Production and Handling -- Preamble

Subpart C - Organic Crop, Wild Crop, Livestock, and Handling Requirements

Description of Regulations

General Requirements

This subpart sets forth the requirements with which production and handling operations must comply in order to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." The producer or handler of an organic production or handling operation must comply with all applicable provisions of subpart C. Any production practice implemented in accordance with this subpart must maintain or improve the natural resources, including soil and water quality, of the operation. Production and handling operations which sell, label, or represent agricultural products as organic in any manner and which are exempt or excluded from certification must comply with the requirements of this subpart, except for the development of an organic system plan.

Production and Handling (General)

The Organic Food Production Act of 1990 (OFPA or Act) requires that all crop, wild crop, livestock, and handling operations requiring certification submit an organic system plan to their certifying agent and, where applicable, the State organic program (SOP). The organic system plan is a detailed description of how an operation will achieve, document, and sustain compliance with all applicable provisions in the OFPA and these regulations. The certifying agent must concur that the proposed organic system plan fulfills the requirements of subpart C, and any subsequent modification of the organic plan by the producer or handler must receive the approval of the certifying agent.

The organic system plan is the forum through which the producer or handler and certifying agent collaborate to define, on a site-specific basis, how to achieve and document compliance with the requirements of certification. The organic system plan commits the producer or handler to a sequence of practices and procedures resulting in an operation that complies with every applicable provision in the regulations. Accreditation qualifies the certifying agent to attest to whether an organic system plan comports with the organic standard. The organic system plan must be negotiated, enacted, and amended through an informed dialogue between certifying agent and producer or handler, and it must be responsive to the unique characteristics of each operation.

An organic system plan contains six components. First, the organic system plan must describe the practices and procedures used, including the frequency with which they will be used, in the certified operation. Second, it must list and characterize each substance used as a production or handling input, including the documentation of commercial availability, as applicable. Third, it must identify the monitoring techniques which will be used to verify that the organic plan is being implemented in a manner which complies with all applicable requirements. Fourth, it must explain the recordkeeping system used to preserve the identity of organic products from the point of certification through delivery to the customer who assumes legal title to the goods. Fifth, the organic system plan must describe 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. Finally, the organic system plan must contain the additional information deemed necessary by the certifying agent to evaluate site-specific conditions relevant to compliance with these or applicable State program regulations. Producers or handlers may submit a plan developed to

comply with other Federal, State, or local regulatory programs if it fulfills the requirements of an organic system plan.

The first element of the organic system plan requires a narrative or other-descriptive format that identifies the practices and procedures to be performed and maintained, including the frequency with which they will be performed. Practices are tangible production and handling techniques, such as the method for applying manure, the mechanical and biological methods used to prepare and combine ingredients and package finished products, and the measures taken to exclude pests from a facility. Procedures are the protocols established for selecting appropriate practices and materials for use in the organic system plan, such as a procedure for locating commercially available, organically produced seed. Procedures reflect the decision-making process used to implement the organic system plan.

By requiring information on the frequency with which production and handling practices and procedures will be performed, the final rule requires an organic system plan, to include an implementation schedule, including information on the timing and sequence of all relevant production and handling activities. The plan will include, for example, information about planned crop rotation sequences, the timing of any applications of organic materials, and the timing and location of soil tests. Livestock management practices might describe development of a rotational grazing plan or addition of mineral supplements to the feed supply. A handling operation might identify steps involved in locating and contracting with farmers who could produce organic ingredients that were in short supply.

The second element that must be included in an organic system plan is information on the application of substances to land, facilities, or agricultural products. This requirement encompasses both natural and synthetic materials allowed for use in production and handling operations. For natural materials which may be used in organic operations under specific restrictions, the organic plan must detail how the application of the materials will comply with those restrictions. For example, farmers who apply manure to their fields must document in their organic system plans how they will prevent that application from contributing to water contamination. A producer and handler who bases the selection of seed and planting stock material under section 205.204 or an agricultural ingredient under section 205.301 on the commercial availability of that substance must provide documentation in the organic system plan.

The third element of the organic system plan is a description of the methods used to evaluate its effectiveness. Producers and handlers are responsible for identifying measurable indicators that can be used to evaluate how well they are achieving the objectives of the operation. For example, production objectives could be measured through regular tallies of bushels or pounds of product sold from the farm or in numbers of cases sold from a handling operation. Indicators that can identify changes in quality or effectiveness of management practices could be relatively simple, such as the information contained in a standard soil test. The specific indicators used to evaluate a given organic system plan will be determined by the producer or handler in consultation with the certifying agent. Thus, if the organic system plan calls for improvements in soil organic matter content in a particular field, it would include provisions for analyzing soil organic matter levels at periodic intervals. If herd health improvement is an objective, factors such as somatic cell count or observations about changes in reproductive patterns might be used as indicators.

The fourth element of the organic system plan is a description of the recordkeeping system used to verify and document an audit trail, as appropriate to the operation. For each crop or wild-crop harvested, the audit trail must trace the product from the field, farm parcel, or area where it is harvested through the transfer of legal title. A livestock operation must trace each animal from its entrance into through removal from the organic operation. A handling operation must trace each product that is handled and sold, labeled, or represented as organic from the receipt of its constituent ingredients to the sale of the processed product.

The fifth element which must be included in an organic system plan pertains to split production or handling operations. This provision requires an operation that produces both organic and nonorganic products to describe the management practices and physical barriers established to prevent commingling of organic and nonorganic products. This requirement addresses contact of organic products, including livestock, organic field units, storage areas, and packaging to be used for organic products, with prohibited substances.

The specific requirements to be included in an organic system plan are not listed here. The accreditation process provides an assurance that certifying agents are competent to determine the specific documentation they require to review and evaluate an operation's organic system plan. Section 205.200(a)(6) allows a certifying agent to request additional information needed to determine that an organic system plan meets the requirements of this subpart. The site-specific nature of organic production and handling necessitates that certifying agents have the authority to determine whether specific information is needed to carry out their function.

Crop Production

Any field or farm parcel used to produce an organic crop must have been managed in accordance with the requirements in sections 205.203 through 205.206 and have had no prohibited substances applied to it for at least 3 years prior to harvest of the crop. Such fields and farm parcels must also have distinct, defined boundaries and buffer zones to prevent contact with the land or crop by prohibited substances applied to adjoining land.

A producer of an organic crop must manage soil fertility, including tillage and cultivation practices, in a manner that maintains or improves the physical, chemical, and biological condition of the soil and minimizes soil erosion. The producer must manage crop nutrients and soil fertility through rotations, cover crops, and the application of plant and animal materials. 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. Plant and animal materials include raw animal manure, composted plant and animal materials, and uncomposted plant materials. Raw animal manure must either be composted, applied to land used for a crop not intended for human consumption, or incorporated into the soil at least 90 days before harvesting an edible product that does not come into contact with the soil or soil particles and at least 120 days before harvesting an edible product that does come into contact with the soil or soil particles. Composted plant or animal materials must be produced through a process that establishes an initial carbon-to-nitrogen (C:N) ratio of between 25:1 and 40:1 and achieves a temperature between 131F and 170F. Composting operations that utilize an in-vessel or static aerated pile system must maintain a temperature within that range for a minimum of 3 days. Composting operations that utilize a windrow composting system must maintain a temperature within that range for a minimum of 15 days, during which time the materials must be turned five times.

In addition to these practices and materials, a producer may apply a crop nutrient or soil amendment included on the National List of synthetic substances allowed in crop production. The producer may apply a mined substance of low solubility. A mined substance of high solubility may only be applied if the substance is used in compliance with the annotation on the National List of nonsynthetic materials prohibited in crop production. Ashes of untreated plant or animal materials which have not been combined with a prohibited substance and which are not included on the National List of nonsynthetic substances prohibited for use in organic crop production may be used to produce an organic crop. A plant or animal material that has been chemically altered by a manufacturing process may be used only if it is included on the National List of synthetic substances allowed for use in organic production. The producer may not use any fertilizer or composted plant and animal material that contains a synthetic substance not allowed for crop production on the National List or use sewage sludge. Burning crop residues as a means of

disposal is prohibited, except that burning may be used to suppress the spread of disease or to stimulate seed germination.

The producer must use organically grown seeds, annual seedlings, and planting stock. The producer may use untreated nonorganic seeds and planting stock when equivalent organic varieties are not commercially available, except that organic seed must be used for the production of edible sprouts. Seed and planting stock treated with substances that appear on the National List may be used when an organically produced or untreated variety is not commercially available. Nonorganically produced annual seedlings may be used when a temporary variance has been established due to damage caused by unavoidable business interruption, such as fire, flood, or frost. Planting stock used to produce a perennial crop may be sold as organically produced planting stock after it has been maintained under a system of organic management for at least 1 year. Seeds, annual seedlings, and planting stock treated with prohibited substances may be used to produce an organic crop when the application of the substance is a requirement of Federal or State phytosanitary regulations.

The producer is required to implement a crop rotation, including but not limited to sod, cover crops, green manure crops, and catch crops. The crop rotation must maintain or improve soil organic matter content, provide for effective pest management in perennial crops, manage deficient or excess plant nutrients, and control erosion to the extent that these functions are applicable to the operation.

The producer must use preventive practices to manage crop pests, weeds, and diseases, including but not limited to crop rotation, soil and crop nutrient management, sanitation measures, and cultural practices that enhance crop health. Such cultural practices include the selection of plant species and varieties with regard to suitability to site-specific conditions and resistance to prevalent pests, weeds, and diseases. Mechanical and biological methods that do not entail application of synthetic substances may be used as needed to control pest, weed, and disease problems that may occur. Pest control practices include augmentation or introduction of pest predators or parasites; development of habitat for natural enemies; and nonsynthetic controls such as lures, traps, and repellents. Weed management practices include mulching with fully biodegradable materials; mowing; livestock grazing; hand weeding and mechanical cultivation; flame, heat, or electrical techniques; and plastic or other synthetic mulches, provided that they are removed from the field at the end of the growing or harvest season. Disease problems may be controlled through management practices which suppress the spread of disease organisms and the application of nonsynthetic biological, botanical, or mineral inputs. When these practices are insufficient to prevent or control crop pests, weeds, and diseases, a biological or botanical substance or a synthetic substance that is allowed on the National List may be used provided that the conditions for using the substance are documented in the organic system plan. The producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes that comes into contact with soil or livestock.

A wild crop that is to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be harvested from a designated area that has had no prohibited substances applied to it for a period of 3 years immediately preceding the harvest of the wild crop. The wild crop must also be harvested in a manner that ensures such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop.

Livestock Production

Any livestock product to be sold, labeled, or represented as organic must be maintained under continuous organic management from the last third of gestation or hatching with three exceptions. Poultry or edible poultry products must be from animals that have been under continuous organic management beginning no later than the second day of life. 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 such products, except for the conversion of an entire, distinct herd to organic production. For the first 9 months of the year of conversion, the producer may provide the herd with a minimum of 80-percent feed that is either organic or produced from land included in the organic system plan and managed in compliance with organic crop requirements. During the final 3 months of the year of conversion, the producer must provide the herd feed in compliance with section 205.237. Once the herd has been converted to organic production, all dairy animals shall be under organic management from the last third of gestation. Livestock used as breeder stock may be brought from a nonorganic operation into an organic operation at any time, provided that, if such livestock are gestating and the offspring are to be organically raised from birth, the breeder stock must be brought into the organic operation prior to the last third of gestation.

