

For Farmers selling products derived from animals you will be contacted by our office and apprised of any applicable livestock stocking rate requirements.

Processors selling processed products in Canada must have a system or policy to verify that their ingredients are not produced with sodium nitrate fertilizers, hydroponics or aeroponics, or livestock stocking rates inconsistent with the Canadian Organic Regulations (ruminants excepted). Such a policy for Handler clients would be to gather statements from suppliers where there is a reasonable possibility of an issue. Note: These statements do not need to be from certifiers.

If you are shipping products to Canada and Baystate determines that your crops, animal products, or processed products are in compliance with these requirements then all shipments to Canada must be accompanied by an attestation stating that your products are "Certified in compliance with the terms of the US-Canada Organic Equivalency Arrangement". Note that this statement must accompany all products crossing the border and must appear on documentation traveling with the shipment.

It is the responsibility of certified parties to make sure that their labels are compliant with Canadian requirements. Please note that all Canadian labels must not use the phrase "Certified Organic". You may call your product or ingredients "organic" or "organically grown", etc. but not "Certified Organic". Retail labels for the Canadian market must be bilingual (written in English and French). You must submit Canadian compliant labels to Baystate Organic Certifiers for approval.

#### <u>European Union – U.S./EU Equivalency Arrangement</u>

Beginning June 1, 2012, organic products certified to the USDA organic or European Union (EU) organic standards may be sold, labeled, and represented as organic in both countries. As long as the operation is certified by a USDA- or EU-accredited certifying agent, this arrangement eliminates the need for U.S. organic operations to have a separate certification to the EU standards and vice versa. Baystate Organic Certifiers is an accredited certifying agent and products certified by Baystate are eligible for shipment to the European Union as long as they conform to the following requirements.

#### Scope of the Arrangement

The arrangement is limited to organic products of U.S. or EU origin. This includes products that have been either (1) produced within the U.S. or EU or (2) products whose final processing or packaging occurs within the U.S. or EU. This includes products processed or packaged in the U.S. or EU that contain organic ingredients from foreign sources that have been certified to the USDA or EU organic standards. Aquatic animals (e.g., fish and shellfish) are not included within the scope of the arrangement.

Products where final processing or packaging occurs within the U.S., may contain organic ingredients (from domestic and foreign sources) that are certified organic by NOP authorized certifiers (direct accreditation and via recognition agreements) as long as final processing or packaging occurs in the U.S.

#### Countries in the EU

The following countries are in the EU: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom.

#### *Wine – Exporting Wine to the EU*

Organic wine and wine "made with organic grapes" may be exported to the EU under the arrangement if the wine meets the following criteria:

- 1. Contains 100 percent organic grapes and organic ingredients. Non-organic substances not allowed under 7 CFR 205.605 are prohibited.
- 2. Have been produced only using the winemaking practices and substances detailed in the EU organic regulations.

Organic wine may be labeled with the USDA organic seal and the EU organic logo.

#### Requirements for U.S. Producers

In addition to certification to the USDA organic regulations, all products traded under the organic trade partnership must meet the following requirements:

- 1. Organic apples, pears, and ingredients from organic apples and pears must be produced without antibiotics. Antibiotics may not be used for at least 3 years prior to the harvest of the organic apple or pear.
- 2. Products must travel with an EU import certificate (Certificate of Inspection) that has been completed by an NOP accredited certifying agent.
- 3. Products must either be produced or have had final processing or packaging occur within the U.S.

#### Requirements for EU Producers

In addition to certification the EU organic regulations, all products traded under the organic trade partnership must meet the following requirements.

- 1. Agricultural products derived from animals treated with antibiotics shall not be marketed as organic in the United States.
- 2. Products must travel with an NOP import certificate that has been completed by an EU accredited certifying agent.
- 3. This arrangement is limited to organic products of the EU, either produced within the EU or where the final processing or packaging occurs within the EU.

# Shipping USDA Organic Products to the EU

Operations certified by Baystate Organic Certifiers, who want to ship certified organic products to the EU must notify Baystate at least 5 business days prior to the shipping date for products being shipped to the EU so that Baystate has enough time to complete the EU Import Certificate that has to accompany the shipment of the product to the EU.

Baystate will work with the certified operation to get the required information to produce the EU Import Certificate. Most of the required information has to do with specific shipping details for the products, but may include proof that the products to be shipped conform to the requirements of the agreement.

# Using EU Organic Products as Ingredients in NOP Certified Products

Processors that want to use EU certified organic products in their NOP certified products must provide both proof of certification for the EU certified organic product and a copy of the NOP Import Certificate for the product. This documentation must be maintained on file for five years.

# Labeling Products for Shipment to the EU

### Retail Products

For retail products, labels must include the code that the EU has assigned to each NOP accredited certifying agent. Baystate's code is US-ORG-003. Labels or stickers may also include the name of the certifying agent.

### Organic Products

Products certified as organic in the U.S. and meet the terms of the arrangement may be sold as organic in the EU. Products may include the EU organic logo and/or the USDA organic seal. Note: if you are using the EU logo then the labeling for the product must conform to all requirements of the EU labeling regulations.

# 100% Organic Products

The EU does not have a labeling category for 100% organic products. Products meeting the terms of the arrangement listed above may be labeled organic and include the EU organic logo and/or the USDA seal. Note: if you are using the EU logo then the labeling for the product must conform to all requirements of the EU labeling regulations.

# "Made with" Organic Products

The EU does not have a labeling category for "made with" organic products. For products containing less than 95% organic ingredients, a percentage statement of organic content may be displayed on the label. Products may not be labeled with the EU organic logo or the USDA organic seal.

#### **Bulk Products**

Lot number must be present that allows for a complete audit trail to verify the product's integrity.

Contact Baystate if you need an export certificate for shipments to the EU.

# Japan – U.S./Japan Organic Equivalence Agreement

Beginning January 1, 2014, U.S. and Japanese organic products certified to the USDA organic standards or Japanese Agricultural Standards (JAS) may be sold, labeled, and represented as organic in both countries. As long as the operation is certified by a USDA-accredited or Japan-accredited certifying agent, this arrangement facilitates access to each country's organic market.

# Scope of the Arrangement

Plant or plant-based products - The arrangement includes organic plant, including fungi, and plant-based processed products of U.S. or Japanese origin. This includes products that were either (1) produced within the U.S. or Japan or (2) products whose final processing or packaging occurs within the U.S. or Japan.

Non-JAS eligible products (e.g., meat, dairy, honey, textiles) certified by a USDA-accredited certifier will continue to enjoy access to the Japanese market. All USDA certified products must comply with the USDA organic regulations, including labeling requirements for the use of the USDA organic seal. These products may be labeled with the word "organic" in English or Japanese. An export certificate is not required. Non-JAS eligible products may be sold as organic in Japan; however, they may not use the JAS seal. The U.S. product may display the USDA organic seal if compliant with USDA organic labeling requirements.

Alcohol products certified to the USDA organic standards may be exported to Japan. The alcoholic beverage may display the USDA organic seal if it is compliant with USDA organic labeling requirements. These products must be accompanied by an export certificate which contains the following information:

- Name of the certified alcoholic beverage
- Name and address of the certified organic farm or brewery
- Certificate number and date
- Name and address of operator
- Country of origin
- Name and address of the organic certifying agent

The USDA TM-11 export certificate issued by a USDA organic certifying agent would meet these requirements.

Using Japan Organic Products as Ingredients in NOP Certified Products

Processors that want to use products certified to the JAS organic standards as ingredients in their organically certified products must provide both proof of certification for the JAS certified organic product and a copy of the NOP Import Certificate for the product. This documentation must be maintained on file for five years.

# Obtaining a TM-11Export Document for Shipments to Japan

All organic plants, including fungi, and plant-based processed products exported from the U.S. to Japan must be accompanied by an export certificate. It is used to document the production location, identify the certifying agent, certify that the terms of the partnership were met, and allow traded products to be tracked.

Export certificates aren't required for products not covered by the Japanese Agricultural Standards, such as meat, dairy products, or alcoholic beverages, though a TM-11 could be used for alcoholic beverages shipments in place of the export certificate required for those products.

If you are applying for certification to Baystate Organic Certifiers or are already certified by Baystate Organic Certifiers, then you must disclose that you are shipping products into Japan. You will be contacted by our office and apprised of the applicable requirements as indicated below:

The following are required to be submitted to BOC before a Japan TM-11 can be issued:

1. TM-11 request form for shipping to Japan from BOC certified entity

All exported product(s) must be certified to "organic" or "100% organic" levels.

If you are shipping products to Japan and Baystate determines that your crops, or processed products are in compliance with these requirements then all shipments to Japan must be accompanied by a TM-11 Export Certificate.

It is the responsibility of certified parties to make sure that their labels are compliant with Japanese requirements. Please note that all organic products shipped to Japan must be certified to the "organic" level or higher.

### Labeling Products for Shipment to Japan

Any plants, including fungi, and plant-based processed products sold, labeled, or represented as organic in Japan must be labeled with the JAS seal. These products must be imported by a JAS-certified importer. The JAS seal may be applied using one of two methods:

*Method 1*. If a U.S.-based farm or business wishes to apply the JAS seal to their products in the U.S., they must contract with a JAS-certified importer.

*Method* 2. If the U.S.-based farm or business doesn't have a contract with a JAS-certified importer, a JAS-certified importer must apply the seal to the product once it arrives in Japan.

Products not covered by the JAS standards—such as meat, dairy products, or alcoholic beverages—can't be labeled with the JAS seal.

# 100% Organic Products

Japan does not have a labeling category for 100% organic products. However, these products may be labeled as organic.

"Made with" Organic Products

Japan does not have a labeling category for "made with" organic products. Only products with 95% or more organic content may be labeled as organic in Japan.

Contact Baystate if you need a TM-11 for shipments to Japan.

# Taiwan – U.S./Taiwan Organic Equivalence Agreement

An export certificate (TM-11s) must accompany organic products shipped to Taiwan from an operation certified to the National Organic Standards.

Requirements for the Export of US Organic Raw and Processed Agricultural Products to Taiwan Effective March 18, 2009, a "one-way" export arrangement whereby raw or processed agricultural products (including livestock products) from US operations certified to the USDA NOP standards can be represented and sold in Taiwan as organic. When exported to Taiwan, organic products must be accompanied by an organic transaction certificate or TM-11. The TM-11 verifies that the product complies with the terms of the trade arrangement. Only products that are eligible and correctly display the USDA Organic Seal are eligible for the issuance of a TM-11 Export Certificate to Taiwan.

All products that are produced under the terms of the Taiwan export arrangement must be accompanied by documentation stating the following information:

- 1. Processed products and crops: "Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances."
- 2. Livestock and meat products: "Organic livestock products, accompanied by this certificate, were managed and produced without the use of systemic pain killers or analgesics, including the use of Lidocaine or Procaine."

Contact Baystate if you need a TM-11 for shipments to Taiwan.

### Korea – U.S./Korea Organic Equivalence Agreement

The U.S. has an organic equivalence arrangement with Korea for organic processed foods. This means that, as long as the terms of the arrangement are met, certified organic operations in Korea or in the U.S. may sell their products as organic in either country.

# Scope of the Agreement

Beginning July 1, 2014, the arrangement covers products which are certified to the USDA or Korean organic regulations, are "processed products" (as defined by the Korean Food Code), contain at least 95 percent organic ingredient, have their final processing (as defined in the Korean Food Code) occur in the U.S. or Korea, and products produced within the U.S. must not contain apples or pears produced with the use of antibiotics.

Products exported to Korea under the arrangement must be accompanied by a NAQS Import Certificate of Organic Processed Foods. A USDA-accredited certifying agent must complete

NAQS Import Certificate for all USDA organic products traded under the arrangement. The documentation must include this statement: "Certified in compliance with the terms of the US-Korea Organic Equivalency Arrangement." The NAQS Import Certificate is required to be included with shipments of organic products.

# Labeling Products for Shipment to Korea

Korean products processed under the terms of the arrangement must be labeled according to USDA organic labeling requirements and may display the USDA organic seal and/or Korean organic food label.

# 100% Organic Products

Korea does not have a labeling category for 100% organic products. Products meeting the terms of the arrangement listed above may be labeled organic and include the NAQS organic logo and/or the USDA seal. Note: if you are using the NAQS logo then the labeling for the product must conform to all requirements of the NAQS labeling regulations.

#### Organic Products

Products certified as organic in the U.S. and meet the terms of the arrangement may be sold as organic in Korea. Products may include the NAQS organic logo and/or the USDA organic seal. Note: if you are using the NAQS logo then the labeling for the product must conform to all requirements of the NAQS labeling regulations.

# "Made with" Organic Products

Korea does not have a labeling category for "made with" organic products. For products containing less than 95% organic ingredients, a percentage statement of organic content may be displayed on the label. Products may not be labeled with the NAQS organic logo or the USDA organic seal.

### **Bulk Products**

Lot number must be present that allows for a complete audit trail to verify the product's integrity.

Contact Baystate if you need an export certificate for shipments to Korea.

### Switzerland – U.S./ Swiss Organic Equivalence Agreement

The United States (U.S.) has an organic equivalency arrangement with Switzerland. This means that as long as the terms of the arrangement are met, organic products certified to the USDA organic regulations or the Swiss organic ordinances may be labeled and sold as organic in both countries.

### Scope of the Agreement

Beginning July 10, 2015, the arrangement covers products which:

- Are certified to the USDA or Swiss organic regulations
- Have their final processing occur in the U.S. or Switzerland
- Swiss products: do not contain livestock products, or any ingredient used in such products, produced with the use of antibiotics

USDA-accredited certifying agent must complete a Swiss Certificate of Inspection for all USDA organic products traded under the arrangement.

# Labeling Products for Shipment to Switzerland

Swiss organic products imported into the U.S. must be labeled according to USDA organic labeling requirements and may display the USDA organic seal.

# 100% Organic Products

Switzerland does not have a labeling category for 100% organic products. Products meeting the terms of the arrangement listed above may be labeled organic and include the Swiss organic logo and/or the USDA seal. Note: if you are using the Swiss logo then the labeling for the product must conform to all requirements of the Swiss labeling regulations.

#### Organic Products

Products certified as organic in the U.S. and meet the terms of the arrangement may be sold as organic in Switzerland. Products may include the Swiss organic logo and/or the USDA organic seal. Note: if you are using the Swiss logo then the labeling for the product must conform to all requirements of the Swiss labeling regulations.

# "Made with" Organic Products

Switzerland does not have a labeling category for "made with" organic products. For products containing less than 95% organic ingredients, a percentage statement of organic content may be displayed on the label. Products may not be labeled with the Swiss organic logo or the USDA organic seal.

#### **Bulk Products**

Lot number must be present that allows for a complete audit trail to verify the product's integrity.

Contact Baystate if you need an export certificate for shipments to Switzerland.

### THE NATIONAL ORGANIC STANDARDS

Note: The National Organic Standards may be updated at any time by the National Organic Program. See the NOP website for the latest copy of the standards.

# **Subpart A - Definitions**

#### § 205.1 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to impart the plural and vice versa, as the case may demand.

### § 205.2 Terms defined.

<u>Accreditation.</u> A determination made by the Secretary that authorizes a private, foreign, or State entity to conduct certification activities as a certifying agent under this part.

Act. The Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 et seq.).

Action level. The limit at or above which the Food and Drug Administration will take legal action against a product to remove it from the market. Action levels are based on unavoidability of the poisonous or deleterious substances and do not represent permissible levels of contamination where it is avoidable. Administrator. The Administrator for the Agricultural Marketing Service, United States Departure of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

<u>Agricultural inputs.</u> All substances or materials used in the production or handling of organic agricultural products.

<u>Agricultural product.</u> Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption.

<u>Agricultural Marketing Service (AMS).</u> The Agricultural Marketing Service of the United States Department of Agriculture.

<u>Allowed synthetic.</u> A substance that is included on the National List of synthetic substances allowed for use in organic production or handling.

AMDUCA. The Animal Medicinal Drug Use Clarification Act of 1994 (Pub L. 103-396).

<u>Animal drug.</u> Any drug as defined in section 201 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 321), that is intended for use in livestock, including any drug intended for use in livestock feed but not including such livestock feed.

<u>Annual seedling.</u> A plant grown from seed that will complete its life cycle or produce a harvestable yield within the same crop year or season in which it was planted.

<u>Area of operation.</u> The types of operations: crops, livestock, wild-crop harvesting or handling, or any combination thereof that a certifying agent may be accredited to certify under this part.

<u>Audit trail.</u> Documentation that is sufficient to determine the source, transfer of ownership, and transportation of any agricultural product labeled as "100 percent organic," the organic ingredients of any agricultural product labeled as "organic" or "made with organic (specified ingredients)" or the organic ingredients of any agricultural product containing less than 70 percent organic ingredients identified as organic in an ingredients statement.

Biodegradable. Subject to biological decomposition into simpler biochemical or chemical components.

Biodegradable biobased mulch film. A synthetic mulch film that meets the following criteria:

- (1) Meets the compostability specifications of one of the following standards: ASTM D6400, ASTM D6868, EN 13432, EN 14995, or ISO 17088 (all incorporated by reference; see §205.3);
- (2) Demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see §205.3); and
- (3) Must be biobased with content determined using ASTM D6866 (incorporated by reference; see §205.3).

