

USDA National Organic Program Rule Summary Outline

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Subpart A – Definitions

See the Glossary for additional definitions.

Subpart B – Applicability

The applicability subpart determines the production and handling operations that must be certified under the NOP. In general, the NOP provides for many exemptions and exclusions from certification. The applicability subpart also includes recordkeeping requirements and a broad list of prohibited substances.

§205.100 What has to be certified.

1. Requires all organic production and handling operations to be certified unless they are exempt or excluded from certification.
2. Provides for continuation of certification if the production or handling operation is certified by an accredited certifier prior to October 21, 2002.
3. Specifies that knowingly selling a product as organic that is not in compliance with the NOP may result in a \$10,000 civil penalty.

§205.101 Exemptions and exclusions from certification.

Exemptions

1. Producers that sell less than \$5,000 worth of organic products are exempted from organic certification requirements.
2. Handlers that sell less than \$5,000 worth of organic products are exempted from organic certification requirements.
3. Organic products from exempt producers and handlers may not be used in processed organic food products.
4. Organic products from exempt producers and handlers may be sold at farmers markets and retail stores as organic.
5. Retail food stores are exempt from organic certification requirements.
6. Processors that produce products with less than 70 percent organic ingredients are exempt from organic certification requirements.
7. Processors that produce products that limit their organic claims to the information panel are exempt from organic certification requirements.

Exclusions

1. Handlers that only sell packaged organic food products are excluded from organic certification requirements. This exclusion would include produce and grocery distributors.
2. Retailers that have in-store bakeries, delicatessen, salad bar or ready to eat food are excluded from the organic certification requirements.

§ 205.102 Use of the term, “organic.”

Specifies that agricultural products sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic ingredients” must be produced and handled in accordance with the National Organic Program standards.

§205.103 Recordkeeping by certified operations.

Specifies that records must be maintained to fully disclose all activities of the certified operation, must demonstrate compliance with the Act, and must be available for inspection.

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

1. Specifies that synthetic substances are prohibited unless specifically allowed under the National List.
2. Specifies that nonsynthetic (natural) substances are allowed unless specifically prohibited under the National List.
3. Specifies that nonagricultural substances used in processed organic food products must be approved on the National List.
4. Specifies that nonorganic agricultural substances used in processed organic food products must be approved on the National List.
5. Prohibits genetically modified crops for use in organic food production or handling except for animal vaccines approved on the National List.
6. Prohibits the use of ionizing radiation.
7. Prohibits the use of sewage sludge in crop production.

Subpart C – Organic Production and Handling Requirements

§205.200 General

Specifies that organic production practices (for crop and livestock operations) must maintain or improve the natural resources of the operation, including soil and water quality.

§205.201 Organic production and handling system plan.

This section requires all producers and handlers to have an organic system plan that must include:

1. A narrative or descriptive format that identifies the practices and procedures performed. Practices include the method for applying manure, fertilizers, or pest control materials; mechanical and biological methods used to prepare and combine ingredients; methods used to package finished products; and measures taken to exclude pests from a facility. Examples of procedures include protocols established for locating commercially available organic seeds, and procedures to inform neighbors about the organic status of the fields.
2. The plan must include a list of all materials that will be applied to the land or within the handling facilities. The plan must also address how the application of these materials meets other requirements of the NOP (e.g. how their plan will prevent any manure applications from contributing to water contamination).
3. The plan must include a description of the monitoring practices used to evaluate the effectiveness of the organic plan. Monitoring practices could include soil tests to monitor effectiveness of plan for maintaining or improving soil quality; production objectives such as pounds of product produced per acre; or number of organic apples distributed; or results of pesticide residue tests.
4. The plan must include a description of the recordkeeping system used to track a product from harvest through sale; or receiving through shipping; or identifying each animal in production.
5. Split operations must describe the management practices and physical barriers that have been established to prevent commingling or contamination of organic food products.

6. Certifying agents may require additional items to be included in the plan to determine if an operation meets the organic requirements.

Crop Production

§205.202 Land requirements.

1. Requires organic crops to have had no prohibited materials applied within three years of harvest of the crop.
2. Requires distinct boundaries and adequate buffer zones to prevent drift. The NOP does not specify a minimum buffer zone requirement.

§205.203 Soil fertility and crop nutrient management practice standard.