Should an animal be brought into an organic operation pursuant to this section and subsequently moved to a nonorganic operation, neither the animal nor any products derived from it may be sold, labeled, or represented as organic. Breeder or dairy stock that has not been under continuous organic management from the last third of gestation may not be sold, labeled, or represented as organic slaughter stock. The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed livestock and all edible and nonedible organic livestock products produced on his or her operation.

Except for nonsynthetic substances and synthetic substances included on the National List that may be used as feed supplements and additives, the total feed ration for livestock managed in an organic operation must be composed of agricultural products, including pasture and forage, that are organically produced. Any portion of the feed ration that is handled must comply with organic handling requirements. The producer must not use animal drugs, including hormones, to promote growth in an animal or provide feed supplements or additives in amounts above those needed for adequate growth and health maintenance for the species at its specific stage of life. The producer must not feed animals under organic management plastic pellets for roughage or formulas containing urea or manure. The feeding of mammalian and poultry slaughter by-products to mammals or poultry is prohibited. The producer must not supply animal feed, feed additives, or feed supplements in violation of the Federal Food, Drug, and Cosmetic Act.

The producer of an organic livestock operation must establish and maintain preventive animal health care practices. The producer must select species and types of livestock with regard to suitability for site-specific conditions and resistance to prevalent diseases and parasites. The producer must provide a feed ration including vitamins, minerals, protein, and/or amino acids, fatty acids, energy sources, and, for ruminants, fiber. The producer must establish appropriate housing, pasture conditions, and sanitation practices to minimize the occurrence and spread of diseases and parasites. Animals in an organic livestock operation must be maintained under conditions which provide for exercise, freedom of movement, and reduction of stress appropriate to the species. Additionally, all physical alterations performed on animals in an organic livestock operation must be conducted to promote the animals' welfare and in a manner that minimizes stress and pain.

The producer of an organic livestock operation must administer vaccines and other veterinary biologics as needed to protect the well-being of animals in his or her care. When preventive practices and veterinary biologics are inadequate to prevent sickness, the producer may administer medications included on the National List of synthetic substances allowed for use in livestock operations. The producer may not administer synthetic parasiticides to breeder stock during the last third of gestation or during lactation if the progeny is to be sold, labeled, or represented as organically produced. After administering synthetic parasiticides to dairy stock, the producer must observe a 90-day withdrawal period before selling the milk or milk products produced from the treated animal as organically produced. Every use of a synthetic medication or parasiticide must be incorporated into the livestock operation's organic system plan subject to approval by the certifying agent.

The producer of an organic livestock operation must not treat an animal in that operation with antibiotics, any synthetic substance not included on the National List of synthetic substances allowed for use in livestock production, or any substance that contains a nonsynthetic substance included on the National List of nonsynthetic substances prohibited for use in organic livestock production. The producer must not administer any animal drug, other than vaccinations, in the absence of illness. The use of hormones for growth promotion is prohibited in organic livestock production, as is the use of synthetic parasiticides on a routine basis. The producer must not administer synthetic parasiticides to slaughter stock or administer any animal drug in violation of the Federal Food, Drug, and Cosmetic Act. The producer must not withhold medical treatment from a sick animal to maintain its organic status. All appropriate medications and treatments must be used to restore an animal to health when methods acceptable to organic production standards fail. Livestock that are treated with prohibited materials must be clearly identified and shall not be sold, labeled, or represented as organic.

A livestock producer must document in his or her organic system plan the preventative measures he or she has in place to deter illness, the allowed practices he or she will employ if illness occurs, and his or her protocol for determining when a sick animal must receive a prohibited animal drug. These standards will not allow an organic system plan that envisions an acceptable level of chronic illness or proposes to deal with disease by sending infected animals to slaughter. The organic system plan must reflect a proactive approach to health management, drawing upon allowable practices and materials. Animals with conditions that do not respond to this approach must be treated appropriately and diverted to nonorganic markets.

The producer of an organic livestock operation must establish and maintain livestock living conditions for the animals under his or her care which accommodate the health and natural behavior of the livestock. The producer must provide access to the outdoors, shade, shelter, exercise areas, fresh air, and direct sunlight suitable to the species, its stage of production, the climate, and the environment. This requirement includes access to pasture for ruminant animals. The producer must also provide appropriate clean, dry bedding, and, if the bedding is typically consumed by the species, it must comply with applicable organic feed requirements. The producer must provide shelter designed to allow for the natural maintenance, comfort level, and opportunity to exercise appropriate to the species. The shelter must also provide the temperature level, ventilation, and air circulation suitable to the species and reduce the potential for livestock injury. The producer may provide temporary confinement of an animal because of inclement weather; the animal's stage of production; conditions under which the health, safety, or well-being of the animal could be jeopardized; or risk to soil or water quality. The producer of an organic livestock operation is required to 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 nutrient recycling.

Handling

Mechanical or biological methods can be used to process an agricultural product intended to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic ingredients" for the purpose of retarding spoilage or otherwise preparing the agricultural product for market. Processed multiingredient products labeled "100 percent organic," may only use wholly organic ingredients, pursuant to paragraph (a) of section 205.301. Nonagricultural substances that are allowed for use on the National List and nonorganically produced agricultural products may be used in or on "organic" and "made with..." products pursuant to paragraphs (b) and (c) of section 205.301, respectively. Documentation of commercial availability of each substance to be used as a nonorganic ingredient in products labeled "organic" must be listed in the organic handling system plan in accordance with section 205.201.

Handlers are prohibited from using: (1) ionizing radiation for the treatment or processing of foods; (2) ingredients produced using excluded methods; or (3) volatile synthetic solvents in or on a

processed product or any ingredient which is sold, labeled, or represented as organic. The prohibition on ionizing radiation for the treatment or processing of foods is discussed under Applicability, section 205.105. This rule does not prohibit an organic handling operation from using Food and Drug Administration (FDA)-approved X-rays for inspecting packaged foods for foreign objects that may be inadvertently commingled in the packaged product.

The two paragraphs on excluded methods and ionizing radiation in section 205.270(c) of the proposed rule are replaced with new paragraph (c)(1) which cross-references those practices under paragraphs (e) and (f) of section 205.105. New section 205.105 clearly specifies that ionizing radiation and excluded methods are two practices that handlers must not use in producing organic agricultural products and ingredients. The prohibition on the use of volatile synthetic solvents, also included under paragraph (c) of section 205.270 does not apply to nonorganic ingredients in "made with..." products.

The practice standard for facility pest management under section 205.271 requires the producer or handler operating a facility to use management practices to control and prevent pest infestations. Prevention practices in paragraph (a) include removing pest habitats, food sources, and breeding areas; preventing access to handling facilities; and controlling environmental factors, such as temperature, light, humidity, atmosphere, and air circulation, to prevent pest reproduction. Permitted pest control methods in paragraph (b) include mechanical or physical controls, such as traps, light, or sound. Lures and repellents using nonsynthetic substances may be used as pest controls. Lures and repellents with synthetic substances that are allowed on the National List also may be used. Prevention and control practices in paragraphs (a) and (b) may be used concurrently.

If the practices in paragraphs (a) and (b) are not effective, amended paragraph (c) provides that handlers may then use a nonsynthetic or synthetic substance consistent with National List. If the measures and substances provided under paragraphs (a), (b), and (c) are not effective, synthetic substances not on the National List may be used to control pest infestations. Under new paragraph (d), the handler and the operation's certifying agent, prior to using such a substance, must agree on the substance to be used to control the pest, measures to be taken to prevent contact with organically produced product, and ingredients that may be in the handling facility.

This rule recognizes that certain local, State, and Federal laws or regulations may require intervention with prohibited substances before or at the same time substances allowed in paragraphs (b) and (c) are used. To the extent that this occurs, this rule permits the handler to follow such laws and regulations to market a product as organically handled, provided that the product does not come into contact with the pest control substance used.

The extent of pest infestation cannot be foreseen when an organic plan is submitted by the certified operation and approved by the certifying agent. A handler who uses any nonsynthetic or synthetic substance to control facility pests must update its organic handling system plan to address all measures taken or intended to be taken to prevent contact between the substance and any organically produced ingredient or finished product.

Section 205.272 provides additional practice standards that must be followed by an organic handling operation to prevent the commingling of organic and nonorganic products and to protect organic products from contact with prohibited substances. An organic handling operation must not use packaging materials and storage containers or bins that contain a synthetic fungicide, preservative, or fumigant in handling an organic product. The operation also must not use or reuse any storage bin or container that was previously in contact with any prohibited substance unless the reusable bin or container has been thoroughly cleaned and poses no risk of prohibited materials contacting the organic product.

Temporary Variances

This subpart establishes conditions under which certified organic operations may receive temporary variances from the production and handling provisions of this subpart. The Administrator may establish temporary variances due to: (1) Natural disasters declared by the Secretary; (2) unavoidable business interruption caused by natural catastrophes such as drought, wind, fire, flood, excessive moisture, hail, tornado, or earthquake; or (3) to conduct research on organic production and handling techniques or inputs. An SOP's governing State official or a certifying agent may recommend that the Administrator establish a temporary variance for various reasons including an unavoidable business interruption. The Administrator will determine how long a temporary variance will be in effect at the time it is established, subject to such extension as the Administrator deems necessary. Temporary variances may not be issued to allow use of any practice, material, or procedure which is prohibited under section 205.105.

The proposed rule inadvertently omitted the SOP's governing State official as having authority to recommend a temporary variance to the Administrator. We have added that authority in paragraph (b) of section 205.290.

Upon notification by the Administrator that a temporary variance has been established, the certifying agent must inform each production and handling operation it certifies that may be affected by the temporary variance. For example, if a drought causes a severe shortage of organically produced hay, a dairy operation may be permitted to substitute some nonorganic hay for a portion of the herd's diet to prevent liquidation of the herd. The producer must keep records showing the source and amount of the nonorganic hay used and the timeframe needed to restore the total feed ration to organic sources. The certifying agent may require that the next organic plan include contingency measures to avoid the need to resort to nonorganic feed in case of a future shortage.

General - Changes Based on Comments

This subpart differs from the proposal in several respects as follows: (1) Maintain or Improve Provision for Production Operations Only. A number of commenters questioned whether the requirement in the proposed rule that an operation must "maintain or improve the natural resources of the operation, including soil and water quality" applied to handling as well as production operations. They stated that handling operations are not integrated into natural systems the way that production systems are. As a result, these commenters were uncertain how handlers could fulfill the "maintain or improve" requirement.

The "maintain or improve" requirement addresses the impact of a production operation on the natural resource base that sustains it and, as such, does not apply to handling operations. We have modified the final rule in section 205.200 by limiting the "maintain or improve" requirement to production practices.

(2) Management Practices and Physical Barriers to Prevent Commingling. Many commenters, including numerous certifying agents, stated that the proposed provisions for an organic system plan were not adequate for the task of certifying an operation that produces both organic and nonorganic products. The commenters requested that the final rule incorporate the provisions established in the OFPA for certifying these split operations. These provisions include separate recordkeeping for the organic and nonorganic operations and the implementation of protective practices to prevent the commingling of product and the unintentional contact of organic product with prohibited substances. We have amended the provisions for an organic system plan in section 205.201(a)(5) to require greater accountability regarding the segregation of organic and nonorganic products in a split operation. The changes we made incorporate language from the OFPA ("physical facilities, management practices") to provide clear criteria for producers,

handlers and certifying agents to agree upon an organic system plan that protects the integrity of organic product.