<u>Biologics.</u> All viruses, serums, toxins, and analogous products of natural or synthetic origin, such as diagnostics, antitoxins, vaccines, live microorganisms, killed microorganisms, and the antigenic or immunizing components of microorganisms intended for use in the diagnosis, treatment, or prevention of diseases of animals.

<u>Breeder stock.</u> Female livestock whose offspring may be incorporated into an organic operation at the time of their birth.

<u>Buffer zone.</u> An area located between a certified production operation or portion of a production operation and an adjacent land area that is not maintained under organic management. A buffer zone must be sufficient in size or other features (e.g., windbreaks or a diversion ditch) to prevent the possibility of unintended contact by prohibited substances applied to adjacent land areas with an area that is part of a certified operation.

<u>Bulk.</u> The presentation to consumers at retail sale of an agricultural product in unpackaged, loose form, enabling the consumer to determine the individual pieces, amount, or volume of the product purchased. <u>Certification or certified.</u> A determination made by a certifying agent that a production or handling operation is in compliance with the Act and the regulations in this part, which is documented by a certificate of organic operation.

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

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

<u>Certifying agent's operation.</u> All sites, facilities, personnel, and records used by a certifying agent to conduct certification activities under the Act and the regulations in this part.

<u>Claims.</u> Oral, written, implied, or symbolic representations, statements, or advertising or other forms of communication presented to the public or buyers of agricultural products that relate to the organic certification process or the term, "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or, in the case of agricultural products containing less than 70 percent organic ingredients, the term, "organic," on the ingredients panel.

Class of animal. A group of livestock that shares a similar stage of life or production.

The classes of animals are those that are commonly listed on feed labels.

<u>Commercially available.</u> The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

<u>Commingling.</u> Physical contact between unpackaged organically produced and nonorganically produced agricultural products during production, processing, transportation, storage or handling, other than during the manufacture of a multiingredient product containing both types of ingredients.

Compost. The product of a managed process through which microorganisms break down plant and animal materials into more available forms suitable for application to the soil. Compost must be produced through a process that combines plant and animal materials with an initial C:N ratio of between 25:1 and 40:1. Producers using an in-vessel or static aerated pile system must maintain the composting materials at a temperature between 131F and 170F for 3 days. Producers using a windrow system must maintain the

composting materials at a temperature between 131 F and 170 F for 15 days, during which time, the materials must be turned a minimum of five times.

<u>Control.</u> Any method that reduces or limits damage by populations of pests, weeds, or diseases to levels that do not significantly reduce productivity.

Crop. Pastures, cover crops, green manure crops, catch crops, or any plant or part of a

plant intended to be marketed as an agricultural product, fed to livestock, or used in the field to manage nutrients and soil fertility.

<u>Crop residues.</u> The plant parts remaining in a field after the harvest of a crop, which include stalks, stems, leaves, roots, and weeds.

<u>Crop rotation.</u> The practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years so that crops of the same species or family are not grown repeatedly without interruption on the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation.

<u>Crop year.</u> That normal growing season for a crop as determined by the Secretary.

Cultivation. Digging up or cutting the soil to prepare a seed bed; control weeds; aerate the soil; or work organic matter, crop residues, or fertilizers into the soil.

<u>Cultivation.</u> Digging up or cutting the soil to prepare a seed bed; control weeds; aerate the soil; or work organic matter, crop residues, or fertilizers into the soil.

<u>Cultural methods</u>. Methods used to enhance crop health and prevent weed, pest, or disease problems without the use of substances; examples include the selection of appropriate varieties and planting sites; proper timing and density of plantings; irrigation; and extending a growing season by manipulating the microclimate with green houses, cold frames, or wind breaks.

<u>Detectable residue.</u> The amount or presence of chemical residue or sample component that can be reliably observed or found in the sample matrix by current approved analytical methodology.

<u>Disease vectors.</u> Plants or animals that harbor or transmit disease organisms or pathogens which may attack crops or livestock.

<u>Drift.</u> The physical movement of prohibited substances from the intended target site onto an organic operation or portion thereof.

<u>Dry lot.</u> A fenced area that may be covered with concrete, but that has little or no vegetative cover.

<u>Dry matter</u>. The amount of a feedstuff remaining after all the free moisture is evaporated out

Dry matter demand. The expected dry matter intake for a class of animal.

<u>Dry matter intake</u>. Total pounds of all feed, devoid of all moisture, consumed by a class of animals over a given period of time.

<u>Emergency pest or disease treatment program.</u> A mandatory program authorized by a Federal, State, or local agency for the purpose of controlling or eradicating a pest or disease.

Employee. Any person providing paid or volunteer services for a certifying agent.

Excipients. Any ingredients that are intentionally added to livestock medications but do not exert therapeutic or diagnostic effects at the intended dosage, although they may act to improve product delivery (e.g. enhancing absorption or controlling release of the drug substance). Examples of such ingredients include fillers, extenders, dilutents, wetting agents, solvents, emulsifiers, preservatives, flavors, absorption enhancers, sustained-release matrices, and coloring agents.

Excluded methods. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

<u>Feed.</u> Edible materials which are consumed by livestock for their nutritional value. Feed may be concentrates (grains) or roughages (hay, silage, fodder). The term, "feed," encompasses all agricultural commodities, including pasture ingested by livestock for nutritional purposes.

<u>Feed additive.</u> A substance added to feed in micro quantities to fulfill a specific nutritional need; i.e., essential nutrients in the form of amino acids, vitamins, and minerals.

Feedlot. A dry lot for the controlled feeding of livestock.

<u>Feed Supplement.</u> A combination of feed nutrients added to livestock feed to improve the nutrient balance or performance of the total ration and intended to be:

- (1) Diluted with other feeds when fed to livestock;
- (2) Offered free choice with other parts of the ration if separately available; or
- (3) Further diluted and mixed to produce a complete feed.

<u>Fertilizer</u>. A single or blended substance containing one or more recognized plant nutrient(s) which is used primarily for its plant nutrient content and which is designed for use or claimed to have value in promoting plant growth.

Field. An area of land identified as a discrete unit within a production operation.

<u>Forage.</u> Vegetative material in a fresh, dried, or ensiled state (pasture, hay, or silage), which is fed to livestock.

<u>Governmental entity.</u> Any domestic government, tribal government, or foreign governmental subdivision providing certification services.

<u>Graze.</u> (1) The consumption of standing or residual forage by livestock.

(2) To put livestock to feed on standing or residual forage.

Grazing. To graze.

<u>Grazing season.</u> The period of time when pasture is available for grazing, due to natural precipitation or irrigation. Grazing season dates may vary because of mid-summer

heat/humidity, significant precipitation events, floods, hurricanes, droughts or winter weather events. Grazing season may be extended by the grazing of residual forage as agreed in the operation's organic

system plan. Due to weather, season, or climate, the grazing season may or may not be continuous. Grazing season may range from 120 days to 365 days, but not less than 120 days per year.

<u>Handle.</u> To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

<u>Handler</u>. Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products.

<u>Handling operation</u>. Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

<u>Immediate family.</u> The spouse, minor children, or blood relatives who reside in the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent. For the purpose of this part, the interest of a spouse, minor child, or blood relative who is a resident of the immediate household of a certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent shall be considered to be an interest of the certifying agent or an employee, inspector, contractor, or other personnel of the certifying agent.

Inclement weather. Weather that is violent, or characterized by temperatures (high or

low), or characterized by excessive precipitation that can cause physical harm to a given species of livestock. Production yields or growth rates of livestock lower than the maximum achievable do not qualify as physical harm.

<u>Inert ingredient.</u> Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient which is intentionally included in any pesticide product (40 CFR 152.3(m)).

<u>Information panel.</u> That part of the label of a packaged product that is immediately contiguous to and to the right of the principal display panel as observed by an individual facing the principal display panel, unless

another section of the label is designated as the information panel because of package size or other package attributes (e.g., irregular shape with one usable surface).

<u>Ingredient.</u> Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

<u>Ingredients statement.</u> The list of ingredients contained in a product shown in their common and usual names in the descending order of predominance.

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

<u>Inspector.</u> Any person retained or used by a certifying agent to conduct inspections of certification applicants or certified production or handling operations.

<u>Label.</u> A display of written, printed, or graphic material on the immediate container of an agricultural product or any such material affixed to any agricultural product or affixed to a bulk container containing an agricultural product, except for package liners or a display of written, printed, or graphic material which contains only information about the weight of the product.

<u>Labeling.</u> All written, printed, or graphic material accompanying an agricultural product at any time or written, printed, or graphic material about the agricultural product displayed at retail stores about the product. <u>Livestock.</u> Any cattle, sheep, goats, swine, poultry, or equine animals used for food or in the production of food, fiber, feed, or other agricultural-based consumer products; wild or domesticated game; or other nonplant life, except such term shall not include aquatic animals for the production of food, fiber, feed, or other agricultural-based consumer products.

<u>Lot.</u> Any number of containers which contain an agricultural product of the same kind located in the same conveyance, warehouse, or packing house and which are available for inspection at the same time.

<u>Manure.</u> Feces, urine, other excrement, and bedding produced by livestock that has not been composted.

<u>Market information.</u> Any written, printed, audiovisual, or graphic information, including advertising, pamphlets, flyers, catalogues, posters, and signs, distributed, broadcast, or made available outside of retail outlets that are used to assist in the sale or promotion of a product.

<u>Mulch.</u> Any nonsynthetic material, such as wood chips, leaves, or straw, or any synthetic material included on the National List for such use, such as newspaper or plastic that serves to suppress weed growth, moderate soil temperature, or conserve soil moisture.

<u>Narrow range oils.</u> Petroleum derivatives, predominately of paraffinic and napthenic fractions with 50 percent boiling point (10 mm Hg) between 415F and 440F.

National List. A list of allowed and prohibited substances as provided for in the Act.

<u>National Organic Program (NOP).</u> The program authorized by the Act for the purpose of implementing its provisions.

<u>National Organic Standards Board (NOSB).</u> A board established by the Secretary under 7 U.S.C. 6518 to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the National Organic Program.

<u>Natural resources of the operation.</u> The physical, hydrological, and biological features of a production operation, including soil, water, wetlands, woodlands, and wildlife.

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

Nonsynthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.

<u>Nonretail container</u>. Any container used for shipping or storage of an agricultural product that is not used in the retail display or sale of the product.

<u>Nontoxic.</u> Not known to cause any adverse physiological effects in animals, plants, humans, or the environment.

Organic. A labeling term that refers to an agricultural product produced in accordance with the Act and the regulations in this part.

Organic matter. The remains, residues, or waste products of any organism.

<u>Organic production.</u> A production system that is managed in accordance with the Act and regulations in this part to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

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

<u>Pasture</u>. Land used for livestock grazing that is managed to provide feed value and maintain or improve soil, water, and vegetative resources.

<u>Peer review panel.</u> A panel of individuals who have expertise in organic production and handling methods and certification procedures and who are appointed by the Administrator to assist in evaluating applicants for accreditation as certifying agents.

Person. An individual, partnership, corporation, association, cooperative, or other entity.

<u>Pesticide</u>. Any substance which alone, in chemical combination, or in any formulation with one or more substances is defined as a pesticide in section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u) <u>et seq</u>).

<u>Petition.</u> A request to amend the National List that is submitted by any person in accordance with this part. <u>Planting stock.</u> Any plant or plant tissue other than annual seedlings but including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation.

<u>Practice standard.</u> The guidelines and requirements through which a production or handling operation implements a required component of its production or handling organic system plan. A practice standard includes a series of allowed and prohibited actions, materials, and conditions to establish a minimum level performance for planning, conducting, and maintaining a function, such as livestock health care or facility pest management, essential to an organic operation.

<u>Principal display panel.</u> That part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale.

<u>Private entity.</u> Any domestic or foreign nongovernmental for-profit or not-for-profit organization providing certification services.

<u>Processing.</u> Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

<u>Processing aid.</u> (a) substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form; (b) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and (c) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

<u>Producer.</u> A person who engages in the business of growing or producing food, fiber, feed, and other agricultural-based consumer products.

<u>Production lot number/identifier.</u> Identification of a product based on the production sequence of the product showing the date, time, and place of production used for quality control purposes.

<u>Prohibited substance.</u> A substance the use of which in any aspect of organic production or handling is prohibited or not provided for in the Act or the regulations of this part.

<u>Records.</u> Any information in written, visual, or electronic form that documents the activities undertaken by a producer, handler, or certifying agent to comply with the Act and regulations in this part.

Residual forage. Forage cut and left to lie, or windrowed and left to lie, in place in the pasture.

<u>Residue testing.</u> An official or validated analytical procedure that detects, identifies, and measures the presence of chemical substances, their metabolites, or degradations products in or on raw or processed agricultural products.

<u>Responsibly connected.</u> Any person who is a partner, officer, director, holder, manager, or owner of 10 percent or more of the voting stock of an applicant or a recipient of certification or accreditation.

<u>Retail food establishment.</u> A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an instore restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat-food.

Routine use of parasiticide. The regular, planned, or periodic use of parasiticides.

<u>Secretary</u>. The Secretary of Agriculture or a representative to whom authority has been delegated to act in the Secretary's stead.

<u>Sewage sludge</u>. A solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. Sewage sludge does not include ash generated during the firing of sewage sludge in a sewage sludge incinerator or grit and screenings generated during preliminary treatment of domestic sewage in a treatment works.

Shelter. Structures such as barns, sheds, or windbreaks; or natural areas such as woods,

tree lines, large hedge rows, or geographic land features, that are designed or selected to provide physical protection or housing to all animals.

<u>Slaughter stock.</u> Any animal that is intended to be slaughtered for consumption by humans or other animals. <u>Soil and water quality.</u> Observable indicators of the physical, chemical, or biological condition of soil and water, including the presence of environmental contaminants.

Split operation. An operation that produces or handles both organic and nonorganic agricultural products.

Stage of life. A discrete time period in an animal's life which requires specific

management practices different than during other periods (e.g., poultry during feathering). Breeding, freshening, lactation and other recurring events are not a stage of life.

<u>State.</u> Any of the several States of the United States of America, its territories, the District of Columbia, and the Commonwealth of Puerto Rico.

<u>State certifying agent.</u> A certifying agent accredited by the Secretary under the National Organic Program and operated by the State for the purposes of certifying organic production and handling operations in the State.

<u>State organic program (SOP).</u> A State program that meets the requirements of section 6506 of the Act, is approved by the Secretary, and is designed to ensure that a product that is sold or labeled as organically produced under the Act is produced and handled using organic methods.

State organic program's governing State official. The chief executive official of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of the State, such official who administers a State organic certification program. Synthetic. A substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Temporary and Temporarily. Occurring for a limited time only (e.g., overnight,

throughout a storm, during a period of illness, the period of time specified by the Administrator when granting a temporary variance), not permanent or lasting.

<u>Tolerance</u>. The maximum legal level of a pesticide chemical residue in or on a raw or processed agricultural commodity or processed food.

<u>Transplant.</u> A seedling which has been removed from its original place of production, transported, and replanted.

<u>Unavoidable residual environmental contamination (UREC).</u> Background levels of naturally occurring or synthetic chemicals that are present in the soil or present in organically produced agricultural products that are below established tolerances.

<u>Wild crop.</u> Any plant or portion of a plant that is collected or harvested from a site that is not maintained under cultivation or other agricultural management.

<u>Yards/Feeding pad.</u> An area for feeding, exercising, and outdoor access for livestock during the non-grazing season and a high traffic area where animals may receive supplemental feeding during the grazing season

# **Subpart B - Applicability**

#### § 205.100 What has to be certified.

- (a) Except for operations exempt or excluded in § 205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.
- (b) Any production or handling operation or specified portion of a production or handling operation that has been already certified by a certifying agent on the date that the certifying agent receives its accreditation under this part shall be deemed to be certified under the Act until the operation's next anniversary date of certification. Such recognition shall only be available to those operations certified by a certifying agent that receives its accreditation within 18 months from February 20, 2001.
- (c) Any operation that:
- (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 per violation.
- (2) Makes a false statement under the Act to the Secretary, a governing State official, or an accredited certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

### § 205.101 Exemptions and exclusions from certification.

- (a) Exemptions.
- (1) A production or handling operation that sells agricultural products as "organic" but whose gross agricultural income from organic sales totals \$5,000 or less annually is exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under § 205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part and the labeling requirements of § 205.310. The products from such operations shall not be used as ingredients identified as organic in processed products produced by another handling operation.
- (2) A handling operation that is a retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from the requirements in this part.
- (3) A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in this part, except:
- (i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;
- (ii) The labeling provisions of §§ 205.305 and 205.310; and
- (iii) The recordkeeping provisions in paragraph (c) of this section.
- (4) A handling operation or portion of a handling operation that only identifies organic ingredients on the information panel is exempt from the requirements in this part, except:
- (i) The provisions for prevention of contact of organic products with prohibited substances set forth in § 205.272 with respect to any organically produced ingredients used in an agricultural product;
- (ii) The labeling provisions of §§ 205.305 and 205.310; and
- (iii) The recordkeeping provisions in paragraph (c) of this section.

