



PRACTICE MANUAL

A Guide for Producers

2020

Including

Organic Practices for Producers

Policies and Administrative Procedures

MOFGA CERTIFICATION SERVICES, LLC

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INTRODUCTION

Organic certification is a regulatory system that allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.

Established in 2002, MOFGA Certification Services LLC (MCS) is a USDA National Organic Program accredited certifier whose mission is to continue MOFGA's program of independent verification of organic food production. Our program encourages production practices that promote soil health, animal welfare, and farm sustainability in accordance with the National Organic Program (NOP) standards.

All crops (including wild harvested), livestock, and processed products labeled "Organic" must comply with NOP Standards. Our administrative procedures must comply with NOP Standards. The NOP regulatory text is reproduced in the Appendix and is available on the web at <https://www.ams.usda.gov/rules-regulations/organic>.

This manual explains organic practice standards for the various scopes and production categories that MCS certifies. We have tried to include as much information regarding compliance of organic production practices as we have available. This manual, and its appendix including the NOP regulatory text, explains MCS policy and procedures.



PRINCIPLES OF ORGANIC PRODUCTION AND HANDLING

National Organic Standards Board, United States Department of Agriculture

- A. Organic agriculture is an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity. It emphasizes the use of management practices in preference to the use of off-farm inputs, taking into account that regional conditions require locally adapted systems. These goals are met, where possible, through the use of cultural, biological, and mechanical methods, as opposed to using synthetic materials to fulfill specific functions within the system.
- B. An organic production system is designed to:
1. Optimize soil biological activity
 2. Maintain long-term fertility
 3. Minimize soil erosion
 4. Maintain or enhance the genetic and biological diversity of the production system and its surroundings
 5. Utilize production methods and breeds or varieties that are well adapted to the region
 6. Recycle materials of plant and animal origin in order to return nutrients to the land, thus minimizing the use of non-renewable resources
 7. Minimize pollution of soil, water, and air
 8. Become established on an existing farm or field through a period of conversion (transition), during which no prohibited materials are applied and an organic plan is implemented.
- C. The basis for organic livestock production is the development of a harmonious relationship between land, plants, and livestock, and respect for the physiological and behavioral needs of livestock. This is achieved by:
1. Providing good quality organically grown feed
 2. Maintaining appropriate stocking rates
 3. Designing husbandry systems adapted to the species' needs
 4. Promoting animal health and welfare while minimizing stress
 5. Avoiding the routine use of chemical allopathic veterinary drugs, including antibiotics
- D. Organic handling practices are based on the following principles:
1. Organic processors and handlers implement good organic manufacturing and handling practices in order to maintain the integrity and quality of organic products through all stages of processing, handling, transport, and storage
 2. Organic products are not commingled with non-organic products, except when combining organic and non-organic ingredients in finished products which contain less than 100% organic ingredients
 3. Organic products and packaging materials used for organic products do not come in contact with prohibited materials
 4. Proper records, including accurate audit trails, are kept to verify that the integrity of organic products is maintained
 5. Organic processors and handlers use practices that minimize environmental degradation and consumption of non-renewable resources. Efforts are made to reduce packaging; use recycled materials; use cultural and biological pest management strategies; and minimize solid, liquid, and airborne emissions
- E. Organic production and handling systems strive to achieve agro-ecosystems that are ecologically, socially, and economically sustainable.
- F. Organic products are defined by specific production and handling standards intrinsic to the identification and labeling of such products.
- G. Organic standards require that each certified operator must complete, and submit for approval by a certifying agent, an organic plan detailing the management of the organic crop, livestock, wild harvest, processing, or handling system. The organic plan outlines the management practices and inputs that will be used by the operation to comply with organic standards.
- H. Organic certification is a regulatory system that allows consumers to identify and reward operators who meet organic standards. It allows consumers to be confident that organic products are produced according to approved management plans in accordance with organic standards. Certification requires informed effort on the part of producers and handlers, and careful vigilance with consistent, transparent decision making on the part of certifying agents.
- I. Organic production and handling operations must comply with all applicable local, state, and federal laws.
- J. Organic certification, production, and handling systems serve to educate consumers regarding the source, quality, and content of organic foods and products. Product labels must be truthful regarding product names, claims, and content.
- K. Genetic engineering (recombinant DNA technology) is a synthetic process designed to control nature at the molecular level, with the potential for unforeseen consequences. As such, it is not compatible with the principles of organic agriculture (either production or handling). Genetically engineered/modified organisms (GEO/GMOs) and products produced by or through the use of genetic engineering are prohibited.
- L. Although organic standards prohibit the use of certain materials such as synthetic fertilizers, pesticides, and genetically engineered organisms, they cannot ensure that organic products are completely free of residues due to background levels in the environment.

THE ORGANIC CERTIFICATION PROCESS

1. WANT TO CERTIFY?

Producers

- Contact MCS (MOFGA Certification Services) to learn about the National Organic Program regulations and the certification process.

MCS

- Communicates information about compliance to the National Organic Program Rule through print, the MCS website, and in-person meetings. Free one-on-one advisement is available through MOFGA's Agricultural Services Department.

2. APPLY FOR, RENEW, OR SURRENDER ORGANIC CERTIFICATION

Producers

- Send completed applications, fees and renewals to the MCS office according to published deadlines.
- Communicate their operation's status annually: renewing or surrendering their organic certificate.

MCS

- Reviews applications and renewals for eligibility and completeness. Contacts clients if more information is needed.

3. SUBMIT ORGANIC FARM/SYSTEM PLANS FOR REVIEW

Producers

- Annually update any changes to farm or system plan to maintain compliance.

MCS

- Reviews all organic system plans (applicants and renewals) for compliance.
- Sends renewing clients updated certificate documents.

4. INSPECTION

Producers

- Prepare for the application inspection (new producers) or annual inspection (renewing certified producers). Organize records and make sure all staff or family members uniquely knowledgeable about aspects of production are available for the on-site verification.

MCS

- Provides inspectors with relevant questions and/or concerns to address and verify. Inspection consists of opening meeting, verification of records and production practices, and exit interview.

NOTE: Inspectors working for MCS are not a part of any certification decisions. The inspector's role is to gather information and verify existing farm or system plans. Inspectors are assigned based on qualifications, geography and conflicts of interest.

5. REVIEW

Producers

- Receive a copy of their inspection report from MCS. Receive a letter detailing any noncompliance points with a timeframe for addressing them.

MCS

- Review completed inspection reports, exit interviews and attachments. Reaches out to producers to obtain more information about any issues raised during inspection.

6. CERTIFICATION

Producers

- Receive organic certificate, product verification, and certification letter.
- Work to improve any minor compliance issues before the next inspection.

MCS

- Sends certificate and related documents to approved operations including links to marketing materials.

7. MAINTAIN COMMUNICATION

Producers

- Immediately notify the certifier of any changes to the Organic System Plan that may affect compliance (scope of work changes, product profile updates, material usages, animal health care, changes in ownership), as required by NOP §205.400(f)(2).

MCS

- Follows up with producers as needed for compliance.
- Answers producers' questions related to NOP compliance as they arise throughout the year.

The Annual Certification Cycle

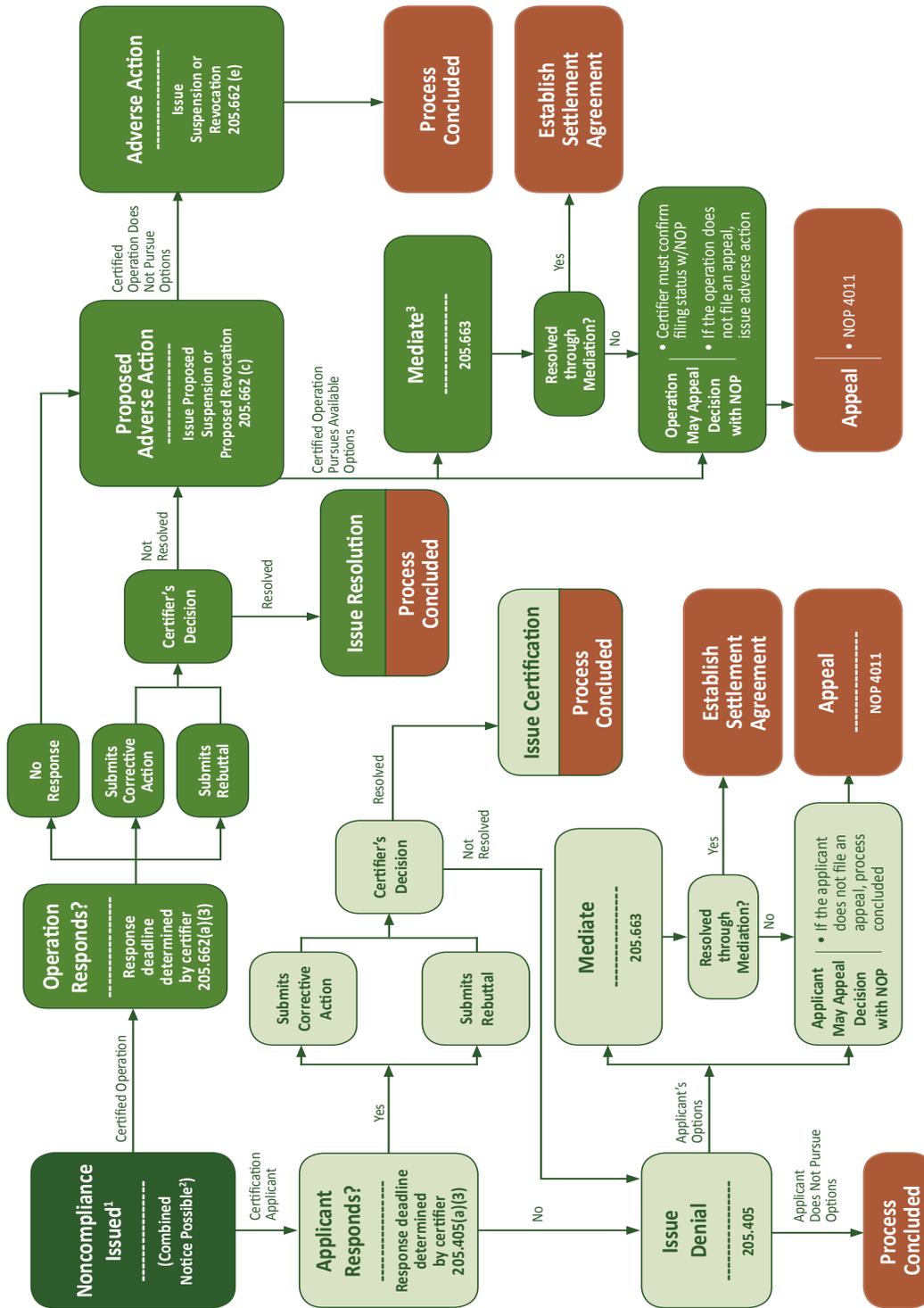
MOFGA Certification Services LLC
(MCS)
Maine's Organic Certifier



NON-COMPLIANCE AND ADVERSE ACTION FLOWCHART - NOP



NONCOMPLIANCE AND ADVERSE ACTIONS FLOW CHART



Note 1. A certified operation may surrender its certification at any time. When certification is surrendered prior to a certifier issuing a proposed adverse action, the certifier accepts the surrender and the process is closed. If an operation surrenders its certification after the certifier issues a proposed adverse action, the certifier accepts the surrender and continues the process for adverse action.

Note 2. For information on combined notices, see §205.662(c) and §205.405(g).

Note 3. Certifiers are required to continue providing certification services during the mediation and appeal processes.

1. ORGANIC SYSTEM PLAN (OSP) NOP §205.201

All certified farms and handling operations must maintain an Organic System Plan (OSP). The OSP is a written management plan for your organic farm and/or handling operation that has been mutually agreed upon by you and MCS. It describes how your farm or handling operation meets NOP standards. The OSP includes production practices, materials lists, recordkeeping methods, and (for farms) a land-use history for the previous 36 months.

The application forms MCS provides first-time applicants make up the framework for your OSP. After certification, you are required to update your OSP annually. You must also contact MCS whenever changes to your OSP could affect your compliance with organic regulations (e.g., adding or removing fields, changing material inputs, updating existing product's labels, and/or selling new products as organic.) You can avoid any noncompliance issues caused by changes to your OSP by communicating anticipated changes to MCS throughout the year.

As part of the OSP, you will sign an Organic Producer Endorsement, affirming that the information you provide is complete and accurate. The Endorsement also affirms you understand the National Organic Program regulations and your obligation to provide MCS with accurate and timely updates about your operation.

Please note that you may substitute a plan prepared to meet the requirements of another Federal State or local government regulatory program for the MCS Organic System Plan, provided that the submitted plan meets all the requirements of NOP §205.201.

2. ALLOWED AND PROHIBITED SUBSTANCES, METHODS, AND INGREDIENTS IN ORGANIC PRODUCTION AND HANDLING NOP §205.105

2.1 The National List of Allowed and Prohibited Substances (NOP §205.600-606)

The National List of Allowed and Prohibited Substances (NOP §205.600-606) herein called the National List, is an important part of the organic standards and impacts your options for material inputs such as pesticides, soil amendments, cleaning agents, livestock medications and food ingredients. Synthetic generic materials are prohibited and natural materials are permitted, except as listed in the National List. As a general rule, materials from a mined (such as crushed limestone) or natural source (like hay or straw) that are minimally processed are allowed. A few single natural ingredient materials are exceptions, such as arsenic or nicotine sulfate (tobacco dust). They are listed as prohibited "non-synthetic" substances in the Appendix (NOP §205.602).

Compound product formulations, on the other hand, require evaluation to make sure that prohibited ingredients have not been added to process, stabilize, or preserve the product. For example, ingredients that serve these functions in pesticides are called "inerts" because they are not the active ingredients. The Environmental Protection Agency (EPA) evaluates inert chemical ingredients. Only EPA List 4 Inerts (those generally recognized as safe) are permitted in organic production. Other synthetic products may be permitted only if they appear in NOP §205.601, §205.603 or §205.605(b).

Because the manufacturer may keep formulations of commercial products proprietary, it is often not easy to determine if a material meets the National List. MCS accepts all products reviewed and approved by the Organic Materials Review Institute (OMRI). You can search the OMRI list online at www.omri.org, or call them at (541) 343-7600.

It is your responsibility to use only NOP National List approved products. If you cannot find your product listed by OMRI, you should always check with MCS before using it.

You should list all products you use or may use on the Material List in your Organic System Plan. Using products or inputs that you have not listed on your Materials List puts your certification at risk and may result in a warning letter, a notice of noncompliance, the disqualification of land from organic production for 36 months, or the ineligibility of animals for organic meat or dairy production. Make sure to get approval from your MCS specialist before using any new products by calling MCS at 207-568-6030 and asking for your specialist.

2.2 Special Clarification for Chlorine Materials

One of the most widely used material inputs for sanitation and food safety in both farms and processing facilities is chlorine. Chlorine advisories will appear several times in this manual. In the context of it being allowed with restrictions in several sections of the National List, we provide an overview here.

- For *crop* operations an APPROVED chlorine material may be used up to the maximum labeled rates for disinfecting and sanitizing equipment or tools. A rinse step is not necessary before sanitized equipment is used unless the label requires a rinse.

- For *livestock* operations an APPROVED chlorine materials may be used up to maximum labeled rates for sanitizing equipment or tools (including dairy pipelines and tanks). Label instructions must be followed regarding requirements for rinsing prior to the equipment's next use.
- For *food handling* facilities and equipment, APPROVED chlorine materials may be used up to maximum labeled rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated by the label. Water used as an ingredient must be potable. It can contain no more than 4ppm chlorine. Additional information for processors can be found on page 30 of this manual.
- Chlorinated water used in direct crop or food contact is permitted to contain chlorine levels approved by FDA or EPA (you must document this in your organic system plan), however, rinsing with potable water (4ppm chlorine or less) MUST follow this step.

Please remember that any material to be used as a sanitizer or disinfectant needs must be, 1) listed in your farm or processing plan and be approved by MCS prior to use, 2) labeled for the intended commercial use, and 3) used according to label instructions.

For processors and handlers, regular chlorine bleach that may contain surfactants and/or fragrances is not allowed. We have reviewed and approved *various bleaches that do not* have inert ingredients and are labeled for a variety of commercial disinfecting uses. Inexpensive chlorine test strips are available which you should use to check the strength of your chlorine solution before each day's use (this is necessary as chlorine molecules are unstable). Please contact MCS if you have any questions or concerns about the use of chlorine materials.

2.3 Genetically Engineered Crops and Livestock Products

Genetically modified organisms are an excluded method under the USDA NOP Rule. No genetically engineered agricultural crop or livestock products may be grown or sold as organic, and no product of genetic engineering may be used as a direct production aid, livestock feed or ingredient.

3. GUIDELINES FOR CROP PRODUCTION

3.1 Land Requirements NOP §205.202

Any field or farm parcel from which harvested crops are intended to be sold, labeled, or represented as organic must meet the following conditions: 1) Have been managed in accordance with the provisions of NOP §§205.203 through 205.206; 2) Have had no prohibited substances, as listed in NOP §205.105, applied to it for a period of 36 months (3 years) immediately preceding harvest of the crop; and 3) Have distinct, defined boundaries and buffer zones (such as runoff diversions) to prevent the unintended application of prohibited substances to crops through contact with substances applied to adjoining land not under organic management.

Waiting Period for Fields Previously Treated with any Non-Permitted Materials

A field is not eligible for production of certified crops for thirty-six (36) months following the application of any prohibited fertilizers, pesticides, or other prohibited items noted in the National Organic Standards.

Documentation

Each growing area or field used to produce crops, including pastures, sugar maple forests for tapping, and wild harvest areas, must have: 1) a completed field history form, showing at least three years of land management activities, land ownership, size, etc.; 2) a landowner affidavit if the field has not been owned/managed by current client for the past 3 years, and; 3) a map showing adjoining land uses, buffers (if needed), access roads, etc. MCS recommends printing annotated color satellite images using Google Maps or those available from your local USDA Service Center.

If you are purchasing land to use in your organic operation, please be sure to obtain a signed land use history for the prior 36 months from the seller and consult with MCS for more information.

3.2 Seeds, Seedlings and Planting Stock NOP §205.204

National Organic Program regulations require the use of organic seeds, seedlings and planting stock, *unless not commercially available* in the form, quantity or quality required by the grower. Annual seedlings and seeds used for edible sprout production must be certified organic.

You must conduct a reasonable search for organic seed. This means contacting at least three seed companies likely to carry organic seed and doing so during the time of year when there is likely to be inventory. Keep records of your efforts. Examples of records include: lists showing which seed companies were researched for organic seed before purchasing conventional seeds, printing dated inventory announcements or email correspondences with companies. Cost cannot be a factor when determining commercial availability.

Seeds and Planting Stock

Planting stock includes rhizomes, leaf/stem cuttings, and roots or tubers (onion sets, seed potatoes, sweet potato slips, garlic bulbs, strawberry/asparagus crowns, raspberry canes, tree and shrub seedlings).

Seeds treated with materials listed on the National List are allowed. Conventional seeds treated/coated with prohibited materials (e.g., fungicides, synthetic fertilizers), genetically engineered seed varieties, and GE legume inoculants are prohibited. Farmers must verify that planting stock has not been treated with prohibited materials for post-harvest transport and storage.

Seed coats are often identified as OMRI approved in catalogues. If this is not the case, producers must contact MCS to verify if that particular seed coating is allowed. Do not plant seeds with coatings unless you know the coating is NOP compliant.

Annual Seedlings

The use of non-organic annual seedlings can only be allowed with a temporary variance granted by the USDA NOP AMS administrator. These variances are seldom granted and generally only in the case of extreme weather or a business disruption beyond the control of the producer. Please note that onion seedlings are considered annual seedlings and therefore must be organic. Onion sets (dormant little bulbs) are planting stock and are subject to the commercial availability requirement.

Perennial Plants

Conventional perennial planting stock must be managed organically for at least 12 months prior to being sold, labeled or represented as organic. Records must be kept to document the transition date. All planting stock is subject to the commercial availability requirement.

Note: 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 the Federal or State phytosanitary regulations.

3.3 Crop Rotation Including Rotation Requirements for Annual Field Crops NOP §205.205

You must implement a crop rotation including, but not limited to, sod, cover crops, green manure crops, and catch crops that provide the following functions as applicable to your operation: maintain or improve soil organic matter content; provide for pest management in annual and perennial crops; manage deficient or excess plant nutrients, and; provide erosion control.