(3) Commercial Availability. The proposed rule required that a raw or processed agricultural product sold, labeled, or represented as organic must contain not less than 95 percent organically produced raw or processed agricultural product. Additionally, section 205.606 of the proposed rule allowed any nonorganically produced agricultural product to be used in the 5 percent nonorganic component of an agricultural product sold, labeled, or represented as organic. Many commenters objected to these provisions and recommended that nonorganically produced agricultural products should only be allowed in an organic product when the organically produced form was not commercially available. Commenters stated that allowing nonorganically produced agricultural products within the 5 percent would significantly weaken demand for many organically produced commodities, especially herbs and spices. These commenters stated that herbs and spices often constitute less than 5 percent of the ingredients in a raw or processed agricultural product and that handlers producing an organic product would instinctively seek out the less expensive nonorganic variety. They also indicated that the 5 percent component is an important market for many products produced from organically produced livestock, such as milk derivatives and meat by-products, that are not typically marketed directly to consumers. Commenters stated that the preponderance of current certification programs use the commercial availability criterion when determining whether a nonorganically produced agricultural product may be used within the 5 percent component. Commenters cited the National Organic Standards Board's (NOSB) recommendation that organic agricultural products be used in this 5 percent component unless they are commercially unavailable and requested that the final rule incorporate the criteria for determining commercial availability that accompanied that NOSB recommendation.

We agree with commenters that a preference for organically produced agricultural commodities, when commercially available, can benefit organic producers, handlers, and consumers in a variety of ways. We believe that the commercial availability requirement may allow consumers to have confidence that processed products labeled as "organic" contain the highest feasible percentage of organic ingredients. Some producers may benefit from any market incentive to supply organically produced minor ingredients that handlers need for their processed products. We recognize that the provision does impose an additional requirement on handlers who must ascertain whether the agricultural ingredients they use are commercially available in organic form. The NOSB recommended that the final rule contain a commercial availability provision based upon the guidelines developed by the American Organic Standards project of the Organic Trade Association. For these reasons, we have amended the final rule to require that an agricultural commodity used as an ingredient in a raw or processed product labeled as organic must be organic when the ingredient is commercially available in an organic form.

While recognizing the potential benefits of applying the commercial availability standard to all agricultural ingredients in a processed product, we are concerned that enforcing this provision could impose an excessive burden on handlers. Although many commenters stated that some existing certifying agents apply a commercial availability standard, we do not have complete information on the criteria used by these certifying agents, and we are unsure whether a consensus exists on criteria for commercial availability within the organic community. Additionally, we are concerned that, unless the standard is clearly articulated and consistently interpreted and enforced, it will not be effective. Disagreement among certifying agents regarding when and under what circumstances an ingredient is commercially available would undermine our intent to create an equitable and enforceable standard.

AMS is soliciting additional comment and information on a number of issues concerning the development of standards for the commercial availability of organically produced agricultural commodities used in processed products labeled as "organic." On the basis of these comments and information and additional recommendations that the NOSB may develop, AMS will develop a commercial availability standard for use in implementing the final rule. AMS intends to develop

the commercial availability standard and incorporate it within the final rule prior to the commencement of certification activities by accredited certifying agents. This approach will provide organic handlers and certifying agents the standard necessary to incorporate the consideration of commercial availability of ingredients in an organic system plan at the time that the USDA organic standard comes into use. Specifically, AMS requests comments and information addressing the following questions:

What factors, such as quantity, quality, consistency of supply, and expense of different sources of an ingredient, should be factored into the consideration of commercial availability? What relative importance should each of these factors possess, and are there circumstances under which the relative importance can change?

What activities and documentation are sufficient to demonstrate that a handler has taken appropriate and adequate measures to ascertain whether an ingredient is commercially available?

How can AMS ensure the greatest possible degree of consistency in the application of the commercial availability standard among multiple certifying agents?

Could potentially adverse effects of a commercial availability standard, such as uncertainty over the cost and availability of essential ingredients, impact or impede the development of markets for organically processed products?

What economic and administrative burdens are imposed by the commercial availability standards found in existing organic certification programs?

How would producers benefit from market incentives to increase use of organic ingredients that result from a commercial availability standard?

Would lack of a commercial availability standard provide a disincentive for handlers of products labeled "organic" to seek out additional organic minor ingredients? What impacts could this have on producers of minor ingredients?

AMS welcomes any new or unpublished research results or information that exists concerning a commercial availability standard. AMS specifically invites comment from establishments which currently operate using commercial availability or a comparable provision in the conduct of their business. AMS will receive comment on this issue until 90 days after publication of the final rule.

(4) Conservation of Biodiversity. Many commenters recommended amending the definition of organic production to include the requirement that an organic production system must promote or enhance biological diversity (biodiversity). Commenters stated that the definitions for organic production developed by the NOSB and the Codex Commission include this requirement. We agree with these commenters and have amended the definition of organic production to require that a producer must conserve biodiversity on his or her operation. The use of "conserve" establishes that the producer must initiate practices to support biodiversity and avoid, to the extent practicable, any activities that would diminish it. Compliance with the requirement to conserve biodiversity requires that a producer incorporate practices in his or her organic system plan that are beneficial to biodiversity on his or her operation.

General - Changes Requested But Not Made

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

Organic Plan Excessively Restrictive. One organic inspector was concerned that the requirements of the organic system plan were too prescriptive and would create an excessive paper work burden for producers and handlers. The commenter stated that the excessive specificity of certain requirements (composition and source of every substance used), combined with the ambiguity of others (soil and tissue testing required but with no mention of the frequency), would confuse the working relationship between a producer or handler and his or her certifying agent. The commenter was concerned that strict adherence to the specifications in the organic system plan would compromise the ability of producers and handlers to run their businesses. While agreeing that flexibility in the development of the organic system plan was valuable, the commenter stated that producers and handlers, not the certifying agent, must retain the primary managerial role for their operation. Other commenters maintained that the organic system plan requirements were too ambiguous and would inhibit certifying agents' efforts to review necessary information. For example, a trade association commented that the absence of specific recordkeeping requirements for livestock feed materials, medications, and health care activities would impair compliance monitoring.

The provisions for an organic system plan were one of the most significantly revised components of the proposed rule, and, with minor changes related to split operations, we have retained them in the final rule. These provisions provide ample discretion for producers, handlers, and certifying agents to perform their duties while recognizing that mutual consent is a prerequisite for them to meet their responsibilities. The organic system plan enables producers and handlers to propose and certifying agents to approve site and operation-specific practices that fulfill all applicable program requirements. Producers and handlers retain the authority to manage their operations as they deem necessary, but any actions they undertake that modify their organic system plan must be approved by the certifying agent. With regard to recordkeeping, certifying agents are authorized to require the additional information, such as the livestock records mentioned in the comment, that they deem necessary to evaluate compliance with the regulations.

One certifying agent stated that the requirement to maintain or improve the natural resources of the operation was worthy in principle but unreasonable to achieve. This commenter stated that the long-term consequences of an organic system plan could not be foreseen and recommended requiring that producers "must endeavor" to maintain or improve the operation's natural resources. We have not changed this requirement because the vast majority of commenters supported an organic system plan that mandated the "maintain or improve" principle. A good working relationship between the producer and his or her certifying agent, including the annual inspection and accompanying revisions to the organic system plan, can rectify the unforeseen and unfavorable conditions that arise.

Crop Production - Changes Based on Comments

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

(1) Crop nutrient management. The fundamental requirement of the soil fertility and crop nutrient management practice standard, that tillage, cultivation, and nutrient management practices maintain or improve the physical, chemical, and biological condition of the soil and minimize erosion, remains unaltered. The proposed rule required that a producer budget crop nutrients by properly utilizing manure or other animal and plant materials, mined substances of low or high solubility, and allowed synthetic amendments. Many commenters disagreed with using the term, "budget," which they considered too limiting to characterize nutrient management in organic systems. These commenters recommended that the practice standard instead emphasize the diverse practices used in organic systems to cycle nutrients over extended periods of time.

We agree with these commenters and have amended the final rule to require that producers manage crop nutrients and soil fertility through the use of crop rotations and cover crops in addition to plant and animal materials. Additionally, we clarified that producers may manage crop

nutrients and soil fertility by applying mined substances if they are used in compliance with the conditions established in the National List. Finally, we removed the word, "waste," from our description of animal and plant materials in the proposed rule to emphasize the importance of these resources in organic soil fertility management.

(2) Compost Practice Standard. The proposed rule required that a composted material used on an organic operation must be produced at a facility in compliance with the Natural Resource Conservation Service (NRCS) practice standard. While many commenters agreed with the need for greater oversight of the feedstocks and procedures used to produce compost, most stated that the NRCS practice standard would not be suitable for this purpose. Commenters stated that the requirements in the NRCS practice standard were not designed for organic operations and would prohibit many established, effective composting systems currently used by organic producers. For example, adoption of the NRCS practice standard would prevent producers from using nonfarm wastes as compost feedstocks. Materials such as food processing by-products and leaves from curbside collection programs have long been used with beneficial results.

Commenters also stated that the minimum acceptable requirements for the design, construction, and operation of a composting facility contained in the practice standard were appropriate for a voluntary cost share program but were excessive as a compliance requirement for organic certification. Commenters questioned whether producers could justify the investment of time and resources needed to comply with the multiple design and operation criteria specified in the NRCS practice standard.

We agree with commenters who stated that, given the diversity of composting systems covered by a national organic standard, requiring full compliance with the NRCS practice standard would be overly prescriptive. We maintain, however, that implementation of the OFPA requires a rigorous, quantitative standard for the production of compost. The OFPA contains significant restrictions on applying raw manure that are reflected in the soil fertility and crop nutrient management practice standard. These restrictions pertain to raw manure and do not apply once fresh animal materials are transformed into a composted material. An organic producer using a composted material containing manure must comply with the nutrient cycling and soil and water conservation provisions in his or her organic system plan but is not constrained by the restrictions that apply to raw manure. Therefore, producers intending to apply soil amendments will require clear and verifiable criteria to differentiate raw manure from composted material. We developed the requirements in the final rule for producing an allowed composted material by integrating standards used by the Environmental Protection Agency (EPA) and USDA's Natural Resources Conservation Service (NRCS). The requirements for the carbon-to-nitrogen (C:N) ratio for composting materials are the same as that found in the NRCS practice standard for a composting facility. The time and temperature requirements for in-vessel, static aerated pile, and windrow composting systems are consistent with that EPA regulates under 40 CFR Part 503 for the production of Class A sewage sludge. Additionally, AMS reviewed these compost production requirements with USDA's Agricultural Research Service (ARS).