#### (b) Exclusions.

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

### § 205.102 Use of the term, "organic."

Any agricultural product that is sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be:

(a)Produced in accordance with the requirements specified in § 205.101 or §§ 205.202 through 205.207 or §§ 205.236 through 205.240 and all other applicable requirements of part 205; and (b) Handled in accordance with the requirements specified in § 205.101 or §§ 205.270 through 205.272 and all other applicable requirements of this part 205.

#### § 205.103 Recordkeeping by certified operations.

- (a) A certified operation must maintain records concerning the production, harvesting, and handling of agricultural products that are or that are intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."
- (b) Such records must:
- (1) Be adapted to the particular business that the certified operation is conducting;
- (2) Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited;
- (3) Be maintained for not less than 5 years beyond their creation; and
- (4) Be sufficient to demonstrate compliance with the Act and the regulations in this part.
- (c) The certified operation must make such records available for inspection and copying during normal business hours by authorized representatives of the Secretary, the applicable State program's governing State official, and the certifying agent.

# § 205.104 [Reserved]

# § 205.105 Allowed and prohibited substances, methods, and ingredients in organic production and handling.

To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of:

- (a) Synthetic substances and ingredients, except as provided in § 205.601 or § 205.603;
- (b) Nonsynthetic substances prohibited in § 205.602 or § 205.604;
- (c) Nonagricultural substances used in or on processed products, except as otherwise provided in § 205.605;
- (d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in § 205.606;
- (e) Excluded methods, except for vaccines, <u>Provided</u>, That, the vaccines are approved in accordance with § 205.600(a);
- (f) Ionizing radiation, as described in Food and Drug Administration regulation, 21 CFR 179.26; and
- (g) Sewage sludge.

# §§ 205.106-205.199 [Reserved]

# **Subpart C - Organic Production and Handling Requirements**

§ 205.200 General. The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must comply with the applicable provisions of this subpart. Production practices implemented in accordance with this subpart must maintain or improve the natural resources of the operation, including soil and water quality.

# § 205.201 Organic production and handling system plan.

- (a) The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:
- (1) A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;
- (2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable;
- (3) A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
- (4) A description of the recordkeeping system implemented to comply with the requirements established in § 205.103;
- (5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances; and
- (6) Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.
- (b) A producer may substitute a plan prepared to meet the requirements of another Federal, State, or local government regulatory program for the organic system plan: <u>Provided</u>, That, the submitted plan meets all the requirements of this subpart.

#### § 205.202 Land requirements.

Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as "organic," must:

- (a) Have been managed in accordance with the provisions of §§ 205.203 through 205.206;
- (b) Have had no prohibited substances, as listed in § 205.105, applied to it for a period of 3 years immediately preceding harvest of the crop; and
- (c) Have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management.

#### § 205.203 Soil fertility and crop nutrient management practice standard.

- (a) The producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.
- (b) The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials.
- (c) The producer must manage plant and animal materials to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances. Animal and plant materials include:

- (1) Raw animal manure, which must be composted unless it is:
- (i) Applied to land used for a crop not intended for human consumption;
- (ii) Incorporated into the soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles; or
- (iii) Incorporated into the soil not less than 90 days prior to the harvest of a product whose edible portion does not have direct contact with the soil surface or soil particles;
- (2) Composted plant and animal materials produced though a process that
- (i) established an initial C:N ratio of between 25:1 and 40:1; and
- (ii) maintained a temperature of between 131 F and 170 F for 3 days using an in-vessel or static aerated pile system; or
- (iii) maintained a temperature of between 131F and 170F for 15 days using a windrow composting system, during which period, the materials must be turned a minimum of five times.
- (3) Uncomposted plant materials.
- (d) A producer may manage crop nutrients and soil fertility to maintain or improve soil organic matter content in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances by applying:
- (1) A crop nutrient or soil amendment included on the National List of synthetic substances allowed for use in organic crop production;
- (2) A mined substance of low solubility;
- (3) A mined substance of high solubility, <u>Provided</u>, That, the substance is used in compliance with the conditions established on the National List of nonsynthetic materials prohibited for crop production;
- (4) Ash obtained from the burning of a plant or animal material, except as prohibited in paragraph (e) of this section: <u>Provided</u>, That, the material burned has not been treated or combined with a prohibited substance or the ash is not included on the National List of nonsynthetic substances prohibited for use in organic crop production; and
- (5) A plant or animal material that has been chemically altered by a manufacturing process: <u>Provided</u>, That, the material is included on the National List of synthetic substances allowed for use in organic crop production established in § 205.601.
- (e) The producer must not use:
- (1) Any fertilizer or composted plant and animal material that contains a synthetic substance not included on the National List of synthetic substances allowed for use in organic crop production;
- (2) Sewage sludge (biosolids) as defined in 40 CFR Part 503; and
- (3) Burning as a means of disposal for crop residues produced on the operation: <u>Except</u>, That, burning may be used to suppress the spread of disease or to stimulate seed germination.

#### § 205.204 Seeds and planting stock practice standard.

- (a) The producer must use organically grown seeds, annual seedlings, and planting stock: **Except**, That,
- (1) Nonorganically produced, untreated seeds and planting stock may be used to produce an organic crop when an equivalent organically produced variety is not commercially available, <u>Except</u>, That, organically produced seed must be used for the production of edible sprouts;
- (2) Nonorganically produced seeds and planting stock that have been treated with a substance included on the National List of synthetic substances allowed for use in organic crop production may be used to produce an organic crop when an equivalent organically produced or untreated variety is not commercially available;
- (3) Nonorganically produced annual seedlings may be used to produce an organic crop when a temporary variance has been granted in accordance with § 205.290(a)(2);
- (4) Nonorganically produced planting stock to be used to produce a perennial crop may be sold, labeled, or represented as organically produced only after the planting stock has been maintained under a system of organic management for a period of no less than 1 year; and
- (5) Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the materials is a requirement of Federal or State phytosanitary regulations.

### § 205.205 Crop rotation practice standard.

The producer must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation:

- (a) Maintain or improve soil organic matter content;
- (b) Provide for pest management in annual and perennial crops;
- (c) Manage deficient or excess plant nutrients; and
- (d) Provide erosion control.

# § 205.206 Crop pest, weed, and disease management practice standard.

- (a) The producer must use management practices to prevent crop pests, weeds, and diseases including but not limited to:
- (1) Crop rotation and soil and crop nutrient management practices, as provided for in §§ 205.203 and 205.205;
- (2) Sanitation measures to remove disease vectors, weed seeds, and habitat for pest organisms; and
- (3) Cultural practices that enhance crop health, including selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases.
- (b) Pest problems may be controlled through mechanical or physical methods including but not limited to:
- (1) Augmentation or introduction of predators or parasites of the pest species;
- (2) Development of habitat for natural enemies of pests;
- (3) Nonsynthetic controls such as lures, traps, and repellents.
- (c) Weed problems may be controlled through:
- (1) Mulching with fully biodegradable materials;
- (2) Mowing;
- (3) Livestock grazing;
- (4) Hand weeding and mechanical cultivation;
- (5) Flame, heat, or electrical means; or
- (6) Plastic or other synthetic mulches: <u>Provided</u>, That, they are removed from the field at the end of the growing or harvest season.
- (d) Disease problems may be controlled through:
- (1) Management practices which suppress the spread of disease organisms; or
- (2) Application of nonsynthetic biological, botanical, or mineral inputs.
- (e) When the practices provided for in paragraphs (a) through (d) of this section are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a substance included on the National List of synthetic substances allowed for use in organic crop production may be applied to prevent, suppress, or control pests, weeds, or diseases: <u>Provided</u>, That, the conditions for using the substance are documented in the organic system plan.
- (f) The producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with soil or livestock.

# § 205.207 Wild-crop harvesting practice standard.

- (a) A wild crop that is intended to be sold, labeled, or represented as organic must be harvested from a designated area that has had no prohibited substance, as set forth in § 205.105, applied to it for a period of 3 years immediately preceding the harvest of the wild crop.
- (b) A wild crop must be harvested in a manner that ensures that such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

# § 205.236 Origin of livestock.

- (a) Livestock products that are to be sold, labeled, or represented as organic must be from livestock under continuous organic management from the last third of gestation or hatching: Except, That, (1) Poultry. Poultry or edible poultry products must be from poultry that has been under continuous organic management beginning no later than the second day of life;
- (2) <u>Dairy animals</u>. Milk or milk products must be from animals that have been under continuous organic management beginning no later than 1 year prior to the production of the milk or milk products that are to be sold, labeled, or represented as organic, <u>Except</u>,
- (i) That, crops and forage from land, included in the organic system plan of a dairy farm, that is in the third year of organic management may be consumed by the dairy animals of the farm during the 12-month period immediately prior to the sale of organic milk and milk products; and
- (ii) That, when an entire distinct herd is converted to organic production, the producer may, provided no milk produced under this subparagraph enters the stream of commerce labeled as organic after June 9, 2007: (a) For the first 9 months of the year, provide a minimum of 80 percent feed that is either organic or raised from land included in the organic system plan and managed in compliance with organic crop requirements; and (b) Provide feed in compliance with § 205.237 for the final 3 months.
- (iii) Once an entire, distinct herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation.
- (3) <u>Breeder stock</u>. Livestock used as breeder stock may be brought from a nonorganic operation onto an organic operation at any time: <u>Provided</u>, That, if such livestock are gestating and the offspring are to be raised as organic livestock, the breeder stock must be brought onto the facility no later than the last third of gestation.
- (b) The following are prohibited:
- (1) Livestock or edible livestock products that are removed from an organic operation and subsequently managed on a nonorganic operation may be not sold, labeled, or represented as organically produced.
- (2) Breeder or dairy stock that has not been under continuous organic management since the last third of gestation may not be sold, labeled, or represented as organic slaughter stock.
- (c) The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed animals and edible and nonedible animal products produced on the operation.

#### § 205.237 Livestock feed.

- (a) The producer of an organic livestock operation must provide livestock with a total feed ration composed of agricultural products, including pasture and forage, that are organically produced and handled by operations certified to the NOP, except as provided in §205.236(a)(2)(i), Except, That, synthetic substances allowed under § 205.603 and nonsynthetic substances not prohibited under § 205.604 may be used as feed additives and feed supplements, Provided, That, all agricultural ingredients included in the ingredients list, for such additives and supplements, shall have been produced and handled organically.
- (b) The producer of an organic operation must not:
- (1) Use animal drugs, including hormones, to promote growth;
- (2) Provide feed supplements or additives in amounts above those needed for adequate nutrition and health maintenance for the species at its specific stage of life;
- (3) Feed plastic pellets for roughage;
- (4) Feed formulas containing urea or manure;
- (5) Feed mammalian or poultry slaughter by-products to mammals or poultry;
- (6) Use feed, feed additives, and feed supplements in violation of the Federal Food, Drug, and Cosmetic Act;
- (7) Provide feed or forage to which any antibiotic including ionophores has been added; or
- (8) Prevent, withhold, restrain, or otherwise restrict ruminant animals from actively

obtaining feed grazed from pasture during the grazing season, except for conditions as described under § 205.239(b) and (c).

- (c) During the grazing season, producers shall:
- (1) Provide not more than an average of 70 percent of a ruminant's dry matter demand from dry matter fed (dry matter fed does not include dry matter grazed from residual forage or vegetation rooted in pasture). This shall be calculated as an average over the entire grazing season for each type and class of animal. Ruminant animals must be grazed throughout the entire grazing season for the geographical region, which shall be not less than 120 days per calendar year. Due to weather, season, and/or climate, the grazing season may or may not be continuous.
- (2) Provide pasture of a sufficient quality and quantity to graze throughout the grazing season and to provide all ruminants under the organic system plan with an average of not less than 30 percent of their dry matter intake from grazing throughout the grazing season: Except, That,
- (i) Ruminant animals denied pasture in accordance with § 205.239(b)(1) through (8), and
- § 205.239(c)(1) through (3), shall be provided with an average of not less than 30 percent of their dry matter intake from grazing throughout the periods that they are on pasture during the grazing season;
- (ii) Breeding bulls shall be exempt from the 30 percent dry matter intake from grazing requirement of this section and management on pasture requirement of § 205.239(c)(2);

Provided, That, any animal maintained under this exemption shall not be sold, labeled, used, or represented as organic slaughter stock.

- (d) Ruminant livestock producers shall:
- (1) Describe the total feed ration for each type and class of animal. The description must include:
- (i) All feed produced on-farm;
- (ii) All feed purchased from off-farm sources;
- (iii) The percentage of each feed type, including pasture, in the total ration; and
- (iv) A list of all feed supplements and additives.
- (2) Document the amount of each type of feed actually fed to each type and class of animal.
- (3) Document changes that are made to all rations throughout the year in response to seasonal grazing changes.
- (4) Provide the method for calculating dry matter demand and dry matter intake.

#### § 205.238 Livestock health care practice standard.

- (a) The producer must establish and maintain preventive livestock health care practices, including:
- (1) Selection of species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites;
- (2) Provision of a feed ration sufficient to meet nutritional requirements, including vitamins, minerals, protein and/or amino acids, fatty acids, energy sources, and fiber (ruminants);
- (3) Establishment of appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites;
- (4) Provision of conditions which allow for exercise, freedom of movement, and reduction of stress appropriate to the species;
- (5) Performance of physical alterations as needed to promote the animal's welfare and in a manner that minimizes pain and stress; and
- (6) Administration of vaccines and other veterinary biologics.
- (b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, That, such medications are allowed under § 205.603. Parasiticides allowed under § 205.603 may be used on
- (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and

- (2) Dairy stock, when used a minimum of 90 days prior to the production of milk or milk products that are to be sold, labeled, or represented as organic.
- (c) The producer of an organic livestock operation must not:
- (1) Sell, label, or represent as organic any animal or edible product derived from any animal treated with antibiotics, any substance that contains a synthetic substance not allowed under § 205.603, or any substance that contains a nonsynthetic substance prohibited in § 205.604.
- (2) Administer any animal drug, other than vaccinations, in the absence of illness;
- (3) Administer hormones for growth promotion;
- (4) Administer synthetic parasiticides on a routine basis;
- (5) Administer synthetic parasiticides to slaughter stock;
- (6) Administer animal drugs in violation of the Federal Food, Drug, and Cosmetic Act; or
- (7) Withhold medical treatment from a sick animal in an effort to preserve its organic status. All appropriate medications must be used to restore an animal to health when methods acceptable to organic production fail. Livestock treated with a prohibited substance must be clearly identified and shall not be sold, labeled, or represented as organically produced.

#### § 205.239 Livestock living conditions.

- (a) The producer of an organic livestock operation must establish and maintain year round livestock living conditions which accommodate the health and natural behavior of animals, including:
- (1) Year-round access for all animals to the outdoors, shade, shelter, exercise areas, fresh air, clean water for drinking, and direct sunlight, suitable to the species, its stage of life, the climate, and the environment: Except, That, animals may be temporarily denied access to the outdoors in accordance with §§ 205.239(b) and (c). Yards, feeding pads, and feedlots may be used to provide ruminants with access to the outdoors during the non-grazing season and supplemental feeding during the grazing season. Yards, feeding pads, and feedlots shall be large enough to allow all ruminant livestock occupying the yard, feeding pad, or feedlot to feed simultaneously without crowding and without competition for food. Continuous total confinement of any animal indoors is prohibited. Continuous total confinement of ruminants in yards, feeding pads, and feedlots is prohibited.
- (2) For all ruminants, management on pasture and daily grazing throughout the grazing season(s) to meet the requirements of § 205.237, except as provided for in paragraphs (b), (c), and (d) of this section.
- (3) Appropriate clean, dry bedding. When roughages are used as bedding, they shall have been organically produced in accordance with this part by an operation certified under this part, except as provided in § 205.236(a)(2)(i), and, if applicable, organically handled by operations certified to the NOP
- (4) Shelter designed to allow for:
- (i) Natural maintenance, comfort behaviors, and opportunity to exercise;
- (ii) Temperature level, ventilation, and air circulation suitable to the species; and
- (iii) Reduction of potential for livestock injury;
- (5) The use of yards, feeding pads, feedlots and laneways that shall be well-drained, kept in good condition (including frequent removal of wastes), and managed to prevent runoff of wastes and contaminated waters to adjoining or nearby surface water and across property boundaries.
- (b) The producer of an organic livestock operation may provide temporary confinement or shelter for an animal because of:
- (1) Inclement weather;
- (2) The animal's stage of life: Except, That lactation is not a stage of life that would exempt ruminants from any of the mandates set forth in this regulation;
- (3) Conditions under which the health, safety, or wellbeing of the animal could be jeopardized;

- (4) Risk to soil or water quality;
- (5) Preventive healthcare procedures or for the treatment of illness or injury (neither the various life stages nor lactation is an illness or injury);
- (6) Sorting or shipping animals and livestock sales: Provided, That, the animals shall be maintained under continuous organic management, including organic feed, throughout the extent of their allowed confinement:
- (7) Breeding: Except, That, bred animals shall not be denied access to the outdoors and, once bred, ruminants shall not be denied access to pasture during the grazing season; or
- (8) 4-H, Future Farmers of America and other youth projects, for no more than one week prior to a fair or other demonstration, through the event and up to 24 hours after the animals have arrived home at the conclusion of the event. These animals must have been maintained under continuous organic management, including organic feed, during the extent of their allowed confinement for the event.
- (c) The producer of an organic livestock operation may, in addition to the times permitted under § 205.239(b), temporarily deny a ruminant animal pasture or outdoor access under the following conditions:
- (1) One week at the end of a lactation for dry off (for denial of access to pasture only), three weeks prior to parturition (birthing), parturition, and up to one week after parturition;
- (2) In the case of newborn dairy cattle for up to six months, after which they must be on pasture during the grazing season and may no longer be individually housed: Provided, That, an animal shall not be confined or tethered in a way that prevents the animal from lying down, standing up, fully extending its limbs, and moving about freely;
- (3) In the case of fiber bearing animals, for short periods for shearing; and
- (4) In the case of dairy animals, for short periods daily for milking. Milking must be scheduled in a manner to ensure sufficient grazing time to provide each animal with an average of at least 30 percent DMI from grazing throughout the grazing season. Milking frequencies or duration practices cannot be used to deny dairy animals pasture.
- (d) Ruminant slaughter stock, typically grain finished, shall be maintained on pasture for each day that the finishing period corresponds with the grazing season for the geographical location: Except, That, yards, feeding pads, or feedlots may be used to provide finish feeding rations. During the finishing period, ruminant slaughter stock shall be exempt from the minimum 30 percent DMI requirement from grazing. Yards, feeding pads, or feedlots used to provide finish feeding rations shall be large enough to allow all ruminant slaughter stock occupying the yard, feeding pad, or feed lot to feed simultaneously without crowding and without competition for food. The finishing period shall not exceed one fifth (1/5) of the animal's total life or 120 days, whichever is shorter.
- (e) The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients and must manage pastures and other outdoor access areas in a manner that does not put soil or water quality at risk.