Crop rotations required if you grow annual crops. Continual production of one type of crop in the same place leads to depletion of specific nutrients, promotes disease and pest problems and can be destructive to soil structure and organic matter content. When designing your crop rotation plan, think about plant families as well as alternating with green manures, legumes (nitrogen fixers), deep rooting versus shallow rooting crops, heavy feeders versus light feeders, biofumigant and allelopathic properties, and mineral accumulators. Winter cover crops are always recommended. Perennials are an exception to the crop rotation rule. Perennial cropping systems should employ strategies to introduce biodiversity such as alley cropping, intercropping and hedgerows.

For organic farmers growing silage, grain, corn or other field crops, MOFGA has a separate guidance document that addresses specific concerns regarding the crop rotation standard. Please request a copy from MCS staff.

3.4 Soil Fertility and Nutrient Management NOP §205.203

Soils and crops must be managed to build soil fertility, manage plant nutrients, protect natural resources and prevent soil erosion. Plant and animal materials (manure, compost, etc.) must be managed so as not to contaminate crops, soil, or water. Fertility inputs must be approved and included in your farm plan. Crop rotation is required (NOP §205.205).

Your primary management goal should be to build healthy soils on your farm. Healthy soil is the foundation for healthy plants, healthy animals, and thus a healthy farm. If a field requested for certification has not had prohibited inputs applied for at least 3 years, the field would be considered certifiable, but once a field is certified, the producer must actively manage the soil fertility. Non-management of a field is not an organic practice. Fertility can be managed through crop rotations, cover crops, manure, compost, plant residues (leaves, hay mulch) and applications of approved soil amendments including:

- Non-synthetic mineral amendments with non-synthetic additives. Rock phosphate, bone and blood meal, limestone, and sul-po-mag are examples of allowed amendments. Synthetic soluble fertilizers and hydrated lime are prohibited.
- Wood ash is allowed from approved sources only—ask MCS staff prior to use.
- Hay or straw mulch—organic sources are not required by the NOP Rule but caution is advised concerning the potential for herbicide residues that may damage or contaminate crops and fields.
- Whey from approved sources is allowed, but is prohibited if the material is mixed with grey water from the processing facilities—ask MCS staff
- Manure (including off-farm sources) is allowed (see next section on waiting periods and composting).
- Synthetic micronutrients (boron, zinc) are restricted and can be used only when a deficiency is documented by soil or tissue testing (see later section on micronutrients).

Soil Tests

The evaluation of soil quality is a major component of both our application review process and our on-site inspections for organic certification. Soil tests by the University of Maine or equivalent laboratory are an excellent and affordable way to demonstrate that your farm practices maintain or improve soil quality. Although MCS does not require soil tests, any submitted test results will be added to your farm plan records. In addition, fees for soil tests performed in the last 12 months and submitted to MCS are eligible for the 75% federal cost-sharing program administered by the State of Maine.

MCS strongly recommends soil testing for monitoring soil fertility. Soil quality is reflected in the physical, chemical, and biological condition of the soil, and soil maintenance and/or improvement is central to organic management. If soil tests are not used, a producer must demonstrate that they are adequately monitoring the fertility of their soils through other methods of ongoing soil quality monitoring. MCS reserves the right to test soil to verify that soil quality is being maintained.

Manure

You may not apply raw, un-composted livestock manure to food crops unless it is:

- Incorporated into the soil a minimum of 120 days prior to harvest for crops whose edible portion has direct contact with the soil (such as lettuce, carrots, or potatoes)
- OR
- Incorporated into the soil a minimum of 90 days prior to harvest for crops whose edible portion does not have direct contact with the soil (such as sweet corn, tomatoes and peppers)

This is often referred to as the **90/120 Day Rule** or “**The Manure Waiting Period**”.

Properly made compost, on the other hand, may be applied at any time during the growing season. Certified farmers must either abide by the 90/120 Day Rule or keep records to document that their compost meets the organic standards (see below).

All manure, regardless of the age of the pile, is considered raw unless the producer can verify via records it has been composted according to the guidelines described below.

The above restrictions do not apply to cover crops or crops used as livestock feed.

Compost

The NOP standard defines compost as “the product of a managed process through which microbes break down plant and animal materials into more available forms suitable for application to the soil.” As long as feedstock (the ingredients) is free from chemical residues that could result in contamination, there are no specific regulations for compost made entirely of plant materials. If the compost contains livestock manure or animal parts or products, then the compost must undergo an increase in temperature to at least 131° F (55°C) and remain there for a minimum of 3 days. The compost pile must be managed to ensure that all of the feedstock is heated to the minimum temperature. Feedstock inputs, temperatures and turning must be detailed in your farm plan and a compost thermometer and composting records made available at your inspection. Please note that any synthetic materials mixed in with compost feedstock, such as plastics or rubber bands in lobster shell waste, must be removed before composting.

Compost teas are permitted, provided that they do not contaminate soil or crops and are made from finished compost products that have met the above production criteria. If you wish to add substances to your tea, please contact MCS first so that we may review your request. Alternatively, you can follow the manure waiting period guidelines above for a manure-based compost that has not undergone a compliant managed process. Teas made from such composts must also follow the manure waiting period guidelines.

Commercial composts must be OMRI or MOFGA approved for organic production. MCS maintains a list of permitted commercial composts. Please contact us for more information.

Imported Soil

Soil that is imported for use on a certified organic farm (e.g., fill in greenhouse projects) needs to be in compliance with the NOP Rule. An affidavit is needed to verify compliance.

Nutrient Balance

The NOP Rule requires farmers to manage plant and animal materials in a manner that does not contribute to contamination of crops, soil, or water. Excessive application of nutrients to your fields can pollute the land and contribute to nutrient-rich runoff that may contaminate surface and groundwater. The Maine Department of Agriculture has issued Nutrient Management Guidelines, which may be helpful in managing nutrients on your land. For assistance in planning nutrient needs on your farm, contact your local Extension Agent or MOFGA’s Agricultural Services department.

Prohibited Materials and Practices

Below is a list of **prohibited** materials and practices that are commonly used for soil fertility management but must not be used by organic growers. It is not an all-inclusive list. Talk to your certification specialist about products before you apply them to crops or soil.

- All chemically synthesized fertilizers and other synthetic sources of minerals, unless listed in NOP §205.601

- Highly soluble nitrate, phosphorous, and chloride, whether natural or synthetic, except as noted in NOP §205.601
- Leather by-products, including leather meal, tankage or dust
- Urea
- Hydrated lime, quicklime, calcium oxide, burned or burnt lime, kiln waste
- Sludge & sludge/ash mixtures. This includes non-municipal septage and “humanure”
- Paper lime/fiber lime—this is a byproduct of paper manufacturing and contains prohibited synthetics
- Algae fiber—this is a byproduct of carrageenan manufacturing and contains prohibited synthetics
- Fly ash
- Other industrial ash sources (e.g., wood burning power plant ash), unless specifically reviewed and approved before application
- Any practice that contributes to contamination of crops, soil or water by plant nutrients, pathogenic organisms, heavy metals or toxic materials
- Manure, unless either composted according to accepted methods (see earlier section) or applied with the appropriate waiting period
- Manure tea, unless a 120-day waiting period is met
- Spreading of raw manure between 1 December and 15 March, as per Maine Nutrient Management Law, unless a variance has been granted by the Maine Department of Agriculture

3.5 Micronutrients and Secondary Nutrients Applications for Soil Fertility NOP §205.601 (j) (6)

The National List identifies substances that may and may not be used in organic crop and livestock production. All natural, non-synthetic sources of secondary nutrients and micronutrients are allowed unless listed as prohibited in NOP §205.602. The Rule (NOP §205.601 (j) (6)) does allow for limited use of *certain* synthetic fertilizers to support the health of the current crop while correcting and enhancing soil fertility with sustainable management practices and natural materials. Restrictions on the use of these materials are explained below:

Secondary Nutrients: *Calcium (Ca), Magnesium (Mg) and Sulfur (S)*

- Calcium chloride produced through the brine process is allowed only as a foliar spray to treat a physiological disorder associated with calcium uptake (e.g., Blossom end rot).
- Magnesium sulfate (including synthetic Epsom salts) is allowed with a documented soil deficiency.
- Elemental Sulfur is allowed with no restrictions.

Micronutrients: *Boron (B), Zinc (Zn), Copper (Cu), Iron (Fe), Manganese (Mn), Molybdenum (Mo) and Cobalt (Co)*

- Synthetic micronutrients (except nitrate and chloride compounds) are only allowed to maintain crop health while soil improvement is ongoing and when a documented deficiency exists, but not as defoliant or herbicides.

In order to use products that contain these synthetic micronutrients, you must: 1) make sure that the product is approved by MOFGA Certification Services before use; 2) list the product on your Material List, which is part of your organic system plan, and; 3) have documentation that shows a deficiency of the micronutrient.

Documenting Deficiencies

The NOP Rule requires documentation of soil deficiencies in order to use most synthetic forms of micronutrients, as noted above. MCS accepts soil tests within 3 years of the last application of a synthetic micronutrient as documentation of a nutrient deficiency. Soil tests must show deficiencies of all micronutrients planned for use in all areas where they will be used. Nutrient levels detected in soil samples should be below the reference values displayed on the tests to support the use of an allowed synthetic input. Alternative forms of documentation may also be considered on a case-by-case basis. These may include plant tissue tests from the current crop, observation and monitoring (documented), and the use of check strips or test plots. We also recognize that soil pH, CEC, and balancing nutrients relative to each other are often important considerations

3.6 Crop Pest, Weed And Disease Management NOP §205.206

You must follow a three-tiered, hierarchical approach in deciding how to deal with pest, weed and disease problems.

Level A – Prevention/avoidance of the problem is the required first line of defense. Crop rotation, cover crops, sanitation and varietal selection are examples of level A approaches.

Level B – If level A methods are not adequate, a producer may use mechanical or physical methods as well as non-synthetic or natural control materials. Examples of level B approaches include row covers, mulching, cultivation, flaming and mowing. Please note that plastic or other synthetic film mulch used on crop growing areas must be removed at the end of the growing season.

Level C – If level A and B methods are not adequate, a producer may use an OMRI or MCS approved pesticide.

Note: A pesticide application log must be maintained and be made available at time of inspection.

Please refer to the *USDA Guide for Organic Crop Producers* (<http://www.ams.usda.gov/sites/default/files/media/GuideForOrganicCropProducers.pdf>) for more details and examples of this hierarchical approach to pest control.

3.7 Preventing Contamination Of Organic Crops Including Post Harvest Handling Concerns NOP §205.272

NOP §205.272 requires production and post-harvest handling practices and procedures that prevent the commingling of organic and nonorganic products and that protect organic products from contact with prohibited substances.

Precautions for preventing commingling and contamination are especially important for “split” operations that raise both organic and conventional crops. Organic crops must be protected from spray drift and contaminants on equipment used on conventional crops. If there are nearby sources of prohibited materials, buffers must be established to reduce the possibility of contamination. Equipment or tools used on conventional land or fields must be cleaned or purged before use on organic fields.

Because it is extremely difficult to remove pesticide residues from sprayers, producers must be able to demonstrate that there are no prohibited pesticide residues remaining in their equipment prior to use in organic farm plan applications. **We strongly encourage producers to dedicate a sprayer to organic applications.**

Equipment, including sprayers, used for prohibited materials may be converted to organic production but you must thoroughly clean equipment to remove residues of prohibited materials and document that cleaning happens before use in organic applications. Records must be available for your inspector. Your strategy must be included in your organic system plan and approved by MCS.

Guidelines For Cleaning Sprayers

OPTION 1: Conversion of conventional sprayer to dedicated organic use:

- Empty sprayer, fill tank with clean water and spray on non-certified area.
- 1) Fill tank with a solution of household ammonia (e.g. 1 qt. ammonia/25 gal. water). Thoroughly agitate a small amount through the system and let stand overnight.
- Spray over non-certified area.
- Fill tank with clean water and spray over non-certified area.
- Replace nozzles and rubber components (hoses, gaskets, etc.).

OPTION 2: Cleanout guidance for hired/dual use sprayer:

- Empty sprayer, fill tank with clean water and spray on non-certified area.
- Fill tank with an approved detergent, solvent, or neutralizer. Commercial tank cleaning agents and detergents help remove both water-soluble and oil-soluble pesticides. Check the labels of the last used material for recommendations on specific cleaning agents.
 - Approved detergents, solvents, neutralizers:
 - household ammonia—1 qt/25 gal water
 - washing soda—1 lb/25 gal water
 - trisodium phosphate—2 lb/25 gal water
 - powdered detergent—1/4 lb/25 gal water
- Consult with resources from state agencies (e.g. Pesticide Education Manual), Cooperative Extension, MOFGA Certification Services, and/or pesticide manufacturers for procedures for the selected cleaning material.
- Remove and clean or replace any removable parts where residues could collect
- Dispose of rinsate as waste pesticide. Organic producers are responsible for preventing contamination of certified land with rinsate containing prohibited materials.
- Document clean-out, including date, material(s) used, procedures followed, and rinsate disposal.

Link to resources on cleanout procedures:

Cornell University Cooperative Extension: Cleaning Your Sprayer
<http://psep.cce.cornell.edu/facts-slides-self/facts/sprayer-clean-91.aspx>

Post-Harvest Handling

Post-harvest handling procedures should ensure organic integrity. Procedures must be detailed in your farm plan and include all cleaners/sanitizers used on food contact tools and equipment. All shipping and storage containers as well as packaging must be free of contaminants. Equipment or tools used for conventional crop handling must be cleaned or purged before organic crops are handled. Water used to rinse produce must be potable.

Manual and mechanical control of the temperature and humidity of the storage atmosphere is permitted. Ice or cold-water cooling is permitted pending MCS approval of the water source and methods utilized. Post-harvest fumigation or any treatment with prohibited materials is not permitted.

Water used in direct crop or food contact is permitted to contain chlorine materials up to the maximum-labeled rate and must immediately be followed with a rinse such that the residual chlorine levels in the rinse water do not exceed 4ppm. Water used in the production of organic products must not contain chlorine in levels exceeding 4ppm.

Facility Pest Management

You must follow a multi-tiered hierarchical approach, similar to the crop pest management approach, when dealing with rodents or other facility pests.

Level A – Prevention/avoidance of the problem is the required first line of defense; includes pest exclusion and removal of habitat and food sources.

Level B – Use of mechanical and physical controls, such as light traps for insects or traps for rodents.

Level C – May only be used after A and B controls have failed. Options include use of materials on the National List such as vitamin D3 bait to kill rodents or diatomaceous earth in grain bins to kill insects. Pest control records must be kept.

Level D – May only be considered if control actions A, B and C are not adequate to control pests. Level D practices include the use of insecticides and rodenticides not on the National List. All materials and methods must be approved by MCS and a protocol to prevent contamination of organic product must be in place.

Special Guidelines to Prevent the Spread of Ring Rot in Potatoes Using Sanitizers

Ring rot bacteria are capable of surviving for many years on the surfaces of storage crates, bins, machinery and other surfaces. It is critical that growers control this threat, but must not contaminate crops or soils with synthetic chemicals while doing so. MOFGA recommends that all surfaces in contact with diseased potatoes be sanitized with an appropriate disinfectant. Seed producers should use extra diligence and may want to regularly disinfect any surface in contact with potatoes. Potato storage containers, equipment, pallet boxes, and bins should be pressure-washed, then disinfected for ten minutes with a sodium or calcium hypochlorite dilution following label guidelines.

NOTE: Quaternary ammonia sanitizers are prohibited on food contact tools, surfaces and equipment. However, MCS does allow their use as a boot disinfectant prior to entering food processing facilities, fields or livestock farms. Disposal of the dip solution must not contaminate soils, water or crops.

Water Quality

Water used to rinse produce or to make processed products must be suitable for drinking and must meet State of Maine drinking water quality standards.

3.8 Buffers NOP §205.202

If adjoining land uses pose a contamination threat, you are required to establish a large enough buffer that will protect your organic crops and land from contamination. You must identify buffers in farm maps and inspectors will evaluate them. Historically, MOFGA recommended a buffer of at least 100 feet between fields on which certified organic crops are to be produced and any field receiving applications of prohibited materials. The National Organic Standards do not mandate a particular buffer size, but state that an adequate buffer must exist to prevent unintended application of prohibited materials (NOP §205.202). A buffer in excess of 100' may be required if there is aerial pesticide spraying taking place or if a GE crop is planted in the proximity of an organic crop of the same family that may cross pollinate. A buffer less than 100' is adequate in certain circumstances. Vegetation (windbreaks and hedgerows) can be beneficial to buffer function. You must be prepared to defend the buffer you have established and you may be required to have documentation to prove the case. An example might be a written “no-spray” agreement with DOT for a stretch of highway that is adjacent to an organic field.

If any drift incident occurs, immediately contact the MCS office at 568-6030 and the Maine State Board of Pesticides Control at 287-2731.

3.9 State Mandated Pesticide Spraying or Other Emergency Treatment

When a prohibited substance is applied to a certified operation due to a Federal or State emergency pest or disease treatment program, the organic status of the operation shall not be affected. However, any crop or product that has had contact with the prohibited material cannot be sold or represented as organically produced or fed to livestock to be sold as organic. Any livestock treated with a prohibited material cannot be sold or represented as organic, except that milk may be labeled as organic beginning 12 months after the treatment. Offspring of treated mammalian breeding stock may be considered organic if the treatment was before the last third of gestation.

3.10 Treated Wood in Organic Production

Treated lumber is any wood product used for construction or other purpose on the farm that has been treated with any prohibited substance. Over the years, treated wood has been controversial for leaching prohibited materials and that is why there is a citation in the National Organic Standards concerning it. The Rule states that “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” (NOP §205.206). There are 3 main types of pressure treated wood/lumber; CCA, ACQ, and CA-B. CCA contains arsenic and is banned by the EPA. ACQ and CA-B contain synthetic materials that are not listed in NOP §205.601 or 205.603 of the Rule. This means they contain synthetic materials not allowed in organic crop and livestock production.

There are cases where treated wood or lumber is permitted without additional inquiry or considerations:

- If you are an organic producer or applicant for certification with pre-existing buildings or perimeter fencing constructed with treated wood before 2002.
- The material is used in a construction project (e.g., garage) where there is no contact with soil, crops, livestock or livestock feed that are part of the organic farm plan.

Treated wood is not allowed in the following applications: plant stakes, trellises, raised beds, greenhouse baseboards, compost bins, livestock feeders, and livestock enclosures (including outdoor lot/yard fencing).

Alternatives to treated wood are long-lasting, natural wood lumber and include species such as cedar, cypress, hemlock, oak, tamarack (larch) and locust. Lumber treated with materials consistent with the National List, such as raw linseed oil, can also be used, however, MCS should be contacted first to evaluate the material.

3.11 Recordkeeping NOP §205.103

All crop producers should keep the following records:

1. Seed/Seedling/ Perennial/Planting Stock Records

- Receipts/invoices of seeds, seedlings, and perennials actually purchased
- Printed correspondences from seed companies regarding requests, inventory, availability, etc.
- Seed packages can serve as a record of seed purchases if dates are printed on them, but keep in mind that producers must keep records for 5 years. If the same info is available on the invoice or packing slip, then there is no need to keep the package.
- Documentation/protocol of effort to procure organic seed/ planting stock
- For seed savers: harvest records showing production of organic seed
- 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).
- Seed catalogs can serve as evidence that producers are shopping broadly for seed, but will not provide evidence of actual purchases, problems encountered with organic seed availability, etc.

2. Material Application Records

Date, input or implement, rate, location, and source for the following:

- Soil amendments, including fertilizer, compost, etc.
- Pesticide/herbicide products.
- Manure application records (this should include date of manure application and date of first harvest yield/ kind of crop from that field).
- Crop production aids, including mulches, foliar sprays etc.
- Invoices or receipts for all materials purchased, including custom applicator invoices.

3. Production Records

- Crop rotation records, especially if this information is not apparent from the field history forms.
- Field activity records. Remember to use your field history sheets to full advantage. Protocols/records on cultivation practices, weeding and planting dates.
- Compost production records are required if feedstocks contain manure or animal parts and the finished product is applied during the growing season on crops intended for human consumption. Records include:
 - Sources and feedstocks
 - Temperature data
 - Turning dates
- If equipment is used on conventionally managed land: equipment clean out log including date, method and who cleaned out the equipment.
- 1 year transition records for perennials.
- Soil, water and tissue analysis reports.