1. Standards require organic producers to select tools (e.g., tillers, plows) and practices that maintain or improve soil quality and minimize soil erosion.
2. Producers are required to utilize crop rotations, cover crops and 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.
3. Prohibits the use of raw manure unless it is incorporated into the soil more than 120 days prior to harvest for products whose edible portion is in direct contact with the soil.
4. Prohibits the use of raw manure unless it is incorporated into the soil more than 90 days prior to harvest for products whose edible portion does not have direct contact with the soil.
5. Defines compost as material that has an initial C:N ratio of between 25:1 and 40:1. Requires compost to reach specific temperature parameters for specific time periods.
6. Allows use of uncomposted plant materials.
7. Allows mined substances of low solubility.
8. There are many questions about allowable materials for managing soil fertility.

§205.204 Seeds and planting stock practice standard.

1. Requires annual transplants to be organically grown from seed.
2. Requires perennial transplants to be organically grown for one year prior to harvest.
3. Requires use of organic seeds unless organic seeds are commercially unavailable. Producers have to choose an "equivalent" organic seed variety that was commercially available. The term, "equivalent," indicates that two seed varieties have similar performance attributes, such as resistance to drought and insects, and production traits, including yield, size, and shape of the commodity.
4. If organic seeds are unavailable, requires use of untreated seeds.
5. If untreated seeds are unavailable, only allows use of seeds treated with a substance included on the National List. There are currently no allowed seed treatments on the National List. Thus, the NOP currently prohibits the use of treated seeds under all circumstances.

§205.205 Crop rotation practice standard.

Crop rotation is required. There is a requirement for cover crops and/or habitat required in perennial crops to provide for pest management.

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

The producer must use practices to prevent crop pests, weeds, and diseases. These practices include crop rotation, sanitation measures, and cultural practices. Producers may use other preventative practices including beneficial insects and natural habitat enhancement. If the preventative practices are not adequate to prevent or control pests the producer may use materials allowed under the National List.

§205.207 Wild-crop harvesting practice standard.

Wild crops harvested from non-agricultural lands can be sold and labeled as organic as long as no prohibited materials have been applied to the land for 3 years and the harvest of the crop is not destructive to the environment.

Livestock Production

§205.236 Origin of livestock.

1. Poultry and edible poultry products (eggs) must be from poultry that has been under organic management since the second day of life.
2. Slaughter stock (animals raised for their meat, e.g. cattle, pigs, sheep) must be under organic management since the last third of gestation.
3. Dairy animals must be under organic management for at least one year prior to the production of organic milk, except When an entire herd is converted to organic the producer may feed 80 percent organic feed for the first 9 months and 100 percent organic feed for the last 3 months.
4. Breeder stock may be brought onto an organic farm from a nonorganic operation prior to the last third of gestation. Breeder stock must be under organic management during the last third of gestation.
5. The producer must maintain records that preserve the identity of all organic animals.

§205.237 Livestock feed.

1. Organic livestock must be fed organic feed.
2. Organic feed may contain feed additives and feed supplements that are allowed on the National List. Approved feed supplements include nonsynthetic substances (e.g. fish meal) and synthetic milk replacers for emergency use only (must not contain antibiotics or be from a BST treated animal) and nonsynthetic.
3. Approved feed additives include trace minerals and vitamins.
4. Prohibits use of animal drugs to promote growth.
5. Prohibits feed supplements or additives in amounts in excess of basic nutritional needs of the animal species.
6. Prohibits plastic pellets for roughage, urea, manure, or mammalian or poultry by-products in feed.

§205.238 Livestock health care practice standard.

1. The producer must establish preventative health care practices such as:
 - Selection of species and types of livestock with regard to resistance to disease and parasites.
 - Providing quality feed.
 - Establishing living conditions that minimize occurrence and spread of disease.
 - Provide conditions that reduce stress.
 - Perform physical alterations (e.g. beak trimming) as needed to promote the animal's welfare.
 - Administer vaccines and veterinary biologics.
2. When preventative practices are not adequate to prevent sickness producers may use synthetic medications allowed on the National List. Approved medications include aspirin; chlorohexidine for surgical procedures and teat dip; electrolytes; glucose; glycerin as a teat dip; iodine; hydrogen peroxide; magnesium sulfate; oxytocin for postparturition; copper sulfate for external use; and mineral oil for external use.
3. Ivermectin may be used on breeder stock prior to the last third of gestation and dairy stock at least 90 days prior to milk production when preventative measures fail.
4. Antibiotics are prohibited for slaughter stock, poultry and dairy stock.
5. It is prohibited to administer any medication or drug in the absence of illness.
6. Hormones are prohibited.