# § 205.240 Pasture practice standard.

The producer of an organic livestock operation must, for all ruminant livestock on the operation, demonstrate through auditable records in the organic system plan, a functioning management plan for pasture.

- (a) Pasture must be managed as a crop in full compliance with §§ 205.202, 205.203(d) and (e), 205.204, and 205.206(b) through (f). Land used for the production of annual crops for ruminant grazing must be managed in full compliance with §§ 205.202 through 205.206. Irrigation shall be used, as needed, to promote pasture growth when the operation has irrigation available for use on pasture.
- (b) Producers must provide pasture in compliance with § 205.239(a)(2) and manage pasture to comply with the requirements of: § 205.237(c)(2), to annually provide a minimum of 30 percent of a ruminant's dry matter intake (DMI), on average, over the course of the grazing season(s); § 205.238(a)(3),

to minimize the occurrence and spread of diseases and parasites; and § 205.239(e) to refrain from putting soil or water quality at risk.

- (c) A pasture plan must be included in the producer's organic system plan, and be updated annually in accordance with § 205.406(a). The producer may resubmit the previous year's pasture plan when no change has occurred in the plan. The pasture plan may consist of a pasture/rangeland plan developed in cooperation with a Federal, State, or local conservation office: Provided, That, the submitted plan addresses all of the requirements of § 205.240(c)(1) through (8). When a change to an approved pasture plan is contemplated, which may affect the operation's compliance with the Act or the regulations in this part, the producer shall seek the certifying agent's agreement on the change prior to implementation. The pasture plan shall include a description of the:
- (1) Types of pasture provided to ensure that the feed requirements of § 205.237 are being met
- (2) Cultural and management practices to be used to ensure pasture of a sufficient quality and quantity is available to graze throughout the grazing season and to provide all ruminants under the organic system plan, except exempted classes identified in § 205.239(c)(1) through (3), with an average of not less than 30 percent of their dry matter intake from grazing throughout the grazing season.
- (3) Grazing season for the livestock operation's regional location.
- (4) Location and size of pastures, including maps giving each pasture its own identification.
- (5) The types of grazing methods to be used in the pasture system.
- (6) Location and types of fences, except for temporary fences, and the location and source of shade and the location and source of water.
- (7) Soil fertility and seeding systems.
- (8) Erosion control and protection of natural wetlands and riparian areas practices.

# §§ 205.241 - 205.269 [Reserved]

# § 205.270 Organic handling requirements.

- (a) Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.
- (b) Nonagricultural substances allowed under § 205.605 and nonorganically produced agricultural products allowed under § 205.606 may be used:
- (1) In or on a processed agricultural product intended to be sold, labeled, or represented as "organic," pursuant to § 205.301(b), if not commercially available in organic form.
- (2) In or on a processed agricultural product intended to be sold, labeled, or represented as "made with organic (specified ingredients or food group(s))," pursuant to § 205.301(c).
- (c) The handler of an organic handling operation must not use in or on agricultural products intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or in or on any ingredients labeled as organic:
- (1) Practices prohibited under paragraphs (e) and (f) of § 205.105.
- (2) A volatile synthetic solvent or other synthetic processing aid not allowed under § 205.605, <u>Except</u>, That, nonorganic ingredients in products labeled "made with organic (specified ingredients or food group(s))" are not subject to this requirement.

# § 205.271 Facility pest management practice standard.

- (a) The producer or handler of an organic facility must use management practices to prevent pests, including but not limited to:
- (1) Removal of pest habitat, food sources, and breeding areas;

- (2) Prevention of access to handling facilities; and
- (3) Management of environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction.
- (b) Pests may be controlled through:
- (1) Mechanical or physical controls including but not limited to traps, light, or sound; or
- (2) Lures and repellents using nonsynthetic or synthetic substances consistent with the National List.
- (c) If the practices provided for in paragraphs (a) and (b) of this section are not effective to prevent or control pests, a nonsynthetic or synthetic substance consistent with the National List may be applied.
- (d) If the practices provided for in paragraphs (a), (b), and (c) of this section are not effective to prevent or control facility pests, a synthetic substance not on the National List may be applied, <u>Provided</u>, That, the handler and certifying agent agree on the substance, method of application, and measures to be taken to prevent contact of the organically produced products or ingredients with the substance used.
- (e) The handler of an organic handling operation who applies a nonsynthetic or synthetic substance to prevent or control pests must update the operation's organic handling plan to reflect the use of such substances and methods of application. The updated organic plan must include a list of all measures taken to prevent contact of the organically produced products or ingredients with the substance used.
- (f) Notwithstanding the practices provided for in paragraphs (a), (b), (c), and (d) of this section, a handler may otherwise use substances to prevent or control pests as required by Federal, State, or local laws and regulations, <u>Provided</u>, That, measures are taken to prevent contact of the organically produced products or ingredients with the substance used.

# § 205.272 Commingling and contact with prohibited substance prevention practice standard.

- (a) The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances.
- (b) The following are prohibited for use in the handling of any organically produced agricultural product or ingredient labeled in accordance with subpart D of this part:
- (1) Packaging materials, and storage containers, or bins that contain a synthetic fungicide, preservative, or fumigant;
- (2) The use or reuse of any bag or container that has been in contact with any substance in such a manner as to compromise the organic integrity of any organically produced product or ingredient placed in those containers, unless such reusable bag or container has been thoroughly cleaned and poses no risk of contact of the organically produced product or ingredient with the substance used.

#### §§ 205.273 - 205.289 [Reserved]

# § 205.290 Temporary variances.

- (a) Temporary variances from the requirements in §§ 205.203 through 205.207, 205.236 through 205.240 and 205.270 through 205.272 may be established by the Administrator for the following reasons:
- (1) Natural disasters declared by the Secretary;
- (2) Damage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire, or other business interruption; and
- (3) Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling.
- (b) A State organic program's governing State official or certifying agent may recommend in writing to the Administrator that a temporary variance from a standard set forth in subpart C of this part for organic production or handling operations be established: <u>Provided</u>, That, such variance is based on one or more of the reasons listed in paragraph (a) of this section.

- (c) The Administrator will provide written notification to certifying agents upon establishment of a temporary variance applicable to the certifying agent's certified production or handling operations and specify the period of time it shall remain in effect, subject to extension as the Administrator deems necessary.
- (d) A certifying agent, upon notification from the Administrator of the establishment of a temporary variance, must notify each production or handling operation it certifies to which the temporary variance
- (e) Temporary variances will not be granted for any practice, material, or procedure prohibited under § 205.105.

### §§ 205.291-205.299 [Reserved]

# Subpart D - Labels, Labeling, and Market Information

# § 205.300 Use of the term, "organic."

- (a) The term, "organic," may only be used on labels and in labeling of raw or processed agricultural products, including ingredients, that have been produced and handled in accordance with the regulations in this part. The term, "organic," may not be used in a product name to modify a nonorganic ingredient in the product.
- (b) Products for export, produced and certified to foreign national organic standards or foreign contract buyer requirements, may be labeled in accordance with the organic labeling requirements of the receiving country or contract buyer: Provided, That, the shipping containers and shipping documents meet the labeling requirements specified in § 205.307(c).
- (c) Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part and labeled pursuant to this subpart D.
- (d) Livestock feeds produced in accordance with the requirements of this part must be labeled in accordance with the requirements of § 205.306.

### § 205.301 Product composition.

- (a) Products sold, labeled, or represented as "100 percent organic." A raw or processed agricultural product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) 100 percent organically produced ingredients. If labeled as organically produced, such product must be labeled pursuant to § 205.303.
- (b) Products sold, labeled, or represented as "organic." A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to § 205.303.
- (c) Products sold, labeled, or represented as "made with organic (specified ingredients or food group(s))." Multiingredient agricultural product sold, labeled, or represented as "made with organic (specified ingredients or food group(s))" must contain (by weight or fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (1), (2), and (3) of § 205.301(f). Nonorganic ingredients may be produced without regard to paragraphs (4), (5), (6), and (7) of § 205.301(f). If labeled as containing organically produced ingredients or food groups, such
- product must be labeled pursuant to § 205.304. (d) Products with less than 70 percent organically produced ingredients. The organic ingredients in
- multiingredient agricultural product containing less than 70 percent organically produced ingredients (by weight or fluid volume, excluding water and salt) must be produced and handled pursuant to requirements in subpart C of this part. The nonorganic ingredients may be produced and handled without regard to the

requirements of this part. Multiingredient agricultural product containing less than 70 percent organically produced ingredients may represent the organic nature of the product only as provided in § 205.305.

- (e) Livestock feed:
- (1) A raw or processed livestock feed product sold, labeled, or represented as "100 percent organic" must contain (by weight or fluid volume, excluding water and salt) not less than 100 percent organically produced raw or processed agricultural product.
- (2) A raw or processed livestock feed product sold, labeled, or represented as "organic" must be produced in conformance with § 205.237.
- (f) All products labeled as "100 percent organic" or "organic" and all ingredients identified as "organic" in the ingredient statement of any product must not:
- (1) Be produced using excluded methods, pursuant to § 201.105(e);
- (2) Be produced using sewage sludge, pursuant to § 201.105(f);
- (3) Be processed using ionizing radiation, pursuant to § 201.105(g);
- (4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: <u>Except</u>, That, products labeled as "100 percent organic," if processed, must be processed using organically produced processing aids;
- (5) Contain sulfites, nitrates, or nitrites added during the production or handling process, Except, That, wine containing added sulfites may be labeled "made with organic grapes";
- (6) Be produced using nonorganic ingredients when organic ingredients are available; or
- (7) Include organic and nonorganic forms of the same ingredient.

# § 205.302 Calculating the percentage of organically produced ingredients.

- (a) The percentage of all organically produced ingredients in an agricultural product sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," or that include organic ingredients must be calculated by:
- (1) Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product.
- (2) Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product.
- (3) For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product.
- (b) The percentage of all organically produced ingredients in an agricultural product must be rounded down to the nearest whole number.
- (c) The percentage must be determined by the handler who affixes the label on the consumer package and verified by the certifying agent of the handler. The handler may use information provided by the certified operation in determining the percentage.

# § 205.303 Packaged products labeled "100 percent organic" or "organic."

- (a) Agricultural products in packages described in § 205.301(a) and (b) may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product, the following:
- (1) The term, "100 percent organic" or "organic," as applicable, to modify the name of the product;
- (2) For products labeled "organic," the percentage of organic ingredients in the product; (The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.)

- (3) The term, "organic," to identify the organic ingredients in multiingredient products labeled "100 percent organic";
- (4) The USDA seal; and/or
- (5) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product and any other certifying agent which certified production or handling operations producing raw organic product or organic ingredients used in the finished product: <a href="Provided">Provided</a>, That, the handler producing the finished product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: <a href="Provided further">Provided further</a>, That, such seals or marks are not individually displayed more prominently than the USDA seal.
- (b) Agricultural products in packages described in § 205.301(a) and (b) must:
- (1) For products labeled "organic," identify each organic ingredient in the ingredient statement with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.
- (2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by...," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product and may display the business address, Internet address, or telephone number of the certifying agent in such label.

### § 205.304 Packaged products labeled "made with organic (specified ingredients or food group(s))."

- (a) Agricultural products in packages described in  $\S 205.301(c)$  may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product:
- (1) The statement:
- (i) "Made with organic (specified ingredients)": <u>Provided</u>, That, the statement does not list more than three organically produced ingredients; or
- (ii) "Made with organic (specified food groups)": <u>Provided</u>, That, the statement does not list more than three of the following food groups: beans, fish, fruits, grains, herbs, meats, nuts, oils, poultry, seeds, spices, sweeteners, and vegetables or processed milk products; and, <u>Provided Further</u>, That, all ingredients of each listed food group in the product must be organically produced; and
- (iii) Which appears in letters that do not exceed one-half the size of the largest type size on the panel and which appears in its entirety in the same type size, style, and color without highlighting.
- (2) The percentage of organic ingredients in the product. The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.
- (3) The seal, logo, or other identifying mark of the certifying agent that certified the handler of the finished product.
- (b) Agricultural products in packages described in § 205.301(c) must:
- (1) In the ingredient statement, identify each organic ingredient with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.
- (2) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by...," or similar phrase, identify the name of the certifying agent that certified the handler of the finished product: Except, That, the business address, Internet address, or telephone number of the certifying agent may be included in such label.
- (c) Agricultural products in packages described in § 205.301(c) must not display the USDA seal.

# § 205.305 Multiingredient packaged products with less than 70 percent organically produced ingredients.

(a) An agricultural product with less than 70 percent organically produced ingredients may only identify the organic content of the product by:

- (1) Identifying each organically produced ingredient in the ingredient statement with the word, "organic," or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced, and
- (2) If the organically produced ingredients are identified in the ingredient statement, displaying the product's percentage of organic contents on the information panel.
- (b) Agricultural products with less than 70 percent organically produced ingredients must not display:
- (1) The USDA seal; and
- (2) Any certifying agent seal, logo, or other identifying mark which represents organic certification of a product or product ingredients.

### § 205.306 Labeling of livestock feed.

- (a) Livestock feed products described in § 205.301(e)(1) and (e)(2) may display on any package panel the following terms:
- (1) The statement, "100 percent organic" or "organic," as applicable, to modify the name of the feed product;
- (2) The USDA seal;
- (3) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the raw or processed organic ingredients used in the finished product, <u>Provided.</u> That, such seals or marks are not displayed more prominently than the USDA seal;
- (4) The word, "organic," or an asterisk or other reference mark which is defined on the package to identify ingredients that are organically produced. Water or salt included as ingredients cannot be identified as organic.
- (b) Livestock feed products described in § 205.301(e)(1) and (e)(2) must:
- (i) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, "Certified organic by...," or similar phrase, display the name of the certifying agent that certified the handler of the finished product. The business address, Internet address, or telephone number of the certifying agent may be included in such label.
- (ii) Comply with other Federal agency or State feed labeling requirements as applicable.

# $\S$ 205.307 Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

- (a) Nonretail containers used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:
- (1) The name and contact information of the certifying agent which certified the handler which assembled the final product;
- (2) Identification of the product as organic;
- (3) Special handling instructions needed to maintain the organic integrity of the product;
- (4) The USDA seal;
- (5) The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.
- (b) Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable.
- (c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: Provided, That, the shipping containers and shipping documents accompanying such organic products are clearly marked "For Export Only" and: Provided further, That, proof of such container marking and export must be maintained by the handler in accordance with recordkeeping requirements for exempt and excluded operations under § 205.101.

# § 205.308 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "100 percent organic" or "organic."

- (a) Agricultural products in other than packaged form may use the term, "100 percent organic" or "organic," as applicable, to modify the name of the product in retail display, labeling, and display containers: <u>Provided</u>, That, the term, "organic," is used to identify the organic ingredients listed in the ingredient statement.
- (b) If the product is prepared in a certified facility, the retail display, labeling, and display containers may use:
- (1) The USDA seal; and
- (2) The seal, logo, or other identifying mark of the certifying agent that certified the production or handling operation producing the finished product and any other certifying agent which certified operations producing raw organic product or organic ingredients used in the finished product: <u>Provided</u>, That, such seals or marks are not individually displayed more prominently than the USDA seal.