4. Harvest, Storage and Sales Records

Audit trails are essential paper trails that allow products to be traced to the farm/field of origin. Inspectors will examine your records to verify that this link can be made on paper. For wholesale sales, an audit trail is accomplished with lot numbers on wholesale shipping containers and sales invoices. Lot numbers should link to the field where the crop was grown and the date of harvest. Audit trail requirements vary depending on the scale and complexity of the farm operation. Producers should work with their certification specialists on an audit trail system that verifies their compliance with the regulation.

Examples of records needed to demonstrate farm traceability include but are not limited to:

- Direct sales through CSA, farm stand, and/or farmers' markets: daily receipt log showing crops sold, CSA share records, harvest records are needed if they differ from sales records. For crops grown and harvested from multiple fields at the same time of the year, records that differentiate between fields must be kept.
- Wholesale to local coops, stores, restaurants: dated invoices, ledger book, wholesale containers with farm name plus lot number or date, harvest records (if different from sales invoices) For crops grown and harvested from multiple fields at the same time of the year, records that differentiate between fields must be kept.
- Wholesaler to processors or distributors: sales invoices with lot numbers, wholesale containers with lot number/date and farm name, inventory records for stored product, crop harvest records.
- Livestock producers should keep crop harvest records by field and date of harvest; audit trail should account for amounts used by farm as feed as well as any crop harvests sold.

If organic product is bought in from other farms, the following must be kept:

- Amounts of crop(s) bought in
- Amounts of "bought in" crop(s) sold
- Verification that bought-in products are certified organic or not sold as organic.

Please make sure to identify products as Organic on sales invoices.

All records must be available at the time of inspection. Records should be saved for 5 years.

NOTE: A parallel producer grows the same crop organically and conventionally. Parallel producers must be prepared to demonstrate with records that the organic crop is produced and marketed separately from the conventional crop. Harvest and sales records must be kept for organic AND conventional crop production. This includes crops grown in buffer zones.

4. GUIDELINES FOR LIVESTOCK AND LIVESTOCK PRODUCTS

Organic livestock production is based on preventative management.

4.1 Animal Purchase and Replacement NOP §205.236

Poultry

Poultry must be organically managed from the second day of life—for practical purposes, when chicks arrive from the hatchery. This applies to birds for egg and meat production. Poultry may be purchased from another organic operation, but cannot be transitioned from non-certified to certified organic production (even if they have been managed organically).

Slaughter Stock

Slaughter stock must be certified organic from the last third of gestation; that is, before the animal is born. Conventional animals cannot be “finished organically” and sold as organic. Organic slaughter stock may be sourced from certified organic operations.

Breeding Stock (non-dairy stock)

Breeding stock may be conventional, but must be managed organically from the last third of gestation for their offspring to be organic and throughout lactation if raising their organic offspring. Conventional practices for breeding stock while not lactating and not in the last third of gestation should be described in the organic system plan. Breeding stock that is managed conventionally cannot be sold as organic either live or slaughtered.

Dairy Stock

Replacements must be managed organically from the last third of gestation—the dam is managed organically before the dairy animal is born. Dairy stock may be purchased from certified organic operations. Conventional dairy herds may be transitioned to organic production on a one-time, herd-wide basis. Dairy herd transition requires 12 months of organic management before milk can enter the organic market. During and after the transition period, all purchased animals must be certified organic. See 4.11 for more information.

Any livestock, including dairy animals that are removed from an organic operation and subsequently managed conventionally may not be sold or labeled as organic, and livestock products from these animals may not be sold or labeled as organic.

4.2 Animal Identification Methods NOP §205.236 & 205.103

Certified producers must reliably identify organic animals to demonstrate that origins and health care practices meet requirements for organic production, sale or slaughter. Consult with Registry Associations for industry accepted and breed appropriate methods of identification. Identification methods that are not easily tampered with and a commitment to record keeping are necessary for organic certification. The following are permitted methods for large animals, including cows, pigs, sheep, and goats.

Ear tags may be permitted. Unique, consecutive long numbers must be used (e.g., DHIA ear tags, USDA 840 ear tags) and an additional identifier such as a farm name, dam name, and/or date of birth should also appear on the tag. Be advised that we are considering phasing out ear tags because they are easily lost and not tamper proof.

Photos (associated with names/numbers) for animals (other than poultry) with distinguishing marks or features. For cattle, a calf stage photo is required, unless the animal arrives as an adult from outside the farm. For animals lacking distinguishing features (e.g., Black Angus), ear tags are recommended.

Ear notching of pigs is permitted when other methods will not work. Notching should be done when piglets are no more than a few days old.

Tattoos are considered permanent ID if appropriate for the breed. A tattoo plus an easily read ear tag is recommended for identification at a glance and for record keeping, but is not a requirement for permanent ID.

For poultry production, use of different breeds and leg bands are methods of flock identification.

Double ID. Forms of ID that are easily removed or impermanent are not considered suitable as the primary form of ID, such as neck chain tags, ankle bands, etc., but may be suitable as a secondary form of ID. For example, collar name tags

alone would not be permitted, but for a herd or flock that also carries tattoo ID in the ears, could be acceptable as a secondary form of ID. Individual animal records tracing back to the last third of gestation must list both primary and secondary IDs if there are two forms.

Acceptable Double ID examples:

- 1) a metal DHIA ear tag plus a neck chain tag with a barn name or unique number
- 2) the same pendant style tag in each ear
- 3) ear tags plus tattoos
- 4) ear tags or tattoos plus photographs or registration sketches

Other reliable methods of identification may be approved, provided that organic inspectors and MCS staff are able to associate animal records with the correct animals in the field or barn without your help. MCS recommends individual animal records contain the origins, health care, breeding, and final fates of each certified animal in one location. Card-type systems designed to fit into a card box or loose-leaf binder, journal style records, calendar based records, electronic systems, and other methods are acceptable and will be approved on a case-by-case basis.

4.3 Feed NOP §205.237

All grains, forages, and other feeds including grazed feeds (both produced on farm and purchased) must be certified organic by MCS or another USDA accredited certifying agent. This includes food waste for pigs and milk for young stock. Milk may be from the offspring's own mother under organic management in the case of breeder stock.

For feeds grown on-farm, organic inspectors will be looking for production records, including seed documentation, tillage, fertility, and harvest totals. For purchased feeds, receipts and organic certificates must be kept and made available as requested by inspectors and certification staff.

Ruminant livestock must receive a minimum of 30% dry matter from pasture averaged over the entire grazing season. The operator of a ruminant livestock operation must keep records that describe the total feed ration for each type and class of animal, and any changes in that ration over the grazing season. Records should indicate the percentage of each feed ingredient in the total ration and/or dates when an ingredient or ingredient percentages changes.

Adding New Fields

When adding new fields for crops or pasture to an OSP, we require maps, field histories, and signed Landholder Affidavits, plus an on-site inspection. Feed should be harvested AFTER certification is granted, or possibly after the inspection for operations that are already certified, provided no concerns were identified at the inspection. Feeds from new fields cannot be stored, or commingled, with certified organic feeds until all verifications can be made and certification of the feed is granted. Verification will include the amounts of feed produced, where it came from, production methods, and storage. There are many ways to accomplish feed separation that are accepted by MCS including: keeping the feed on the field where it came from, keeping the feed on the field edge where it was made, keeping the feed in a separate location such as a trusted neighbor's yard, keeping the feed in a separate silo, barn or pile at your own operation, or labeling the feed in the case of baleage. Ruminant livestock subject to the pasture rule may be turned onto new pastures at the beginning of the grazing season at your own risk, pending verifications of certification paperwork including pasture maps, field histories, signed Landholder Affidavits, and an on-site inspection. Consult with your certification specialist to create a plan for certification of new fields and feeds.

Supplements:

Mineral and vitamin supplements, including salt blocks, are recommended for preventative nutrition. Restrictions apply to ingredients in feed supplements, and all products must be approved by MCS prior to use. Kelp must be certified organic. Sodium bicarbonate is permitted.

Prohibited Feeds and Practices:

The following are examples of **prohibited** feeds and feeding practices:

- Conventionally raised forage or grain for any reason
- Uncertified hay, baleage, or grain (except transitioning dairies, contact MCS)
- Any feed or milk replacer with added medication, hormones, or ionophores
- Any natural or synthetic growth hormones
- Plastic pellets for roughage
- Urea
- Manure re-feeding
- Milk from lactating mothers receiving antibiotics or other prohibited materials
- Feeding of mammalian or poultry slaughter by-products to mammals or poultry
- Feeds that have been in direct contact with prohibited materials (e.g., commingled with conventional feeds; arsenate treated lumber)
- Feed supplements or additives **provided in amounts above those needed for adequate nutrition and health maintenance** for the species at its stage of life
- Feed, feed additives and feed supplements used in violation of the Federal Food, Drug and Cosmetic Act

4.4 Pasture Rule NOP §205.237(c) and Pasture Management NOP §205.240

The pasture rule establishes minimum grazing requirements for organic ruminants (cattle, goats, sheep, llamas, alpacas, and deer). Pasture has to have high quality forage available for grazing.

Key Components of the Pasture Rule

1. All ruminants must be managed daily on pasture throughout the grazing season. (Some exceptions of this requirement exist and can be found in NOP §4205.239 Living Conditions.)

Ruminant animals must consume a minimum of 30% dry matter intake (DMI) from pasture averaged over the grazing season. Pasture is land used for grazing that consists of standing rooted forage, and residual forage cut and left to lie in place.

Dry matter (i.e. grain, hay, baleage) fed to animals cannot exceed 70% of the ruminant animals' diet over the pasture/grazing season. Dry matter fed is the grain, hay, baleage, silage, or other forage crops that are brought to the animal, minus the water that may be in those feeds.

2. The DMI percentage from pasture will be calculated as a weighted average over the entire grazing season. You can do your own pasture DMI calculations, but you need to share your figures with inspectors and certification staff who will verify the minimum grazing requirement is met.

3. The grazing season must be defined with beginning and ending dates for each individual farm. The grazing season is considered to be the period of time when pasture is available for grazing in the geographical region. The grazing season must be at least 120 days, but does not have to be continuous (for example, dry weeks during mid summer can be excluded from the grazing season, but grazing days may need to be "made up" in the fall to achieve at least 120 days on pasture).

4. Yards and feeding pads can be used to provide outdoor access during the non-grazing season, and supplemental feeding during the grazing season. These yards have to be large enough to hold the entire herd or flock, without crowding or competition for food. They need to be kept in good condition and managed to prevent nutrient runoff.

5. Breeding bulls do not have to be managed on pasture, but if they are not, they cannot be sold as organic.

6. After 6 months of age, dairy stock must be housed and managed in groups—no individual housing. This is also the age when year-round access to the outdoors is required and the pasture rule must be met (minimum average 30% DMI from pasture for the entire grazing season).

7. Finishing ruminant slaughter stock may be fed 100% of their diet from organic feeds, but must still have access to pasture (if it is pasture season during finishing). In other words, there is no minimum requirement for grazing. The finishing period can be no longer than 1/5 of the animal's lifespan, or 120 days, whichever is shorter. Yards, feeding pads or feedlots may be used to provide finish feed rations. During the finishing period, ruminant slaughter stock can be exempt from the minimum 30% DMI requirement from grazing. The yards, feeding pads or feedlots used to provide finish feeding rations should be large enough to allow all ruminant slaughter stock to occupy the yard, feeding pad or feed lot to feed simultaneously without crowding and without competition for food.

8. Pasture must be managed as a crop and be in full compliance with NOP §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.

9. Pasture must be managed to minimize the occurrence and spread of diseases and parasites. Management must refrain from putting soil or water quality at risk.

Dry Matter Intake Calculations

MCS uses the subtraction method to estimate dry matter intake from pasture:

Dry matter demand (DMD) – Dry matter fed (DM fed) = Dry matter intake (DMI) from pasture

We will be happy to send you the forms we are using, and to show you how to use them. The math involved is addition, subtraction, and multiplication. This is the simplest method that we have determined for your operation to show compliance with the NOP requirement, however we are open to operators using other methods as long as they are technically correct and easily audited by inspectors and certification staff.

Dry matter demand (DMD) is an estimate of the need of the individual or group of animals. It is most often based on bodyweight, stage of growth, and productivity (if lactating). You may use our DMD tables or other resources to determine DMD figures for each group of livestock on your operation.

Ruminant Groups: DMD as a Percentage of Body Weight	
Dairy cows	3.5%
Dry dairy cows	1.8%
Bred dairy heifers (14-24 months of age)	2.5%
Unbred dairy heifers (6-14 months of age)	2.5%
Beef cattle (more than 1 year of age)	2.25%
Beef cattle (weaned, less than 1 year of age)	2.75%
Sheep (brooding or milking animals)	3.65%
Goats (brooding or milking animals)	4%
Sheep (weaned, slaughter or replacement stock)	3.3%
Goats (weaned, slaughter or replacement stock)	2.25%

DRY MATTER DEMAND (DMD) TABLES for Ruminants Dairy Cows—Daily DMD based on milk production		
Average milk per day	Small breed <900-1200# body weight DMD	Large breed 1200-1400#+ bodyweight DMD
10#	21#	27#
15#	23#	28#
20#	24#	30#
25#	26#	31#
30#	28#	33#
35#	30#	34#
40#	31#	36#
45#	33#	37#
50#	35#	39#
55#	36#	40#
60#	38#	42#
65#	40#	43#
70#	42#	45#
75#	43#	46#
80#	45#	48#

BEEF CATTLE Current body weight (lbs)	Daily DMD	
	Lbs of DM	% bodyweight
300	10.1	3.35%
350	11.3	3.23%
400	12.5	3.12%
450	13.6	3.03%
500	14.8	2.95%
550	15.9	2.89%
600	16.9	2.82%
650	17.9	2.76%
700	18.0	2.58%
750	18.9	2.53%
800	20.2	2.51%
850	21.0	2.47%
900	21.8	2.44%
950	22.6	2.39%
1050	24.5	2.33%
1150	26.1	2.27%

Dry matter fed (DM fed) is the grain and forages you provide to organic livestock during the grazing season. It is best if you have dry matter figures/percent moisture from feed tests for your own stored forages, but you can use average book figures. MCS MAY also accept other methods of demonstrating pasture rule compliance, such as subtraction from the winter ration or direct pasture measurements on a case-by-case basis with appropriate justification. To demonstrate your compliance, you must record the amounts of stored feeds fed out during the grazing season (pounds of silage, hay, and grain).

Dry matter intake (DMI) from pasture is estimated on a per-animal or per-group basis. One calculation will be done for each management group that is fed a different ration. Ration changes will result in varying DMI from pasture as the growing season progresses, so we determine compliance based on the weighted average for the entire grazing season. If you have questions about dry matter calculations, please feel free to call us at 568-6030.

Pasture Rule Recordkeeping

Producers must keep the following records to demonstrate compliance with the pasture rule

1. Turn out dates and feed records to show the length of the grazing season
2. Ration records indicating the amounts of hay, silage and grain fed to animals during the grazing season and non-grazing season. This can be group records or on an individual cow basis. Include dates rations are changed for calculating the weighted average
3. Evidence that pasture quality is being maximized
4. Records noting days when animals are confined from pasture and the reason for confinement

Pasture rotation records are NOT a requirement for organic certification, since operations executing complex grazing systems or management intensive grazing would face a much heavier recordkeeping load than a producer with a simpler grazing system. Rotational grazing systems will be observed during on-site inspections. Pasture maps with the seasons' grazing notes on them are encouraged.

Pasture Plan

All the required information is contained in questions already in your certification paperwork (OSP). However, another plan such as a NRCS Prescribed Grazing Plan may be accepted. Your plan must address the following considerations for organic pasture management:

1. What kinds of pastures do you provide to your livestock?
2. What practices do you use to make sure that there is plenty of feed on the pasture for the whole season?
3. How long is your grazing season?
4. How many acres of permanent pasture are there?
5. How many cropped acres do you graze?
6. What kinds of grazing methods do you use?
7. How do you manage pasture soil fertility?
8. Do you re-seed pasture?
9. What do you do to prevent erosion?

4.5 Living Conditions NOP §205.239

You must maintain living conditions for your organic livestock that promote the health and natural behavior of the animals, including adequate light, ventilation, and appropriate clean, dry bedding.

Bedding. When bedding is agriculturally produced (hay, straw, etc.), it must be certified organic. Wood chips and shavings derived from virgin wood (no treated or composite wood) can be approved. Paper is synthetic in nature and contains residues of many chemicals and chemical inks, however shredded newspaper is recycled and may be permitted as bedding. The reasoning is that newspaper is allowed as a compost feedstock, and bedding often winds up being composted. Please note this allowance does not extend to office paper because there is no assurance that all the contents would be of recycled content, and would contain no glossy and colored inks. In addition, we are concerned that the livestock will pick up the paper in their mouths and eat it. Sources of bedding must be approved by MCS prior to use.

Although there are not restrictions on types of housing, it is important to consider challenges to meeting the requirements that may be inherent in some kinds of housing (e.g. dairy heifers over age 6 months in tie-stall housing need winter outdoor access). When managing the living conditions of your organic livestock, you must consider the following:

1. All livestock (cattle, goats, sheep, camelids, deer, pigs, poultry, rabbits, etc.) must have **year-round access to outdoor areas** (suitable to the species, stage of life, climate and environment) that provide shade, shelter, opportunity to exercise, fresh air, clean water for drinking, and direct sunlight.
2. Shelters should have temperature levels, ventilation and air circulation suitable to the species housed and should be built to reduce any potential for livestock injury. Animals must always have enough room to stand up, lie down, stretch, and move about freely.
3. Temporary confinement is acceptable for:
 - a. Stage of life (e.g., chickens during feathering, molting). Lactation is not a stage of life.
 - b. Inclement weather (e.g., violent weather, extreme high or low temperatures, excessive precipitation). Weather events are short-term events as opposed to seasonal patterns, which are long-term events—confinement during an entire season is prohibited. You know when your animals are stressed; good judgment is in order. Icy ground is a temporary condition that can be rectified by sanding, etc.
 - c. Risk to the health, safety, or wellbeing of the animals (e.g., predator observed)
 - d. Risk to soil or water quality
 - e. Preventative healthcare procedures, such as treating an illness or injury
 - f. Sorting and shipping animals
 - g. 4-H and other youth projects—1 week before, during, and 1 day after the event
 - h. Breeding—animals confined for breeding (AI or a bull) must still have daily access to the outdoors, and must achieve 30% DMI from pasture for 120 days during that season.
 - i. Prior to birthing—for 3 weeks, during birthing, and one week just after birthing
 - j. Short periods for shearing fiber animals
 - k. During milking for dairy animals
 - l. 1 week for drying off dairy animals (restricting pasture with outdoor access)
 - m. Newborn dairy cattle up to age 6 months old, provided that calves are not confined or tethered in a way that prevents them from standing up, lying down, fully extending their limbs, and moving freely in the space

Temporary is defined as “occurring for a limited time only (e.g. overnight, throughout a storm, during a period of illness...), not permanent or lasting.” MCS recommends taking the minimal approach to recordkeeping by describing your outdoor access protocol and documenting occasional compliant confinement as the exceptions to the rule.

4.6 Animal Health NOP §205.238

Prevention

Organic health management is first preventative, using good farming practices including sanitation, minimizing stress, high quality feed, approved minerals and supplements, approved probiotics, pasture rotation, access to the outdoors, shade, shelter, exercise areas, fresh air, clean water for drinking, direct sunlight, ventilation, and clean dry bedding. Vaccinations are considered preventative and are permitted.

Natural Treatments

When preventative measures are not enough, natural treatments may be used. A current list of allowed and restricted treatments for livestock is available from MCS.

Allowed Synthetic Substances and Medications §205.603

Certain “National List” allowed or restricted synthetic substances may be considered under specific circumstances. Some items have restrictions, for example, oxytocin is allowed for retained placenta but not for milk let-down.

Synthetic parasiticides on the National List (e.g., moxidectin, fenbendazole) can be used:

- On breeder stock if not administered during the last third of gestation or during lactation if rearing organic young
- On dairy stock provided milk or milk products from a treated animal cannot be sold as organic for 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species
- On fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic

Synthetic parasiticides **cannot** be used on organic slaughter stock, including dairy cull animals for beef. Synthetic parasiticides must be used on a per-animal, as-needed basis, not routinely for groups. If it is determined that use of a synthetic parasiticide is necessary, preventative practices on the operation must be reconsidered. Products must be approved prior to use. Be sure to call MCS when considering the use of synthetic parasiticides.