7. It is prohibited to withhold medical treatment to a sick animal in an effort to preserve its organic status.

§205.239 Livestock living condition.

1. Producers must establish living conditions that accommodate the health and natural behavior of the animals, including:
 - Access to the outdoors, shade, shelter, fresh air as suitable to the species.
 - Access to pasture for ruminants.
 - Appropriate clean, dry bedding. If the bedding is consumed it must be organic.
2. The producer may provide temporary confinement because of inclement weather, the animal's stage of production (e.g. young birds, finishing cattle), risk to the animal's health or safety, or risk to soil or water quality.
3. The producer must manage manure in a manner that does not contribute to the contamination of crops, soil or water.

Handling**§205.270 Organic handling requirements.**

This section provides general requirements for ingredients used in organic processing.

1. All ingredients and processing aids used in 100% organic food must be organic.
2. All agricultural ingredients in organic food (at least 95% organic ingredients) must be either organic or not commercially available in organic form. These ingredients must also not be genetically engineered; irradiated; produced from sewage sludge; or be produced with a volatile synthetic substance.
3. All non-agricultural ingredients and processing aids used in organic food (at least 95% organic ingredients) must be approved on the National List.
4. All agricultural ingredients in made with organic food (at least 70% organic ingredients) must not be genetically engineered; irradiated; or produced from sewage sludge.
5. All non-agricultural ingredients and processing aids used in made with organic food (at least 70% organic ingredients) must be approved on the National List.

§205.271 Facility pest management practice standard.

1. The handler must use practices to prevent pests, including removal of pest habitat; prevention of access to facilities; and managing environmental factors to prevent pest reproduction.
2. The handler may use mechanical traps; lures and repellants (must be natural or on National List).
3. If preventative practices are not adequate, the handler may use materials approved on the National List.
4. If the preventative practices and the materials approved on the National List are not adequate to control pests, the handler may use a synthetic substance that is not on the National List as long as the material does not contact the organic products (e.g. the organic products are removed during treatment or the organic products are in sealed steel drums).

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

1. The handler must implement procedures to prevent commingling.
2. The handler must implement procedures to prevent organic products from contacting nonorganic products.
3. Containers must not contain preservatives or fungicides.

4. Containers may be reused as long as they are thoroughly cleaned and pose no risk of contact with prohibited substances.

§205.290 Temporary variances.

1. Temporary variances to the requirements in the organic production and handling requirements may be granted by the NOP for natural disasters; damage from drought, flood, hail, tornado, earthquake or other business interruption; and for research.
2. A State organic program or state certifying agent may recommend to the NOP that a temporary variance should be granted.
3. Temporary variances will not be granted for the use of prohibited synthetic or natural substances; genetically modified organisms; irradiation; or sewage sludge.

Subpart D - Labels, Labeling and Market Information

The National Organic Program has created five label categories for organic food:

1. **100 percent organic** – All ingredients and processing aids must be organic.
2. **Organic** – At least 95% of ingredients must be organic.
3. **Made with organic ingredients** – At least 70% of ingredients must be organic.
4. **Products with less than 70% organic ingredients.**
5. **Organic Livestock feed.**

Key definitions –

Processing aid – A substance used during processing that does not become an ingredient or is present at insignificant levels in the finished food product.

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.

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 that principal display panel, unless another section of the label is designated as the information panel because of package size or other package attributes.

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

§205.300 Use of the term, “organic.”

This section specifies that the term “organic” may only be used on labels that comply with the National Organic Program regulations. Products for export may be labeled to meet the receiving countries specifications as long as they are labeled “for export only.” Products imported to the United States from foreign countries must be certified and labeled according to the NOP regulations.

§205.301 Product Composition

1. **100 percent organic** – All ingredients and processing aids used in 100% organic food must be organic.
2. **Organic** – At least 95% of ingredients must be organic. All agricultural ingredients in the product must be either organic or not commercially available in organic form. All non-organic agricultural ingredients must not be genetically engineered; irradiated; produced from sewage sludge; or be produced with a volatile synthetic substance. All non-agricultural ingredients and processing aids used must be approved on the National List.