# § 205.309 Agricultural products in other than packaged form at the point of retail sale that are sold, labeled, or represented as "made with organic (specified ingredients or food group(s))."

- (a) Agricultural products in other than packaged form containing between 70 and 95 percent organically produced ingredients may use the phrase, "made with organic (specified ingredients or food group(s))," to modify the name of the product in retail display, labeling, and display containers.
- (1) Such statement must not list more than three organic ingredients or food groups, and
- (2) In any such display of the product's ingredient statement, the organic ingredients are identified as "organic."
- (b) If prepared in a certified facility, such agricultural products labeled as "made with organic (specified ingredients or food group(s))" in retail displays, display containers, and market information may display the certifying agent's seal, logo, or other identifying mark.

# § 205.310 Agricultural products produced on an exempt or excluded operation.

- (a) An agricultural product organically produced or handled on an exempt or excluded operation must not:
- (1) Display the USDA seal or any certifying agent's seal or other identifying mark which represents the exempt or excluded operation as a certified organic operation, or
- (2) Be represented as a certified organic product or certified organic ingredient to any buyer.
- (b) An agricultural product organically produced or handled on an exempt or excluded operation may be identified as an organic product or organic ingredient in a multiingredient product produced by the exempt or excluded operation. Such product or ingredient must not be identified or represented as "organic" in a product processed by others.
- (c) Such product is subject to requirements specified in paragraph (a) of § 205.300, and paragraphs (f)(1) through (f)(7) of § 205.301.

### § 205.311 USDA Seal.

- (a) The USDA seal described in paragraphs (b) and (c) of this section may be used only for raw or processed agricultural products described in paragraphs (a), (b), (e)(1), and (e)(2) of § 205.301.
- (b) The USDA seal must replicate the form and design of the example in figure 1 and must be printed legibly and conspicuously:
- (1) On a white background with a brown outer circle and with the term, "USDA," in green overlaying a white upper semicircle and with the term, "organic," in white overlaying the green lower half circle; or
- (2) On a white or transparent background with black outer circle and black "USDA" on a white or transparent upper half of the circle with a contrasting white or transparent "organic" on the black lower half circle.
- (3) The green or black lower half circle may have four light lines running from left to right and disappearing at the point on the right horizon to resemble a cultivated field.

# §§ 205.312-205.399 [Reserved]

# **Subpart E - Certification**

# § 205.400 General requirements for certification.

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

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

# § 205.401 Application for Certification.

A person seeking certification of a production or handling operation under this subpart must submit an application for certification to a certifying agent. The application must include the following information:

- (a) An organic production or handling system plan, as required in § 205.200;
- (b) 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;
- (c) The name(s) of any organic certifying agent(s) to which application has previously been made; the year(s) of application; the outcome of the application(s) submission, including, when available, a copy of any notification of noncompliance or denial of certification issued to the applicant for certification; and a description of the actions taken by the applicant to correct the noncompliances noted in the notification of noncompliance, including evidence of such correction; and
- (d) Other information necessary to determine compliance with the Act and the regulations in this part.

### § 205.402 Review of application.

- (a) Upon acceptance of an application for certification, a certifying agent must:
- (1) Review the application to ensure completeness pursuant to § 205.401;
- (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;
- (3) Verify that an applicant who previously applied to another certifying agent and received a notification of noncompliance or denial of certification, pursuant to § 205.405, has submitted documentation to support the correction of any noncompliances identified in the notification of noncompliance or denial of certification, as required in § 205.405(e); and
- (4) Schedule an on-site inspection of the operation to determine whether the applicant qualifies for certification if the review of application materials reveals that the production or handling operation may be in compliance with the applicable requirements of subpart C of this part.
- (b) The certifying agent shall within a reasonable time: (1) Review the application materials received and communicate its findings to the applicant;
- (2) 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

- (3) Provide the applicant with a copy of the test results for any samples taken by an inspector.
- (c) The applicant may withdraw its application at any time. An applicant who withdraws its application shall be liable for the costs of services provided up to the time of withdrawal of its application. An applicant that voluntarily withdrew its application prior to the issuance of a notice of noncompliance will not be issued a notice of noncompliance. Similarly, an applicant that voluntarily withdrew its application prior to the issuance of a notice of certification denial will not be issued a notice of certification denial.

# § 205.403 On-site inspections.

- (a) <u>On-site inspections</u>. (1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.
- (2) (i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.
- (ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.
- (iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.
- (b) <u>Scheduling</u>. (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: <u>Except</u>, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.
- (2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.
- (c) Verification of information. The on-site inspection of an operation must verify:
- (1) The operation's compliance or capability to comply with the Act and the regulations in this part;
- (2) That the information, including the organic production or handling system plan, provided in accordance with §§ 205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;
- (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.
- (d) Exit interview. The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.
- (e) <u>Documents to the inspected operation</u>. (1) At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.
- (2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.

#### § 205.404 Granting certification.

(a) Within a reasonable time after completion of the initial on-site inspection, a certifying agent must 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. If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall grant certification. The certification may include requirements for the correction of minor noncompliances within a specified time period as a condition of continued certification.

- (b) The certifying agent must issue a certificate of organic operation which specifies the:
- (1) Name and address of the certified operation;
- (2) Effective date of certification;
- (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and
- (4) Name, address, and telephone number of the certifying agent.
- (c) 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 State organic program's governing State official, or the Administrator.

#### § 205.405 Denial of certification.

- (a) When the certifying agent has reason to believe, based on a review of the information specified in § 205.402 or § 205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification. The notification of noncompliance shall provide:
- (1) A description of each noncompliance;
- (2) The facts upon which the notification of noncompliance is based; and
- (3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.
- (b) Upon receipt of such notification of noncompliance, the applicant may:
- (1) Correct noncompliances and submit a description of the corrective actions taken with supporting documentation to the certifying agent;
- (2) Correct noncompliances and submit a new application to another certifying agent: <u>Provided</u>, That, the applicant must include a complete application, the notification of noncompliance received from the first certifying agent, and a description of the corrective actions taken with supporting documentation; or
- (3) Submit written information to the issuing certifying agent to rebut the noncompliance described in the notification of noncompliance.
- (c) After issuance of a notification of noncompliance, the certifying agent must:
- (1) Evaluate the applicant's corrective actions taken and supporting documentation submitted or the written rebuttal, conduct an on-site inspection if necessary, and
- (i) When the corrective action or rebuttal is sufficient for the applicant to qualify for certification, issue the applicant an approval of certification pursuant to § 205.404; or
- (ii) When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.
- (2) Issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.
- (3) Provide notice of approval or denial to the Administrator, pursuant to § 205.501(a)(14).
- (d) A notice of denial of certification must state the reason(s) for denial and the applicant's right to:
- (1) Reapply for certification pursuant to §§ 205.401 and 205.405(e);
- (2) Request mediation pursuant to § 205.663 or, if applicable, pursuant to a State organic program; or
- (3) File an appeal of the denial of certification pursuant to § 205.681 or, if applicable, pursuant to a State organic program.

- (e) An applicant for certification who has received a written notification of noncompliance or a written notice of denial of certification may apply for certification again at any time with any certifying agent, in accordance with §§ 205.401 and 205.405(e). When such applicant submits a new application to a certifying agent other than the agent who issued the notification of noncompliance or notice of denial of certification, the applicant for certification must include a copy of the notification of noncompliance or notice of denial of certification and a description of the actions taken, with supporting documentation, to correct the noncompliances noted in the notification of noncompliance.
- (f) A certifying agent who receives a new application for certification, which includes a notification of noncompliance or a notice of denial of certification, must treat the application as a new application and begin a new application process pursuant to § 205.402.
- (g) Notwithstanding paragraph (a) of this section, if a certifying agent has reason to believe that an applicant for certification has willfully made a false statement or otherwise purposefully misrepresented the applicant's operation or its compliance with the certification requirements pursuant to this part, the certifying agent may deny certification pursuant to paragraph (c)(1)(ii) of this section without first issuing a notification of noncompliance.

#### § 205.406 Continuation of certification.

- (a) To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent:
- (1) An updated organic production or handling system plan which includes:
- (i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and
- (ii) Any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to § 205.200;
- (2) Any additions to or deletions from the information required pursuant to § 205.401(b);
- (3) An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and
- (4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.
- (b) Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to § 205.403: Except, 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: Provided, That, the annual on-site inspection, required pursuant to § 205.403, is conducted within the first 6 months following the certified operation's scheduled date of annual update.
- (c) If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in § 205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with § 205.662.
- (d) If the certifying agent determines that the certified operation is complying with the Act and the regulations in this part and that any of the information specified on the certificate of organic operation has changed, the certifying agent must issue an updated certificate of organic operation pursuant to § 205.404(b).

### §§ 205.407-205.499 [Reserved]

# Subpart F - Accreditation of Certifying Agents

### § 205.500 Areas and duration of accreditation.

- (a) The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.
- (b) Accreditation shall be for a period of 5 years from the date of approval of accreditation pursuant to § 205.506.
- (c) In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if:
- (1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or
- (2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.

# § 205.501 General requirements for accreditation.

- (a) A private or governmental entity accredited as a certifying agent under this subpart must:
- (1) Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part;
- (2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart;
- (3) Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and § 205.670;
- (4) Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;
- (5) Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.
- (6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;
- (7) Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation;
- (8) Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;
- (9) Maintain all records pursuant to § 205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State organic program's governing State official;
- (10) Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in § 205.504(b)(5);
- (11) Prevent conflicts of interest by: (i) Not certifying a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;

- (ii) Excluding any person, including contractors, with conflicts of interest from work, discussions, and decisions in all stages of the certification process and the monitoring of certified production or handling operations for all entities in which such person has or has held a commercial interest, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification;
- (iii) Not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected, <u>Except</u>, That, a certifying agent that is a not-for-profit organization with an Internal Revenue Code tax exemption or, in the case of a foreign certifying agent, a comparable recognition of not-for-profit status from its government, may accept voluntary labor from certified operations;
- (iv) Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification;
- (v) Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report; and
- (vi) Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.
- (12) (i) Reconsider a certified operation's application for certification and, if necessary, perform a new onsite inspection when it is determined, within 12 months of certifying the operation, that any person participating in the certification process and covered under § 205.501(a)(11)(ii) has or had a conflict of interest involving the applicant. All costs associated with a reconsideration of application, including onsite inspection costs, shall be borne by the certifying agent.
- (ii) Refer a certified operation to a different accredited certifying agent for recertification and reimburse the operation for the cost of the recertification when it is determined that any person covered under § 205.501(a)(11)(i) at the time of certification of the applicant had a conflict of interest involving the applicant.
- (13) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to § 205.500;
- (14) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;
- (15) Submit to the Administrator a copy of: (i) Any notice of denial of certification issued pursuant to § 205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to § 205.662 simultaneously with its issuance and
- (ii) A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year;
- (16) Charge applicants for certification and certified production and handling operations only those fees and charges for certification activities that it has filed with the Administrator;
- (17) Pay and submit fees to AMS in accordance with § 205.640;
- (18) Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor noncompliances;
- (19) Accept all production or 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 without regard to size or membership in any association or group; and
- (20) Demonstrate its ability to comply with a State's organic program to certify organic production or handling operations within the State.
- (21) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.

- (b) A private or governmental entity accredited as a certifying agent under this subpart may establish a seal, logo, or other identifying mark to be used by production and handling operations certified by the certifying agent to indicate affiliation with the certifying agent: <u>Provided</u>, That, the certifying agent:
- (1) Does not require use of its seal, logo, or other identifying mark on any product sold, labeled, or represented as organically produced as a condition of certification and
- (2) Does not require compliance with any production or handling practices other than those provided for in the Act and the regulations in this part as a condition of use of its identifying mark: <u>Provided</u>, That, certifying agents certifying production or handling operations within a State with more restrictive requirements, approved by the Secretary, shall require compliance with such requirements as a condition of use of their identifying mark by such operations.
- (c) A private entity accredited as a certifying agent must: (1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;
- (2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and
- (3) Transfer to the Administrator and make available to any applicable State organic program's governing State official all records or copies of records concerning the person's certification activities in the event that the certifying agent dissolves or loses its accreditation; <u>Provided</u>, That, such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.
- (d) No private or governmental entity accredited as a certifying agent under this subpart shall exclude from participation in or deny the benefits of the National Organic Program to any person due to discrimination because of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, or marital or family status.

#### § 205.502 Applying for accreditation.

- (a) A private or governmental entity seeking accreditation as a certifying agent under this subpart must submit an application for accreditation which contains the applicable information and documents set forth in §§ 205.503 through 205.505 and the fees required in § 205.640 to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, PO Box 96456, Washington, DC 20090-6456.
- (b) Following the receipt of the information and documents, the Administrator will determine, pursuant to § 205.506, whether the applicant for accreditation should be accredited as a certifying agent.

#### § 205.503 Applicant information.

A private or governmental entity seeking accreditation as a certifying agent must submit the following information:

- (a) The business name, primary office location, mailing address, name of the person(s) responsible for the certifying agent's day-to-day operations, contact numbers (telephone, facsimile, and Internet address) of the applicant, and, for an applicant who is a private person, the entity's taxpayer identification number;
- (b) The name, office location, mailing address, and contact numbers (telephone, facsimile, and Internet address) for each of its organizational units, such as chapters or subsidiary offices, and the name of a contact person for each unit;
- (c) Each area of operation (crops, wild crops, livestock, or handling) for which accreditation is requested and the estimated number of each type of operation anticipated to be certified annually by the applicant along with a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant;
- (d) The type of entity the applicant is (e.g., government agricultural office, for-profit business, not-for-profit membership association) and for:
- (1) A governmental entity, a copy of the official's authority to conduct certification activities under the Act and the regulations in this part,
- (2) A private entity, documentation showing the entity's status and organizational purpose, such as articles of incorporation and by-laws or ownership or membership provisions, and its date of establishment; and

(e) A list of each State or foreign country in which the applicant currently certifies production and handling operations and a list of each State or foreign country in which the applicant intends to certify production or handling operations.

## § 205.504 Evidence of expertise and ability.

A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§ 205.100 and 205.101, §§ 205.201 through 205.203, §§ 205.300 through 205.303, §§ 205.400 through 205.406, and §§ 205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in § 205.501: (a) Personnel. (1) A copy of the applicant's policies and procedures for training, evaluating, and supervising

- personnel; (2) The name and position description of all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent;
- (3) A description of the qualifications, including experience, training, and education in agriculture, organic production, and organic handling, for:
- (i) Each inspector to be used by the applicant and
- (ii) Each person to be designated by the applicant to review or evaluate applications for certification; and
- (4) A description of any training that the applicant has provided or intends to provide to personnel to ensure that they comply with and implement the requirements of the Act and the regulations in this part.
- (b) <u>Administrative policies and procedures</u>. (1) A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates;
- (2) A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part and the reporting of violations of the Act and the regulations in this part to the Administrator;
- (3) A copy of the procedures to be used for complying with the recordkeeping requirements set forth in § 205.501(a)(9);
- (4) A copy of the procedures to be used for maintaining the confidentiality of any business-related information as set forth in § 205.501(a)(10);
- (5) A copy of the procedures to be used, including any fees to be assessed, for making the following information available to any member of the public upon request:
- (i) Certification certificates issued during the current and 3 preceding calendar years;
- (ii) A list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calendar years;
- (iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years; and
- (iv) Other business information as permitted in writing by the producer or handler; and
- (6) A copy of the procedures to be used for sampling and residue testing pursuant to  $\S~205.670$ .
- (c) <u>Conflicts of interest.</u> (1) A copy of procedures intended to be implemented to prevent the occurrence of conflicts of interest, as described in § 205.501(a)(11).
- (2) For all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent, a conflict of interest disclosure report, identifying any food- or agriculture-related business interests, including business interests of immediate family members, that cause a conflict of interest.
- (d) <u>Current certification activities</u>. An applicant who currently certifies production or handling operations must submit: (1) A list of all production and handling operations currently certified by the applicant;

- (2) Copies of at least 3 different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested; and
- (3) The results of any accreditation process of the applicant's operation by an accrediting body during the previous year for the purpose of evaluating its certification activities.
- (e) <u>Other information</u>. Any other information the applicant believes may assist in the Administrator's evaluation of the applicant's expertise and ability.

#### § 205.505 Statement of agreement.

- (a) A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including:
- (1) Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to section 205.500;
- (2) Refrain from making false or misleading claims about its accreditation status, the USDA accreditation program for certifying agents, or the nature or qualities of products labeled as organically produced;
- (3) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;
- (4) Have an annual internal program review conducted of its certification activities by certifying agent staff, an outside auditor, or a consultant who has the expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part;
- (5) Pay and submit fees to AMS in accordance with § 205.640; and
- (6) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.
- (b) A private entity seeking accreditation as a certifying agent under this subpart must additionally agree to:
- (1) Hold the Secretary harmless for any failure on the part of the certifying agent to carry out the provisions of the Act and the regulations in this part;
- (2) Furnish reasonable security, in an amount and according to such terms as the Administrator may by regulation prescribe, for the purpose of protecting the rights of production and handling operations certified by such certifying agent under the Act and the regulations in this part; and
- (3) Transfer to the Administrator and make available to the applicable State organic program's governing State official all records or copies of records concerning the certifying agent's certification activities in the event that the certifying agent dissolves or loses its accreditation; <u>Provided</u>, That such transfer shall not apply to a merger, sale, or other transfer of ownership of a certifying agent.