No animal drugs other than vaccinations may be administered in the absence of illness. Animal drugs cannot be administered in violation with the Federal Food, Drug and Cosmetic Act.

In emergency situations, prohibited synthetic medications (including antibiotics, prohibited parasiticides and hormones) may be necessary to save an animal. **Certified producers must never deny treatment to an animal so that its product may be labeled “organic.”** If synthetic medication or antibiotics are needed to save the life of an animal they must be given. Treated animals or animal products must then be identified, removed from organic production, and diverted to conventional markets. Upon treatment with prohibited materials, notification to the certifier is required and records must be kept to reflect treatment and removal of animal(s) from organic production.

4.7 Dehorning

The National Organic Standards allow “physical alterations as needed to promote the animal’s welfare and in a manner that minimizes pain and stress” NOP §205.238(a)(5). Dehorning prevents cattle from being injured by one another, and also protects the people working around them.

A dehorning standard procedure will be part of your organic farm plan. Dehorning should appear in every individual animal’s health history in a manner that allows methods to be evaluated for compliance with this standard.

The following dehorning considerations show compliance with the organic standards:

- Disbudding calves at the youngest age possible is preferred.
- Local anesthesia should be considered when using other methods of dehorning and in circumstances when young age is not possible. Lidocaine (Xylocaine) and procaine (Novocaine) are allowed with withholding periods required by NOP §205.603(b)(3)—8 days for slaughter stock and 6 days for dairy stock. Lidocaine and procaine use and withholdings are expected to be shown in recordkeeping. Producers who administer an analgesic during the disbudding process should be trained by a veterinarian.
- Avoiding “fly season,” stress and humid weather
- Professional hire by a veterinarian
- Dehorning pastes are **not** permitted.

4.8 Parasite Control NOP §205.603(a)(18)

The key to organic management of parasites is implementing as many strategies as possible. It may be more feasible to manage for low parasites and parasite resistance in livestock, rather than attempting to maintain a no-parasite strategy.

When synthetic parasiticides become necessary, it is time to review your farm’s preventative management plan and address any weaknesses in order to avoid routine use of these restricted use products.

Preventative Management

Preventative management practices can consist of:

- Selective genetics for resistance (especially in small ruminants) and culling
- A grazing plan to decrease exposure to parasites including methods such as intensive rotational grazing, low stocking densities, high residual grazing height, and allowing refusal areas by avoiding harrowing or chain-dragging pastures
- Multi-species grazing (e.g. cows followed by sheep in pasture rotation)
- Complete nutrition: Vitamins A, D, and B complex; Minerals cobalt and iron

Control Options

Check the most recent Livestock Materials List and contact MCS staff for approval before using parasiticide products.

Keep in mind that:

- Plant-based parasiticides may be allowed.
- Products with natural active ingredients may be allowed.
- Synthetic parasiticides (ivermectin, moxidectin, fenbendazole) may be used on a **non-routine** basis along with preventative management. **Restrictions apply** NOP §205.603(a)(18).
- **Please note, Ivermectin is now prohibited for use for organic livestock.**

Moxidectin and fenbendazole are prohibited in slaughter stock, but allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. 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 nursing their own young. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

(i) Fenbendazole (CAS #43210-67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

(ii) Moxidectin (CAS #113507-06-5)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

Some synthetic parasiticide products have confusing labels. To be certain that the product's ingredients meet the organic standards, please contact MCS before purchasing or using. Use of prohibited parasiticides will result in the loss of certification of the treated animal(s).

Common Prohibited Materials

- IVOMECE Eprinex/Eprinomectin
- Dectomax/Doramectin
- Prohibit Drench/Levasole

4.9 Livestock Products—Processing & Handling (Slaughter, meat, eggs, etc.)

Processing and handling regulations may be applicable to your livestock products. See section 8 below for processing and handling guidance.

Meat

Organic meat must come from animals that meet the requirements for organic slaughter stock. Organic meat must be processed at a certified organic facility. If you need help finding an organic slaughterhouse, please contact our office.

Value Added/Processed Products

On-farm processing (such as cheese making, slaughter, etc.) can be certified organic when properly licensed by the State of Maine. Processing standards in the organic regulations will apply.

Handling

For split operations, systems must be in place to prevent contact with prohibited substances and to prevent commingling of organic and conventional product. For example, conventional layers or layers that are ineligible for certification must be kept separate from organic layers, since eggs will be easily commingled. Contact MCS for approval of any egg washes.

Label Requirements

Organic label requirements apply to all livestock processed products. Submit draft labels to be sure that requirements are met before labels go to print. State requirements, federal requirements, and requirements for all claims other than those in the organic standards (such as non-GMO claims) are your responsibility as the producer.

4.10 Recordkeeping Requirements NOP §205.103

Certified operations are required to maintain records adapted to their particular business concerning the production of organic products (milk, eggs, meat, replacement stock, etc.). The purpose of these records is to demonstrate your operation's compliance with the organic standards. Records may be requested at your annual inspection, at unannounced inspections, or for other inquiries by MCS. Records must be maintained for at least five years beyond their creation.

An MCS inspector will annually perform spot checks of animals on your farm and will ask to see records. Records should include origins, healthcare, and management. An inspector may ask to see records for an animal that was on the farm the previous year. In the case of an animal that is recently deceased, sold, or shipped for slaughter, the inspector expects to be able to see all records associated with the animal. Inspectors will also ask to see receipts and other documentation for new animals in order to verify organic status.

MCS recommends a system of individual animal records that contains the origins, health care, breeding, and final fates of each dairy or meat animal that is certified on the farm. There are a number of card-type systems designed to fit into a loose-leaf binder. Your milk distributor may have cards for you to use. Electronic recordkeeping systems must be accessible for your inspector to review at length as needed (e.g. computer programs, apps on a phone, etc.) and the content of such records must be readily understood.

MCS accepts a variety of systems provided that the producer demonstrates a commitment to using it and that the inspector can access and interpret records without great effort. MCS will evaluate recordkeeping systems on a case-by-case basis, with the help of the inspector's evaluation.

Required Recordkeeping

1. Production records: milk shipments, bottling records for milk, egg production records, meat production records that link to ID records, sales records for organic livestock on the hoof, etc.
2. Crop & feed records: seed receipts showing organic status/documentation of seed search effort, planting records, cultivation records, material application records, harvest totals, receipts for inputs (including inoculants), crop rotation records.
3. Feed receipts: for all purchased feeds, including grain, forages, etc.
4. Animal identification: individual ID for ruminants and slaughter stock (such as digital photos, ear tags, etc.), flock ID for poultry, birth/calving records linking offspring to parents to demonstrate origins and flock ID for poultry. The purpose of animal ID is to demonstrate origins and track management, so IDs must be preserved.
5. Bill of sale and organic certificates for purchased animals: to demonstrate status for organic dairy or livestock production, slaughter eligibility, or as breeder stock. Poultry producers are expected to keep records about the purchase of eggs (for incubation), day old chicks or already certified organic chicks or birds. For purchased dairy stock to be considered for organic slaughter, the date of birth and dam must be obtained in original records from the seller along with transition status and full health history indicating slaughter eligibility (never treated with restricted synthetic parasiticides, withholding times are met for restricted materials). Consult with your certification specialist about the status of dairy stock for slaughter and the necessary recordkeeping.
6. Health care records: routine treatments, non-routine treatments with individual animal ID linked, accounts of use of prohibited materials for appropriate reasons (such as prohibited wormer used for horses). For dairy operations, we recommend this information be kept in herd records/a herd book. Poultry producers must keep records on flocks of birds that can verify compliance with the Standards.
7. Ration records for ruminants: amount and type of each feed provided for any time frame. Verification that not more than 70% of the animals dry matter is fed during the grazing season.
8. Equipment cleanout records: needed to demonstrate prevention of contamination if equipment is shared between organic and conventional production.

4.11 Dairy Herd Conversion to Organic

There are two routes to organic certification for dairy operations to enter the organic milk market. These apply to operations of any scale/species, regardless of type of marketing (commercial, direct to consumer, etc).

Route 1: Dairy Herd 12-month Transition to Organic

Route 2: Dairy Farm Certification and Purchase of Organic Herd

Route 1: Dairy Herd Transition to Organic

Transition of dairy animals requires 12 months under full organic management while working with MCS. This includes **100% organic feed for the entire 12-month transition period**. All purchased or off-farm feeds must be certified organic by a USDA-accredited certifier. Feeds produced on-farm from land that is certifiable or in the last year of the 3-year transition may be used. Bedding material that is grown on 3rd year transition land may be used. During this 12-month transition period, all other management (health care, outdoor access, etc.) must be in compliance with the standards. Once converted to organic production, all animals shall be managed organically from the last third of gestation.

Steps to Transition Dairy Animals to Organic:

1. Complete the 4-page *Intent to Transition* form and submit it to MCS staff at the start of the transition year. This form generally addresses organic management.

2. Farms are responsible for documentation demonstrating the date after which organic practices are followed, for example dated grain slips, feed receipts, etc.
3. MCS and/or MOFGA Ag Services staff typically follow-up with a farm visit, providing an opportunity to meet with certification staff and ask questions about the organic standards. Please be aware that MOFGA has an Agricultural Services department that can provide consultation and technical advice that the certifier is not permitted to give. You can contact staff from Agricultural Services by calling MOFGA at 568-4142.
4. The full application for certification is due on or before the 3rd month of your transition year. Fees are also due at this time.
5. MCS will review the application and communicate questions or missing information by letters, emails, phone calls, etc.
6. Once complete, your application is assigned to an inspector, who will contact you directly to set up a day and time for the inspection. This is usually in the last few months of the transition year and is typically conducted during the growing season.
7. The inspection can take from 2-5 hours depending on the complexity of the farm and how organized and prepared the producer is.
8. The inspection report is sent back to MCS.
9. MCS reviews the inspection report and communicates any questions or concerns through letters, email, and calls, as necessary.
10. Once all concerns have been adequately addressed, certification is granted upon completion of the 12- month transition. At this time milk can enter the organic market.

Applications from dairy operations that have not submitted an *Intent to Transition* form at the start of their transition year may be accepted, but acceptance of the application in this instance will mark the start of the transition year.

Addition of new conventional animals into the herd during the transition year will require starting the 12-month transition period over again. Certified organic animals may be acquired during the transition year, and maintained under full organic management.

Route 2: Dairy Farm Certification with Purchased Organic Herd

If you intend to purchase certified organic animals, you must first certify the farm (pasture, feed crops, etc.) prior to the arrival of certified organic animals on the farm. Land must meet all of the requirements for organic crops production (free of prohibited substances for 36 months, etc.). You must either (a) apply for and obtain certification at the start of the growing season in order for us to inspect your cropping systems and your approach to organic land management, or (b) purchase feed that is certified organic by a USDA-accredited certifier. Keep in mind that animals will need access to pasture and pasture must be certified prior to grazing by certified organic animals.

Steps to Certify Your Farm and Purchase Organic Animals:

1. Complete a full application for certification of organic crops (hay, silage, pasture, etc). The forms are available directly from the MCS office and are also on the MCS website. Fees are due with the application so that we can begin the certification process. You may submit the Dairy Supplement at any point prior to 6-8 weeks from when you want the cattle to be inspected and certified.
2. MCS reviews the application and communicate any questions or concerns regarding compliance with the organic standards.
3. Your application is assigned to an inspector, who will contact you directly to set up the inspection.
4. The inspection can take from 2-5 hours depending on the complexity of the farm and how prepared and organized the records are.
5. The inspection report is sent back to MCS staff.
6. Once any concerns are resolved, certification is granted for the land and crops. Crops and forages produced after the date on the organic certificate are considered certified organic feed for organic livestock.
7. Once the crops and land are certified, organic cattle can be brought to the farm.
8. The Dairy Supplement is reviewed by the same process as above, and assigned to an inspector. This person contacts you to schedule the livestock portion of the inspection.
9. The report about the livestock portion of your farm is sent to our office for review. We review the inspection report and communicate any questions or concerns we have regarding compliance with the organic standards through letters, email, and calls as necessary.
10. Once any concerns can be resolved certification is granted and milk can enter the organic market.

If you are not transitioning a herd to organic, but instead buying certified organic animals to create an organic dairy herd, you do not have to file an *Intent to Transition* form. Once certified organic all new animals shall be managed organically from the last third of gestation.

5. GUIDELINES FOR ORGANIC MAPLE SYRUP PRODUCTION

MCS guidelines for maple syrup production are consistent with the USDA National Organic Program (NOP) standard. Weed and pest control, fertilization, cleaners, sanitizers and facility and forest management must all be in compliance. You must complete a field history for each stand that is tapped. A field history must document management activities that maintain and improve soil and water quality and biodiversity, including materials/products applied to trees or land for the past three years. Please note that if you plan to market organic syrup to Canada, Chilean (sodium) nitrate is not allowed as a fertility input.

Species diversity provides stability to forest communities. Producers are expected to manage the sugar bush using accepted forestry practices such as thinning that selects for healthy, vigorous trees and a stand composed of a mixture of young and mature tree species. Soil disturbance and erosion should be minimized throughout the year. Water quality must be maintained or improved and silting or sedimentation of streams must be prevented.

Producers are expected to minimize impact to the forest and trees. Nails and other hardware inserted into tree trunks to hold up lines are not allowed in tapped trees. Paint cannot be applied to tapped trees as it is a synthetic substance that is not permitted in organic production (NOP §205.601). Producers are expected to select healthy trees and to tap in a sustainable manner. Only sap collected from an inspected sugar bush may be used in production of organic maple syrup.

Many maple syrup producers do not own the sugar bush they tap. Each landowner may have their own standards concerning tapping and forest management. If you seek certification from MCS, you must be prepared to meet our standards regardless of what the landowner permits or what you have negotiated in your lease agreement. For instance, we do not allow tapping of trees that are less than 10 inches in diameter at breast height (DBH). Please review our standards carefully before applying for certification.

5.1. Inspection and Fees

Inspection of maple syrup operations will take place during spring production. We must receive new applications and updates by mid-February. Certified maple syrup producers will automatically receive their renewal paperwork in the mail in January. Application forms are available on our website in January OR you can call or email us and we will send the paperwork to you. Fees are based on estimated gross syrup (or sap) sales for the calendar year.

5.2 Lead

MCS recommends that producers periodically test their equipment and products for lead contamination. MCS reserves the right to test for lead if inspectors observe equipment that may pose a lead risk. Evaporator pans and galvanized buckets manufactured before 1995 may contain lead. Evaporator pans should have smooth, non-corroded surfaces. Pits, crevices and poor welds raise concerns about lead contamination. For more information about keeping lead out of maple syrup see the University of Vermont publication <http://www.uvm.edu/~pmrc/LeadOut.pdf>.

5.3 Tapping

Recommended

- Health spouts (5/16" or smaller)
- One tap per tree per season

Permitted

- Standard spouts (7/16")
- Lead free metal sap buckets and food grade plastic buckets
- Plastic tubing system
- Vacuum pumps with monitoring of pressure levels at taps; producers should maintain as low a pressure as possible
- Multiple taps per tree based on the DBH of the tree (see chart below)

Guidelines for Number of Taps Per Tree

Trunk Diameter at Breast Height (DBH) in inches	Trunk Circumference at Breast Height in inches	Number of Taps
10-18	31-56	1
18.1-25	57-79	2
>25	>79	3

(DBH is tree diameter at breast height which is 54 inches from tree base).

Not Permitted

- Galvanized buckets that pose a risk of lead contamination
- Synthetic fungicides, antibiotics, fumigants, sterilants, etc. in contact with trees
- Tapping trees in poor health or with weak crowns.
- Tapping trees less than 10" DBH
- Successive year tap holes closer than 4" side to side and 6" up/down
- Sap collection containers previously used for holding a prohibited substance
- Leaving spouts in trees more than 60 days after the end of sap flow
- Re-tapping a previously tapped tree during the same season ("double tapping") or reaming (freshening) the tap hole

5.4 Pump Stations and Sap Storage

Recommended

- Stainless steel tank
- Lids to prevent debris from falling into sap

Permitted

- Food-grade plastic holding tank

Not Permitted

- Equipment that routinely emits oil or other prohibited materials into environment
- Gas and diesel engines in the same enclosed space as the sap collection tank
- Galvanized metal storage tanks or containers

5.5. Filtration and Processing of Sap

Permitted

- Sand, cloth or felt filters*
- Reverse osmosis systems*

** How filters and filtering equipment are maintained, cleaned and stored must be disclosed in the organic system plan. All materials and products used to clean, disinfect and store filters must be listed. Only those approved by MCS can be used.*

Not Permitted

- Use of materials that release toxic substances by oxidation, chemical reaction, or diffusion
- Cleaning agents and sanitizers that are persistent; fabric filters must be well rinsed before reusing

5.6 Evaporation of Sap

Permitted

- Certified organic defoaming agents are required.

CAUTION! Dairy products and oils derived from soybeans and peanuts are known allergens. If an allergen-containing defoamer is used, we recommend providing information about it on your label.

- Air injectors in evaporator are permitted provided that a carbon filter is used and the air intake is outside the building and away from exhaust fumes. A protocol for changing the filter is required and records must be kept.

Not Permitted

- Synthetic defoaming agents

IMPORTANT: Please contact MCS if changing your defoamer. MCS cannot certify syrup made with a synthetic defoamer.

- Meat products for defoaming
- Defoaming agents that are not certified organic
- Evaporator pans in poor condition. Evaporator pans manufactured prior to 1995 may require additional verification to rule out potential lead contamination.

5.7 Filtration of Syrup

Permitted

- Paper, felt, or synthetic fiber used to filter syrup. If filters are washed and reused, cleaning agents and rinsing protocols must be disclosed in the organic system plan.
- Food-grade diatomaceous earth or silica powder as a filtering aid. *Syrup filtered with diatomaceous earth or silica powder may be labeled "Organic". The "100% Organic" label cannot be used.*

Not Permitted

- Use of asbestos as a filtering material
- Products added to syrup to enhance taste, color, or texture
- Preservatives

CAUTION! Remember that syrup having a density reading below 66% Brix is a violation of Maine state law. Such syrup is more likely to ferment. Syrup with a density above 68% Brix may crystallize.

5.8 Storage and Canning

Recommended

- Stainless steel drums for bulk storage
- Glass containers for retail packaging

Permitted

- Metal containers with food-grade coatings and plastic tops
- Epoxy painted metal drums provided that the paint is not flaking, chipping or cracking. Producers must have a protocol to check for this prior to filling each barrel.
- Food grade plastic containers

Not Permitted

- Galvanized metal storage barrels
- Drums with chipped epoxy paint, rust or other imperfections that can impact syrup quality

5.9 Product Labeling

Barrels should be labeled with a lot number that can be traced back to a production date. Organic syrup should be identified as such and include the name of the certifier. The “Certified Organic By MOFGA” statement must appear directly beneath the contact information for the producer.

5.10 Cleaning & Storage of Equipment

Permitted

- Approved chlorine materials may be used up to the maximum labeled rate for disinfecting and sanitizing lines, pans, tanks and other sap or syrup contact surfaces. Rinsing is not required unless mandated by the label. Please be sure to check that your chlorine product has been approved by MCS and any requirements for such use.
- Biodegradable detergents, vinegar, sodium bicarbonate, food-grade hydrogen peroxide, sodium hydroxide and phosphoric acid. Producer must take steps to ensure that equipment is thoroughly rinsed to avoid contamination.
- Propylene glycol for storage of osmosis filter is allowed provided that adequate rinsing is done before sap is processed.

Not Permitted

- Storing filters or equipment near pesticides, fumigants, or other volatile substances. For example, mothballs, a common household pest repellent, must not be used inside production facilities for rodent control or for any other purposes. Items used in maple syrup production must be kept clean and free from contaminants.

5.11 Recordkeeping

Section NOP §205.103 of the National Organic Standards specifies that certified operations must maintain records concerning the production and handling of agricultural products that are intended to be sold, labeled or represented as organic. Records must be sufficient to demonstrate compliance with the NOP Rule.