The conditions in the final rule for producing an allowed composted material begin with the selection of appropriate feedstocks. The producer's first responsibility is to identify the source of the feedstocks used in the composting system. This requirement ensures that only allowed plant and animal materials are included in the composting process, that they are not contaminated with prohibited materials, and that they are incorporated in quantities suitable to the design of the composting system. Certifying agents will exercise considerable discretion for evaluating the appropriateness of potential feedstock materials and may require testing for prohibited substances before allowing their use. For example, a certifying agent could require a producer to monitor off-farm inputs such as leaves collected through a municipal curbside program or organic wastes from a food processing facility. Monitoring may be necessary to protect against contamination from residues of prohibited substances, such as motor oil or heavy metals, or gross inert materials such as glass shards that can enter the organic waste stream.

The final rule further requires that the producer adhere to quantitative criteria when combining and managing the plant and animal materials that are being composted. When combining feedstocks to initiate the process, producers must establish a C:N ratio of between 25:1 and 40:1. This range allows for very diverse combinations of feedstock materials while ensuring that, when properly managed, the composting process will yield high quality material. While some commenters maintained that specifying any C:N ratio in the final rule would be too restrictive, it would be far more problematic not to establish a range. The 25:1 to 40:1 range ensures that producers will establish appropriate conditions under which the additional requirements in this practice standard, most notably the time and temperature criteria, can be achieved with minimal producer oversight. Composting operations using a C:N ratio lower than 25:1 require increasingly intensive management as the ratio drops due to the risk of putrefaction. Operations in excess of the 40:1 range may achieve the minimum temperature but are likely to drop off quickly and result in a finished material that is inadequately mature and deficient in nitrogen. The producer is not required to perform a physical analysis of each feedstock component if he or she can demonstrate that an estimated value is reliable. For example, estimates of the carbon and nitrogen content in specific manures and plant materials are generally recognized. Other feedstocks of consistent quality may be tested once and assumed to approximate that value.

The producer must develop in his or her organic system plan the management strategies and monitoring techniques to be used in his or her composting system. To produce an allowed composted material, the producer must use an in-vessel, static aerated pile, or windrow composting system. Producers using an in-vessel or static aerated pile system must document that the composting process achieved a temperature between 131F and 170F and maintained that level for a minimum of 3 days. Producers using a windrow composting system must document that the composting process achieved a temperature between 131F and 170F and maintained that level for a minimum of 15 days. Compost produced using a windrow system must be turned five times during the process. These time and temperature requirements are designed to minimize the risk from human pathogens contained in the feedstocks, degrade plant pathogens and weed seeds, and ensure that the plant nutrients are sufficiently stabilized for land application.

The final rule does not contain provisions for the use of materials commonly referred to as "compost teas." A compost tea is produced by combining composted plant and animal materials with water and a concentrated nutrient source such as molasses. The moisture and nutrient source contribute to a bloom in the microbial population in the compost, which is then applied in liquid form as a crop pest or disease control agent. The microbial composition of compost teas are difficult to ascertain and control and we are concerned that applying compost teas could impose a risk to human health. Regulation of compost teas was not addressed in the proposed rule. The National Organic Program (NOP) will request additional input from the NOSB and the agricultural research community before deciding whether these materials should be prohibited in organic production or whether restrictions on their use are appropriate.

In addition to managing crop nutrients with raw manure and composted plant and animal materials, a producer may use uncomposted plant materials. These are materials derived exclusively from plant sources that a producer manages in a manner that makes them suitable for application in a cropping system. For example, plant materials that are degraded and stabilized through a vermicomposting process may be used as a soil fertility and crop nutrient amendment.

(3) Mined Substances of High Solubility. The proposed rule treated mined substances of high solubility as a single category of soil amendment and allowed their use where warranted by soil and crop tissue testing. Many commenters objected to the general allowance for this category of substances and were particularly disappointed that the NOSB annotations on two such materials, sodium (Chilean) nitrate and potassium chloride, were not included. Commenters cited the potential detrimental effects of these highly soluble and saline substances on soil quality and stated that several international organic certification programs severely prescribe or prohibit their use. One certifying agent recommended that natural substances of high solubility and salinity be

handled comparably to similar synthetic materials such as liquid fish products and humic acids that appear on the National List, complete with their original NOSB annotations.

At its June 2000 meeting, the NOSB recommended that the NOP delete general references to mined substances of high solubility from the final rule, and incorporate the NOSB's specific annotations for materials of this nature. We have adopted this recommendation by retaining a place for mined substances of high solubility in the soil fertility and crop nutrient management practice standard but restricting their use to the conditions established for the material as specified on the National List of prohibited natural substances. Under this approach, mined substances of high solubility are prohibited unless used in accordance with the annotation recommended by the NOSB and added by the Secretary to the National List. We deleted the provision from the proposed rule that use of the substance be "justified by soil or crop tissue analysis." The final rule contains two materials--sodium nitrate and potassium chloride--that may be used in organic crop production with the annotations developed the NOSB.

While "mined substances of high solubility" is not a discrete, recognized category such as crop nutrients, the proposed rule mentioned sodium nitrate, potassium chloride, potassium nitrate (niter), langbeinite (sulfate of potash magnesia), and potassium sulfate in this context. Based on the recommendation of the NOSB, the final rule would prohibit use of these materials, unless the NOSB developed recommendations on conditions for their use and the Secretary added them to the National List. The NOP would welcome further guidance from the NOSB on these materials.

(4) Burning crop residues. The proposed rule prohibited burning as a means of crop disposal, except for burning prunings from perennial crops to suppress the spread of disease. Many commenters supported the principle behind the prohibition but maintained that the proposed language was too restrictive and would preclude certain beneficial agronomic practices. Several producers stated that the proposed rule would prevent them from collecting and burning residues from diseased annual crops, which they felt was an effective and beneficial practice. Other producers cited their use of prescriptive burning as a management practice for certain native or wild crops. As evidenced by the allowance for burning to suppress disease with perennial crops, the proposed rule was not designed to preclude the selective use of fire in organic production. We agree with the commenters that a more flexible allowance for the practice is warranted, and we have amended the provision to allow burning of annual and perennial crop residues for the suppression of disease and to stimulate seed germination. Producers must establish their need and procedures for burning in their organic system plan, and the practice cannot be used solely to remove crop debris from fields. (5) Requirement for Organic Seed in Sprout Production. The proposed rule allowed nonorganically produced seeds for all purposes, including sprout production, when the certifying agent concurred with the producer that organically produced seeds were not commercially available. While commenters predominately supported this approach with seed used for planting, they were virtually unanimous in stating that it is never appropriate to allow nonorganically produced and handled seeds in organic sprout production. Commenters cited the NOSB's June 1994 recommendation that seed used for the production of edible sprouts shall be organically produced and stated that existing certification standards do not provide an exemption based on commercial availability. We agree with these commenters and have modified the final rule to require that organic seed must be used for the production of edible sprouts.

(6) Mitigating the Effects of a Biological, Botanical, or Synthetic Substance. The proposed rule required that producers who used a biological or botanical substance or an allowed synthetic substance to control crop pests, weeds, or disease evaluate and mitigate the effects of repetitive use of the same or similar substances. While agreeing that pest resistance and shifts in pest populations were important considerations, commenters stated that managing these issues was beyond the ability of individual operations. Commenters recommended that the NOP develop principles and practices for managing pest resistance and shifts in pest types that would apply to all production operations. We agree with these comments and have deleted the requirement to

evaluate and mitigate the effects of using the same or similar crop pest, weed, or disease control substances. The final rule requires that producers document the use of such substances in their organic systems plans, subject to the approval of their certifying agent.

(7) Prohibition on Use of Treated Lumber. The proposed rule did not specifically address the use of lumber that had been treated with a prohibited substance, such as arsenic, in organic production. Citing the explicit prohibition on these substances in existing organic standards, many commenters felt that treated lumber should be excluded in the final rule. Commenters also cited the NOSB's recommendation to prohibit the use of lumber treated with a prohibited substance for new construction and replacement purposes effective upon publication of the final rule. We have included a modified version of the NOSB's recommendation within the crop pest, weed, and disease management practice standard. This provision prohibits the use of lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with an organic production site. We included this modification to clarify that the prohibition applies to lumber used in direct contact with organically produced and handled crops and livestock and does not include uses, such as lumber for fence posts or building materials, that are isolated from production. The prohibition applies to lumber used in crop production, such as the frames of a planting bed, and for raising livestock, such as the boards used to build a farrowing house. (8) Greater Rigor in the Wild Harvest Production Organic System Plan. A number of commenters stated that the wild-crop harvesting practice standard was insufficiently descriptive and that the proposed rule failed to apply the same oversight to wild harvest operations as it did to those producing crops and livestock. Some commenters maintained that the proposed rule did not require a wild harvest producer to operate under an approved organic system plan. These commenters proposed specific items, including maps of the production area that should be required in a wild harvest operation's organic system plan. One commenter recommended that the definition for "wild crop" be modified to allow the harvest of plants from aquatic environments.

We amended the practice standard for wild-crop harvesting to express the compliance requirements more clearly. Wild-crop producers must comply with the same organic system plan requirements and conditions, as applicable to their operation, as their counterparts who produce crops and livestock. Wild harvest operations are production systems, and they must satisfy the general requirement that all practices included in their organic system plan must maintain or improve the natural resources of the operation, including soil and water quality. We modified the practice standard to emphasize that wild harvest production is linked to a designated site and expect that a certifying agent would incorporate mapping and boundary conditions into the organic system plan requirements. Finally, we changed the definition of "wild crop" to specify that harvest takes place from a "site" instead of "from land," thereby allowing for aquatic plant certification.

Crop Production - Changes Requested But Not Made

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

(1) Application of Raw Manure. The soil fertility and crop nutrient management practice standard in the proposed rule permitted the application of raw manure to crops not intended for human consumption and established restrictions for applying it to crops used for human food. For human food crops, the proposed rule required a 120-day interval between application and harvest of crops whose edible portion had direct contact with the soil or soil particles, and a 90-day interval for crops that did not. These provisions reflected the recommendations developed by the NOSB at its June 1999 meeting. The practice standard also required that raw manure must be applied in a manner that did not contribute to the contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances.

The majority of commenters supported the provisions for applying raw manure. Some commenters stated that the provisions effectively balanced the benefits of applying raw manure to the soil with the environmental and human health risks associated with its use. These commenters stated that the lengthy intervals between application and harvest would not impose an unreasonable or unfeasible burden on organic producers. The NOSB strongly supported the provisions in the proposed rule, emphasizing that raw manure contributed significant benefits to soil nutrient, structure, and biological activity that other soil fertility practices and materials do not provide. Other commenters stated that the provisions were consistent with the requirements in existing organic standards and added that the restrictions were justifiable because they reflected responsible management practices.

For differing reasons, a number of commenters disagreed with the proposed provisions. Some commenters cited the human health risks associated with pathogenic organisms found in raw manure and stated that the proposed intervals between application and harvest were not adequately protective. These commenters recommended that the NOP conduct more extensive risk assessment procedures before determining what, if any, intervals between application and harvest would adequately protect human health. Some of these commenters identified the risk assessment methodology and pathogen treatment procedures governing the production and use of sewage sludge as the most suitable precedent for guiding the additional work required in this area. Conversely, a number of commenters stated that the provisions in the proposed rule were excessive because they exceeded the minimum 60-day interval between application and harvest established in the OFPA. Many of these commenters recommended eliminating the distinction between crops that come into contact with soil or soil particles and those that don't and applying a uniform 60-day interval between harvest and application for any crop to which raw manure had been applied. Some commenters stated that the 120-day interval severely limited the flexibility of producers who operated in regions such as the Northeast where the growing season lasted only slightly longer. Other commenters maintained that the practice standard did not address specific practices, such as applying raw manure to frozen fields, that they maintained should be expressly prohibited.