#### § 205.506 Granting accreditation.

- (a) Accreditation will be granted when: (1) The accreditation applicant has submitted the information required by §§ 205.503 through 205.505;
- (2) The accreditation applicant pays the required fee in accordance with § 205.640(c); and
- (3) The Administrator determines that the applicant for accreditation meets the requirements for accreditation as stated in § 205.501, as determined by a review of the information submitted in accordance with §§ 205.503 through 205.505 and, if necessary, a review of the information obtained from a site evaluation as provided for in § 205.508.
- (b) On making a determination to approve an application for accreditation, the Administrator will notify the applicant of the granting of accreditation in writing, stating:
- (1) The area(s) for which accreditation is given;
- (2) The effective date of the accreditation;
- (3) Any terms and conditions for the correction of minor noncompliances; and

- (4) For a certifying agent who is a private entity, the amount and type of security that must be established to protect the rights of production and handling operations certified by such certifying agent.
- (c) The accreditation of a certifying agent shall continue in effect until such time as the certifying agent fails to renew accreditation as provided in § 205.510(c), the certifying agent voluntarily ceases its certification activities, or accreditation is suspended or revoked pursuant to § 205.665.

#### § 205.507 Denial of accreditation.

- (a) If the Program Manager has reason to believe, based on a review of the information specified in §§ 205.503 through 205.505 or after a site evaluation as specified in § 205.508, that an applicant for accreditation is not able to comply or is not in compliance with the requirements of the Act and the regulations in this part, the Program Manager shall provide a written notification of noncompliance to the applicant. Such notification shall provide:
- (1) A description of each noncompliance;
- (2) The facts upon which the notification of noncompliance is based; and
- (3) The date by which the applicant must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.
- (b) When each noncompliance has been resolved, the Program Manager will send the applicant a written notification of noncompliance resolution and proceed with further processing of the application.
- (c) If an applicant fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, fails to file a rebuttal of the notification of noncompliance by the date specified, or is unsuccessful in its rebuttal, the Program Manager will provide the applicant with written notification of accreditation denial. An applicant who has received written notification of accreditation denial may apply for accreditation again at any time in accordance with § 205.502, or appeal the denial of accreditation in accordance with § 205.681 by the date specified in the notification of accreditation denial. (d) If the certifying agent was accredited prior to the site evaluation and the certifying agent fails to correct the noncompliances, fails to report the corrections by the date specified in the notification of noncompliance, or fails to file a rebuttal of the notification of noncompliance by the date specified, the Administrator will begin proceedings to suspend or revoke the certifying agent's accreditation. A certifying agent who has had its accreditation 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 the regulations in this part. A certifying agent whose accreditation is revoked will be ineligible for accreditation for a period of not less than 3 years following the date of such determination.

#### § 205.508 Site evaluations.

(a) Site evaluations of accredited certifying agents shall be conducted for the purpose of examining the certifying agent's operations and evaluating its compliance with the Act and the regulations of this part. Site evaluations shall include an on-site review of the certifying agent's certification procedures, decisions, facilities, administrative and management systems, and production or handling operations certified by the certifying agent. Site evaluations shall be conducted by a representative(s) of the Administrator.

(b) An initial site evaluation of an accreditation applicant shall be conducted before or within a reasonable period of time after issuance of the applicant's "notification of accreditation." A site evaluation shall be conducted after application for renewal of accreditation but prior to the issuance of a notice of renewal of accreditation. One or more site evaluations will be conducted during the period of accreditation to determine whether an accredited certifying agent is complying with the general requirements set forth in § 205.501.

### § 205.509 Peer review panel.

The Administrator shall establish a peer review panel pursuant to the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 et seq.). The peer review panel shall be composed of not less than 3 members who shall annually evaluate the National Organic Program's adherence to the accreditation procedures in subpart

F of these regulations and ISO/IEC Guide 61, General requirements for assessment and accreditation of certification/registration bodies, and the National Organic Program's accreditation decisions. This shall be accomplished through the review of accreditation procedures, document review and site evaluation reports, and accreditation decision documents or documentation. The peer review panel shall report its finding, in writing, to the National Organic Program's Program Manager.

#### § 205.510 Annual report, recordkeeping, and renewal of accreditation.

- (a) <u>Annual report and fees</u>. An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees:
- (1) A complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504;
- (2) Information supporting any changes being requested in the areas of accreditation described in § 205.500;
- (3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation;
- (4) The results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and
- (5) The fees required in § 205.640(a).
- (b) Recordkeeping. Certifying agents must maintain records according to the following schedule:
- (1) Records obtained from applicants for certification and certified operations must be maintained for not less than 5 years beyond their receipt;
- (2) Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation; and
- (3) Records created or received by the certifying agent pursuant to the accreditation requirements of this subpart F, excluding any records covered by §§ 205.510(b)(2), must be maintained for not less than 5 years beyond their creation or receipt.
- (c) <u>Renewal of accreditation</u>. (1) The Administrator shall send the accredited certifying agent a notice of pending expiration of accreditation approximately 1 year prior to the scheduled date of expiration.
- (2) An accredited certifying agent's application for accreditation renewal must be received at least 6 months prior to the fifth anniversary of issuance of the notification of accreditation and each subsequent renewal of accreditation. The accreditation of certifying agents who make timely application for renewal of accreditation will not expire during the renewal process. The accreditation of certifying agents who fail to make timely application for renewal of accreditation will expire as scheduled unless renewed prior to the scheduled expiration date. Certifying agents with an expired accreditation must not perform certification activities under the Act and these regulations.
- (3) Following receipt of the information submitted by the certifying agent in accordance with paragraph (a) of this section and the results of a site evaluation, the Administrator will determine whether the certifying agent remains in compliance with the Act and the regulations of this part and should have its accreditation renewed.
- (d) <u>Notice of renewal of accreditation</u>. Upon a determination that the certifying agent is in compliance with the Act and the regulations of this part, the Administrator will issue a notice of renewal of accreditation. The notice of renewal will specify any terms and conditions that must be addressed by the certifying agent and the time within which those terms and conditions must be satisfied.
- (e) <u>Noncompliance</u>. Upon a determination that the certifying agent is not in compliance with the Act and the regulations of this part, the Administrator will initiate proceedings to suspend or revoke the certifying agent's accreditation.
- (f) <u>Amending accreditation</u>. Amendment to scope of an accreditation may be requested at any time. The application for amendment shall be sent to the Administrator and shall contain information applicable to the requested change in accreditation, a complete and accurate update of the information submitted pursuant to §§ 205.503 and 205.504, and the applicable fees required in § 205.640.

## **Subpart G - Administrative**

The National List of Allowed and Prohibited Substances – This information is current as of 2/20/14. The National List is updated several times a year. Check the NOP website for the current version of the National List – 205.600-205.607.

#### § 205.600 Evaluation criteria for allowed and prohibited substances, methods, and ingredients.

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

- (a) Synthetic and nonsynthetic substances considered for inclusion on or deletion from the National List of allowed and prohibited substances will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).
- (b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:
- (1) The substance cannot be produced from a natural source and there are no organic substitutes;
- (2) The substance's manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;
- (3) The nutritional quality of the food is maintained when the substance is used, and the substance, itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;
- (4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;
- (5) The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and
- (6) The substance is essential for the handling of organically produced agricultural products.
- (c) Nonsynthetics used in organic processing will be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

# § 205.601 Synthetic substances allowed for use in organic crop production.

In accordance with restrictions specified in this section, the following synthetic substances may be used in organic crop production: Provided, That, use of such substances do not contribute to contamination of crops, soil, or water. Substances allowed by this section, except disinfectants and sanitizers in paragraph (a) and those substances in paragraphs (c), (j), (k), and (l) of this section, may only be used when the provisions set forth in §205.206(a) through (d) prove insufficient to prevent or control the target pest.

- (a) As algicide, disinfectants, and sanitizer, including irrigation system cleaning systems.
- (1) Alcohols.

- (i) Ethanol.
- (ii) Isopropanol.
- (2) Chlorine materials— For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act, except that chlorine products may be used in edible sprout production according to EPA label directions.
- (i) Calcium hypochlorite.
- (ii) Chlorine dioxide.
- (iii) Sodium hypochlorite.
- (3) Copper sulfate—for use as an algicide in aquatic rice systems, is limited to one application per field during any 24-month period. Application rates are limited to those which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.
- (4) Hydrogen peroxide.
- (5) Ozone gas—for use as an irrigation system cleaner only.
- (6) Peracetic acid— for use in disinfecting equipment, seed, and asexually propagated planting material. Also permitted in hydrogen peroxide formulations as allowed in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label.
- (7) Soap-based algicide/demossers.
- (8) Sodium carbonate peroxyhydrate (CAS#-15630-89-4)-Federal law restricts the use of this substance in food crop production to approved food uses identified on the product label.
- (b) As herbicides, weed barriers, as applicable.
- (1) Herbicides, soap-based—for use in farmstead maintenance (roadways, ditches, right of ways, building perimeters) and ornamental crops.
- (2) Mulches.
- (i) Newspaper or other recycled paper, without glossy or colored inks.
- (ii) Plastic mulch and covers (petroleum-based other than polyvinyl chloride (PVC)).
- (iii) Biodegradable biobased mulch film as defined in §205.2. Must be produced without organisms or feedstock derived from excluded methods.
- (c) As compost feedstocks—Newspapers or other recycled paper, without glossy or colored inks.
- (d) As animal repellents—Soaps, ammonium—for use as a large animal repellant only, no contact with soil or edible portion of crop.
- (e) As insecticides (including acaricides or mite control).
- (1) Ammonium carbonate—for use as bait in insect traps only, no direct contact with crop or soil.
- (2) Aqueous potassium silicate (CAS#-1312-76-1)-the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
- (3) Boric acid—structural pest control, no direct contact with organic food or crops.
- (4) Copper sulfate—for use as tadpole shrimp control in aquatic rice production, is limited to one application per field during any 24-month period. Application rates are limited to levels which do not increase baseline soil test values for copper over a timeframe agreed upon by the producer and accredited certifying agent.

- (5) Elemental sulfur.
- (6) Lime sulfur—including calcium polysulfide.
- (7) Oils, horticultural—narrow range oils as dormant, suffocating, and summer oils.
- (8) Soaps, insecticidal.
- (9) Sticky traps/barriers.
- (10) Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4)—in accordance with approved labeling.
- (f) As insect management. Pheromones.
- (g) As rodenticides. Vitamin D3.
- (h) As slug or snail bait. Ferric phosphate (CAS # 10045–86–0).
- (i) As plant disease control.
- (1) Aqueous potassium silicate (CAS#-1312-76-1)-the silica, used in the manufacture of potassium silicate, must be sourced from naturally occurring sand.
- (2) Coppers, fixed—copper hydroxide, copper oxide, copper oxychloride, includes products exempted from EPA tolerance, Provided, That, copper-based materials must be used in a manner that minimizes accumulation in the soil and shall not be used as herbicides.
- (3) Copper sulfate—Substance must be used in a manner that minimizes accumulation of copper in the soil.
- (4) Hydrated lime.
- (5) Hydrogen peroxide.
- (6) Lime sulfur.
- (7) Oils, horticultural, narrow range oils as dormant, suffocating, and summer oils.
- (8) Peracetic acid— for use to control fire blight bacteria. Also permitted in hydrogen peroxide formulations as allowed in §205.601(i) at concentration of no more than 6% as indicated on the pesticide product label.
- (9) Potassium bicarbonate.
- (10) Elemental sulfur.
- (i) As plant or soil amendments.
- (1) Aquatic plant extracts (other than hydrolyzed)—Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount used is limited to that amount necessary for extraction.
- (2) Elemental sulfur.

- (3) Humic acids—naturally occurring deposits, water and alkali extracts only.
- (4) Lignin sulfonate—chelating agent, dust suppressant.
- (5) Magnesium sulfate—allowed with a documented soil deficiency.
- (6) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil deficiency must be documented by testing.
- (i) Soluble boron products.
- (ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.
- (7) Liquid fish products—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.
- (8) Vitamins, B1, C, and E.
- (9) Sulfurous acid (CAS#7782-99-2) for on farm generation of substances utilizing 99% purity elemental sulfur per paragraph (j)(2) of this section.
- (k) As plant growth regulators. Ethylene gas—for regulation of pineapple flowering.
- (l) As floating agents in postharvest handling.
- (1) Lignin sulfonate.
- (m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
- (1) EPA List 4—Inerts of Minimal Concern.
- (2) EPA List 3—Inerts of Unknown Toxicity for use in passive pheromone dispensers.
- (n) Seed preparations. Hydrogen chloride (CAS # 7647–01–0)—for delinting cotton seed for planting.
- (o) As production aids: Microcrystalline cheesewax (CAS#s 64742–42–3, 8009–03–08, and 8002–74–2) for use in log grown mushroom production. Must be made without either ethylene-propylene co-polymer or synthetic colors.
- (p)–(z) [Reserved]

### § 205.602 Nonsynthetic substances prohibited for use in organic crop production.

The following nonsynthetic substances may not be used in organic crop production:

- (a) Ash from manure burning.
- (b) Arsenic.

- (c) Calcium chloride, brine process is natural and prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.
- (d) Lead salts.
- (e) Potassium chloride—unless derived from a mined source and applied in a manner that minimizes chloride accumulation in the soil.
- (f) Sodium fluoaluminate (mined).
- (g) Sodium nitrate—unless use is restricted to no more than 20% of the crop's total nitrogen requirement; use in spirulina production is unrestricted until October 21, 2005.
- (h) Strychnine.
- (i) Tobacco dust (nicotine sulfate).
- (j)–(z) [Reserved] [68 FR 61992, Oct. 31, 2003]

## § 205.603 Synthetic substances allowed for use in organic livestock production.

In accordance with restrictions specified in this section the following synthetic substances may be used in organic livestock production:

- (a) As disinfectants, sanitizer, and medical treatments as applicable.
- (1) Alcohols.
- (i) Ethanol-disinfectant and sanitizer only, prohibited as a feed additive.
- (ii) Isopropanol-disinfectant only.
- (2) Aspirin-approved for health care use to reduce inflammation.
- (3) Atropine (CAS #-51-55-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR Part 205, the NOP requires:
- (i) Use by or on the lawful written order of a licensed veterinarian; and
- (ii) A meat withdrawal period of at least 56 days after administering to livestock intended for slaughter; and a milk discard period of at least 12 days after administering to dairy animals.
- (4) Biologics—Vaccines.
- (5) Butorphanol (CAS #-42408-82-2)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR Part 205, the NOP requires:
- (i) Use by or on the lawful written order of a licensed veterinarian; and
- (ii) A meat withdrawal period of at least 42 days after administering to livestock intended for slaughter; and a milk discard period of at least 8 days after administering to dairy animals.
- (6) Chlorhexidine—Allowed for surgical procedures conducted by a veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
- (7) Chlorine materials—disinfecting and sanitizing facilities and equipment. Residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act.
- (i) Calcium hypochlorite.
- (ii) Chlorine dioxide.

- (iii) Sodium hypochlorite.
- (8) Electrolytes—without antibiotics.
- (9) Flunixin (CAS #-38677-85-9)—in accordance with approved labeling; except that for use under 7 CFR Part 205, the NOP requires a withdrawal period of at least two-times that required by the FDA.
- (10) Glucose.
- (11) Glycerine—Allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.
- (12) Hydrogen peroxide.
- (13) Iodine.
- (14) Magnesium hydroxide (CAS #-1309-42-8)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires use by or on the lawful written order of a licensed veterinarian.
- (15) Magnesium sulfate.
- (16) Oxytocin—use in postparturition therapeutic applications.
- (17) Paraciticides. Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock.
  - (i) Fenbendazole (CAS #43210-67-9)—only for use by or on the lawful written order of a licensed veterinarian.
  - (ii) Ivermectin (CAS #70288-86-7).
  - (iii) Moxidectin (CAS #113507-06-5)—for control of internal parasites only.
- (18) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.
- (19) Phosphoric acid—allowed as an equipment cleaner, Provided , That, no direct contact with organically managed livestock or land occurs.
- (20) Poloxalene (CAS #-9003-11-6)—for use under 7 CFR Part 205, the NOP requires that poloxalene only be used for the emergency treatment of bloat.
- (21) Tolazoline (CAS #-59-98-3)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR Part 205, the NOP requires:
- (i) Use by or on the lawful written order of a licensed veterinarian;
- (ii) Use only to reverse the effects of sedation and analgesia caused by Xylazine; and
- (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.
- (22) Xylazine (CAS #-7361-61-7)—federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR Part 205, the NOP requires:

- (i) Use by or on the lawful written order of a licensed veterinarian;
- (ii) The existence of an emergency; and
- (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.
- (b) As topical treatment, external parasiticide or local anesthetic as applicable.
- (1) Copper sulfate.
- (2) Formic acid (CAS # 64-18-6)—for use as a pesticide solely within honeybee hives.
- (3) Iodine.
- (4) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.
- (5) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.
- (6) Mineral oil—for topical use and as a lubricant.
- (7) Procaine—as a local anesthetic, use requires a withdrawal period of 90 days after administering to livestock intended for slaughter and 7 days after administering to dairy animals.
- (8) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling.
- (c) As feed supplements—None.
- (d) As feed additives.
- (1) DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following maximum levels of synthetic methionine per ton of feed: Laying and broiler chickens—2 pounds; turkeys and all other poultry—3 pounds.
- (2) Trace minerals, used for enrichment or fortification when FDA approved.
- (3) Vitamins, used for enrichment or fortification when FDA approved.
- (e) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
- (1) EPA List 4—Inerts of Minimal Concern.
- (2) [Reserved]
- (f) Excipients, only for use in the manufacture of drugs used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application.