All producers must keep the following records and have them available at the time of inspection:

1. Field activity log for all forest activities such as thinning, line and pump station maintenance, tapping and tap removal
2. A field history for each separate maple stand that is tapped
3. Receipts for purchased inputs (defoamers, filters, DE, cleaning materials)
4. Standard operating procedures for cleaning/sanitizing of equipment, pans etc., including full names of all materials used OR cleaning logs
5. Pest control records (if applicable)
6. Traceable lot numbers must be displayed on retail and wholesale containers
7. Production and sales records for the current and previous year. These records may be kept by the barrel or by pounds produced and sold. We expect that sales records will balance with production records, meaning that you can account for all syrup produced. Please track any amounts going to friends and family.
8. Current State of Maine maple license

6. GUIDELINES FOR HONEYBEES AND HONEY

Apiculture is not specifically addressed in the current NOP regulation. NOP has been working on draft standards for rule making at some future date.

To address this gap in the regulation, multiple certifiers examined organic apiculture standards from around the world, including draft guidance to the USDA. This group collaborated on writing a document to foster agreement amongst NOP accredited certifiers. MCS participated in this process and this document is available upon request.

Please be aware that honey is difficult to certify to a recognized organic standard in the northeastern United States where it is challenging to isolate hives from conventionally managed crops or vegetation as well as from other sources of contamination. Harsh winters also pose challenges to hive health and longevity, which forces apiculturists to frequently seek replacement bees. Replacement bees, which are typically non-organic, become another area of complexity for an

organic standard. If you are interested in certifying your organic apiculture operation, please contact MCS so we may discuss these key areas for compliance.

7. GUIDELINES FOR ORGANIC MUSHROOMS

Mushroom production, packaging and record keeping, etc., shall conform to all applicable NOP standards as defined elsewhere in this manual. These include insect and disease control, water source approval, and other processes. You must maintain a production environment that prevents contact between organically produced mushrooms and prohibited substances throughout the entire growing cycle, harvesting and post harvesting process. Records must be kept to verify practices, production and sales. Specific standards, unique to mushroom growing, are described in the following text.

7.1 Growing Media

Permitted

- Logs and sawdust documented as free from treatment with prohibited substances ; this also applies to wooden plugs used to cover inoculation sites on logs
- Organically produced grains and plant derived materials used as either media or supplements
- Compost made in conformance with organic standards
- Naturally derived mineral buffers & supplements, such as gypsum, lime
- Previously inoculated media from certified organic sources
- Organically produced spawn
- Non-organically produced spawn that have not been treated with a prohibited substance and have not been raised on a substrate produced with genetic engineering, when organically produced spawn are not commercially available

Not Permitted

- Logs and sawdust sources known or suspected to be contaminated with prohibited materials
- Non-organic grain or plant-derived materials (e.g., straw)
- Uncomposted manure
- Treated wood in contact with growing media

7.2 Insect Control

Recommended

- Materials and practices described as recommended in the Crops Production (Section 3) of this manual
- Air filtration, in indoor cultivation
- Netting, in outdoor cultivation
- Removal of fungal debris
- Close trim of harvested mushrooms to reduce potential sites for infestation

Permitted

- Materials and practices described as permitted in the Crops Production section of this manual

Not Permitted

- Materials and practices listed as not permitted in Crops Production section of this manual

7.3 Disease Control

Recommended

- Materials and practices listed as recommended in the Crops Production (Section 3) of this manual
- Proper environmental management (i.e., temperature, humidity, and air flow to favor the desired fungus while inhibiting competitors)
- For indoor cultivation, adequate air filtration to exclude disease-bearing insects, spores of unwanted molds/fungi and other air born contaminants
- Removal of supportive substrates, such as infected media, and crop debris
- Close trimming of harvested mushrooms to reduce potential sites for infestation
- Hot water or steam for sanitizing

Permitted

- Materials and practices listed as permitted in the Crops Production section of this manual

Not Permitted

- Materials and practices listed as not permitted in the Crops Production section of this manual
- Synthetic fungicides or antibiotics either in the growing media or soak water

7.4 Other Production Materials

Permitted

- Natural, food-quality waxes (e.g., carnauba, beeswax) for covering plugs
- Plastic film, for either media or crop packaging
- Naturally occurring acids or bases for the purpose of adjusting the pH of soak tank water
- Sanitizers and disinfectants permitted by the National List for use on crops and/or substrates and/or food contact surfaces

Not Permitted

- Paint for log-end coating
- Sanitizers and disinfectants that do not meet NOP guidelines
- Paraffin wax

8. GUIDELINES FOR ORGANIC PROCESSING AND HANDLING

Processing is the modification of raw agricultural products. Handling is the processing, packaging and/or selling of agricultural products. The NOP standard requires processors and handlers of organic products to be certified unless they meet the exemption or exclusions noted in NOP §205.101.

Types of processing and handling covered under this section include but are not limited to:

- Milling (grain), freezing, chilling, dehydrating, drying, pickling, canning, preservation
- Fermenting (wine, cheese, yogurt, etc.), churning, pasteurizing
- Mixing, separating, combining ingredients to create new product (jams, spreads, syrups)
- Cooking, baking, curing, heating
- Pressing (cider or oil), extracting, distilling
- Slaughtering, grinding, eviscerating
- Packaging or repackaging

Please note that minimal modification as part of normal on-farm post harvest handling is permitted without processing certification. Minimal modification includes washing, filtering, cleaning and trimming, bagging, boxing or labeling of produce. Please include all post harvest handling details in your organic handling plan.

Processors/handlers who are **not** primarily a farm must complete an organic handling plan and include a product profile and label for each organic product. Farms with livestock and/or crops, who also process products, must also submit an organic handling plan, though an on farm processing supplement may also be submitted. Please talk with your specialist. If you are a certified livestock producer and also make organic pork sausage, your sausage is not automatically certified as part of your crop/livestock application.

8.1 Processing Facility Requirements

1. All applicable state/federal licenses must be current and available at your inspection.
2. Water must meet State of Maine drinking water quality standards. Water quality test results must be available at your inspection.
3. A processor may rent/share a processing facility as part of a contractual relationship. The following conditions apply for contracted facilities:
 - A separate organic handling plan must be completed for each contracted facility. The applicant is responsible for organic compliance at each facility.
 - The applicant or designated representative must host the on-site inspection and is responsible for all record keeping.
 - Organic certification of a contracted facility only applies to products produced by the certified client. It does not imply certification of the entire facility or other products.
4. A processor may subcontract the processing of their organic product provided the sub-contracted facility is certified organic by an accredited certifier to produce the processor's product.

8.2 Facility Pest Control

Pest control inside processing facilities must be accomplished using practices and materials that adhere to the organic standards. These practices consist of:

- Preventive management practices, including but not limited to, removal of pest habitat, food sources, breeding areas, use of screens, etc. are **required**. Additional preventive methods include control of temperature, light, humidity, or other environmental factors.
- Mechanical methods such as traps, lures or repellants
- If the methods listed in 1 and 2 above are not sufficient, use of materials consistent with the National List may be used.
- Additional pest control materials not consistent with the National List may be used if the above methods have failed. However, MCS must first review and approve the materials/methods before use and determine that there

is no contact with organic ingredients or products. The handler of an organic handling operation who applies a non-synthetic 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.

8.3 Facility Sanitation

Required

- Sanitation Standard Operating Procedures (SSOP) must be followed and documented by either logs or employee training.
- Materials used in direct contact with organic products, such as sanitizers in hydro-coolers or flume water must be listed in section NOP §205.605 of the rule.
- All cleaning and sanitizing materials must be listed in the organic handling plan. Protocols for use of materials should be documented in the SSOP.

Permitted

- Materials not listed on the National List may be used to clean food contact equipment provided the equipment is subject to an intervening rinse or purge event prior to use for organic production. Any producer wishing to use a material not on the National List must check with MCS first to ensure the intervening event meets the standards.
- Surfaces that are not in contact with organic products (floors, walls, drains, areas outside of production areas) may be cleaned with any material.

8.4 Use of Chlorine Materials in Organic Handling

For food handling facilities and equipment, APPROVED chlorine materials may be used up to maximum label rates for disinfecting and sanitizing food contact surfaces. Rinsing is not required unless mandated on the label. Water used as an ingredient or for rinsing must be potable and may contain no more than 4ppm chlorine.

Chlorine concentrations in water used in direct crop or food contact (washing lettuce, greens etc.) must meet FDA or EPA guidelines and must be documented in the organic system plan. Rinsing of the crop or food product with potable water (4ppm chlorine or less) MUST occur immediately following sanitation

In order to meet MCS requirements, all sanitizers and disinfectants need to be: 1) listed in your processing plan and approved by MCS prior to use; 2) labeled for the intended commercial use, and; 3) used according to label instructions.

NOTE: We have had instances of certified processors using regular household bleach as a sanitizer. Regular bleach contains surfactants and/or fragrances that are not allowed in organic production and these bleaches are not labeled for sanitization. We do allow various bleaches that do not have additional ingredients and are labeled as a commercial sanitizer. Inexpensive chlorine test strips are available to check the strength of your chlorine solution before use (chlorine molecules are unstable). Please contact MCS if you have any questions or concerns about the use of chlorine materials.

8.5 Product Formulation/Ingredients

1. Ingredients in products labeled as "100% Organic" must be 100% organic and all processing aids must be certified organic.
2. Products labeled "Organic" must have a minimum of 95% organic agricultural ingredients by weight or fluid volume (excluding water and salt) and may contain:
 - Non-synthetic and synthetic ingredients listed on the National List 205.605, according to any annotation or restriction
 - Non-organic agricultural ingredients listed in NOP §205.606, provided records are kept to indicate lack of commercially available organic sources
3. Products labeled "Made with Organic [specified ingredients or food groups]" must contain a minimum of 70% organic agricultural ingredients by weight or fluid volume (excluding water and salt). Other ingredients or processing aids may be:
 - Non-synthetic and synthetic ingredients listed on the National List 205.605, according to any annotation or restriction
 - Non-organic agricultural ingredients listed in NOP §205.606, provided records are kept to indicate lack of commercially available organic sources
 - No excluded methods as defined in NOP §205.105 are allowed (see below)

For additional information please refer to the National Organic Program Rule sections NOP §205.105, §205.300-205.311, §205.605-205.606.

Steps to Calculate the Percentage of Organic Ingredients:

1. a.) [Solids] Divide the total net weight of combined organic ingredients at formulation by the total weight of the ingredients in the finished product (excluding water and salt).
b.) [Liquids] Divide the fluid volume of all organic ingredients by the fluid volume of all ingredients in the finished product (excluding water and salt). If ingredients are reconstituted from concentrates, the calculation should be made on the basis of single strength concentrations of the ingredients and finished product.
c.) [Mixed Solids and Liquids] Divide the combined weight of the solid and the liquid organic ingredients by the total weight of ingredients in the finished product (excluding water and salt).
2. Round percentages down to the nearest whole number.

NOTE: Percentages must be determined by the handler who affixes the label to the consumer package and verified by the certifying agent. The handler may use information provided by the certified operation in determining the percentages.

Prohibited in Organic Product Formulation

- Genetically engineered ingredients; genetic engineering is an excluded method in organic production
- Ingredients made with the use of sewage sludge
- Ingredients treated with ionizing radiation
- Volatile synthetic solvents used in or on a processed product or organic ingredient
NOTE: Non-organic ingredients in products labeled "made with organic" are not subject to this requirement.
- Sulfites, nitrates, or nitrites in products labeled "Organic" and "100% Organic".
NOTE: Sulfites may be used in wine labeled as "made with organic grapes".
- Non-organic agricultural ingredients for products labeled "100% Organic" and "Organic", unless the ingredient is listed on NOP §205.606 and is documented to be not commercially available in the form, quantity, or quality required
- Inclusion of both non-organic and organic forms of the same ingredient
- Synthetic and non-synthetic ingredients or materials except those listed on The National List (NOP §205.605)

8.6 Processing Methods

Processing should not excessively diminish the nutritional value of the food.

Permitted Methods:

- Drying, dehydrating, canning
- Freezing, chilling, heating, cooking
- Fermenting, pressing, distilling, pasteurizing
- Smoking, curing, vacuum packing
- Milling, cutting, mixing
- Packaging, repackaging
- Other methods

Prohibited Methods:

- Irradiation (*FDA-approved ionizing radiation for food inspection (i.e. x-rays) is permitted, as is UV light for disinfection, and microwave radiation for cooking. Prohibited forms are described at 21CFR 179.26).*

8.7 Packaging and Handling

Required

- Packaging free of fungicides, preservatives, fumigants, and contaminants
- Only FDA-approved food grade materials
- Lot numbers on all products for traceability

Recommended

- Use of new containers or packages

Permitted

- Recycled containers that are properly cleaned, sanitized and labeled

8.8 Labeling

Growers, wholesale distributors, parallel growers, processors and growers selling crops bought from other growers, must label all products and maintain an audit trail.

Required

1. Use of the terms "100% Organic", "Organic" or "Made with organic [specified ingredients or food groups]" **only** in labeling of raw or processed agricultural products that have been produced and handled in accordance with the NOP regulations

2. Labels that identify the certifier of the product with the phrase, “Certified Organic by MOFGA” or similar. *NOTE: The “Certified Organic by...” (COB) statement must appear on the information panel directly below the name of the handler or distributor. Only the contact information for the handler/distributor may separate the company name and the COB statement.*
3. Labels that indicate all organic ingredients for products labeled “100% Organic”, “Organic” or “Made with Organic [specified ingredients or food groups]”
NOTE: An asterisk or other reference mark, which is defined below the ingredient statement may be used to indicate organic ingredients.
4. Approval of all labels by MCS prior to printing. You must keep written permission from MCS for all current labels used on your products.

Permitted

- The term “100 Percent Organic” or “Organic” as applicable to modify the name of the product
- The term “Organic” to identify the organic ingredients in multi-ingredient products labeled “100% Organic”

Prohibited

- Use of the term “organic” in a product name to modify a non-organic ingredient in the product

Other Important Considerations:

- A “Made with Organic [specified ingredients]” product must not list more than three organically produced ingredients or a “Made with Organic [specified food group] must 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 milled product. The “Made with Organic...” statement must not exceed one-half the size of the largest type size on the panel and must appear in its entirety in the same type size, style and color without highlighting).
- For products labeled “Organic” and “Made with Organic (specified ingredient or food groups)” the percentage of organic ingredients in the product. This statement must not exceed one-half the size of the largest type size on the panel and must appear in its entirety in the same type size, style and color without highlighting.

Use of USDA and MOFGA Certification Logos



Figure 1. USDA Seal and MOFGA Certification Organic logo. USDA Organic seals can be found on the NOP website: www.ams.usda.gov/nop/. The MOFGA logo can be downloaded from the MCS website: <https://mofgacertification.org/organic-marketing-tools/>.

- The USDA seal must replicate the form and design as found on the USDA website: <https://www.ams.usda.gov/rules-regulations/organic/organic-seal>
- If you use a color version of either seal, the colors may not be changed. The USDA Organic Seal Pantone Matching System (PMS) Colors are Green = PMS 348 and Brown = PMS 175. **The white background must be white, it must not be transparent.** The PMS color for the MCS logo is Green = PMS 349, CMYK = 85 3 91 44 (Coated) and PMS 356, CMYK 80 3 93 17 (Uncoated). Web and Screens = RGB 18 112 60, Hex 12703C.
- The black and white USDA seal may be transparent or white.
- To resemble a cultivated field the lower half of either the green or black USDA seal may have 4 light lines running from left to right and disappearing at the point on the right horizon.
- The certifier’s logo(s) **must not** be displayed more prominently than the USDA seal.
- The USDA seal **must not** be used on products labeled “Made with Organic...[specified ingredient(s)]”.

Agricultural Products in Other Than Packaged Form

Agricultural products in other than packaged form in retail displays, labeling and display containers may use the term, “100% Organic” or “Organic” as applicable, to modify the name of the product provided that the term “organic” is used to identify the organic ingredients in the ingredient statement. If the product is prepared in a certified facility, the retail display, labeling and display containers may use the USDA seal, the MCS logo or 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.

Agricultural products in other than packaged form in retail display, labeling, and display containers that contain between 70 percent or more organically produced ingredients may use the phrase, “Made with Organic [specified ingredients or food group(s)],” to modify the name of the product. Such statement must not list more than three organic ingredients or food groups and in any such display of the product’s ingredient statement, the organic ingredients are identified as “organic”. 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 MCS logo.

8.9 Labeling and Composition of Multi-Ingredient Packaged Products With Less Than 70% Organically Produced Ingredients

The organic ingredients in multi-ingredient agricultural products with less than 70%, labeled as “Made with Organic [specified ingredients or food groups]” must be produced and handled pursuant to the NOP rule. The non-organic ingredients may be produced and handled without regard to the requirements of the rule.

Permitted

- Labels that identify organically produced ingredients in the ingredients statement with the word “organic” or with an asterisk or other reference mark, which is defined below the ingredient statement to indicate the ingredient (s) were organically produced
- Labels that display only the percentage of organic content on the information panel

Prohibited

- Both the USDA and MOFGA seal

8.10 Labeling and Composition of Livestock Feed

Livestock feed is only eligible for labeling as “100% Organic” or “Organic”. When labeled “100% Organic” it must contain (by weight or fluid volume, excluding water and salt) not less than 100% organically produced raw or processed agricultural product. When labeled as organic it must be produced in conformance with NOP §205.237. See sections NOP §205.237, 205.301(a), and 205.306 of the NOP rule for more information.

Required

- Compliance with all Federal and State feed labeling requirements
- Labels that state “Certified Organic by MOFGA” (or similar phrase) below the handler/distributor name on the information panel

NOTE: Kelp as an ingredient must be certified organic.

Recommended

Livestock feed labels may display the following information:

- The statement “100% Organic” or “Organic”, as appropriate
- Organic ingredients identified in the ingredients list by use of the word “organic” or by use of an asterisk to identify organic ingredients
- The USDA seal
- The MOFGA Certified organic logo, which cannot be more prominent than the USDA seal

Prohibited

- Use of nonorganic agricultural ingredients
- Use of any feed additives or supplements that are not listed in NOP §205.603(c-d)

8.11 Recordkeeping

All aspects of organic production must be verifiable with records. Purchase, production, inventory and sales records are all necessary. Standard operating protocols for processing, cleaning, and pest control must be written and available for employees. Written logs documenting cleaning and pest control should be established. Documentation for purchased

ingredients must include quantity and date of purchase, lot number and certification status. Current organic certificates for all purchased certified ingredients need to be available for inspection (computer files are fine).

Your inspector must be able to complete both a trace-back and a mass balance audit.

Trace-Back Audits

A trace-back audit verifies that records are sufficient to track finished products back to the ingredients used to produce them. To conduct this audit, the inspector will choose a finished product and will trace the product lot numbers through the production system to the ingredient lot number received or the harvest date. Please make sure that all necessary records and lot numbers are in place to support a trace-back audit.

Mass Balance Audits

A mass balance audit verifies that sufficient quantities of organic ingredients are produced or purchased and match the amount used in the production of finished products. To conduct this audit, your inspector will examine inventory records of both ingredients and finished product, production records, and sales records. Using your ingredient inventory records the inspector will determine the expected amount of ingredient used over a time period, using batch/production records and finished product inventory the inspector will determine the actual amount of ingredient used and the expected amount of finished product sold. Finally, the inspector will verify the expected amount of finished product sold with actual sales records. Please be sure that ingredient inventory, batch/production records, finished product inventory and sales records are in place to support a mass balance audit.

Lot Numbers

The ability to track products and ingredients through handling and processing is vital to assure product compliance. Using lot numbers to track products and ingredients allows for a successful audit trail. Each ingredient received should either have a lot number with it or should be assigned a lot number. Any time organic ingredients are combined or blended, a lot number must be assigned to the finished product. For example, if you were making jam, you would record the lot numbers of the sugar, the pectin and the other ingredients as they were received. A new lot number is then assigned to the finished jam. If an ingredient is purchased from several sources, the production or batch record should list the source and lot number of each ingredient. Lot numbers can be used to facilitate a product recall if there is a complaint or a food safety issue after a product is produced and/or sold.

9. CONVENTIONAL (NON-ORGANIC) PRODUCTION

Some farmers and processors sell products produced by conventional agricultural (non-organic) methods in addition to the products they produce organically. Although this practice is permitted, MCS needs information about the non-organic production happening at your farm or facility. You need to provide MCS information on how systems and products are kept separate to maintain the organic integrity of your certified organic products.

9.1 Definitions

There are several categories of conventional production.

Parallel Producers—produce and market the same product(s) organically and non-organically (e.g., organic and conventional apples).

Split Producers—produce and market some conventional products, but these products are not the same as the organic products (e.g., organic tomatoes and conventional sweet corn).