3. **Made with organic ingredients** – At least 70% of ingredients must be organic. All non-organic agricultural ingredients must not be genetically engineered; irradiated; or produced from sewage sludge. All non-agricultural ingredients and processing aids must be approved on the National List.
4. **Products with less than 70% organic ingredients.** All organic ingredients must be produced in compliance with the NOP regulations. There are no restrictions on the non-organic ingredients used in this labeling category.
5. **Livestock feed** – Organic livestock feed must include only organic agricultural ingredients and approved feed additives and supplements.

§205.302 Calculating the percentage of organically produced ingredients.

This section describes the procedure for determining the percentage of organic ingredients in a food product. Water and salt are not included in the calculation of the percentage of organic ingredients.

§205.303 Packaged products labeled “100 percent organic” or “organic.”

Optional labeling provisions - Products in these categories may display on the principal display panel:

- The percentage of organic ingredients,
- The USDA seal,
- The seal of the state or private certification agency,
- The term “100 percent organic” or “organic” as appropriate,

Required labeling provisions – Products in these categories must:

- Identify each organic ingredient with the word , “organic,” or with an asterisk that identifies the ingredient as organic.
- Water and salt cannot be identified as organic.
- On the information panel, the statement “Certified organic by ... (name of certifying agent).

§205.304 Packaged products labeled “made with organic (specified ingredients or food groups(s)).”

Optional labeling provisions - Products in this category may display on the principal display panel:

- The percentage of organic ingredients,
- The seal of the state or private certification agency,
- The term “made with organic (specified ingredients)” as appropriate. The term “made with organic (specified ingredients)” must appear in letters that do not exceed one-half the size of the product identity.

Required labeling provisions – Products in this category must:

- Identify each organic ingredient with the word , “organic,” or with an asterisk that identifies the ingredient as organic.
- Water and salt cannot be identified as organic.
- On the information panel, the statement “Certified organic by ... (name of certifying agent).

Prohibited labeling provisions – Products in this category must not display:

- The USDA seal,

§205.305 Multi-ingredient packaged products with less than 70 percent organically produced ingredients.

Optional labeling provisions - Products in this category may display on the information panel:

- Identify each organic ingredient with the word , “organic,” or with an asterisk that identifies the ingredient as organic.
- If the organic ingredients are identified on the ingredients statement then the percentage of organic ingredients may be displayed on the information panel

Prohibited labeling provisions – Products in this category must not display:

- The word “organic,” on the principal display panel,

- The USDA seal,
- The seal of the state or private certification agency,
- The statement “Certified organic by ... (name of certifying agent).

§205.306 Labeling of livestock feed.

Optional labeling provisions – Organic livestock feed may display on any package panel:

- The USDA seal,
- The seal of the state or private certification agency,
- The term “100 percent organic” or “organic” as appropriate,
- Identify each organic ingredient with the word , “organic,” or with an asterisk that identifies the ingredient as organic.
- Water and salt cannot be identified as organic.

Required labeling provisions – Organic livestock feed must display:

- On the information panel, the statement “Certified organic by ... (name of certifying agent).

§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)).”

Optional labeling provisions – These products may display:

- The name of the certifying agent.
- Identification of the product as organic.
- The seal of the state or private certification agency.
- The USDA seal.

Required labeling provisions – These products must display:

- The production lot number to maintain identity of organic products.

Export labeling provisions – Products for export may display:

- May be labeled in accordance with foreign labeling requirements provided that they are labeled “For Export Only.”

§205.308 Agricultural products in other than packaged form (e.g. produce, bulk food) at the point of retail sale that are sold, labeled, or represented as “100 percent organic” or “organic.”

Optional labeling provisions – Retailers may display on non-packaged “100 percent organic” and “organic” products (e.g. produce, bulk food):

- The term “100 percent organic” or “organic” as appropriate.
- The seal of the state or private certification agency.
- The USDA seal.

§205.309 Agricultural products in other than packaged form (e.g. bulk food) at the point of retail sale that are sold, labeled, or represented as “made with organic (specified ingredients or food groups (s)).”