The responsibility to use raw manure in a manner that is protective of human health applies to all producers, whether organic or not, who apply such materials. We acknowledge the commenters who noted that the OFPA cites food safety concerns relative to manure use and, therefore, that food safety considerations should be reflected in the practice standard for applying raw manure in the final rule. Some of the commenters favored more extensive risk assessment procedures or lengthening the interval between application and harvest. We have not, however, changed the provisions for applying raw manure.

Although public health officials and others have identified the use of raw manure as a potential food safety concern, at the present time, there is no science-based, agreed-upon standard for regulating the use of raw manure in crop production. The standard in this rule is not a public health standard. The determination of food safety demands a complex risk assessment methodology, involving extensive research, peer review, and field testing for validation of results. The only comparable undertaking in Federal rulemaking has been EPA's development of treatment and application standards for sewage sludge, an undertaking that required years of dedicated effort. The NOP does not have a comparable capacity with which to undertake a comprehensive risk assessment of the safety of applying raw manure to human food crops. To delegate the authority to determine what constitutes safe application of raw manure to certifying agents would be even more problematic. A certifying agent cannot be responsible for establishing a Federal food safety standard. Therefore, the standard in this rule is a reflection of AMS' view and of the public comments that this standard is reasonable and consistent with current organic industry practices and NOSB recommendations for organic food crop production. Should additional research or Federal regulation regarding food safety requirements for applying raw manure emerge, AMS will ensure that organic production practice standards are revised to reflect the most up-to-date food safety standard.

Neither the identification of food safety as a consideration in the OFPA nor the inclusion of this practice standard in the final rule should be construed to suggest that organically produced agricultural products are any safer than nonorganically produced ones. USDA has consistently stated that certification is a process claim, not a product claim, and, as such, cannot be used to differentiate organic from nonorganic commodities with regard to food safety. National organic standards for manure use cannot be used to establish a food safety standard for certified commodities in the absence of as uniform Federal regulation to ensure the safety of all human food crops to which raw manure has been applied. The OFPA was designed to certify a process for informational marketing purposes.

Neither have we changed the practice standard in response to comments that the requirement in the final rule should not exceed the 60-day interval contained in the OFPA. The OFPA clearly establishes that the interval must be no less than 60 days and does not preclude a longer standard. The NOSB has strongly supported the proposed 90- and 120-day intervals, and the vast majority of commenters indicated that these provisions would be feasible for virtually all organic cropping systems. The requirement in the practice standard that raw manure must be applied in a manner that does not contribute to the contamination of crops, soil, or water by plant nutrients, pathogenic organisms, heavy metals, or residues of prohibited substances provides certifying agents the discretion to prohibit specific practices that would not be in compliance. With this discretion, a certifying agent could prohibit practices, such as applying manure to frozen ground or too close to water resources, that many commenters stated were not appropriate for organic production.

(2) No Prohibition on Manure from Nonorganic Operations. The proposed rule identified animal and plant waste materials as important components in soil fertility and crop nutrient management without providing criteria for distinguishing allowed and prohibited sources. A large number of commenters objected to this provision and stated that manure from nonorganic sources may contain residues from prohibited substances, including animal medications. These commenters maintained that some of these residues, such as antibiotics, may remain active for extended intervals, and others, such as heavy metals, could accumulate on the organic operation. Commenters stated that if either or both conditions prevailed, the integrity of the organic operation would be jeopardized. Many producers and certifying agents emphasized that the proposed rule conflicted with the Codex guidelines that prohibit the use of manure from factory farms. These commenters were concerned that failure to restrict the use of manure from nonorganic operations would put their products at a competitive disadvantage, particularly in European markets. When raising this issue, most commenters requested that the final rule either prohibit the use of manure from factory farms or state that certifying agents could regulate the practice by requiring residue testing and restrictions on application.

We have not changed the provisions for using manure from nonorganic operations in the final rule. In many discussions on the subject throughout the years, the NOSB has never recommended that manure from nonorganic farms be prohibited. Existing organic certification standards routinely permit the use of manure from nonorganic operations with appropriate oversight, and the final rule incorporates a similar approach. Under the final rule, a certifying agent can require residue testing when there is reasonable concern that manure, either raw or as a component of compost, contains sufficient quantities of prohibited materials to violate the organic integrity of the operation. Providing certifying agents the discretion to require screening for prohibited materials will minimize the risk of introducing contaminants while maintaining the ecologically important practice of recycling organic material from nonorganic operations. Additionally, the final rule requires that producers apply manure and compost in a manner that maintains or improves the soil and water quality of their operation. This provision provides an additional safeguard that certifying agents may use to ensure that the application of any form of manure protects the natural resources of the operation.

(3) Rotating a Field in and out of Organic Production. Some commenters stated that a producer should not be allowed to rotate fields on their operation in and out of organic production. These commenters were concerned that producers could apply prohibited substances that persisted for many years, such as soil fumigants, and begin harvesting organically produced crops after 3 years. They stated that, without a prohibition on the rotation of fields in this manner, organic producers could effectively use a prohibited substance on their operation.

We have not amended the final rule to prohibit the rotation of a field on an operation in and out of organic production. The statutory prohibition on the application of a prohibited substance is 3 years, and this requirement is contained in section 205.202(b). This prohibition restricts the application of a prohibited substance, not its residual activity. If AMS receives evidence that the rotation of fields in this manner threatens to compromise organic production, the NOP and NOSB will collaborate on developing standards to remedy it. (4) Use of Seed Treatments on the National List. The seed and planting stock practice standard in the proposed rule generated a very diverse array of responses that, while largely favorable, highlighted a potentially disruptive impact on organic producers. The practice standard favored organic seed and planting stock over nonorganically produced but untreated varieties and nonorganically produced, untreated seed and planting stock over nonorganically produced seeds and planting stock treated with an allowed synthetic substance. Producers could use the less preferable seed or planting stock variety if they demonstrated to their certifying agent that an equivalent variety in the preferred form was not commercially available. Most commenters endorsed the principle of requiring organic seed and planting stock and agreed that the proposed provisions were a workable approach to enforcement. They stated that the provisions created an incentive for seed and planting stock providers to develop supplies for organic markets, yet enabled producers who made a good faith effort but failed to locate seed or planting stock in the preferred form the ability to continue producing organically. Most commenters indicated that this approach would support the existing market for organic seed and planting stock while fostering its continued development.

A number of commenters, however, stated that the seed and planting stock practice standard was unreasonable and unworkable and would adversely affect organic producers. These effects would include significantly reduced planting options due to the nonavailability of seed in any allowed form and higher seed costs, which represent a significant percentage of the total production cost for some commodities. These commenters maintained that the three categories of seed and planting stock allowed in the order of preference could not reliably provide producers with many commercial varieties currently being planted. They pointed out that there were no synthetic seed treatments on the National List in the proposed rule, thereby eliminating the use of treated seed in organic production. Commenters stated that producers often rely upon seed and planting stock varieties that are uniquely well adapted for their growing conditions or marketing requirements and that these particular varieties would very often not be available in untreated form. These commenters concluded that the proposed practice standard would compel many producers to abandon many tried and true varieties of seed and planting stock and perhaps phase out organic production entirely. One commenter maintained that the proposed rule's stated intention of using the practice standard to stimulate production of organic seed and planting stock was not within the purpose of the OFPA.

We have not changed the seed and planting stock practice standard in response to these commenters because the prohibition on using synthetic materials not on the National List is a requirement of the OFPA. The final rule cannot allow producers to use synthetic seed treatments that have not been reviewed, favorably recommended by the NOSB, and added to the National List by the Secretary. The practice standard creates incentives for producers to seek out seed and planting stock inputs that are the most compatible with organic production, yet includes allowances when preferred forms are not commercially available. While no seed treatments are included on the National List in the final rule, individuals may petition the NOSB for review of such substances. Additionally, the practice standard creates an incentive for seed and planting stock producers and suppliers to develop natural treatments suitable for organic systems that would not

need to appear on the National List. The objectives of spurring production of organically grown seed and promoting research in natural seed treatments are compatible with the OFPA's purpose of facilitating commerce in organically produced and processed food. We designed the practice standard to pursue these objectives while preventing the disruption that an ironclad requirement for organically produced seed and planting stock may have caused. (5) Practice Standard for Maple Syrup. Many commenters stated that the proposed rule lacked production and handling standards for operations that produce maple syrup. Commenters stated that maple syrup production is a significant enterprise for many organic producers and that the absence of a practice standard in the final rule would adversely affect existing markets for organic products. Many commenters recommended that the final rule incorporate the maple syrup practice standard from an existing certification program or the American Organic Standards.

We have not included a practice standard for the production and handling of maple syrup because the final rule contains sufficient provisions for the certification of these types of operations. After reviewing existing practice standards for maple syrup, we determined that the standards in the final rule for crop production, handling operations, and allowed and prohibited materials on the National List provided comparable guidance.

Crop Production - Clarifications

Clarification is given on the following issues raised by commenters:

(1) Applicability of Crop Rotation Requirement to all Operations. One State program commented that the crop rotation practice standard in the proposed rule was unreasonable for producers who operated in regions where limited rainfall and irrigation resources or unique soil conditions made cover cropping impractical. This commenter stated that certain dryland cropping systems, such as aloe vera production, function as "semi-perennial" systems that do not include rotations, yet fulfill the objectives of the crop rotation practice standard. A certifying agent expressed a similar concern by suggesting that the crop rotation practice standard be changed by adding "may include, but is not limited to" prior to the list of allowed management practices. This commenter felt that the "may include" clause afforded individual growers greater discretion by acknowledging that not every allowed management practice would be applicable to all operations.

We have retained the language from the proposed rule because it already provides the flexibility to develop site-specific crop rotation practices requested by these commenters. The regulation as originally written includes the " but not limited to" clause that allows producers to include alternative management practices in their organic system plan. Additionally, the regulation states that the producer must implement a crop rotation that provides the required functions "that are applicable to the operation." This further establishes that the crop rotation component of an organic system plan must be considered within the context of site-specific environmental conditions including climate, hydrology, soil conditions, and the crops being produced. The final rule requires implementation of a crop rotation, but the producer and certifying agent will determine the specific crops and the frequency and sequencing of their use in that rotation. Crop rotations must fulfill the requirements of this practice standard--to maintain or improve soil organic matter content, provide for pest management, manage deficient or excess plant nutrients, and control erosion--and are not obligated to use any specific management practice. We structured this and other practice standards, as well as the requirements of the organic system plan, to enable producers and certifying agents to develop organic system plans adapted to natural variation in environmental conditions and production systems.