Transitional Producers—produce products from fields that have entered the 36-month transition period from conventional management to organic management. From a practical standpoint, transitional farms or fields are being managed organically and current production should not pose a risk to certified organic production. However, please note that these products cannot yet be certified organic. Date of harvest of product as organic must be at least 36 months from the last date of application of any prohibited materials or products.

9.2 Operative Principle

Recommended

- Manage entire operation and produce all products organically

Permitted

- Parallel growers, producers, and processors who maintain an audit trail for all crop and product sales, both organic and conventional, and have all records available so the inspector can perform audit trail exercises.
- Use of equipment and facilities in parallel or split production provided that you uphold sufficient care to minimize risk of contamination and commingling of the organic product
NOTE: The organic integrity of the product is of utmost importance. An equipment clean-out log should be kept for all field equipment used in organic production. An SSOP that adequately addresses all possible areas of possible commingling and/or contamination is required for production facilities.
- For parallel or split processing facilities; running organic products at the beginning of a shift or day's operation, in order to separate organic from non-organic product and document necessary intervention after use of cleaning materials

Considerations for Parallel Producers

Because of the possibility of confusion, no product can be certified if the same crop is also produced elsewhere on the farm using non-organic methods unless you can clearly demonstrate to MCS that both the physical facilities and the organizational ability exists to ensure that there is no possibility of mixing. Production will be expected to coincide with acreage. A map or plan is required for greenhouse production and processing facilities where there is a question about separation of organic products.

9.3 Mixed Use Processing and Handling Facilities (Organic and Conventional)

Recommended

- Separate organic/conventional processing and handling facilities
- Use of new containers or packages

Permitted

- Shared facilities with clearly marked, physically separated lots of organic and non-organic crops, provided that no unauthorized materials (disinfectants, fungicides, etc.) are applied
- Use of recycled bags or containers if they have been thoroughly cleaned

Prohibited

- Use of packaging/storage containers or bins that contain synthetic preservatives, fumigants, or fungicides.
- Storage of organic ingredients or finished products in areas subject to fumigation or sanitation with prohibited materials.
- Use of unapproved pest control materials in a processing facility.
- Use of unapproved sanitizing/cleaning materials in contact with organic product.
- Storage of organic apples in a controlled atmosphere (CA) storage unit with conventional apples if the conventional apples have been treated with diphenylamine (DPA)

10. COLLECTING WILD CROPS (WILDCRAFTING)

Wildcrafting or wildcropping is the act of gathering plants, fungi or algae in their native habitat or site that is not managed or otherwise farmed. A “wild crop” is the actual material harvested (e.g., leaves, berries, shoots, fruiting bodies). A wild crop species may be terrestrial or aquatic and must be fixed to a defined location by a species part; a species part being defined as a root, holdfast, mycelial thread etc. Only minimal agricultural practices may be employed including re-seeding, pruning and removal of non-native or invasive species from the habitat. Management practices that go beyond these are indicators of crop production and the crop production standards for soil fertility practices (NOP §205.203), crop rotation (NOP §205.205) and pest, weed and disease control standards (NOP §205.206) must be met.

The following are the components of wild crop harvesting that should be a part of your organic system plan:

- Map of the harvest area showing boundaries, borders, buffer zones if necessary, and any point or non-point sources of contamination
- Field History and Landowner Affidavit (if needed) indicating that the area has been free of prohibited materials for 3 years
- Proof of permission to collect on land that you do not own
- Description of the natural environment (e.g. hardwood forest)
- Proposed ecosystem management and harvesting practices
- Statement of the impact of harvesting on the long-term viability of the wild crop
- Information on any equipment used to manage the ecosystem and/or harvest the wild crop
- Monitoring system in place to document the sustainable harvest and maintenance of the habitat/ecosystem
- List of any rare, threatened or endangered species that occur in the harvested area
- Procedures employed to prevent contamination from adjoining land use
- Training and monitoring procedures for all collectors of wild crops

We expect wild crafters to know their plants, algae or mushrooms. There are toxic plants and mushrooms in Maine and these must not be mistaken for edible ones. If the State passes laws regulating wild mushroom collecting, certified organic wild crafters must be in compliance with these laws. As a general rule, the majority of a population must not be harvested. The actual percentage of what is left behind (untouched) will vary by species. You must do your research and justify the percentage you plan to take. If you collect on public, state or federally owned lands, you must get a permit or written permission. Avoid collecting plants from areas with heavy use, such as along roadways or popular recreational trails.

If you purchase wild crafted products/ingredients please be aware that under NOP Instruction NOP-4009 – Who Needs to be Certified? “...an uncertified operation may not produce or process, on its own land or premises, agricultural products to be sold, labeled, or represented as organic on behalf of a certified operation...”.

11. GUIDELINES FOR SEA VEGETABLES

MOFGA Certification Services, LLC certifies both cultured and wild crafted sea vegetables harvested from Maine's coastal waters based on the relevant crop sections of the USDA-NOP rule as described below. We do not certify sea vegetables grown in recirculating systems.

11.1 Definitions

Sea Vegetables—Edible seaweeds which include but are not limited to alaria (*Alaria esculenta*), dulse (*Palmaria palmata*), laver/nori (*Porphyra spp*), sea lettuce (*Ulva lactuca*), rockweed (*Ascophyllum nodosum*), digitata (*Laminaria digitata*), sugar kelp (*Saccharina latissima*) and fucus (*Fucus spp*) among others.

Propagule—The biological material used to grow the edible crop. In most cases, propagules refer to propagules that develop into diploid sea vegetables and the harvestable crop. In rare cases, a propagule is a haploid gametophyte. For our purposes, propagules are analogous to seeds.

11.2 NOP §205.202 Land Requirements

How we apply NOP §205.202 to Sea Vegetable Cultivation is as follows: Organic sea vegetables must be cultured or wild crafted from defined ocean areas with waters of high ecological quality. Growing areas or beds must not be located near known sources of radioactive, chemical, or bacteriological contamination. The following buffers apply to both cultured and wild crafted sea vegetables harvesting sites:

The following buffers apply to both cultured and wild crafted sea vegetables:

- Twenty (20) miles from any nuclear facility
- Three (3) miles from any commercial boat building facility
- Three (3) miles from any industrial waste water discharge area
- Three (3) miles from any city or town sewage discharge
- Three (3) miles from any major harbor or thoroughfare.
- Three-quarters ($\frac{3}{4}$) mile from a small harbor entry. We define a small harbor as having moorings for up to twenty (20) boats.
- Three-quarters ($\frac{3}{4}$) mile from a minor waste water treatment facility (these are denoted on DEP maps)
- One-quarter ($\frac{1}{4}$) mile from any overboard discharge area or special circumstance (i.e. fish farm, small boat builder, etc.)

NOTE: A bed's location relative to prevailing winds and currents may make the above distances more or less critical. Doubts should be settled by tissue testing for suspected contaminants.

11.3 NOP §205.203 Soil Fertility and Crop Nutrient Management Practice Standard.

Fertility and crop nutrients allowed under NOP §205.103 and NOP §205.601 may be used only during the time sporophytes are being cultured in indoor facilities and only at levels necessary for healthy plant growth. Fertility and crop nutrient applications are prohibited in outdoor sea vegetable growing areas.

11.4 NOP §205.204 Seed and Planting Stock Standard

Certified organic propagules must be used unless not commercially available in the form, quality or quantity needed. You must document your attempts to source organic propagules. Conventionally raised male and female gametophytes must be transferred to pure seawater or an approved growth medium prior to fertilization and production of propagules.

Growth media must meet the requirements of NOP §205.103 and NOP §205.601.

Propagules may be cultured indoors until the juvenile sporophytes of kelp, juvenile tetrasporophytes of dulse, or propagules of laver or dulse are 5mm to 10mm in size.

Juvenile seaweed should be collected from the wild on a regular basis to supplement culture stock and maintain a diverse gene pool.

11.5 NOP §205.205 Crop Rotation Practice Standard

Not applicable.

11.6 NOP §205.206 Crop Pest, Weed and Disease Management Standard.

The producer must use management practices to prevent invasive algae, epiphytes, invertebrates and diseases. Management practices include cultural, mechanical and physical controls. If management practices fail, substances on the National List NOP 205.601 may be used. Bio-fouling shall be removed by mechanical means and disposed of appropriately or, if necessary, by substances allowed under NOP §205.605.

11.7 NOP §205.207. Wild Crop Harvesting Practice Standard

Harvesting shall be from designated areas that have had no prohibited substances, as set forth in NOP 205.105, applied for one growing cycle immediately preceding the harvest of the sea vegetables. Sea vegetables shall be harvested in a sustainable manner that is not destructive to the environment and will sustain the growth and production of the sea vegetables. Sea vegetable harvesting should follow the “Harvester’s Field Guide to Maine Seaweeds” of the Maine Seaweed Council.

11.8 NOP §205.272 Commingling and Contact with Prohibited Substances Practice Standard.

The producer must implement measures to prevent the commingling of organic and non-organic product and contact of organic product with prohibited substances. Organic integrity of sea vegetables will be maintained from fertilization through cultured growing of sporophytes, deployment in ocean, harvesting, transporting, processing and storing product.

11.9 NOP §205.103 Recordkeeping by Certified Operations.

A sea vegetable operation must maintain records that demonstrate compliance with the organic standards, including but not necessarily limited to documentation concerning the production, harvesting, handling and sales of cultured and wild crafted sea vegetables.

NOTE: If you are drying, packaging or otherwise handling/processing the sea vegetables, you will need to complete an organic handling plan.

12. AUDIT TRAIL AND RECORDKEEPING NOP §205.103

Recordkeeping is an important aspect of being certified organic. Recordkeeping guidance has been provided in earlier sections of this manual according to production scope. Please review these. Reminders are provided again here.

Producers are expected to keep track of the organic crops, livestock, livestock products or processed products they produce. Harvest and production amounts must be recorded as well as amounts used and/or sold. **What constitutes sufficient detail in an audit trail record system will depend on the complexity and scale of the farm or handling operation.** A lot numbering system may be required that enables an inspector to trace a finished product back to ingredient lots. Similarly, your record keeping system should allow an inspector to trace the sale of an organic crop (e.g., a pallet of potatoes) back to the field it was grown in and the date it was harvested, or trace a processed product back to reception of all ingredients and lot numbers received at the facility.

NOTE: All parallel growers must maintain an audit trail for all crop sales, both organic and conventional, and submit a sample of the audit trail system with their application.

All records must be complete, up to date and made available to the inspector at the time of inspection. Producers must keep records pertaining to their operation and verifying compliance for at least five years.

13. TEMPORARY VARIANCES NOP §205.290

Temporary variances from the requirements set forth in the Rule may be established by the USDA NOP Administrator for the following reasons:

- Natural disasters declared by the secretary
- Damage caused by drought, wind, flood, excessive moisture, hail, tornado, earthquake, fire or other business interruption
- Practices used for the purpose of conducting research or trials of techniques, varieties, or ingredients used in organic production or handling

When a temporary variance is requested and granted, the Administrator will provide written notification to MCS and specify the period of time it shall remain in effect. MCS will then notify each certified production or handling operation to which the temporary variance applies.

14. ADMINISTRATIVE PROCEDURES AND POLICIES

14.1 Certification Fees NOP §205.642

Certification fees are based on **gross** income from sale of organic products for the calendar year (Jan – Dec). Please have sales and income records available at your inspection. This information is kept confidential. For new applicants income level is based on estimated gross income.

The current fee schedule is available online at <https://mofgacertification.org/mofga-certification-fees/>.

The Maine Department of Agriculture administers the USDA-NOP Organic Certification Cost-Share Program, which reimburses certified organic Maine farmers and processor/handlers **75%** of their certification expenses, up to **\$750 per**

certification scope. Payments are issued twice a year in early summer and late fall. In addition to the federal reimbursement, MOFGA further offsets certification costs for producers grossing under \$10,000 per year. Interested eligible producers should check the MOFGA Reimbursement box on the fee sheet; otherwise the funds will go towards MOFGA agricultural programs.

In addition to certification fees, the following fees may apply:

New Applicant Fee—Operations not certified the previous year must pay a \$75 new applicant fee.

Late Fee—Renewal paperwork submitted after the deadline must enclose a late fee. **Late fees increase over time** and are described in greater detail on the fee schedule. Late fees are excluded from reimbursement.

Early Bird Discount—Get your renewal paperwork to us within 30 days of receipt and take \$25 off your fees!

Supplemental Fee—Due to additional administrative costs that arise in some circumstances, we will be assessing a supplemental fee for any additional work that is required by the MCS office or Certification Inspector. Conditions that may require a supplemental fee are; a repeat inspection to gather new information or to inspect another part of the operation; an additional audit trail review of a farm or processing application; out of state travel; or an inspection of a farmer/processor whose facilities are in different locations. The supplemental fee is assessed on a case-by-case basis.

Insufficient Funds Fee—\$25 is due for each bounced check.

Adding a New Scope or Facility After Your Annual Inspection—This may involve an additional fee to cover the expense of a second inspection. These situations are considered on a case-by-case basis.

We prefer that fees be paid in full when the application (or renewal paperwork) is submitted. Partial payment plans are possible, but please contact MCS *before* your paperwork is due. Our policy is that you must include a minimum payment of \$100 with your application. You must then work out an agreed upon payment plan with your staff specialist.

14.2 Refund Policy

Fees are due at the time you submit your application except as noted above. Refunds are based on the total certification fee for your operation and the status of your update/application at the time of withdrawal.

- 80% refund if the request to withdraw your update/application comes before a certification specialist has reviewed your organic system plan (OSP)
- 50% refund if the request comes after your specialist has review your OSP, but before an inspector has been assigned
- 25% refund if the request takes place after your file has been queued to an inspector, but before the scheduled day of inspection
- 0% refund if update/application is withdrawn during or after your inspection
- 0% refund if a Denial of Certification has been issued

14.3 Deadlines

If you are **renewing** your certificate, your deadline is found on your “update letter”. If you have questions, please call MCS. Your forms must be postmarked by the deadline to avoid late fees. Noncompliances may be issued to operations that fail to file 30 days after the deadline.

If you are a **new applicant**, here are your deadlines:

TYPE OF PRODUCTION

DEADLINES

Dairy Farms	Contact MCS Staff, special planning is required
Crop Farms	30 June
Livestock Only Farms	Contact MCS; 30 June deadline may apply
Processors/Handlers	Applications accepted year round
Maple Syrup Operations	15 February
Winter Greenhouse Producers	Veteran’s Day (11 November)
Sea Vegetables	Applications accepted year round

14.4 Review of Applications for Certification

See *THE ORGANIC CERTIFICATION PROCESS* (p. 6) for an overview of the certification process and annual cycle.

14.5 MOFGA Certification Logo

All certified organic growers, producers and processors are entitled to use the MOFGA Certification logo on products that we have listed as certified on the product verification portion of your two-part certificate, which is provided to each client annually or as updated.

14.6 Duration of Certificate: Your Responsibility to Annually Renew or Surrender §205.403

Certification is valid from the effective date on the certificate and does not expire. Organic Certificates are valid until surrendered by the producer, or suspended or revoked by the certifying agent or NOP Administrator. At least annually MCS will provide you with a Product Verification that lists the certified crops and products listed in your OSP that are certified organic. Product Verifications can be updated during the year if MCS is notified of the new crop/product and all required documentation is supplied to MCS.

Certified operations must file an annual update according to the deadlines and policies set by MCS. The annual update involves forms and a fee. If you do not file an update by the deadline, additional late fees may be assessed.

Certified operations that are more than 30 days late with an update will receive a Notice of Noncompliance. Failure to resolve the noncompliance with MCS in the time frame identified will result in a notice of proposed suspension of your certificate. Failure to resolve this notice will result in suspension from certification. Please be advised that all notices are copied to USDA National Organic Program and that suspension or revocation of your certification may have consequences on future organic certification. **If you decide not to continue to be certified organic, you need to contact the MCS office immediately and surrender your certificate.** Surrendering the certificate can be accomplished by signing a one-page form available from MCS, or by other methods. The surrender must occur in writing.

14.7 Keeping MCS Informed of Changes to Your Operation §205.400(f)(2)

Any significant changes to the management of your operation, such as adding input materials, adding crops, adding processed products etc. need to be communicated to MCS **prior to use or sale**. Fields and processed products may be added to your farm plan depending on the timing of your inspection and at the discretion of your specialist. You will need to provide all necessary documentation to MCS as soon as possible.

It is your responsibility to keep the certifying agent (MCS) informed of changes to your operation.

You must immediately notify MCS of:

- Application, including possible drift, of a prohibited substance to any field, production unit, site, facility, livestock or product that is part of your organic operation
- Any changes to your operation, as noted above, that may affect compliance with the USDA-NOP rule

14.8 Inspection and Inspectors §205.403

Your operation will be inspected at least once annually. Inspections are MCS's way to verify that you are following the practices and procedures you state in your organic system plan. Inspectors submit inspection reports to MCS staff. MCS staff review and respond to inspection reports in writing, with input as appropriate from review committees.

MCS employs inspectors and determines inspector assignments. The inspector expects to conduct an inspection with at least one person named as either the applicant or the certificate holder. The inspector also expects the person leading the inspection to be knowledgeable about all aspects of the operation and to have access to all records. If there are responsibilities delegated to specific employees, these employees and any applicable records should be available during the inspection. The applicant or certificate holder may designate another knowledgeable individual to lead the inspection provided that applicant or certificate holder inform MCS in writing as to the name, contact information and responsibilities of the individual authorized to conduct the inspection. Farms must be willing to accommodate an inspection during the growing season.

The inspector role is to be an impartial and independent reporter of your operation's practices and procedures used to implement the OSP. Information gathered during an inspection is considered confidential and is meant for application evaluation only. Everyone involved in inspection and/or application evaluation has signed an inspector contract, which requires non-disclosure of information to any third party or use of confidential information for personal gain.

- The inspector will tour the farm or plant and review audit trails.
- Inspectors may provide sufficient information to persons seeking certification to enable them to understand the requirements of the Rule. Inspectors are **not permitted** to provide advice regarding production practices or specific methods that would meet compliance of the Rule.
- An inspector may be instructed by MCS to make unannounced inspection visits.
- An inspector may be instructed by MCS to take samples for residue tests at MCS's expense.

14.9 Inspector Qualifications §205.504

Inspectors shall be professional, objective observers competent to evaluate and report on the conditions and practices on the farm and to verify information submitted in the application. The inspector shall have professional training or equivalent experience in agriculture and organic farming and/or processing practices. MCS encourages its inspectors to enroll in formal certification inspector training. There shall be no conflict of interest in that the inspector shall be financially independent of both the farmer's and the buyer's interests. Inspectors are bound by confidentiality. MCS pays the inspectors. The inspector may not assist a producer by offering advice on organic practices and he or she may not endorse specific commercial products. Consultation with an organic producer for an additional fee at any time within the certification year is unacceptable and constitutes grounds for dismissing the inspector.

14.10 Cancellation of Inspection

Cancellation of an inspection appointment is both costly and inconvenient because inspectors often schedule multiple inspections in a geographical area during a limited timeframe. Return visits to an area are costly to MCS and may require extra fees.

MCS's cancellation policy is:

- Scheduled inspections may be cancelled up to one week prior to the appointment without penalty.
- Scheduled inspections that are cancelled within one week to one day prior to the inspection will be charged a \$150 cancellation fee.
- Producers who cancel the day of the inspection or who fail to show up for their inspection will be charged \$300.

Please note the following:

- You may authorize a representative to conduct your inspection in your place but this person must be knowledgeable about the operation, have access to everything the inspector needs to see, and your authorization needs to be made in writing to MCS.
- You are responsible for communicating **directly** with your inspector about the scheduled inspection or your need to cancel it. MCS cannot serve as an intermediary for these messages between you and your inspector. **Please make sure you get contact information, including cell phone, for your inspector when you are discussing an inspection appointment.** Most inspectors work as contractors and do not work out of MCS's offices.

14.11 Open Door Policy

All applicants and certified producers shall adhere to the "open door policy" and shall permit inspection of operations to determine their conformity to the current standards. This includes unannounced inspections. See the Organic Producers Endorsement form (located in your update packet), which clients must sign if they are to receive our certification services.

14.12 Conflict of Interest §205.501(11)

All participants in the certification program (staff, committee members, inspectors and MCS Management Committee members) are expected to provide MCS with an annual list of certification clients with whom they may have conflicts of interest and sign a confidentiality agreement. Individuals may not participate in the evaluation, inspection or final decision-making concerning any producer with whom they have a conflict of interest.