Optional labeling provisions – Retailers may display on non-packaged “made with organic (specified ingredients)” products (e.g. bulk food):

- The seal of the state or private certification agency,
- The term “made with organic (specified ingredients)” as appropriate. The term “made with organic (specified ingredients)” must appear in letters that do not exceed one-half the size of the product identity, provided that each organic ingredient is identified with the word , “organic,” or with an asterisk that identifies the ingredient as organic.

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

Optional labeling provisions – Organic products from exempt or excluded operations may:

- Identify organic products as organic. These organic products may not be used as an organic ingredient in processed organic foods.

Prohibited labeling provisions – Organic products from exempt or excluded operations must not display:

- The USDA seal.
- The seal of the state or private certification agency.
- Be represented as a certified organic product.

§205.311 USDA Seal.

It's round and it says "USDA ORGANIC."

Subpart E - Certification

The Certification subpart specifies the requirements for certification including the application requirements, inspection procedures and conditions for granting and denying certification.

§205.400 General Requirements for certification

Persons seeking to receive or maintain organic certification must:

1. Comply with the standards.
2. Establish and implement an organic production and handling system plan.
3. Update the plan on an annual basis.
4. Permit on-site inspections.
5. Maintain records for five years.
6. Pay annual application fees.
7. Certified operations are required to immediately notify the certifying agent concerning any application, including drift, of any prohibited substance.

§205.401 Application for certification

Application – Must contain organic production and handling system plan and appropriate fees.

§205.402 Review of application

1. The certifying agent is responsible for reviewing application and responding to applicant within a reasonable amount of time. The response to the application must communicate whether the applicant appears to comply with the organic regulations.
2. The certifying agent must schedule an inspection to determine whether the applicant qualifies for certification.
3. The applicant may withdraw application at any time.

§205.402 On-site inspections.

1. Initial inspection must be conducted within a reasonable period of time. Inspection must be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.
2. Initial inspection must be conducted within 6 months of application or time of renewal.
3. Additional announced or unannounced inspections may be conducted at the discretion of the certifying agent.
4. All inspections must be conducted with an authorized representative who is knowledgeable about the inspected operation.
5. The inspection must verify that the operation is in compliance or has the capability to comply with the organic regulations.

6. The inspection must verify that the organic production and handling system plan accurately reflects the practices used by the applicant.
7. The inspection must verify that no prohibited substances have been applied.
8. Inspectors must conduct an exit interview with an authorized representative who is knowledgeable about the inspected operation. The purpose of the exit interview is to discuss known issues of concern regarding their application for organic certification.
9. The certifying agent must provide a copy of the inspection report to the inspected operation within a reasonable time frame.

§205.404 Granting certification

1. The certifying agent must review the on-site inspection report within a reasonable time frame and grant certification if the operation is in compliance with the organic regulations.
2. The criteria for granting certification are 1) the applicant's operation is in compliance with the organic standards and 2) that the applicant is able to conduct operations in accordance with its organic system plan.
3. Once certified, a producer's or handler's organic certification continues until it is suspended or revoked by the State Organic Program, or voluntarily withdrawn from the program by the applicant.

§205.405 Denial of certification (Note: This pertains to new applicants only)

1. When an applicant is not in compliance or not able to comply with the organic regulations, the certifying agent must issue a notification of noncompliance that specifies 1) each noncompliance and 2) the date by which the rebuttal or correction of the noncompliance must occur .
2. Upon receipt of the notice of noncompliance the applicant may 1) Correct the noncompliance, or 2) Submit information to rebut the noncompliance.
3. A notice of denial of certification is issued when a correction of noncompliance is not possible, when an applicant fails to respond to a notice of noncompliance, or when the corrective actions are not sufficient for qualifying for certification.
4. A notice of denial of certification must state the reasons for denial, include information about the applicants right to reapply for certification, request mediation, or file an appeal of the denial.
5. An applicant may be denied certification for willfully making a false statement or misrepresenting the applicant's operation.

§205.406 Continuing of certification (Note: This pertains to renewal applicants only)

1. To continue certification an operation must annually pay certification fees and submit an updated organic production and handling system plan.
2. An on-site inspection must be conducted within six months of the renewal date.
3. The Rule seems to prohibit the placement of an expiration date on the certificate – (see page 80595).
4. When a certified operation is not in compliance with the organic regulations, the certifying agent must issue a notification of noncompliance that specifies 1) each noncompliance and 2) the date by which the rebuttal or correction of the noncompliance must occur.
5. Upon receipt of the notice of noncompliance the certified operation may 1) Correct the noncompliance, or 2) Submit information to rebut the noncompliance.
6. A notice of proposed revocation of certification is issued when a certified operation fails to take the corrective actions within the prescribed time period.
7. A notice of proposed revocation of certification must state the reasons for the proposed revocation, the proposed effective date, and the right to request mediation.