(g)–(z) [Reserved]

## § 205.604 Nonsynthetic substances prohibited for use in organic livestock production.

The following nonsynthetic substances may not be used in organic livestock production:

- (a) Strychnine.
- (b)–(z) [Reserved]

# § 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

The following nonagricultural substances may be used as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" only in accordance with any restrictions specified in this section.

(a) Nonsynthetics allowed:

Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).

Agar-agar.

Animal enzymes—(Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).

Attapulgite—as a processing aid in the handling of plant and animal oils

Bentonite.

Calcium carbonate.

Calcium chloride.

Calcium sulfate—mined.

Carageenan.

Dairy cultures.

Diatomaceous earth—food filtering aid only.

Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Gellan Gum (CAS#71010-52-1)-high acyl form only.

Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.

Kaolin.

L-Malic acid (CAS # 97–67–6).

Magnesium sulfate, nonsynthetic sources only.

| Microorganisms—any food grade bacteria, fungi, and other microorganism.   |
|---|
| Nitrogen—oil-free grades.   |
| Oxygen—oil-free grades.   |
| Perlite—for use only as a filter aid in food processing.  |
| Potassium chloride.   |
| Potassium iodide.   |
| Sodium bicarbonate.   |
| Sodium carbonate.   |
| Tartaric acid – made from grape wine.   |
| Waxes—nonsynthetic (Carnauba wax; and Wood resin).  |
| Yeast— When used as food or a fermentation agent in products labeled as "organic," yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented. |
| (b) Synthetics allowed:   |
| Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.  |
| Activated charcoal (CAS #s 7440–44–0; 64365–11–3)—only from vegetative sources; for use only as a filtering aid.  |
| Alginates.  |
| Ammonium bicarbonate—for use only as a leavening agent.   |
| Ammonium carbonate—for use only as a leavening agent.   |
| Ascorbic acid.  |
| Calcium citrate.  |
| Calcium hydroxide.  |
| Calcium phosphates (monobasic, dibasic, and tribasic).  |
| Carbon dioxide.   |
| Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.   |

Chlorine materials—disinfecting and sanitizing food contact surfaces, Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.

Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).

Glycerides (mono and di)—for use only in drum drying of food.

Glycerin—produced by hydrolysis of fats and oils.

Hydrogen peroxide.

Magnesium chloride—derived from sea water.

Magnesium stearate—for use only in agricultural products labeled "made with organic (specified ingredients or food group(s))," prohibited in agricultural products labeled "organic".

Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

Ozone.

Peracetic acid/Peroxyacetic acid (CAS # 79–21–0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.

Phosphoric acid—cleaning of food-contact surfaces and equipment only.

Potassium acid tartrate.

Potassium carbonate.

Potassium citrate.

Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.

Potassium phosphate—for use only in agricultural products labeled "made with organic (specific ingredients or food group(s))," prohibited in agricultural products labeled "organic". Silicon dioxide.

Silicon Dioxide – Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

Sodium acid pyrophosphate (CAS # 7758–16–9)—for use only as a leavening agent.

Sodium citrate.

Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.

Sodium phosphates—for use only in dairy foods.

Sulfur dioxide—for use only in wine labeled "made with organic grapes," Provided, That, total sulfite concentration does not exceed 100 ppm.

Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.

Xanthan gum.

(c)–(z) [Reserved]

# § 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as "organic," only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

- (a) Casings, from processed intestines.
- (b) Celery powder. .
- (c) Colors derived from agricultural products Must not be produced using synthetic solvents and carrier systems or any artificial preservative.
- (1) Beet juice extract color (pigment CAS # 7659–95–2).
- (2) Beta-carotene extract color, derived from carrots (CAS # 1393–63–1).
- (3) Black currant juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (4) Black/Purple carrot juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (5) Blueberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (6) Carrot juice color (pigment CAS # 1393–63–1).
- (7) Cherry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (8) Chokeberry—Aronia juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (19) Elderberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).

- (10) Grape juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (11) Grape skin extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (12) Paprika color (CAS # 68917–78–2)—dried, and oil extracted.
- (13) Pumpkin juice color (pigment CAS # 127–40–2).
- (14) Purple potato juice (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (15) Red cabbage extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (16) Red radish extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).
- (17) Saffron extract color (pigment CAS # 1393–63–1).
- (18) Turmeric extract color (CAS # 458–37–7).
- (d) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.
- (e) Fructooligosaccharides (CAS # 308066–66–2).
- (f) Gelatin (CAS # 9000–70–8).
- (g) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
- (h) Inulin-oligofructose enriched (CAS # 9005–80–5).
- (i) Kelp—for use only as a thickener and dietary supplement.
- (j) Konjac flour (CAS # 37220–17–0).
- (k) Lecithin—de-oiled.
- (1) Orange pulp, dried.
- (m) Orange shellac-unbleached (CAS # 9000–59–3).
- (n) Pectin (non-amidated forms only).
- (o) Seaweed, Pacific kombu.
- (p) Starches.
- (1) Cornstarch (native).
- (2) Sweet potato starch—for bean thread production only.

- (q) Tragacanth gum (CAS#-9000-65-1)
- (r) Turkish bay leaves.
- (s) Wakame seaweed (Undaria pinnatifida).
- (t) Whey protein concentrate.

#### § 205.607 Amending the National List.

- (a) Any person may petition the National Organic Standard Board for the purpose of having a substance evaluated by the Board for recommendation to the Secretary for inclusion on or deletion from the National List in accordance with the Act.
- (b) A person petitioning for amendment of the National List should request a copy of the petition procedures from the USDA at the address in § 205.607(c).
- (c) A petition to amend the National List must be submitted to: Program Manager, USDA/AMS/TMP/NOP, 1400 Independence Ave., SW., Room 4008-So., Ag Stop 0268, Washington, DC 20250.

#### **State Organic Programs**

## § 205.620 Requirements of State organic programs.

- (a) A State may establish a State organic program for production and handling operations within the State which produce and handle organic agricultural products.
- (b) A State organic program must meet the requirements for organic programs specified in the Act.
- (c) A State organic program may contain more restrictive requirements because of environmental conditions or the necessity of specific production or handling practices particular to the State or region of the United States.
- (d) A State organic program must assume enforcement obligations in the State for the requirements of this part and any more restrictive requirements approved by the Secretary.
- (e) A State organic program and any amendments to such program must be approved by the Secretary prior to being implemented by the State.

# § 205.621 Submission and determination of proposed State organic programs and amendments to approved State organic programs.

- (a) A State organic program's governing State official must submit to the Secretary a proposed State organic program and any proposed amendments to such approved program.
- (1) Such submission must contain supporting materials that include statutory authorities, program description, documentation of the environmental conditions or specific production and handling practices particular to the State which necessitate more restrictive requirements than the requirements of this part, and other information as may be required by the Secretary.
- (2) Submission of a request for amendment of an approved State organic program must contain supporting materials that include an explanation and documentation of the environmental conditions or specific production and handling practices particular to the State or region, which necessitates the proposed amendment. Supporting material also must explain how the proposed amendment furthers and is consistent with the purposes of the Act and the regulations of this part.
- (b) Within 6 months of receipt of submission, the Secretary will: Notify the State organic program's governing State official of approval or disapproval of the proposed program or amendment of an approved program and, if disapproved, the reasons for the disapproval.
- (c) After receipt of a notice of disapproval, the State organic program's governing State official may submit a revised State organic program or amendment of such a program at any time.

### § 205.622 Review of approved State organic programs.

The Secretary will review a State organic program not less than once during each 5-year period following the date of the initial program approval. The Secretary will notify the State organic program's governing State official of approval or disapproval of the program within 6 months after initiation of the review.

#### Fees

#### § 205.640 Fees and other charges for accreditation.

Fees and other charges equal as nearly as may be to the cost of the accreditation services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation in accordance with the following provisions:

(a) Fees-for-Service. (1) Except as otherwise provided in this section, fees-for-service shall be based on the time required to render the service provided calculated to the nearest 15-minute period, including the review of applications and accompanying documents and information, evaluator travel, the conduct of on-site evaluations, review of annual reports and updated documents and information, and the time required to prepare reports and any other documents in connection with the performance of service. The hourly rate shall be the same as that charged by the Agricultural Marketing Service, through its Quality Systems Certification Program, to certification bodies requesting conformity assessment to the International Organization for Standardization "General Requirements for Bodies Operating Product Certification Systems" (ISO Guide

- (2) Applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation during the first 18 months following the effective date of subpart F of this part shall receive service without incurring an hourly charge for service.
- (3) Applicants for initial accreditation and renewal of accreditation must pay at the time of application, effective 18 months following the effective date of subpart F of this part, a nonrefundable fee of \$500.00 which shall be applied to the applicant's fees-for-service account.
- (b) Travel charges. When service is requested at a place so distant from the evaluator's headquarters that a total of one-half hour or more is required for the evaluator(s) to travel to such place and back to the headquarters or at a place of prior assignment on circuitous routing requiring a total of one-half hour or more to travel to the next place of assignment on the circuitous routing, the charge for such service shall include a mileage charge administratively determined by the U.S. Department of Agriculture and travel tolls, if applicable, or such travel prorated among all the applicants and certifying agents furnished the service involved on an equitable basis or, when the travel is made by public transportation (including hired vehicles), a fee equal to the actual cost thereof. Travel charges shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F of this part. The applicant or certifying agent will not be charged a new mileage rate without notification before the service is rendered. (c) Per diem charges. When service is requested at a place away from the evaluator's headquarters, the fee for such service shall include a per diem charge if the employee(s) performing the service is paid per diem in accordance with existing travel regulations. Per diem charges to applicants and certifying agents will cover the same period of time for which the evaluator(s) receives per diem reimbursement. The per diem rate will be administratively determined by the U.S. Department of Agriculture. Per diem charges shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F of this part. The applicant or certifying agent will not be charged a new per diem rate without notification before the service is rendered.
- (d) Other costs. When costs, other than costs specified in paragraphs (a), (b), and (c) of this section, are associated with providing the services, the applicant or certifying agent will be charged for these costs. Such costs include but are not limited to equipment rental, photocopying, delivery, facsimile, telephone, or translation charges incurred in association with accreditation services. The amount of the costs charged will be determined administratively by the U.S. Department of Agriculture. Such costs shall become effective for all applicants for initial accreditation and accredited certifying agents on the effective date of subpart F of this part.

### § 205.641 Payment of fees and other charges.

- (a) Applicants for initial accreditation and renewal of accreditation must remit the nonrefundable fee, pursuant to § 205.640(a)(3), along with their application. Remittance must be made payable to the Agricultural Marketing Service, USDA, and mailed to: Program Manager, USDA-AMS-TMP-NOP, Room 2945-South Building, P.O. Box 96456, Washington, DC 20090-6456 or such other address as required by the Program Manager.
- (b) Payments for fees and other charges not covered under paragraph (a) of this section must be:
- (1) Received by the due date shown on the bill for collection;
- (2) Made payable to the Agricultural Marketing Service, USDA; and
- (3) Mailed to the address provided on the bill for collection.
- (c) The Administrator shall assess interest, penalties, and administrative costs on debts not paid by the due date shown on a bill for collection and collect delinquent debts or refer such debts to the Department of Justice for litigation.

### § 205.642 Fees and other charges for certification.

Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.

## §§ 205.643-205.659 [Reserved]

## Compliance

## § 205.660 General.

- (a) The National Organic Program's Program Manager, on behalf of the Secretary, may inspect and review certified production and handling operations and accredited certifying agents for compliance with the Act or regulations in this part.
- (b) The Program Manager may initiate suspension or revocation proceedings against a certified operation:
- (1) When the Program Manager has reason to believe that a certified operation has violated or is not in compliance with the Act or regulations in this part; or
- (2) When a certifying agent or a State organic program's governing State official fails to take appropriate action to enforce the Act or regulations in this part.
- (c) The Program Manager may initiate suspension or revocation of a certifying agent's accreditation if the certifying agent fails to meet, conduct, or maintain accreditation requirements pursuant to the Act or this part.
- (d) Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to § 205.662, § 205.663, and § 205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.

### § 205.661 Investigation of certified operations.

(a) A certifying agent may investigate complaints of noncompliance with the Act or regulations of this part concerning production and handling operations certified as organic by the certifying agent. A certifying agent must notify the Program Manager of all compliance proceedings and actions taken pursuant to this part.

(b) A State organic program's governing State official may investigate complaints of noncompliance with the Act or regulations in this part concerning organic production or handling operations operating in the State.

## § 205.662 Noncompliance procedure for certified operations.

- (a) <u>Notification</u>. When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide:
- (1) A description of each noncompliance;
- (2) The facts upon which the notification of noncompliance is based; and
- (3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.
- (b) <u>Resolution</u>. When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution.
- (c) <u>Proposed suspension or revocation</u>. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When 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. The notification of proposed suspension or revocation of certification shall state:
- (1) The reasons for the proposed suspension or revocation;
- (2) The proposed effective date of such suspension or revocation;
- (3) The impact of a suspension or revocation on future eligibility for certification; and
- (4) The right to request mediation pursuant to § 205.663 or to file an appeal pursuant to § 205.681.
- (d) <u>Willful violations</u>. Notwithstanding paragraph (a) of this section, 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.
- (e) <u>Suspension or revocation</u>. (1) If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation.
- (2) 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 § 205.663 or filed an appeal pursuant to § 205.681, while final resolution of either is pending.
- (f) <u>Eligibility</u>. (1) 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 regulations in this part.
- (2) A certified operation or a person responsibly connected with an operation whose certification has been revoked will be ineligible to receive certification for a period of 5 years following the date of such revocation, <u>Except</u>, That, the Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.
- (g) Violations of Act. In addition to suspension or revocation, any certified operation that:
- (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 per violation.

(2) Makes a false statement under the Act to the Secretary, a State organic program's governing State official, or a certifying agent shall be subject to the provisions of section 1001 of title 18, United States Code.

### § 205.663 Mediation.

Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent. If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation. The written notification shall advise the applicant for certification or certified operation of the right to request an appeal, pursuant to § 205.681, 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 shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. 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. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to § 205.681. Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and these regulations. The Secretary may review any mediated agreement for conformity to the Act and these regulations and may reject any agreement or provision not in conformance with the Act or these regulations.

## § 205.664 [Reserved]

## § 205.665 Noncompliance procedure for certifying agents.

- (a) <u>Notification</u>. When an inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certifying agent. Such notification shall provide:
- (1) A description of each noncompliance;
- (2) The facts upon which the notification of noncompliance is based; and
- (3) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible.
- (b) <u>Resolution</u>. When the certifying agent demonstrates that each noncompliance has been resolved, the Program Manager shall send the certifying agent a written notification of noncompliance resolution.
- (c) <u>Proposed suspension or revocation</u>. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent. The notification of proposed suspension or revocation shall state whether the certifying agent's accreditation or specified areas of accreditation are to be suspended or revoked. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation may be combined in one notification. The notification of proposed suspension or revocation of accreditation shall state:
- (1) The reasons for the proposed suspension or revocation;
- (2) The proposed effective date of the suspension or revocation;
- (3) The impact of a suspension or revocation on future eligibility for accreditation; and
- (4) The right to file an appeal pursuant to § 205.681.
- (d) <u>Willful violations</u>. Notwithstanding paragraph (a) of this section, if the Program Manager has reason to believe that a certifying agent has willfully violated the Act or regulations in this part, the Program Manager shall send a written notification of proposed suspension or revocation of accreditation to the certifying agent.
- (e) <u>Suspension or revocation.</u> When the accredited certifying agent fails to file an appeal of the proposed suspension or revocation of accreditation, the Program Manager shall send a written notice of suspension or revocation of accreditation to the certifying agent.
- (f) Cessation of certification activities. A certifying agent whose accreditation is suspended or revoked must:

- (1) Cease all certification activities in each area of accreditation and in each State for which its accreditation is suspended or revoked.
- (2) Transfer to the Secretary and make available to any applicable State organic program's governing State official all records concerning its certification activities that were suspended or revoked.
- (g) <u>Eligibility</u>. (1) A certifying agent whose accreditation is suspended by the Secretary 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 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 the regulations in this part.
- (2) A certifying agent whose accreditation is revoked by the Secretary shall be ineligible to be accredited as a certifying agent under the Act and the regulations in this part for a period of not less than 3 years following the date of such revocation.