14.13 Code of Conduct Policy

MCS is dedicated to providing professional and affordable certification services to Maine organic farmers and processors. We expect both clients and MCS representatives to conduct themselves in a respectful and business appropriate manner. Verbal abuse, threatening conduct, and other antagonistic behavior that affect anyone's ability to provide certification services or which creates an unsafe workplace will not be tolerated. Such behavior will be interpreted as refusing service and denying access and may result in a noncompliance and/or adverse action procedures.

14.14 Gifts

Employees, inspectors, contractors, Management Committee members, Advisory Committee members, and other personnel are prohibited from accepting payments, gifts, or favors other than the prescribed fees for the certification process.

14.15 Non-Discrimination Policy

MCS does not discriminate on the basis of race, color, national or ethnic origin, gender, religion, age, disability, political beliefs, sexual orientation, marital or family status, or veteran status in any of its policies, functions, or activities.

14.16 Geographical Scope of Operation

MCS's focus is to provide cost effective certification services to Maine's organic producers and accordingly we accept applications from producers who have operations based in Maine. If we have the available labor resources, we may accept clients from other areas in the northeast.

14.17 Timetable for Certification Process

The process for making a certification decision may take several weeks to several months. A complete application and good communication tends to make the process shorter. An inspection should take place during production, which means that for some producers (e.g., farmers producing crops in fields) there are times of the year when an inspection is not feasible. If questions or compliance issues are identified at any point in the process, these must be addressed in writing. Because of these factors, it is not possible to guarantee certification within a certain time frame, but our advice to potential applicants is to plan ahead and submit a complete application six to ten weeks before you anticipate needing certification. **Dairy farmers need to be aware that we require a 4 page "Intent To Transition Form" at the start of the 12-month transition process for a herd.** Dairy farmers should go to page 22 of this manual to read more about the specific application requirements for this category of organic production.

14.18 Review Committees

There are several Review Committees consisting of volunteers specializing in different areas of agricultural production and processing. Together they comprise the MCS Advisory Committee. Committee members provide staff with important insights about areas of production, assist staff when questions arise, and help the program develop policies. Members include farmers, regulators, university researchers, and MOFGA technical staff. All uphold the required confidentiality.

14.19 Infraction of Standards

As an accredited USDA-NOP certifier it is MCS's job to ensure that the operations we certify comply with the National Organic Standard (the Act). If a certified grower or processor violates the Act, certification may be suspended or revoked and use of the MOFGA Certification Organic logo or the NOP-USDA seal is prohibited. If a grower or processor seeking or renewing organic certification violates the National Organic Standards the noncompliance and denial procedures outlined in the National Organic Standards (NOP §205.405 & §205.662) will be followed. **An operation may surrender its organic certification and an applicant may withdraw their application at any time.**

14.19.1 Issuing a Notice of Noncompliance

When MCS has reason to believe that a client is not able to comply or is not in compliance with the requirements of the National Organic Standard, we will provide a written Notification of Noncompliance to the client (NOP §205.662(a)). When correction of a noncompliance is not possible, MCS will issue a combined notification of noncompliance and notification of denial of certification to applicants or a combined notification of noncompliance and notification of proposed suspension/revocation to a certified operation (NOP §205.662(c)). All Notices are copied to the NOP Administrator.

A notice of noncompliance may be issued when:

- review of an operation's application for certification/organic system plan reveals a noncompliance or an inability of the operation to comply with the Act;
- an inspector's report identifies a noncompliance; or
- inspection and testing of a certified operation reveals a noncompliance or substantiates a report of a violation.

The notice of noncompliance will provide the operation with a description of the noncompliance(s) and a time frame for response. The response to the notice may include a corrective action or rebuttal. If resolved to the satisfaction of MCS and/or the review committees, a notice of noncompliance resolution (NOP §205.662(b)) will be sent to the operation.

14.19.2 Issuing a Notice of Proposed Suspension/Revocation/Denial

Failure of a certified operation to resolve a Notice of Noncompliance will result in a written Notice of Proposed Suspension or Proposed Revocation (NOP §205.662(c)).

The notice will list:

- the reasons for the proposed suspension, proposed revocation, or denial;
- the proposed effective date of such suspension, revocation or denial,
- the impact of a suspension or revocation,
- identify the rights of the applicant or operator to mediation (NOP §205.663)
- provide the operation with instructions for appealing the adverse action (NOP §205.681).

The proposed action may be for the entire operation or a portion of the operation. In some cases a notice of noncompliance and of proposed suspension or proposed revocation may be issued. In the case of applicants seeking certification, unresolved noncompliances will result in a Notice of Denial (NOP §205.405).

14.19.3 Issuing a Notice of Suspension/Revocation/Denial

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, MCS will:

- send a written Notice of Suspension/Revocation/Denial (NOP § 205.662(e) (§ 205.405)) of the entire operation or portion of the operation, as applicable;
- will list the reasons for the suspension, revocation, or denial;
- identify the rights of the applicant or operator to mediation (NOP §205.663);
- provide the operation with instructions for appealing the adverse action (NOP §205.681) to the USDA-NOP

Failure of the operation to resolve this notice will result in suspension or revocation of certification. MCS will refrain from sending a notification of suspension or revocation to a certified operation that has requested mediation or appeal.

14.19.4 Willful Violations

If MCS has reason to believe that a certified operation has willfully violated the NOP Regulations (NOP § 205.662(d)), the certified operation will be sent a Notice of Proposed Suspension/Revocation (NOP §205.662(c)) for the entire operation or portion of the operation, as applicable. If MCS 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 MCS may deny certification without first issuing a notification of noncompliance.

14.20 Request for Mediation and the Appeals Process with the USDA

Producers may request mediation for a negative decision (e.g., a proposed suspension). The producer must submit a written request for mediation to MCS within the time frame specified in the Notice. MCS may decide to accept or reject mediation. If MCS accepts mediation, the producer will meet with MCS staff and representatives.

If mediation is accepted by MCS, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. There shall be no more than 30 days to reach an agreement following a mediation session. Any agreement reached during or as a result of the mediation process shall be in compliance with the act and these regulations. If MCS accepts mediation but decides to uphold the negative decision, the producer may submit a written appeal to the USDA NOP Administrator within 30 days of termination of mediation.

If MCS rejects the request for mediation, MCS shall provide written notification to the certified operation or applicant for certification. If MCS rejects the request for mediation, the producer may submit a written appeal to the USDA within 30 days of receipt of the written notice of mediation rejection from MCS. If the USDA-NOP Administrator sustains a certification applicant's or certified operation's appeal of an MCS 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 MCS. MCS will send all written communications to the recipient's place of business by a delivery service that provides dated returned receipts. For more information about the appeals process with the USDA, see NOP §205.680, which can be found in Appendix of this manual.

14.21 Reinstatement of Suspended/Revoked Operations

A certified operation whose certification has been suspended may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary of Agriculture for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective action taken to comply with and remain in compliance, with the Act and the regulations.

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, except that the Secretary may, when in the best interest of the certification program, reduce or eliminate the period of ineligibility.

14.22 Violations

Knowingly selling or labeling a product as organic if it does not comply with the USDA-NOP regulations can result in civil penalties. Making a false statement under the Act to the Secretary or MCS shall be subject to the provisions of section 1001 of title 18, United States Code.

14.21 Grower Applications, Files, Records, and Public Information

Certified operations must keep their records for 5 years. All operations are expected to make a copy of their completed certification forms and keep them as part of their records. The operator must allow authorized representatives of the USDA Secretary of Agriculture and MCS to access such records during inspections.

MOFGA publishes information about certified producers in print publications and on the web. The information we publish is limited to contact information (name, address, phone, email and web site), what is certified organic, and where consumers can find your products (markets).

The NOP maintains an Organic Integrity database. It provides marketing information about operations licensed to use the organic seal. The public can see if an operation has had its organic certificate suspended or revoked.

14.22 Confidentiality

MCS must keep files and applications for 10 years. MCS maintains strict confidentiality with respect to the information in the organic system plan. The only information that is available to members of the public is certificates, crops or products produced, grower's name, address, email, phone number, website and marketing outlets during the current and 3 preceding calendar years.

Results of all analyses, tests and test results performed during the current and 3 preceding calendar years will be available for public access unless testing is part of an ongoing investigation.

Information requests should be addressed to the MCS Director and will be responded to in a timely fashion. MCS keeps information in a secure database. Paper files are kept securely in filing cabinets and are only accessible by MCS staff. All confidential files and papers are shredded when they are no longer required. If a certified operator wants MCS to release information other than the above, MCS will need a signed document stating the allowance of the release of the information. This should include a statement on what information can be released and to whom.

14.23 Policy on Testing of Organic Agricultural Products

All agricultural products that are to be sold, labeled, or represented as "100% Organic," "Organic," or "Made with Organic [specified ingredients or food groups]" must be made accessible by the producer to the certifying agent and representatives of the USDA Administrator.

While residue level is not MOFGA's measure of organic, every effort should be made to prevent contamination.

If there is reason to believe that the agricultural product or input has come into contact with a prohibited substance or has been produced using excluded methods or materials, MCS or the NOP Administrator may require pre-harvest and post-harvest testing. In addition, USDA NOP requires all certifiers to collect samples from at least 5% of their clients each year and test those samples for pesticide residues or other prohibited materials and methods. MCS pays for these tests. MCS arranges to have a staff member or inspector take samples. All residue testing is performed at an accredited laboratory. Positive lab results will be reported immediately to the NOP Administrator and will be made available for public access, except in instances where testing is part of an ongoing compliance investigation. A copy of any test results will be sent to the inspected operation as well.

If test results reveal residue levels that exceed 5% of the Food and Drug Administration's or the Environmental Protection Agency's regulatory tolerances for that substance, then MCS will report the data to the appropriate federal health agency. In the event that residue testing reveals greater than 5% of tolerance of prohibited substances, excluded materials and/or excluded methods, the product in question must not be sold, labeled or represented as organically produced. MCS has the right to investigate the operation to determine the cause of the contamination. The NOP Administrator has this right as well. For guidance on the appropriate action to take, MCS follows USDA document NOP 2613.

14.23.1 Sampling and Laboratory Testing Procedure

MCS will periodically collect samples from certified operations for laboratory analysis for prohibited materials and methods. Samples may include soil, agricultural products, or livestock products. Tests include those for the presence of genetic modification, antibiotics, or pesticides not allowed for use in organic production. Sample collections will include those that meet periodic pesticide residue testing required by § 205.670 - Inspection and testing of agricultural product to be sold or labeled as "100% Organic," "Organic," or "Made with Organic (specified ingredients or food group(s))" and further explained in the USDA guidance document NOP 2610.

MCS will develop sampling plans, as needed, to meet the following conditions:

- When it is suspected that a prohibited pesticide/herbicide has been applied, whether intentional or accidental
- When it is suspected that pesticide drift has occurred
- To gather evidence as part of an investigation
- To monitor compliance with USDA-NOP
- To conduct periodic residue testing per NOP §205.670(d) and NOP 2610
- When it is suspected that genetically modified organisms have been used

MCS will select an accredited laboratory that can perform the analysis necessary based on the nature of the sampling and the sample matrix and in accordance with NOP lab selection criteria (see NOP 2611). Results of all analyses will be reported and made available per NOP §205.670(f). If analysis indicates a specific agricultural product contains prohibited materials, MCS will follow NOP instruction (See USDA document NOP 2613).

14.23.2 Periodic Pesticide Residue Testing Protocol

In accordance with NOP rules a minimum of 5% of MCS clients will undergo periodic pesticide residue sampling each year. Samples may be collected from farm fields, on-farm storage areas, farmers' markets or farm stands. Processed or handled products may also be sampled. Additional information on periodic pesticide residue sampling can be found in USDA document NOP 2610, which is available online or by request from our office.

14.24 Transaction and Export Certificates

14.24.1 Requirements for Requesting Transaction and Export Certificates

MOFGA Certification Services has initiated the following procedures to supply Transaction Certificates or Export Certificates for our producers.

Transaction Certificates can be provided for documentation of a foreign customer's purchase of organic product from a producer. Transaction Certificates will be generated only for products listed in the producer's current organic system plan on file with MCS at the time of the request.

Export Certificates will be provided to document production of products produced under the USDA-NOP rule that also meet the requirements of Export Agreements with Taiwan and Japan and Equivalency Arrangements with Canada, EU, Switzerland and Korea. Export Certificates will be generated only for products listed in the producer's current Organic System Plan on file with MCS at the time of the request. In addition, producers must document that the product meets the requirements for export as noted in 14.24.2 below. Producers with an interest in exporting to international markets should indicate this on their certification application or update. Contact your MCS Staff Specialist for more information.

The US-Canada Equivalency agreement does not require an export certificate however your organic system plan must contain information pertinent to the verification that the terms of the agreement have been met. Only products that meet the US-Canada Equivalency arrangement will be added to a producer's Organic Certificate. See Section 14.24.2. For verification by the inspector at your annual inspection, you must keep copies of the shipping documents to provide verification that the statement "Certified in compliance with the US-Canada Equivalency Arrangement" was included with the shipment.

To obtain an Export Certificate for Taiwan/Japan/European Union/Switzerland/Korea:

1. Contact your MCS Staff Specialist.
2. Provide an invoice or bill of lading for shipment.
3. For Export Certificates enclose a completed export form for the appropriate agreement or arrangement. (See Section 2 below)
4. Enclose appropriate fees: \$20.00 for each Export or Transaction Certificate.
5. Original, signed Export Certificates will be sent to the producer and must accompany the shipment. Producers should keep copies of all certificates for review during their annual inspection.
6. The European Union is now using the online TRACES system to generate export certificates. You will need to establish a TRACES account and submit requests through that system. Please contact your specialist for more information.

Please note that products for export produced and certified to foreign national organic standards or foreign contract buyer requirements, must 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 NOP §205.307 (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 record keeping requirements for exempt and excluded operations under NOP §205.101.

Please note that MCS is only accredited to certify products to the USDA-NOP Rule (standard) and does not certify any product to any foreign standard. MCS will however verify whether or not a product meets the requirements of an Equivalency Agreement or Arrangement.

Designated Staff Persons Responsible for Issuing Transaction and Export Certificates

Primary Person: MCS Certification Specialist (currently Corinne Wesh) Email: cwesh@mofga.org PO Box 170 Unity, ME 04988 207-568-6032	Primary Person: MCS Certification Specialist (currently Joan Cheetham) email: jcheetham@mofga.org PO Box 170 Unity, ME 04988 207-568-6034
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14.24. 2 – Compliance Requirements for Export Certificates to Canada, EU, Taiwan, Japan, Switzerland or Korea

Country	Terms of Arrangement	Labeling	Required Paperwork for Export
Canada	<ol style="list-style-type: none"> 1. Produce products without use of sodium nitrate 2. Products not produced by hydroponic/aeroponic methods 3. Produce livestock (except ruminants) according to specified stocking rates 	<p>For packaged retail products labels <u>must</u>:</p> <ul style="list-style-type: none"> • Comply with Canada’s labeling requirements including its dual language (English and French) requirement • State the name of the USDA authorized certifier • May use USDA organic seal and/or Canada organic logo 	<p>Shipping Documents accompanying the shipment <u>must</u> state: “Certified in compliance with the terms of the US-Canada Organic Equivalency Arrangement”</p> <p>Documentation from the certifier that the products are certified to the Terms of the Arrangement (i.e. Organic Certification Documents indicating compliance to the US-Canada Equivalency)</p>
European Union	<ol style="list-style-type: none"> 1. Products must be produced or have had their final processing or packaging within the US. 2. Crops produced without the use of antibiotics 3. Meet additional requirements for wine exports 	<p>For packaged retail products, labels <u>must</u> state the name of the USDA authorized certifier and may use USDA organic seal and/or EU organic logo.</p> <p>Packaged retail products must contain a label or sticker identifying the certifier code for MCS (US-ORG-027).</p>	<p>Shipping documents <u>must</u> include an “EU Certificate of Inspection” completed through the online TRACES system.</p> <p>EU Import Certificate must be signed by the certifier in blue ink and the original sent with the shipping documents.</p>
Taiwan	<ol style="list-style-type: none"> 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 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.” 	<p>For packaged retail products labels <u>must</u> state the name of the USDA authorized certifier and may use USDA organic seal</p>	<p>Shipping documents <u>must</u> include a “TM-11 Export Certificate” completed by MCS.</p> <p>Exported processed products and crops must state, “Organic agricultural products and organic processed products accompanied by this certificate, were produced or processed using zero prohibited substances.</p> <p>Exported livestock and meat products must state, “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.”</p>
Japan	<ol style="list-style-type: none"> 1. Applies only to organic plants, fungi and plant-based processed products. 2. Products not regulated include meat, dairy products, and alcoholic beverages. These products may be exported without a export certificate. These products must not use the JAS logo. 	<ol style="list-style-type: none"> 1. For organic packaged retail products labels <u>must</u> state the name of the USDA authorized certifier and may use USDA organic seal. 2. JAS logo is <u>required</u> on regulated products. 3. JAS logo must be applied by either a Japanese Agricultural Standards (JAS) certified importer or a USDA certified operation that has a JAS labeling contract with a JAS certified importer. 	<p>Shipping documents <u>must</u> include a “TM-11 Export Certificate” completed by MCS.</p> <p>TM-11 must contain the statement “Certified in compliance with the terms of the US-Japan Organic Equivalency Arrangement.”</p> <p>TM-11 should contain the name of the RCB applying the JAS logo.</p>
Switzerland	<ol style="list-style-type: none"> 1. Products must be produced or have had their final packaging within the US. 	<ol style="list-style-type: none"> 1. For packaged retail products labels <u>must</u> state the name of the USDA authorized certifier and may use USDA organic seal. 	<p>Shipping documents must include a “Swiss Import Certificate” completed MCS.</p>

	2. Meet additional specifications for wine	2. Meet labeling requirements applicable in Switzerland 3. Lot number must be present on Bulk Products.	
Korea	Processed Products as defined by the Korean Food Code. Contain at least 95 percent organic ingredients. Have their final processing or packaging occur in the United States. Don't contain apples and pears produced using antibiotics.	1. Organic products must be labeled according to Korea's Ministry of Agriculture Food and Rural Affairs (MAFRA) organic labeling requirements. 2. Processed products may display the Korean and/or USDA organic seal.	Shipping documents must include a "NAQS Import Certificate of Organic Processed Foods" completed by MCS. NAQS Import Certificate <u>must</u> state: "Certified in compliance with the terms of the US-Korea Organic Equivalency Arrangement."

14.24.3 Compliance Requirements for Importing Organic Products from outside the US that are not certified to the USDA-NOP program.

All imported products **must** meet the USDA-NOP Organic labeling requirements. All documents should indicate "Organic" for all organic products. Questions regarding imports should be directed to your MCS Specialist.

If importing organic product from the European Union, Japan, Korea, Switzerland or Mexico the product **must** ship with both an "NOP Import Certificate" signed by the supplier's certifier and the supplier's Organic Certificate.

If importing organic product from Canada the shipment **must** be accompanied by documentation (bill of lading, packing slip etc.) that states "Certified in compliance with the terms of the US-Canada Organic Equivalency Arrangement." You must also obtain the current Organic Certificate for each Canadian supplier.

Appendix

National Organic Program Rule

The following data is current as of December 20, 2019. The rule is available online at www.ecfr.gov.

Title 7: Agriculture

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Authority: 7 U.S.C. 6501-6522.

Source: 65 FR 80637, Dec. 21, 2000, unless otherwise noted.

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.

Accreditation. 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 unavailability 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 Department of Agriculture, or the representative to whom authority has been delegated to act in the stead of the Administrator.

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

Agricultural product. 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.

Agricultural Marketing Service (AMS). The Agricultural Marketing Service of the United States Department of Agriculture.

Allowed synthetic. 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).

Animal drug. 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.

Annual seedling. 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.

Area of operation. 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.

Audit trail. 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).

Biologics. 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.

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

Buffer zone. 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.

Bulk. 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.

Certification or certified. 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.

Certified operation. 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.

Certifying agent. 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.

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

Claims. 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.

Commercially available. 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.

Commingling. 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 131 °F and 170 °F 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.

Control. 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.

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

Crop rotation. 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.

Crop year. 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.

Cultural methods. 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.

Detectable residue. 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.

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

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

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

Dry matter. 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.

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

Emergency pest or disease treatment program. 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, diluents, 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.

Feed. 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.