(2) Excluding Annual Seedlings from Planting Stock. The proposed rule allowed a producer to use nonorganically produced seeds and planting stock if organically produced equivalent varieties were not commercially available. Several commenters, including the NOSB, were concerned that the definition of planting stock as "any plant or plant tissue, including rhizomes, shoots, leaf or stem cuttings, roots, or tubers, used in plant production or propagation" was sufficiently broad to

be applied to annual seedlings. While many commenters, including the NOSB, supported the commercial availability exemption in the case of seeds and planting stock, they objected to extending it to annual seedlings. The proposed rule did not intend to include annual seedling within the definition of planting stock and included a separate definition of "annual seedling" as "a plant grown from seed that will complete its life cycle or produce a harvestable crop yield within the same crop your or season in which it is planted." The proposed rule addressed annual seedlings as a distinct category within the seed and planting stock practice standard. There was no allowance for using nonorganically produced annual seedlings based on commercial availability, and such seedlings can only be used when a temporary variance has been issued due to a catastrophic business interruption. The growth of markets for organically produced annual seedlings, unlike those for seeds and planting stock, obviates the need for the commercial availability provision. We have retained this approach in the final rule.

Livestock Production - Changes Based on Comments

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

(1) Whole Herd Conversion. The proposed rule required that livestock receive 1 year of continuous organic management prior to the milk or milk products they produce being labeled as organic. Based on the feed provisions in that proposal, producers would be required to provide a 100-percent organic feed ration (exclusive of National List substances allowed as feed supplements and additives) for that entire year. Many producers, consumers, State certification programs, and certifying agents commented that the full year organic feed requirement created an insurmountable barrier for small and medium-size dairy operations wishing to convert to organic production. They maintained that the added expense of a full year, 100-percent organic feed requirement was economically prohibitive. These commenters stated that "new entry" or "whole herd" conversion provisions in existing certification standards have been instrumental in enabling established nonorganic dairies to make the transition to organic production. Commenters stated that these provisions typically allow producers to provide livestock 80-percent organic or self-raised feed for the first 9 months of a herd's transition, before requiring 100-percent organic feed for the final 3 months. Some commenters stated that many current organic dairies had capitalized on this whole herd conversion provision and that the consistent growth in demand for organic milk and milk products reflected consumer acceptance of the principle.

At its June 2000 meeting, the NOSB reiterated its prior endorsement of the conversion principle for operations that jointly convert dairy herds and the land on which they are raised. The NOSB recommended allowing a producer managing an entire, distinct herd to provide 80-percent organic or self-raised feed during the first 9 months of the final year of conversion, and 100-percent organic feed for the final 3 months. The recommendation further required that dairy animals brought onto an organic dairy must be organically raised form the last third of gestation, except that feed produced on land managed under an organic system plan could be fed to young stock up to 12 months prior to milk production.

While the preponderance of comments supported the whole herd conversion provision, a significant number of individuals, certifying agents, and State certification programs opposed it. Some commenters felt that requiring less than 1 full year of 100-percent organic feed would not satisfy consumer expectations for an organically managed dairy. Other commenters stated that the whole herd conversion merely favored one segment of organic producers over another. They maintained that the full year, 100-percent organic feed requirement would stimulate markets for organically produced hay and grain, thereby rewarding good row crop rotation. One certifying agent was concerned that the conversion provision would create a permanent exemption and that split operation dairies could use it repeatedly to bring nonorganic animals into the organic operation.

The final rule contains a provision for whole herd conversion that closely resembles those found in the NOSB recommendation and the existing certification standards. The final rule requires that an entire, distinct dairy herd must be under organic management for 1 year prior to the production of organic milk. During the first 9 months of that year, the producer must provide a feed ration containing a minimum of 80-percent organic feed or feed that is raised from land included in the organic system plan and managed in compliance with organic crop requirements. The balance of the feed ration may be nonorganically produced, but it must not include prohibited substances including antibiotics or hormones. The producer must provide the herd 100-percent organic feed for the final 3 months before the production of organic milk. The producer must comply with the provisions in the livestock health and living conditions practice standard during the entire year of conversion. After the dairy operation has been certified, animals brought on to the operation must be organically raised from the last third of gestation. We did not incorporate the NOSB's recommendation to provide young stock with nonorganic feed up to 12 months prior to the production of certified milk. By creating an ongoing allowance for using nonorganic feed on a certified operation, this provision would have undermined the principle that a whole herd conversion is a distinct, one-time event.

We anticipate that the provisions added to the final rule will address the concerns of commenters who objected to the conversion principle. Consumers have embraced milk and milk products from dairies certified under private whole herd conversion provisions essentially identical to that in the final rule. While the conversion provision may temporarily reduce demand for organic feed materials, it encourages producers to develop their own supplies of organic feed. The conversion provision also rewards producers for raising their own replacement animals while still allowing for the introduction of animals from off the farm that were organically raised from the last third of gestation. This should protect existing markets for organically raised heifers while not discriminating against closed herd operations. Finally, the conversion provision cannot be used routinely to bring nonorganically raised animals into an organic operation. It is a one-time opportunity for producers working with a certifying agent to implement a conversion strategy for an established, discrete dairy herd in conjunction with the land resources that sustain it.

(2) Organic Management for Livestock from the Last Third of Gestation. The proposed rule required that organically managed breeder and dairy stock sold, labeled, or represented as organic slaughter stock must be under continuous organic management from birth. Many commenters stated that this requirement was an inappropriate relaxation of most existing organic standards, which require organic management for all slaughter stock from the last third of gestation. These commenters cited the NOSB's 1994 recommendation that all slaughter stock must be the progeny of breeder stock under organic management from the last third of gestation or longer. Commenters also recommended extending the organic management provision to cover the last third of gestation to make it consistent with the requirements in section 205.236(a)(4) for the organically raised offspring of breeder stock. We agree with the argument presented by commenters and have changed the final rule to require that breeder or dairy stock be organically raised from the last third of gestation to be sold as organic slaughter stock.

(3) Conversion Period for Nonedible Livestock Products. The proposed rule required that livestock must be under continuous organic management for a period not less than 1 year before the nonedible products produced from them could be sold as organic. Several commenters questioned the basis for creating different origin of livestock requirements based on whether the operation intended to produce edible or nonedible products. These commenters stated that the OFPA does not sanction such a distinction, nor is it contained in existing certification standards. They questioned why the proposed rule created such a provision in the absence of a favorable NOSB recommendation. We agree that the creation of a separate origin of livestock requirement for animals intended to provide nonedible products could be confusing. We have changed this provision in the final rule to require that nonedible products be produced from livestock that have been organically managed from the last third of gestation.

(4) Provisions for Feed Supplements and Feed Additives. The proposed rule provided that nonagricultural products and synthetic substances included on the National List could be used as feed additives and supplements. Many commenters stated that allowing nonagricultural products and synthetic substances as feed supplements contradicted the definition for "feed supplement" found in the proposed rule. That definition stipulated that a feed supplement must, itself, be a feed material, and the definition for "feed" in the proposed rule precluded using nonagricultural products and synthetic substances. These commenters requested that either the definition of "feed supplement" be changed to make it consistent with the allowance for nonagricultural products and synthetic substances or else that the term be dropped from the final rule. The Food and Drug Administration (FDA) recommended modifying the definitions for "feed additive" and "feed supplement" and further specifying the components required in a feed ration under the livestock health care practice standard.

We amended the definition in the final rule to state that a feed supplement is "a combination of feed nutrients added to livestock feed to improve the nutritional balance or performance of the total ration." We retained the second component of the proposed definition, which described how a feed supplement could be offered to livestock. We amended the definition of "feed additive" to "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." The definitions for "feed supplement" and "feed additive" in the proposed rule were originally recommended by the NOSB. While our intent in the proposed rule was to codify as fully as possible the recommendations of the NOSB, we agree with commenters that the proposed definitions were was incompatible with the overall provisions for livestock feed. The definitions in the final rule are consistent with the NOSB's objective to create clear distinctions between feed, feed supplements, and feed additives while clarifying the role for each within an organic livestock ration. We also incorporated FDA's recommendation to include protein and/or amino acids, fatty acids, energy sources, and fiber for ruminants as required elements of a feed ration in the livestock health care practice standard. These additions make the livestock health care practice standard more consistent with the National Research Council's Committee on Animal Nutrition's Nutrient Requirement series, which we cited in the proposed rule as the basis for feed requirements.

Many commenters addressed provisions in the proposed rule to allow or prohibit specific materials and categories of materials used in livestock feed. Among these, some commenters questioned whether enzymes were defined as a feed additive and, therefore, allowed. One certifying agent requested guidance on the status of supplementing livestock feed with amino acids. At its October 1999 meeting, the NOSB discussed the Technical Advisory Panel (TAP) reviews on the use of enzymes and amino acids in livestock feed. The NOSB determined that natural sources of enzymes exist and that their use should be allowed in organic production. Their discussion of natural sources of enzymes concluded that enzymes derived from edible, nontoxic plants and nonpathogenic bacteria or fungi that had not been genetically engineered should be allowed as a nonorganic feed additive. The NOSB did not take a position on amino acids during this meeting but indicated that it would revisit the subject in the near future. Based on these recommendations, the final rule allows the use of natural enzymes but not amino acids as nonorganic feed additives. The NOSB's recommendation that natural sources of enzymes existed and were compatible with organic livestock production supports allowing them without adding them to the National List. Some commenters discussed the animal welfare and environmental benefits associated with providing amino acids in livestock feed and supported allowing them. However, without a recommendation from the NOSB that amino acids are natural or should be added to the National List as a synthetic, the final rule does not allow their use.

Commenters questioned whether nonsynthetic but nonagricultural substances, such as ground oyster shells and diatomaceous earth, would be allowed in agricultural feed. In 1994, the NOSB recommended that natural feed additives can be from any source, provided that the additive is not classified as a prohibited natural on the National List. We agree with this recommendation and have amended the final rule to allow such materials as feed additives and supplements. The

only additional constraint on these materials is that every feed, feed additive, and feed supplement be used in compliance with the Federal Food, Drug, and Cosmetic Act, as stated in section 205.237(b)(6).

The NOSB recommended that ruminants maintained under temporary confinement must have access to dry, unchopped hay. Although this position was an NOSB recommendation and not part of the proposed rule, several commenters responded to it. Most of these commenters stated that the language was too restrictive and could preclude the use of many suitable forage products. One dairy producer stated that the requirement would not be practical for operations that mix hay with other feed components. We agree that the NOSB's proposed language is too prescriptive and have not included it in the final rule.

(5) Provisions for Confinement. The proposed rule established the health, nutritional, and behavioral needs of the particular species and breed of animal as the primary considerations for determining livestock living conditions. The proposed rule also identified essential components of the practice standard, including access to shade, shelter, exercise areas, fresh air, and direct sunlight, while stating that species-specific guidelines would be developed in conjunction with future NOSB recommendations and public comment. Finally, the proposed rule outlined the conditions pertaining to animal welfare and environmental protection under which producers could temporarily confine livestock.

While supportive of the underlying principles of this practice standard, the vast majority of commenters stated that the actual provisions suffered from a lack of clarity and specificity. Many commenters were concerned that the proposed rule did not adequately ensure access to the outdoors for all animals. While supportive of the access to pasture requirement for ruminant production, commenters stated that the final rule needed a clear definition of pasture to make the provision meaningful. Conversely, some commenters supported the less prescriptive approach adopted in the proposed rule. The NOSB added considerably to its earlier recommendations on livestock living conditions during its June 2000 meeting.