Subpart F – Accreditation of Certifying Agents

205.500 Areas and duration of accreditation.

1. The NOP shall accredit qualified domestic or foreign applicants to certify production or handling operations.
2. Accreditation may be issued for crop certification, livestock certification, wild crop certification, handling certification or any combination of certification areas.
3. Accreditation shall be for five years.
4. Foreign certifying agents may be accepted by USDA under the following criteria:
 - the foreign certifier is accredited by the foreign government authority to meet similar requirements, or
 - the foreign government that accredited the certifier has an equivalency agreement with the United States.

205.501 General Requirements for accreditation.

This section contains the criteria that must be met for a private or state certifier to obtain accreditation, the certifier must:

1. have sufficient expertise in organic production and handling.
2. demonstrate the ability to comply with the requirements for accreditation.
3. carry out the provisions of the National Organic Program.
4. use a sufficient number of adequately trained personnel.
5. ensure that personnel have sufficient expertise in organic production and handling.
6. ensure that all personnel have an annual performance evaluation.
7. conduct an annual program review of its certification activities.
8. provide sufficient information to persons seeking certification to enable them to comply with the regulations.
9. Maintain required records.
10. Maintain confidentiality of records.
11. Prevent conflict of interest.
12. Accept the certification decisions made by another certifying agent accredited or accepted by USDA.
13. Submit to the NOP any notice of denial of certification, notification of noncompliance, notification of proposed revocation; and an annual list of the name address and telephone number of all operations granted certification.
14. Pay the accreditation fees to USDA.
15. Provide the inspector with copies of previous inspection reports, and decisions regarding the certification of production and handling operations that they inspect.
16. Comply with a State's organic program for the states that the certifier operates within.
17. Certifiers may establish a seal or logo to identify products certified by that certifier.
18. Certifiers may not require any additional requirements as a condition for allowing the use of its seal or logo.

205.502 Applying for accreditation.

This section specifies where the application for accreditation must be sent.

205.503 Applicant information.

This section specifies the information that must be submitted by the applicant for accreditation.

205.504 Evidence of expertise and ability.

This section specifies the information that must be submitted to demonstrate its expertise in organic production and handling.

205.505 Statement of agreement.

This section specifies the conditions that state and private certification agencies need to agree to in order to obtain accreditation. A state certifier must agree to accept the certification decisions made by another USDA accredited certifier; refrain from making false or misleading claims in regards to its accreditation status; conduct annual performance evaluations of all persons; have an internal review process; pay required fees; and meet other terms and conditions. In addition to these criteria, private certifiers must hold the Secretary harmless and furnish reasonable security to protect the rights of certified operations.

205.506 Granting accreditation.

1. Accreditation is granted when 1) the required information is submitted, 2) the fees are paid, and 3) the NOP determines that the accreditation criteria have been met.
2. Accreditation is granted for one or more specific areas such as crops, livestock, wild crops or handling.

205.507 Denial of accreditation.

This section specifies process that the NOP must follow in order to deny accreditation to a certifier.

205.508 Site evaluations.

Site evaluations of certifiers are conducted to examine a certifier's compliance with the NOP. Site evaluations are conducted by NOP staff and involve reviewing certification procedures and production and handling operations certified by the certifier. Site evaluations are conducted at least once during the five year accreditation period.

205.509 Peer review panel.

The NOP will establish a peer review panel to review the NOP accreditation policies and procedures and ensure the procedures meet ISO Guide 61 standards (General requirements for assessment and accreditation of certification/registration bodies).

205.510 Annual report, recordkeeping, and renewal of accreditation.

1. Accredited certifiers must submit an annual report that includes any changes to the certification program; a description of measures taken to address the terms and conditions of the accreditation; the most recent performance evaluations; the annual program review; and the required fees.
2. Certifiers must maintain required records (most records must be maintained for ten years).
3. Renewal of accreditation occurs every five years. Certifiers must apply to renew their accreditation at least six months prior to the expiration date of their accreditation.