Feed additive. 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.

Feed supplement. 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.

Fertilizer. 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.

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

Governmental entity. Any domestic government, tribal government, or foreign governmental subdivision providing certification services.

Graze. (1) The consumption of standing or residual forage by livestock.

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

Grazing. To graze.

Grazing season. 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.

Handle. 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.

Handler. 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.

Handling operation. 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.

Immediate family. 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.

Inert ingredient. 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)).

Information panel. 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).

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

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

Inspection. 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.

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

Label. 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.

Labeling. 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.

Livestock. 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.

Lot. 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.

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

Market information. 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.

Mulch. 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.

Narrow range oils. Petroleum derivatives, predominately of paraffinic and naphthenic fractions with 50 percent boiling point (10 mm Hg) between 415 °F and 440 °F.

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

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

National Organic Standards Board (NOSB). 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.

Natural resources of the operation. 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.

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

Nontoxic. 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.

Organic production. 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.

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

Peer review panel. 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.

Pesticide. 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) *et seq.*)

Petition. A request to amend the National List that is submitted by any person in accordance with this part.

Planting stock. 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.

Practice standard. 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.

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

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

Processing. 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.

Processing aid. (1) 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;

(2) 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

(3) 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.

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

Production lot number/identifier. 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.

Prohibited substance. 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.

Records. 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.

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

Responsibly connected. 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.

Retail food establishment. A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store 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.

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

Sewage sludge. 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.

Slaughter stock. Any animal that is intended to be slaughtered for consumption by humans or other animals.

Soil and water quality. 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.

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

State certifying agent. 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.

State organic program (SOP). 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.

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

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

Unavoidable residual environmental contamination (UREC). 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.

Wild crop. 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.

Yards/Feeding pad. 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.

[65 FR 80637, Dec. 21, 2000, as amended at 72 FR 70484, Dec. 12, 2007; 75 FR 7192, Feb. 17, 2010; 79 FR 58662, Sept. 30, 2014; 80 FR 6429, Feb. 5, 2015]

§205.3 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, we must publish notice of change in the Federal Register and the material must be available to the public. All approved material is available for inspection at the USDA Agricultural Marketing Service, National Organic Program, 1400 Independence Avenue SW., Washington, DC 20250; (202) 720-3252, and is available from the sources listed below. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741-6030 or go to http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428; phone 1-877-909-2786; <http://www.astm.org/>.

(1) ASTM D5988-12 (“ASTM D5988”), “Standard Test Method for Determining Aerobic Biodegradation of Plastic Materials in Soil,” approved May 1, 2012, IBR approved for §205.2.

(2) ASTM D6400-12 (“ASTM D6400”), “Standard Specification for Labeling of Plastics Designed to be Aerobically Composted in Municipal or Industrial Facilities,” approved May 15, 2012, IBR approved for §205.2.

(3) ASTM D6866-12 (“ASTM D6866”), “Standard Test Methods for Determining the Biobased Content of Solid, Liquid, and Gaseous Samples Using Radiocarbon Analysis,” approved April 1, 2012, IBR approved for §205.2.

(4) ASTM D6868-11 (“ASTM D6868”), “Standard Specification for Labeling of End Items that Incorporate Plastics and Polymers as Coatings or Additives with Paper and Other Substrates Designed to be Aerobically Composted in Municipal or Industrial Facilities,” approved February 1, 2011, IBR approved for §205.2.

(c) European Committee for Standardization; Avenue Marnix, 17-B-1000 Brussels; phone 32 2 550 08 11; www.cen.eu.

(1) EN 13432:2000:E (“EN 13432”), September, 2000, “Requirements for packaging recoverable through composting and biodegradation—Test scheme and evaluation criteria for the final acceptance of packaging,” IBR approved for §205.2.

(2) EN 14995:2006:E (“EN 14995”), December, 2006, “Plastics—Evaluation of compostability—Test scheme and specifications,” IBR approved for §205.2.

(d) International Organization for Standardization, 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland; phone 41 22 749 01 11; www.iso.org.

(1) ISO 17088:2012(E), (“ISO 17088”), “Specifications for compostable plastics,” June 1, 2012, IBR approved for §205.2.

(2) ISO 17556:2012(E) (“ISO 17556”), “Plastics—Determination of the ultimate aerobic biodegradability of plastic materials in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide evolved,” August 15, 2012, IBR approved for §205.2.

[79 FR 58662, Sept. 30, 2014]

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 the amount specified in §3.91(b)(1) of this title 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.

[65 FR 80637, Dec. 21, 2000, as amended at 70 FR 29579, May 24, 2005; 80 FR 6429, Feb. 5, 2015]

§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.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7193, Feb. 17, 2010]

§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: *Provided*, 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.

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: *Provided*, 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 through 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 131 °F and 170 °F 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: *Provided*, 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: *Provided*, 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: *Provided*, 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: *Except*, 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: *Except*, 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.
- (b) [Reserved]

§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: *Provided*, 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: *Provided*, 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.

§§205.208-205.235 [Reserved]

§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) *Dairy animals*. 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, *Except*,

(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) *Breeder stock.* Livestock used as breeder stock may be brought from a nonorganic operation onto an organic operation at any time: *Provided*, 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.

[65 FR 80637, Dec. 21, 2000, as amended at 71 FR 32807, June 7, 2006]

§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.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7193, Feb. 17, 2010]

§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 animals, as allowed under §205.603.

(3) Fiber bearing animals, as allowed under §205.603.

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 83 FR 66571, Dec. 27, 2018]

§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 well-being 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 ($\frac{1}{5}$) 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.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7193, Feb. 17, 2010]

§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.

[75 FR 7194, Feb. 17, 2010]

§§205.243-205.269 [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: *Except*, 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: *Provided*, 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: *Provided*, 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: *Provided*, 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 applies.

(e) Temporary variances will not be granted for any practice, material, or procedure prohibited under §205.105.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7194, Feb. 17, 2010]

§§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 (f)(1), (2), and (3) of §205.301. Nonorganic ingredients may be produced without regard to paragraphs (f)(4), (5), (6), and (7) of §205.301. 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 §205.105(e);

(2) Be produced using ionizing radiation, pursuant to §205.105(f);

(3) Be processed using sewage sludge, pursuant to §205.105(g);

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, 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.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

§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: *Provided*, That, the handler producing the finished product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: *Provided further*, 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 §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)”: *Provided*, That, the statement does not list more than three organically produced ingredients; or

(ii) “Made with organic (specified food groups)”: *Provided*, 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, *Provided further*, 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 Multi-ingredient 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, *Provided*, 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:

(1) 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.

(2) Comply with other Federal agency or State feed labeling requirements as applicable.

§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: *Provided*, 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: *Provided*, 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.



Figure 1

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 §205.103;
- (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.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

§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) *On-site inspections.* (1) A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.

(2)(i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part.

(ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.

(iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.

(b) *Scheduling.* (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: *Except*, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.

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

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

(1) The operation's compliance or capability to comply with the Act and the regulations in this part;

(2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;

(3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.

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

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

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

§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: *Provided*, 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: *Except*, 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 on-site 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: *Provided*, 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: *Provided*, 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; *Provided*, 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-NOP, 1400 Independence Ave. SW., Room 2648 So. Bldg., Ag Stop 0268, Washington, DC 20250-0268.

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

§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) *Administrative policies and procedures.* (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 §205.670.

(c) *Conflicts of interest.* (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) *Current certification activities.* 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) *Other information.* 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 §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; *Provided*, 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 this subpart F 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) *Annual report and fees.* 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) *Renewal of accreditation.* (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 the regulations of this part.

(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) *Notice of renewal of accreditation.* 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) *Noncompliance.* 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) *Amending accreditation.* 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.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

§§205.511-205.599 [Reserved]

Subpart G—Administrative

The National List of Allowed and Prohibited Substances

§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) Hypochlorous acid—generated from electrolyzed water.
 - (iv) 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 repellent 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.
- (1) Ferric phosphate (CAS # 10045-86-0).
- (2) Elemental sulfur.
- (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.

(11) Polyoxin D zinc salt.

(j) 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 oxide (CAS # 1309-48-4)—for use only to control the viscosity of a clay suspension agent for humates.

(6) Magnesium sulfate—allowed with a documented soil deficiency.

(7) Micronutrients—not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Micronutrient deficiency must be documented by soil or tissue testing or other documented and verifiable method as approved by the certifying agent.

(i) Soluble boron products.

(ii) Sulfates, carbonates, oxides, or silicates of zinc, copper, iron, manganese, molybdenum, selenium, and cobalt.

(8) 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.

(9) Vitamins, B₁, C, and E.

(10) Squid byproducts—from food waste processing only. 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.

(11) Sulfurous acid (CAS # 7782-99-2) for on-farm generation of substance 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. Sodium silicate—for tree fruit and fiber processing.

(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 only 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]

[65 FR 80637, Dec. 21, 2000, as amended at 68 FR 61992, Oct. 31, 2003; 71 FR 53302 Sept. 11, 2006; 72 FR 69572, Dec. 10, 2007; 75 FR 38696, July 6, 2010; 75 FR 77524, Dec. 13, 2010; 77 FR 8092, Feb. 14, 2012; 77 FR 33298, June 6, 2012; 77 FR 45907, Aug. 2, 2012; 78 FR 31821, May 28, 2013; 79 FR 58663, Sept. 30, 2014; 80 FR 77234, Dec. 14, 2015; 82 FR 31243, July 6, 2017; 83 FR 66571, Dec. 27, 2018; 84 FR 56677, Oct. 23, 2019]

§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) Rotenone (CAS # 83-79-4).
- (g) Sodium fluoaluminatate (mined).
- (h) 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.
- (i) Strychnine.
- (j) Tobacco dust (nicotine sulfatate).

[68 FR 61992, Oct. 31, 2003, as amended at 83 FR 66572, Dec. 27, 2018]

§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) Activated charcoal (CAS # 7440-44-0)—must be from vegetative sources.
 - (7) Calcium borogluconate (CAS # 5743-34-0)—for treatment of milk fever only.
 - (8) Calcium propionate (CAS # 4075-81-4)—for treatment of milk fever only.
 - (9) Chlorhexidine (CAS # 55-56-1)—for medical procedures conducted under the supervision of a licensed veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.
 - (10) 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) Hypochlorous acid—generated from electrolyzed water.
 - (iv) Sodium hypochlorite
 - (11) Electrolytes—without antibiotics.
 - (12) 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.
 - (13) Glucose.

(14) Glycerin—allowed as a livestock teat dip, must be produced through the hydrolysis of fats or oils.

(15) Hydrogen peroxide.

(16) Iodine.

(17) Kaolin pectin—for use as an adsorbent, antidiarrheal, and gut protectant.

(18) 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.

(19) Magnesium sulfate.

(20) Mineral oil—for treatment of intestinal compaction, prohibited for use as a dust suppressant.

(21) Nutritive supplements—injectable supplements of trace minerals per paragraph (d)(2) of this section, vitamins per paragraph (d)(3), and electrolytes per paragraph (a)(11), with excipients per paragraph (f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.

(22) Oxytocin—use in postparturition therapeutic applications.

(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. 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. Allowed for fiber bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

(i) Fenbendazole (CAS #43210-67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

(ii) Moxidectin (CAS #113507-06-5)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

(24) Peroxyacetic/peracetic acid (CAS #-79-21-0)—for sanitizing facility and processing equipment.

(25) Phosphoric acid—allowed as an equipment cleaner, *Provided*, That, no direct contact with organically managed livestock or land occurs.

(26) 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.

(27) Propylene glycol (CAS #57-55-6)—only for treatment of ketosis in ruminants.

(28) Sodium chlorite, acidified—allowed for use on organic livestock as a teat dip treatment only.

(29) 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.

(30) 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; and,

(ii) 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) Elemental sulfur—for treatment of livestock and livestock housing.

(3) Formic acid (CAS # 64-18-6)—for use as a pesticide solely within honeybee hives.

(4) Iodine.

(5) Lidocaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.

(6) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.

(7) Mineral oil—for topical use and as a lubricant.

(8) Procaine—as a local anesthetic. Use requires a withdrawal period of 8 days after administering to livestock intended for slaughter and 6 days after administering to dairy animals.

(9) Sodium chlorite, acidified—allowed for use on organic livestock as teat dip treatment only.

(10) Sucrose octanoate esters (CAS #s-42922-74-7; 58064-47-4)—in accordance with approved labeling.

(11) Zinc sulfate—for use in hoof and foot treatments only.

(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 pounds of synthetic 100 percent methionine per ton of feed in the diet, maximum rates as averaged per ton of feed over the life of the flock: Laying chickens—2 pounds; broiler chickens—2.5 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 and biologics used to treat organic livestock when the excipient is: (1) Identified by the FDA as Generally Recognized As Safe; (2) Approved by the FDA as a food additive; (3) Included in the FDA review and approval of a New Animal Drug Application or New Drug Application; or (4) Approved by APHIS for use in veterinary biologics.

(g)-(z) [Reserved]

[72 FR 70484, Dec. 12, 2007, as amended at 73 FR 54059, Sept. 18, 2008; 75 FR 51924, Aug. 24, 2010; 77 FR 28745, May 15, 2012; 77 FR 45907, Aug. 2, 2012; 77 FR 57989, Sept. 19, 2012; 80 FR 6429, Feb. 5, 2015; 82 FR 31243, July 6, 2017; 83 FR 66572, Dec. 27, 2018; 84 FR 18136, Apr. 30, 2019]

§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 (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).

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

Bentonite.

Calcium carbonate.

Calcium chloride.

Calcium sulfate—mined.

Carrageenan.

Dairy cultures.

Diatomaceous earth—food filtering aid only.

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

Flavors—nonsynthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or 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 chloride.

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 (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.

Alginic acid (CAS #9005-32-7)

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 (CAS #9004-34-6)—for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.

Chlorine materials—disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act.

i. Calcium hypochlorite.

ii. Chlorine dioxide.

iii. Hypochlorous acid—generated from electrolyzed water.

iv. 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.

Hydrogen peroxide.

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 carbonate.

Potassium citrate.

Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

Potassium lactate—for use as an antimicrobial agent and pH regulator only.

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—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 lactate—for use as an antimicrobial agent and pH regulator only.

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]

[68 FR 61993, Oct. 31, 2003, as amended as 68 FR 62217, Nov. 3, 2003; 71 FR 53302, Sept. 11, 2006; 72 FR 58473, Oct. 16, 2007; 73 FR 59481, Oct. 9, 2008; 75 FR 77524, Dec. 13, 2010; 77 FR 8092, Feb. 14, 2012; 77 FR 33298, June 6, 2012; 77 FR 45907, Aug. 2, 2012; 78 FR 31821, May 28, 2013; 78 FR 61161, Oct. 3, 2013; 81 FR 51709, Aug. 3, 2016; 82 FR 31244, July 6, 2017; 83 FR 66573, Dec. 27, 2018; 84 FR 18136, Apr. 30, 2019; 84 FR 56677, Oct. 23, 2019]

§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) Carnauba wax

(b) Casings, from processed intestines.

(c) Celery powder.

(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(1) Beet juice extract color—derived from *Beta vulgaris* L., except must not be produced from sugarbeets.

(2) Beta-carotene extract color—derived from carrots (*Daucus carota* L.) or algae (*Dunaliella salina*).

(3) Black currant juice color—derived from *Ribes nigrum* L.

(4) Black/purple carrot juice color—derived from *Daucus carota* L.

(5) Blueberry juice color—derived from blueberries (*Vaccinium spp.*).

(6) Carrot juice color—derived from *Daucus carota* L.

(7) Cherry juice color—derived from *Prunus avium* (L.) L. or *Prunus cerasus* L.

(8) Chokeberry, aronia juice color—derived from *Aronia arbutifolia* (L.) Pers. or *Aronia melanocarpa* (Michx.) Elliott.

(9) Elderberry juice color—derived from *Sambucus nigra* L.

(10) Grape juice color—derived from *Vitis vinifera* L.

(11) Grape skin extract color—derived from *Vitis vinifera* L.

(12) Paprika color—derived from dried powder or vegetable oil extract of *Capsicum annum* L.

(13) Pumpkin juice color—derived from *Cucurbita pepo* L. or *Cucurbita maxima* Duchesne.

(14) Purple sweet potato juice color—derived from *Ipomoea batatas* L. or *Solanum tuberosum* L.

- (15) Red cabbage extract color—derived from *Brassica oleracea* L.
- (16) Red radish extract color—derived from *Raphanus sativus* L.
- (17) Saffron extract color—derived from *Crocus sativus* L.
- (18) Turmeric extract color—derived from *Curcuma longa* L.
- (e) 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.
- (f) Fructooligosaccharides (CAS # 308066-66-2).
- (g) Gelatin (CAS # 9000-70-8).
- (h) Glycerin (CAS # 56-81-5)—produced from agricultural source materials and processed using biological or mechanical/physical methods as described under §205.270(a).
- (i) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).
- (j) Inulin-oligofructose enriched (CAS # 9005-80-5).
- (k) Kelp—for use only as a thickener and dietary supplement.
- (l) Konjac flour (CAS # 37220-17-0).
- (m) Lecithin—de-oiled.
- (n) Orange pulp, dried.
- (o) Orange shellac-unbleached (CAS # 9000-59-3).
- (p) Pectin (non-amidated forms only).
- (q) Potassium acid tartrate.
- (r) Seaweed, Pacific kombu.
- (s) Starches.
 - (1) Cornstarch (native).
 - (2) Sweet potato starch—for bean thread production only.
- (t) Tragacanth gum (CAS #-9000-65-1).
- (u) Turkish bay leaves.
- (v) Wakame seaweed (*Undaria pinnatifida*).
- (w) Whey protein concentrate.

[72 FR 35140, June 27, 2007, as amended at 75 FR 77524, Dec. 13, 2010; 77 FR 8092, Feb. 14, 2012; 77 FR 33299, June 6, 2012; 77 FR 44429, July 30, 2012; 78 FR 31821, May 28, 2013; 79 FR 58663, Sept. 30, 2014; 80 FR 77234, Dec. 12, 2015; 82 FR 31244, July 6, 2017; 83 FR 66571, Dec. 27, 2018; 84 18136, Apr. 30, 2019]

§205.607 Amending the National List.

(a) Any person may petition the National Organic Standards 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-NOP, 1400 Independence Ave. SW., Room 2648 So. Bldg., Ag Stop 0268, Washington, DC 20250-0268.

[65 FR 80637, Dec. 21, 2000, as amended at 68 FR 61993, Oct. 31, 2003; 80 FR 6429, Feb. 5, 2015]

§§205.608-205.619 [Reserved]

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.

§§205.623-205.639 [Reserved]

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 65).

(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 February 20, 2001, 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 February 20, 2001. 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 February 20, 2001. 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 February 20, 2001.

§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 USDA, AMS Livestock Program and mailed to: USDA, AMS Livestock, Poultry and Seed Program, QAD, P.O. Box 790304 St. Louis, MO 63179-0304 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.

[65 FR 80637, Dec. 21, 2000, as amended at 80 FR 6429, Feb. 5, 2015]

§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.

§§205.643-205.649 [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) *Notification.* 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) *Resolution.* 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) *Proposed suspension or revocation.* 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) *Willful violations.* 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) *Suspension or revocation.* (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) *Eligibility.* (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, *Except*, 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 the amount specified in §3.91(b)(1) of this title 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.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 17560, Apr. 7, 2010; 79 FR 6430, Feb. 5, 2015]

§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 the regulations in this part. The Secretary may review any mediated agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.

§205.664 [Reserved]

§205.665 Noncompliance procedure for certifying agents.

(a) *Notification.* 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) *Resolution.* 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) *Proposed suspension or revocation.* 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) *Willful violations.* 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) *Suspension or revocation.* 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) *Eligibility.* (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.

§§205.666-205.667 [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]

Inspection and Testing, Reporting, and Exclusion from Sale

§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,” “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.

[77 FR 67251, Nov. 9, 2012]

§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: *Provided, 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: *Provided, 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.

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, *Except*, 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) *Certification appeals.* 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, *Except*, 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, 7 CFR part 1, subpart H, or the State organic program's rules of procedure.

(b) *Accreditation appeals.* 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) *Filing period.* 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 Team, 1400 Independence Avenue SW., Room 2648-So., Stop 0268, Washington, DC 20250-0268.

(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.

[65 FR 80637, Dec. 21, 2000, as amended at 75 FR 7195, Feb. 17, 2010]

§§205.691-205.699 [Reserved]