Many commenters stated that the criteria identified as required elements in the provisions for livestock living conditions did not specifically include access to the outdoors. One commenter stated that the requirement that animals receive direct sunlight could be interpreted to simply require windows in livestock confinement facilities. Commenters were virtually unanimous that, except for the limited exceptions for temporary confinement, all animals of all species must be afforded access to the outdoors. Commenters also maintained that the outdoor area must accommodate natural livestock behavior, such as dust wallows for poultry and, in the case of ruminants, provide substantial nutrition. Many commenters specifically opposed dry lots as an allowable outdoor environment. The NOSB recommended that the final rule state that all livestock shall have access to the outdoors. As a result of these comments, we have revised the final rule to establish that access to the outdoors is a required element for all organically raised livestock.

We further amended the final rule to include a definition of "pasture." The definition of "pasture" we included emphasizes that livestock producers must manage their land to provide nutritional benefit to grazing animals while maintaining or improving the soil, water, and vegetative resources of the operation. The producer must establish and maintain forage species-appropriate for the nutritional requirements of the species using the pasture.

Numerous commenters requested clarification on species-specific living conditions, such as the use of cages for poultry and confinement systems for veal production. The use of continuous confinement systems including cages for poultry and veal production is incompatible with the requirement that organically raised livestock receive access to the outdoors and the ability to engage in physical activity appropriate to their needs. There will be times when producers must temporarily confine livestock under their care, but these instances must be supported by the exemptions to the outdoor access requirement included in the final rule. Other commenters

requested additional guidance on whether confinement for the purpose of finishing slaughter stock would be allowed, and, if so, how long that confinement could last. Commenters who supported an allowance for finishing most often recommended that, in the case of cattle, confinement should not exceed 90 days. The final rule does not include a specific length of time that cattle or other species may be confined prior to slaughter. We will seek additional input from the NOSB and public comment before developing such standards.

Several commenters questioned whether a Federal, State, or local regulation that required confinement would supersede the requirement for outdoor access. These commenters were aware of county ordinances that prohibited free ranging livestock production to protect water quality. Organic operations must comply with all Federal, State, and local regulations. At the same time, to sell, label, or represent an agricultural commodity as "100 percent organic," "organic," or "made with...," the producer or handler must comply with the all applicable requirements set forth in this regulation. Federal, State, or local regulations that prohibit a required practice or require a prohibited one will essentially preclude organic certification of the affected commodity within that jurisdiction.

(6) Prohibition on Parasiticides During Lactation. The proposed rule provided that breeder stock could receive synthetic parasiticides included on the National List, provided that the treatment occurred prior to the last third of gestation for progeny that were to be organically managed. Many commenters supported this principle but were concerned that the wording would allow producers to administer parasiticides to lactating breeder stock while the offspring were still nursing. These commenters felt that such an allowance violated the intent of the provision because offspring could be exposed to systemic parasiticides or their residues through their mother's milk. The NOSB recommended a prohibition on using allowed synthetic parasiticides during lactation for progeny that are organically managed. We agree with these commenters and have modified the final rule to prohibit the treatment of organically managed breeder stock with allowed synthetic parasiticides during the last third of gestation or lactation.

Livestock Production - Changes Requested But Not Made

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

(1) Prohibition on Factory Farms. Many commenters requested that the final rule prohibit the certification of "factory farms." These commenters stated that factory farms are dependent upon practices and materials that are inconsistent with or expressly prohibited in the OFPA. The final rule does not contain such a prohibition because commenters did not provide a clear, enforceable definition of "factory farm" for use in the final rule. All organic operations, regardless of their size or other characteristics, must develop and adhere to an approved organic system plan that complies with these regulations in order to be certified. (2) Nonorganic Feed Protocol. The proposed rule required that, except for nonagricultural products and synthetic substances included on the National List, a producer must provide livestock with a total feed ration composed of agricultural feed products, including pasture and forage, that is organically produced and, if applicable, handled. It also included provisions for temporary variances that, under very limited circumstances and with the approval of the certifying agent and the Administrator, would provide an exemption from specific production and handling standards. The preamble of the proposed rule described an emergency resulting in the unavailability of organic agricultural feed products as an example of a situation in which a temporary variance could be issued. Many commenters recommended that the final rule require a producer who received a temporary variance for a feed emergency to follow the order of preference for noncertified organic feed developed by the NOSB. This order of preference requires a producer to procure agricultural feed products from sources that are as close to complying with the standards for organic certification as possible. Commenters stated that adherence to the order of preference would most closely conform with

the expectation of consumers that organically raised livestock received organic feed and would create an incentive for livestock feed producers to pursue certification.

We have not included the NOSB's feed emergency order of preference in the final rule because it would be too prescriptive and difficult to enforce during an emergency. Receiving a temporary variance categorically exempts a producer from the provision for which it was issued, although that producer may not substitute any practice, material, or procedure that is otherwise prohibited, although that producer may not substitute any practice, material, or procedure that is otherwise prohibited under section 205.105 . Additionally, certified organic feed is far more available in terms of quantity and affordability than when the NOSB developed its order of preference in 1994. We anticipate that producers whose original supply of organic agricultural feed products is interrupted will be able to fill the shortfall through the marketplace.

(3) Prohibition on Physical Alterations. The proposed rule required that producers perform physical alterations as needed to promote animal welfare and in a manner that minimizes pain and stress. This provision was one component of the health care practice standard that required producers to establish and maintain preventive livestock health care practices. We stated in the preamble that there was insufficient consensus from previous public comment to designate specific physical alterations as allowed or prohibited and envisioned working with producers, certifying agents, and consumers to achieve that goal. We requested comment on techniques to measure animal stress that could be used to evaluate whether specific physical alterations were consistent with the conditions established in the proposed rule.

We received significant numbers of comments both opposing and supporting the provision in the proposed rule for performing physical alterations. Many commenters opposed any allowance for physical alterations and argued that such practices are cruel and debilitating to animals. These commenters maintained that modifications in breed selection, stocking densities, and the configuration of living conditions could achieve results similar to physical alterations without harming the animal. They stated that by adapting their production systems to promote the physical and psychological welfare of animals, producers could obviate the need for physical alterations. In particular, commenters cited physical alterations to the beaks and feet of poultry as unnecessary due to the availability of alternative production systems. Many commenters expressed concern that the allowance for physical alterations would facilitate the certification of large confinement operations. Commenters also stated that performing physical alterations was inconsistent with Codex guidelines and objected to the allowance before full public deliberation on the subject through the NOSB process.

A large number of commenters stated that, if reasonable guidelines could be established, the allowance for physical alterations would be a beneficial, and even necessary, condition for organic livestock production. These commenters maintained that producers engage in physical alterations for the overall welfare of the flock or herd and that the pain and stress of performing them must be weighed against the pain and stress of not doing so. For example, these commenters cited the traumatic effect of cannibalism on poultry flocks that had not undergone beak trimming or the injuries caused by animals whose horns had not been removed. Many of these commenters stated that producers could reduce but not eliminate the need for physical alterations through alternative production practices such as breed selection and stocking densities. The NOSB supported the provision as written in the proposed rule, stating that it met the animal welfare requirements while allowing practices necessary for good animal husbandry.

We have retained the proposed provision for physical alterations without taking any further position on whether specific practices are allowed or prohibited. We did not receive substantial new guidance on techniques to measure stress in animals due to physical alterations and have made no revisions in that regard. The final rule establishes that, when appropriately performed and within the context of an overall management system, specific physical alterations are

allowed. It also mandates that, as an element of a preventative health care program, physical alterations must benefit the ultimate physical and psychological welfare of the affected animal.

(4) Withdrawal for Synthetic Parasiticides in Lactating Livestock. The proposed rule required a 90-day withdrawal period before milk and milk products produced from livestock treated with an allowed synthetic parasiticide could be labeled as organic. Referencing the statement in the preamble to the proposed rule that the 90-day withdrawal period was attributable to "consumer expectations of organically raised animals," a dairy producer commented that the provision ignored animal welfare and farm economic sustainability considerations. The commenter considered the 90-day withdrawal period capricious and problematic since, for bovine dairy operations, it would compel producers to either shorten an animal's natural drying off period, or lose 30 days of organic milk production. The commenter stated that the optimal extended withdrawal period for this situation would be 60 days since this is the approximate duration of a dairy cow's natural dry period. Under this approach, livestock requiring treatment could receive an allowed synthetic parasiticide at the time of drying off, thus allowing the withdrawal period to coincide with the natural 60-day period when the livestock were not lactating. Livestock could complete the withdrawal period prior to the birth of their offspring in approximately 60 days, at which time the mother's milk could again be sold as organic. The commenter maintained that the 60-day period would satisfy consumer expectation for an extended withdrawal period after treatment with an allowed synthetic parasiticide without imposing an unnecessary constraint on the producer.

We have retained the 90-day withdrawal period in the final rule. The provisions in the final rule for treating livestock with an allowed synthetic parasiticide reflect the 90-day withdrawal period recommended by the NOSB at its October 1999 meeting. The NOSB has the authority to reconsider this issue and propose an alternative annotation for the Secretary's consideration.

(5) Delineation of Space Requirements for Animal Confinement. The proposed rule did not establish space requirements for livestock living conditions but stated that a producer must accommodate the health and natural behavior of animals under his or her care. Some commenters stated their preference for space requirements because they are more uniform and enforceable. These commenters stated that some existing certification standards include space requirements in standards for livestock living conditions and that Codex guidelines support this approach. While not disagreeing that space requirements could be an effective certification tool for organic livestock production systems, we have not incorporated any such provisions in the final rule. We anticipate that additional NOSB recommendations and public comment will be necessary for the development of space requirements. At its June 2000 meeting, the NOSB agreed that it would be premature to include space requirements in the final rule.

(6) Access to pasture versus pasture-based. Commenters stated that the proposed rule's requirement that ruminants receive "access to pasture" did not sufficiently characterize the relationship that should exist between ruminants and the land they graze. Many of these commenters recommended that the final rule require that ruminant production be "pasture-based." Many commenters stated that the final rule needed a more explicit description of the relationship between livestock and grazing land. The NOSB shared this perspective and recommended that the final rule require that ruminant production systems be "pasture-based." In contrast, an organic dairy producer maintained that a uniform, prescriptive definition of pasture would not be appropriate in a final rule. This commenter stated that the diversity of growing seasons, environmental variables, and forage and grass species could not be captured in a single definition and that certifying agents should define pasture on a case-by-case basis. This commenter also disagreed with the "pasture-based" requirement, stating that pasture should be only one of several components of balanced livestock nutrition. Singling out pasture as the foundation for ruminant management would distort this balance and deprive other producers of the revenue and rotation benefits they generate by growing livestock feed.

We retained the "access to pasture" requirement because the term, "pasture-based," has not been sufficiently defined to use for implementing the final rule. The final rule does include a definition for pasture, and retention of the "access to pasture" provision provides producers and certifying agents with a verifiable and enforceable standard. The NOP will work with the NOSB to develop additional guidance for managing ruminant production operations.

(7) Stage of Production. The proposed rule contained provisions for temporary confinement, during which time livestock would not receive access to the outdoors. Many commenters were concerned that the stage-of-production justification for temporary confinement could be used to deny animals access to the outdoors during naturally occurring life stages, including lactation. Commenters overwhelmingly opposed such an allowance and stated that the stage of production exemption should be narrowly applied. One commenter stated that a dairy operation, for example, might have seven or eight distinct age groups of animals, with each group requiring distinct living conditions. Under these circumstances, the commenter maintained that a producer should be allowed to temporarily house one of these age groups indoors to maximize use of the whole farm and the available pasture. At its June 2000 meeting, the NOSB stated that the allowance for temporary confinement should be restricted to short-term events such as birthing of newborn or finish feeding for slaughter stock and should specifically exclude lactating dairy animals.