#### §§ 205.666 and 205.667 [Reserved]

### § 205.668 Noncompliance procedures under State organic programs.

- (a) A State organic program's governing State official must promptly notify the Secretary of commencement of any noncompliance proceeding against a certified operation and forward to the Secretary a copy of each notice issued.
- (b) A noncompliance proceeding, brought by a State organic program's governing State official against a certified operation, shall be appealable pursuant to the appeal procedures of the State organic 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.
- (c) A State organic program'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 State organic program's governing State official shall send a written report of noncompliance to the Program Manager. The report shall provide a description of each noncompliance and the facts upon which the noncompliance is based. §205.669 [Reserved]

# §205.670 Inspection and testing of agricultural products to be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))."

- (a) All agricultural products that are to be sold, labeled, or represented as "100 percent organic," "or "made with organic (specified ingredients or food group(s))" must be made accessible by certified organic production or handling operations for examination by the Administrator, the applicable State organic program's governing State official, or the certifying agent.
- (b) The Administrator, applicable State organic program's governing State official, or the certifying agent may require preharvest or postharvest testing of any agricultural input used or agricultural product to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" when there is reason to believe that the agricultural input or product has come into contact with a prohibited substance or has been produced using excluded methods. Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the applicable State organic program's governing State official or the certifying agent at the official's or certifying agent's own expense.
- (c) A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense.
- (d) A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number. A certifying agent that certifies fewer than thirty

operations on an annual basis must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.

- (e) Sample collection pursuant to paragraphs (b) and (c) of this section must be performed by an inspector representing the Administrator, applicable State organic program's governing State official, or certifying agent. Sample integrity must be maintained throughout the chain of custody, and residue testing must be performed in an accredited laboratory. Chemical analysis must be made in accordance with the methods described in the most current edition of the *Official Methods of Analysis of the AOAC International* or other current applicable validated methodology for determining the presence of contaminants in agricultural products.
- (f) Results of all analyses and tests performed under this section will be available for public access, unless the testing is part of an ongoing compliance investigation.
- (g) If test results indicate a specific agricultural product contains pesticide residues or environmental contaminants that exceed the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances, the certifying agent must promptly report such data to the Federal health agency whose regulatory tolerance or action level has been exceeded. Test results that exceed federal regulatory tolerances must also be reported to the appropriate State health agency or foreign equivalent.

### § 205.671 Exclusion from organic sale.

When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced. The Administrator, the applicable State organic program's governing State official, or the certifying agent may conduct an investigation of the certified operation to determine the cause of the prohibited substance.

## § 205.672 Emergency pest or disease treatment.

When a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program and the certified operation otherwise meets the requirements of this part, the certification status of the operation shall not be affected as a result of the application of the prohibited substance: <u>Provided</u>, That:

- (a) Any harvested crop or plant part to be harvested that has contact with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program cannot be sold, labeled, or represented as organically produced; and
- (b) Any livestock that are treated with a prohibited substance applied as the result of a Federal or State emergency pest or disease treatment program or product derived from such treated livestock cannot be sold, labeled, or represented as organically produced: Except, That:
- (1) Milk or milk products may be sold, labeled, or represented as organically produced beginning 12 months following the last date that the dairy animal was treated with the prohibited substance; and
- (2) The offspring of gestating mammalian breeder stock treated with a prohibited substance may be considered organic: <u>Provided</u>, That, the breeder stock was not in the last third of gestation on the date that the breeder stock was treated with the prohibited substance.

### §§ 205.673-205.679 [Reserved]

# Adverse Action Appeal Process § 205.680 General.

- (a) Persons subject to the Act who believe they are adversely affected by a noncompliance decision of the National Organic Program's Program Manager may appeal such decision to the Administrator.
- (b) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a State organic program may appeal such decision to the State organic program's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.

- (c) Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator, <u>Except</u>, That, when the person is subject to an approved State organic program, the appeal must be made to the State organic program.
- (d) All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts.
- (e) All appeals shall be reviewed, heard, and decided by persons not involved with the decision being appealed.

## § 205.681 Appeals.

- (a) <u>Certification appeals</u>. An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or revocation of certification to the Administrator, <u>Except</u>, That, when the applicant or certified operation is subject to an approved State organic program the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary.
- (1) If the Administrator or State organic program sustains a certification applicant's or certified operation's appeal of a certifying agent's decision, the applicant will be issued organic certification, or a certified operation will continue its certification, as applicable to the operation. The act of sustaining the appeal shall not be an adverse action subject to appeal by the affected certifying agent.
- (2) If the Administrator or State organic program denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice or the State organic program's rules of procedure.
- (b) <u>Accreditation appeals</u>. An applicant for accreditation and an accredited certifying agent may appeal the Program Manager's denial of accreditation or proposed suspension or revocation of accreditation to the Administrator.
- (1) If the Administrator sustains an appeal, an applicant will be issued accreditation, or a certifying agent will continue its accreditation, as applicable to the operation.
- (2) If the Administrator denies an appeal, a formal administrative proceeding to deny, suspend, or revoke the accreditation will be initiated. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR Part 1, Subpart H.
- (c) <u>Filing period</u>. An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or by the State organic program. A decision to deny, suspend, or revoke certification or accreditation will become final and nonappealable unless the decision is appealed in a timely manner.
- (d) Where and what to file. (1) Appeals to the Administrator must be filed in writing and addressed to Administrator, USDA-AMS, c/o NOP Appeals Staff, Stop 0203, Room 302-Annex, 1400 Independence Ave., SW, Washington, DC 20250-0203.
- (2) Appeals to the State organic program must be filed in writing to the address and person identified in the letter of notification.
- (3) All appeals must include a copy of the adverse decision and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures.

# §§ 205.682-205.689 [Reserved]

### Miscellaneous

## § 205.690 OMB control number.

The control number assigned to the information collection requirements in this part by the Office of Management and Budget pursuant to the Paperwork Reduction Act of 1995, 44 U.S C. Chapter 35, is OMB number 0581-0191.

§§ 205.691-205.699 [Reserved] PARTS 206-209 [Reserved]

### **GUIDANCE DOCUMENTS**

The Baystate Organic Certification Program has prepared the following Guidance Documents to assist operations in complying with the National Organic Program. These guidance documents either address site specific issues or offer guidance in areas where the National Organic Program does not yet have applicable standards. These documents are recommendations and are not binding on certified operations. If they conflict with the National Organic Standards, then the National Organic Standards take precedence.

These Guidance documents include:

Buffer Zones and Environment Contaminants Livestock Guidelines for Nitrogen Loading and Manure Calculations

# GUIDANCE DOCUMENT: BUFFER ZONES AND ENVIRONMENTAL CONTAMINANTS

Growers have very limited direct control over the purity of the air and water which pass through and over their fields. Similarly, they cannot influence previous uses of their land that may cause long term contamination of the soil. However, it is extremely important to consider the potential for spray drift or other sources of airborne contamination, sources of irrigation water and the drainage patterns of a farm, and previous uses of agricultural land. Contamination from these sources may be reason to deny certification. Section 205.202(c) of the National Organic Standards states that a grower must "Have distinct, defined boundaries and buffer zones such as runoff diversions to prevent the unintended application of a prohibited substance to the crop or contact with a prohibited substance applied to adjoining land that is not under organic management." This guidance document will assist growers in complying with the buffer zone requirement of the National Organic Program. However, if a grower does not wish to comply with this guidance document, they may submit alternative evidence as part of their Organic System Plan that they have complied with the requirements of section 205.202(c) of the National Organic Program.

#### Air

To avoid the possibility of pesticide or herbicide drift onto organic fields, growing areas must be situated at least 50' feet from non-organically managed land and unmanaged land. Non-organically managed land may include, but is not limited to, farm land, lawn, playgrounds, power lines, nurseries, golf courses, and pastures. Unmanaged land may include, but is not limited to pasture, lawn, and fields. The 50 feet provides a buffer zone between organically managed crops and potential sources of contamination.

The 50' foot buffer zone requirement may be reduced or eliminated for the following reasons:

- 1. The abutting land is clearly unmanaged pasture, field, or lawn.
- 2. A physical barrier such as a solid fence, hedgerow, or tall annual crop exists between the non-organic and organic growing areas.
- 3. The only pesticides, herbicides, or fungicides used on the non-organically managed land are allowed under these standards and there is no reason to expect movement of fertilizers in surface water from field to field.
- 4. Prohibited pesticides, herbicides, fungicides or fertilizers that are used on the non-organically managed fields are applied in such a manner as to produce minimal risk of drift. Examples include a soil-applied granular pesticide, a granular incorporated herbicide or pesticide, or a soil applied pesticide drench or liquid herbicide that is applied with large volumes of water and a nozzle design that produces large droplet size.

5. Prohibited pesticides, herbicides, fungicides, or fertilizers are applied at a time of the season when the organic crop is either not in the ground or has no marketable above ground parts present. The application is made with careful attention to weather conditions and equipment design so as to minimize the risk of drift.

## How do you get a buffer reduction?

You must list every buffer you want to reduce in your Organic Farm Plan. You must also list the reason why you believe the buffer should be reduced. If you are trying to get a buffer reduction for reasons 3, 4 or 5 then an Abutter Form must be signed by the owner or manager of the adjoining land. In addition, for reasons 3, 4, or 5 the owner or manager of the adjoining land must detail the materials to be applied to the land, and the method and expected dates of application. For reason #5, the organic grower must also submit a plan detailing expected crops, planting dates, and dates when marketable above ground parts will be present in the field.

Once your Farm Plan and Abutter Forms have been submitted, the buffers will be reviewed at your inspection. After the inspection, the inspection report will be reviewed and a determination made as to whether the reduced buffer is in compliance with the standards.

Once granted, buffer zone reductions granted for reasons 1, 2 or 3 remain in force for as long as ownership of the adjoining land, or management practices on the adjoining land, including crops grown and inputs used, remain unchanged. If buffer reductions are granted for reasons 4 or 5, the certified grower must submit a new Abutter Form each and every year in order to continue the buffer reduction. It is the responsibility of the certified applicant to notify Baystate Organic Certifiers of any change in ownership or management practices that may affect a granted buffer reduction.

## Water

The quality of surface or ground water used for irrigation of crops or watering of livestock must not be compromised by natural or synthetic contaminants. Appropriate measures must be taken to prevent the contamination of surface or ground water by runoff. Baystate Organic Certifiers may require cranberry operations and operations with questionable sources of water to submit a water test as part of their application packet.

# GUIDANCE DOCUMENT: LIVESTOCK GUIDELINES FOR NITROGEN LOADING AND MANURE CALCULATIONS

The National Standards specify that "The producer of an organic livestock operation must manage manure in a manner that does not contribute to contamination of crops, soil, or water by plant nutrients, heavy metals, or pathogenic organisms and optimizes recycling of nutrients". **Livestock Living Conditions (National Standards Section 205.239)**. In past years, the Baystate Organic Certification Program has used a maximum allowable limit of 200 lb. N/year/acre to determine the limit of manure applied to a pasture or other livestock management area. The Program will continue to use this limit to measure compliance with these standards. Reprinted below are the Nitrogen Loading Calculations and the Days Per Year on Pasture/Nitrogen Loading Restrictions.

## **Nitrogen Loading Calculations**

A. Maximum Nitrogen Load

200 lb. N/year/acre

0.5479452 lb. N/day/acre

0.0000126 lb. N/day/square foot

B. Nitrogen in Manure and Urine

Sheep, Goats, Swine 0.340 lb. N/day/1000 lbs. body weight Cattle 0.400 lb. N/day/1000 lbs. body weight

Poultry 0.105 lb. N/day/100 birds of 4 lb. average weight

C. Minimum Space Required to Remain Below Maximum Annual Nitrogen Load

Sheep, Goats, Swine 27.03 square feet/lb. animal weight Cattle 31.80 square feet/lb. animal weight Poultry 20.87 square feet/lb. animal weight

D. Maximum Animal Average Weight Allowable to Remain Below 200 lb. N/year/acre

Sheep, Goats, Swine 0.037 lb. per square foot 1612 lb. per acre Cattle 0.031 lb. per square foot 1370 lb. per acre Poultry 0.048 lb. per square foot 2087 lb. per acre

To Calculate Minimum Space Requirement for One Year:

Determine average animal load in lbs. live weight per year (actual animal load on your farm), multiply by the minimum space required per lb. (answer will be in square feet).

Example: 1000 lbs. of sheep, goats, and swine combined multiplied by 27.03 square feet/lb. (from C. above) = 27,030 square feet minimum for 1 year

To Calculate Allowable Animal Loading for a Given Space

Determine the area in square feet (as it exists on the farm) and multiply by maximum average weight allowable (answer will be lbs. of animal per year)

Example: 87120 square feet (2 acres) paddock to be used for cattle multiplied by .031 (from D. above)
= 2,701 lbs. of cattle maximum for 1 year

# Days Per Year On Pasture/Nitrogen Loading Restrictions

(Maximum number of days per year that stock of a given average weight can remain on a given area of pasture in order to keep below the limit of 200 lbs. of Nitrogen per acre per year.)

**Sheep, Goats, Swine** (if each day 0.34 lb. N in manure and urine per 1,000 lb. of body weight)

| WEIGHT | AREA OF CONFINEMENT (SQUARE FEET) |      |      |      |      |      |      |       |       |  |  |
|--------|-----------------------------------|------|------|------|------|------|------|-------|-------|--|--|
| (lbs.) | 500                               | 1000 | 1500 | 2000 | 2500 | 3000 | 4356 | 21780 | 43560 |  |  |
|        | (days)                            |      |      |      |      |      |      |       |       |  |  |
| 100    | 68                                | 135  | 203  | 270  | 338  | 365  | 365  | 365   | 365   |  |  |
| 500    | 14                                | 27   | 41   | 54   | 68   | 81   | 118  | 365   | 365   |  |  |
| 1000   | 7                                 | 14   | 20   | 27   | 34   | 41   | 59   | 294   | 365   |  |  |
| 2000   | 3                                 | 7    | 10   | 14   | 17   | 20   | 29   | 147   | 294   |  |  |
| 3000   | 2                                 | 5    | 7    | 9    | 11   | 14   | 20   | 98    | 196   |  |  |
| 4000   | 2                                 | 3    | 5    | 7    | 8    | 10   | 15   | 74    | 147   |  |  |
| 5000   | 1                                 | 3    | 4    | 5    | 7    | 8    | 12   | 59    | 118   |  |  |
| 10000  | 1                                 | 1    | 2    | 3    | 3    | 4    | 6    | 29    | 59    |  |  |

Cattle (if each day 0.4 lb. N in manure and urine per 1,000 lb. body weight)

| WEIGHT AREA OF CONFINEMENT (SQUARE FEET) (A |        |      |      |      |      |      |      |       |       |  |
|---|--------|------|------|------|------|------|------|-------|-------|--|
| (lbs.)                                      | 500    | 1000 | 1500 | 2000 | 2500 | 3000 | 4356 | 21780 | 43560 |  |
|   | (days) |      |      |      |      |      |      |       |       |  |
| 100   | 57     | 115  | 172  | 230  | 287  | 344  | 365  | 365   | 365   |  |
| 500   | 11     | 23   | 34   | 46   | 57   | 69   | 100  | 365   | 365   |  |
| 1000  | 6      | 11   | 17   | 23   | 29   | 34   | 50   | 250   | 365   |  |
| 2000  | 3      | 6    | 9    | 11   | 14   | 17   | 25   | 125   | 250   |  |
| 3000  | 2      | 4    | 6    | 8    | 10   | 11   | 17   | 83    | 167   |  |
| 4000  | 1      | 3    | 4    | 6    | 7    | 9    | 13   | 63    | 125   |  |
| 5000  | 1      | 2    | 3    | 5    | 6    | 7    | 10   | 50    | 100   |  |
| 10000                                       | 1      | 1    | 2    | 2    | 3    | 3    | 5    | 25    | 50    |  |

**Poultry** (if each day 0.105 lb. N in manure from 100 birds – 4 lb. average weight)

| WEIGHT | AREA OF CONFINEMENT (SQUARE FEET) |      |      |      |      |      |      |       | (ACRE) |  |
|--------|-----------------------------------|------|------|------|------|------|------|-------|--------|--|
| (lbs.) | 500                               | 1000 | 1500 | 2000 | 2500 | 3000 | 4356 | 21780 | 43560  |  |
|        | (days)                            |      |      |      |      |      |      |       |        |  |
| 100    | 87                                | 175  | 262  | 350  | 365  | 365  | 365  | 365   | 365    |  |
| 200    | 44                                | 87   | 131  | 175  | 219  | 262  | 365  | 365   | 365    |  |
| 300    | 29                                | 58   | 87   | 117  | 146  | 175  | 254  | 365   | 365    |  |
| 400    | 22                                | 44   | 66   | 87   | 109  | 131  | 190  | 365   | 365    |  |
| 500    | 17                                | 35   | 52   | 70   | 87   | 105  | 152  | 365   | 365    |  |
| 1000   | 9                                 | 17   | 26   | 35   | 44   | 52   | 76   | 365   | 365    |  |