Subpart G – Administrative

The National List of Allowed and Prohibited Substances

The National List within the NOP is constructed very differently than most organic materials lists (e.g. Organic Material Review Institute's Generic and Brand Name Lists). Under the NOP all nonsynthetic substances (= natural materials) are allowed to be used unless they are specifically prohibited. Conversely, all synthetic substances are prohibited unless specifically allowed. The difficulty with this approach is that it is often difficult to determine whether a material is natural or synthetic. In addition, many materials that are approved for use in organic crop production are not included on the National List because they are nonsynthetic (= natural).

The NOP definition of synthetic is "a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring sources, except that such term shall not apply to substances created by naturally occurring biological processes." It may be difficult to determine whether materials such as calcium chloride, humic acid, fish emulsion and mined materials are synthetic or natural under this definition. The NOP has left a lot of materials open to interpretation. Who will determine whether a material is synthetic or natural? It appears that the NOP has given that discretion to the certifying agent.

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

The criteria for adding a synthetic substance to the National List for use in organic crop production or for adding to processed organic food is:

1. The substance cannot be produced from a natural source.
2. The substance's manufacture, use and disposal does not have an adverse effect on the environment.
3. The nutritional quality of the food is maintained when the substance is used.
4. The substance's breakdown products do not have an adverse effect on human health.
5. The substance's primary use is not as a preservative or to recreate flavors lost during processing.
6. If used in food, the substance is listed as generally regarded as safe (GRAS) by FDA.
7. The substance is essential to the handling of organic food products.

205.601 Synthetic substances allowed for use in organic crop production.

1. This section contains a list of synthetic materials allowed to be used for pest control, weed control, disease control and soil management.
2. The Organic Materials Review Institute (OMRI) *Generic Materials List* includes allowed non-synthetic and prohibited synthetic substances, as well as substances that appear on the National List.
3. The only inert ingredients allowed on the National List are List 4 Inert Ingredients (Inerts of Minimal Concern). Many currently approved brand name materials will be prohibited because they contain List 3 inerts. Manufacturers of these materials will need to either a) reformulate their products; b) expedite the review of the List 3 inerts to List 4 status, or c) petition the NOSB to have the material added to the list of approved synthetic substances.

205.602 Nonsynthetic substances prohibited for use in organic crop production.

This section contains a list of natural materials prohibited for use as pest control substances or soil amendments. The prohibited natural materials list includes strychnine, sodium fluoaluminat (cryolite), tobacco dust (nicotine), arsenic, and ash from manure burning.

This section also includes restrictions on the use of sodium nitrate (only for up to 20% of nitrogen inputs) and potassium chloride (mined sources only).

205.603 Synthetic substances allowed for use in organic livestock production.

This section contains a list of synthetic materials allowed as feed additives, feed supplements, parasiticides, disinfectants and medicines in organic livestock production.

205.604 Nonsynthetic substances prohibited for use in organic livestock production.

This section contains a list of natural materials that are prohibited for use in organic livestock production. At the present time, only strychnine appears on the list.

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)).”

1. Many food products contain both agricultural and nonagricultural ingredients. Nonagricultural ingredients include substances such as salt, pectin, baking soda and citric acid. Under the NOP, nonagricultural ingredients and processing aids must be listed in this section in order to be used in an “organic” food (more than 95% organic ingredients) or “made with organic” food (more than 70% organic ingredients).
2. Approved natural nonagricultural ingredients and processing aids include citric acid, non GMO enzymes, sodium bicarbonate (baking soda), nutritional and baking yeast.
3. Approved synthetic nonagricultural ingredients and processing aids include ascorbic acid, lecithin, and pectin.

205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Requires agricultural ingredients used in an “organic” food (more than 95% organic ingredients) to be organically produced unless the ingredient is not commercially available in organic form.

205.607 Amending the National List.

This section states that any person may petition the National Organic Standards Board to add materials to the National List.

State Organic Programs

The NOP provides four options for States.