We have not changed the provision in the final rule for the stage-of-production allowance in response to these comments. The NOSB has supported the principle of a stage-of-production allowance but has not provided sufficient guidance for determining, on a species-specific basis, what conditions would warrant such an allowance. Without a clearer foundation for evaluating practices, we have not identified any specific examples of practices that would or would not warrant a stage-of-production allowance. We will continue to explore with the NOSB specific conditions under which certain species could be temporarily confined to enhance their well-being.

In the final rule, temporary confinement refers to the period during which livestock are denied access to the outdoors. The length of temporary confinement will vary according to the conditions on which it is based, such as the duration of inclement weather. The conditions for implementing temporary confinement for livestock do not minimize the producer's ability to restrain livestock in the performance of necessary production practices. For example, it is allowable for a producer to restrain livestock during the actual milking process or under similar circumstances, such as the administration of medication, when the safety and welfare of the livestock and producer are involved.

Handling - Changes Based on Comments

The following changes are made based on comments received.

(1) Commercial Availability. A large number of commenters, including organic handlers and certifying agents, stated that "commercial availability" must be included as a requirement for the 5 percent of nonorganic ingredients that are used in products labeled "organic."

We agree and have added a commercial availability requirement as part of a handler's organic system plan under section 205.201 of this subpart. Up to 5 percent (less water and salt) of a product labeled "organic," may be nonorganic agricultural ingredients. However, handlers must document that organic forms of the nonorganic ingredients are not commercially available before using the nonorganic ingredients.

(2) Prohibited Practices. Commenters were unclear about the extent of the prohibition on use of excluded methods and ionizing radiation. To make that prohibition clear, we have moved the handling prohibitions in proposed rule sections 205.270 (c) to 205.105, Applicability, subpart B.

Paragraphs (c)(1) and (c)(2) which listed excluded methods and ionizing radiation in the proposed rule are combined into paragraph (c)(1) that cross-references new section 205.105.

(3) Use of Predator Pests and Parasites. Paragraph (b)(1) of section 205.271 proposed that predator pests and parasites may be used to control pests in handling facilities. Under FDA's Good Manufacturing Practice, 21 CFR part section 110.35(c), it states that "No pests shall be allowed in any area of a food plant." Some commenters believed use of predator pests in handling facilities is prohibited by the FDA regulation. Other commenters stated that predator pests could be used in certain handling facilities under the FDA regulation. One commenter claimed that the FDA regulation in 21 CFR part 110.19 allows exemptions for certain establishments that only harvest, store, or distribute raw agricultural product. Another commenter suggested that use of predator pests should be allowed when FDA does not prohibit their use.

We do not intend to be inconsistent with the FDA requirement and, thus, have removed proposed paragraph (b)(1) of section 205.271. Use of predator pests in various organic handling and storage areas is subject to FDA's Good Manufacturing Practice. Paragraphs (b)(2) and (b)(3) are redesignated.

(4) Use of Synthetic Pheromone Lures. Proposed paragraph (b)(3) provided for use of nonsynthetic lures and repellant. A few handlers and certifying agents commented that nearly all pheromone lures use synthetic substances. Because pheromone lures do not come into contact with products in a handling facility, commenters argued that such lures should be allowed, provided that the synthetic substance used is on the National List.

We agree and have added "synthetic substances" to redesignated paragraph (b)(2) for use in lures and repellents. The synthetic substances used must be consistent with the National List. (5) Restrict Initial Use of Synthetics to National List Substances. Paragraph (c) in the proposed rule provided for use of any synthetic substance to prevent or control pests. Several handlers and certifying agents stated that use of nonsynthetic and synthetic substances should initially be limited first to substances which are allowed on the National List. This would mean that substances not allowed for use on the National List could not be used initially to control or prevent pest infestations.

We agree with these comments. Use of allowed substance before use of other substances is a fundamental principle of organic agriculture. Therefore, if preferred practices under paragraphs (a) and (b) are not successful in preventing or controlling pest infestations, handlers may then use, under amended paragraph (c), only nonsynthetic or synthetic substances which are allowed for use on the National List.

We have removed the proviso that applications of a pest control substance must be consistent with the product's label instructions. This requirement is readily understood and does not need to be explicitly stated in the regulations.

Because paragraph (c) now provides for use only of allowed National List substances, a new paragraph (d) is added to allow for use of other synthetic substances, including synthetic substances not on the National List, to prevent or control pest infestations. These substances may be used only if the practices in paragraphs (a), (b), and (c) are ineffective. Before the substance is used, the handler and the operation's certifying agent must agree on the synthetic substance to be used and the measures to be taken to prevent contact of the substance with organic products and ingredients in the facility. We expect that this communication can be accomplished with telephone calls or by electronic means.

This regulation does not preempt Federal, State, or local health and sanitation requirements. We recognize that inspectors who monitor compliance with those regulations may require immediate

intervention and use of synthetic substances, not on the National List, before or at the same time as the methods specified in paragraphs (b) and (c). Therefore, to make this clear, we have added a new paragraph (f). To ensure that the use of the substances does not destroy a product's organic integrity, we are requiring that the handler take appropriate measures to prevent contact of the product with the pest control substance used.

(6) Preventing Contact with Prohibited Substances. Commenters recommended that, if prohibited substances are applied by fogging or fumigation, the organic product and packaging material must be required to be completely removed from the facility and reentry of the product or packaging be delayed for a period three times longer than that specified on the pesticide label. Commenters believed removal and reentry should be mandatory, regardless of the organic product or container.

We understand the commenters' concerns. However, their recommendations are not appropriate for all pest infestations. We believe that measures needed to be taken to prevent contact with a synthetic substance must be determined on a case-by-case basis by the handler and certifying agent. As stated earlier, new paragraph (d) of section 205.271 requires a handler and certifying agent to agree on control and prevention measures prior to application of a synthetic substance. We believe that such an agreement will help safeguard a product's organic integrity. Use of a synthetic substance in fogging or fumigation should be based on, among other things, location of the pest relative to the organic products in the facility; the extent of the pest infestation; the substance and application method to be used; the state of the organically produced product or ingredient (raw, unpackaged bulk, canned, or otherwise sealed); and health and sanitation requirements of local, State, and Federal authorities.

Paragraph (e) is changed to clarify that an operation's organic handling plan must be updated to document all measures taken to prevent contact between synthetic pest control substances and organically produced products and ingredients.

(7) Repetitive Use of Pest Control Measures. One commenter suggested a change in the paragraph (e) requirement that handlers' organic plans must include "an evaluation of the effects of repetitive use" of pest prevention and control materials. The commenter believed that the requirement was excessive and beyond what should be expected of handlers. The commenter indicated that handlers' organic plans should address the "techniques that will be used to minimize" the negative effects of repetitive use of pest control materials.

We agree that "an evaluation of the effects of repetitive use" is more than what is reasonable to expect of handlers in their organic plans. We do not agree, however, that an organic plan should be required to address the "techniques" used to minimize the effects of repetitive use of pest control materials. However, we believe that handlers should update their organic handling plans to account for the use of pest control or prevention substances, particularly if the substances are prohibited substances. The update should include a description of the application methods used and the measures taken to prevent contact between the substance used and the organic product. We have added these requirements in redesignated paragraph (e). Proposed paragraph (e) of section 205.271 is removed.

Handling - Changes Requested But Not Made

(1) Exceptions to Handling Processes. A commenter stated that many herbal products are extracted from organically produced herbs but that the extraction of those products "can employ significantly different methods than those used in the manufacture of more traditional foods." To be labeled as "organic" ingredients, substances such as herbs, spices, flavorings, colorings, and other similar substances, must be derived from a certified organic source and be extracted without the use of prohibited substances.

(2) Allowed Synthetics Used in Packaging Materials and Storage Containers. A State department of agriculture commented that section 205.272(b)(1) prohibits use of synthetic fungicides, preservatives, or fumigants in packaging materials and storage containers or bins. The comment stated that it is inconsistent to permit use of allowed substances as ingredients in processed products but prohibit their use as a preservative or fumigant in the packaging materials and storage containers and bins. The commenter suggested that paragraph (b)(1) be amended to permit use of National List-allowed substances in section 205.605, particularly carbon dioxide and ozone, in packaging materials and storage containers or bins.

We understand the commenter's concern. However, section 6510(a)(5) of the Act specifically prohibits use of any packaging materials, storage containers, or bins that contain synthetic fungicides, preservatives, or fumigants.

(3) Additional Measures to Prevent Product Contamination. A few commenters suggested changing paragraph (e) of section 205.271 to require that handlers' organic handling plans specify measures that would be taken to prevent contact between a pest control substance and "packaging materials." This would be in addition to measures preventing contamination of "any ingredient or finished product" in the handling facility.

We understand the commenters' objective. However, for the reasons stated earlier in regard to commenters' request that mandatory removal of product during pest control treatment be required, we believe that such a requirement should not be mandatory for all packaging materials. Measures to prevent contamination of packaging material should be left to the handler and certifying agent to specify in the handling plan.

Handling - Clarifications

Clarification is given on the following issues raised by commenters.

(1) Use of Nonorganic Ingredients in Processed Products. We have corrected paragraph (c) of section 205.270 to clarify what must not be used in or on organically produced ingredients and nonorganically produced ingredients used in processed organic products. The prohibition on use of ionizing radiation, excluded methods, and volatile synthetic solvents applies to all organically produced ingredients. The 5 percent of nonorganic ingredients in products labeled "organic," also are subject to the three prohibited practices. The nonorganic ingredients in products labeled "made with organic ingredients" must not be produced using ionizing radiation or excluded methods but may be produced using volatile synthetic solvents. The nonorganic ingredients in products containing less than 70 percent organically produced ingredients may be produced and processed using ionizing radiation, excluded methods, and synthetic solvents.

(2) Water Quality Used in Processing. A handler questioned whether public drinking water containing approved levels of chlorine, pursuant to the Safe Drinking Water Act, is acceptable for use in processing products labeled "100 percent organic." Water meeting the Safe Drinking Water Act may be used in processing any organically produced products.

Temporary Variances - Changes Based on Comments

Additional Causes for Issuing Temporary Variance. A few State department of agriculture commenters suggested that "drought" should be added to the regulatory text as a natural disaster warranting a temporary variance from regulations.

We agree and have added drought to the regulatory text in paragraph (a)(2) of section 205.290. We have also added "hail" as a natural disaster warranting a temporary variance. Both drought

and hail were mentioned in the preamble of the proposed rule but were unintentionally left out of the regulatory text.

Temporary Variances - Changes Requested But Not Made

Allowance of Temporary Variances. A few commenters suggested that SOP's governing State officials should be able to authorize temporary variances due to local natural disasters which may occur in a State. We do not agree that with these comments. For consistency of application, we believe that only the Administrator should have the authority to grant a temporary variance. Citing local conditions, an SOP's governing State official and certifying agents may recommend a temporary variance to the Administrator. We are committed to providing quick responses to such recommendations.