1. A state may be a state certifying agent. States that currently run state certification agencies include Washington, Idaho, Texas, Maryland, Louisiana, Nevada, Iowa, and Kentucky.
2. A state may have a State organic program. The State of California is a good example of a State with a State organic program that does not provide certification services. The California Department of Food and Agriculture enforces California’s Organic Food Products Act and obtains money for enforcement through registration fees.
3. A state may be a state certifying agent and have a State organic program.
4. A state may choose to not have a State organic program or be a state certifying agent (e.g. Wyoming, New York, Arkansas, Kansas)

205.620 Requirements of State organic programs.

1. Specifies that any State may establish a State organic program .
2. Specifies that State organic programs must meet the NOP requirements.
3. Allows a State to have more restrictive requirements because of environmental conditions or specific production or handling practices.
4. Requires a State organic program to assume enforcement obligations of the NOP.
5. Requires a State organic program to be approved by the USDA Secretary prior to implementing its state program.

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

This section includes the details of the information that must be submitted by a State in order for a State organic program to be approved under the NOP.

205.622 Review of approved State organic programs.

Specifies that NOP must review State organic programs at least once every five years.

Fees**Sections 205.640 and 205.641 205.642**

These sections specify the costs for accreditation. Accreditation costs for initial accreditation (until August 2002) will be \$500 plus travel and per diem charges for site visits. There will be no hourly rate charged for the initial accreditation.

After August 2002, an hourly rate will be charged for site visits (Note: the current hourly rate is \$42/hour).

205.642 Fees and other charges for certification.

1. Certifiers are required to charge reasonable fees for the certification services they provide.
2. Certifiers are required to publish their fee schedules, provide justification for any nonrefundable fees that are charged.

Compliance

The NOP compliance proceedings are similar to administrative procedures of many states.

205.660 General

This section specifies that the NOP may conduct inspections or initiate revocation proceedings against a certified operation or a certifying agents accreditation.

205.661 Investigation of certified operations.

Allows certifying agents and State organic programs to investigate complaints of noncompliance with the NOP regulations.

205.662 Noncompliance procedure for certified operations.

Specifies the procedures that certifiers and State organic programs must take for any compliance action. The procedures provide due process for certified operations. The procedures outline notification procedures, resolution options, proposed suspension or revocation notices, and procedures for willful violations.

205.663 Mediation.

This section specifies the procedures for a mediated settlement of noncompliance proceedings. Mediation is not mandated but offered as an option for settlement of a noncompliance proceeding.

205.665 Noncompliance procedure for certifying agents and 205.668 Noncompliance procedures under State organic programs.

These sections specify the procedures for noncompliance proceedings against certifying agents and State organic programs respectively.

205.670 Inspection and testing of agricultural product to be sold or labeled “organic.”

1. Organic food products must be available for sampling for pesticide residues.
2. State organic programs or certifying agents may require preharvest or postharvest testing when there is reason to believe that the product has come into contact with a prohibited substance or has been produced using genetically modified ingredients.
3. Sampling may only be conducted when there is reason to believe that there may be residues present. This may require the SOP's and state certification agencies to only sample producers where there is a risk of pesticide drift, residual soil contamination, or misapplication of prohibited substances. On the other hand, it could probably be demonstrated that in all situations there is a reason to believe that the product may have come into contact with prohibited substances.
4. Sampling must be done by qualified inspectors and must maintain chain of custody.
5. Chemical analysis must be done by official methods of analysis.
6. Results of all analyses must be provided to the National Organic Program and must be available for public access.

205.671 Exclusion from organic sale.

1. The NOP establishes an organic tolerance level at 5% of the Environmental Protection Agency's tolerance levels for registered pesticides.
2. The NOP establishes the FDA action level as the organic tolerance level for pesticides that are no longer registered (e.g. DDT, dieldrin, chlordane).
3. When residues are detected that exceed these levels the products must not be sold, labeled or represented as organic.

205.672 Emergency pest or disease treatment.

1. Allows a prohibited substance to be applied to a certified organic operation as part of a Federal or State emergency pest or disease control program.
2. Prohibits any crop or product that has come into contact with a prohibited substance to be labeled, represented or sold as organic.
3. This section protects consumers by prohibiting any organic crops from having prohibited substances applied to them while also protecting the organic producer from losing their organic certification due to an emergency pest control program outside of their control.

Adverse Action Appeal Process**§205.680 General and §205.681 Appeals.**

This section describes the appeals process for person's that believe that they are adversely affected by a noncompliance decision of the National Organic Program, a State organic program, or a certifying agent. The primary difference between the NOP appeal process and the current state process is that appeals would be appealed to a U.S. District Court rather than a State court. This section is currently the subject of an appeal by an accredited certification agent.

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