



FSMA

Food Safety Modernization Act (FSMA)



Cornell University

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 112

Foods, Fruits and vegetables, Incorporation by reference, Packaging and containers, Recordkeeping requirements, Safety.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 11, 16, and 112 are amended as follows:

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 1. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262.

■ 2. In § 11.1, add paragraph (k) to read as follows:

§ 11.1 Scope.

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(k) This part does not apply to records required to be established or maintained by part 112 of this chapter. Records that satisfy the requirements of part 112 of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

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PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

■ 3. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

■ 4. Amend § 16.1 by:

■ a. In paragraph (b)(1), adding an entry in numerical order.

■ b. In paragraph (b)(2), adding an entry in numerical order.

The additions read as follows:

§ 16.1 Scope.

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(b) * * *

(1) * * *

Section 419(c)(2)(D) of the Federal Food, Drug, and Cosmetic Act relating to the modification or revocation of a variance from the requirements of section 419 (see part 112, subpart P of this chapter).

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(2) * * *

§§ 112.201 through 112.213, (see part 112, subpart R of this chapter), relating to withdrawal of a qualified exemption.

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■ 5. Add part 112 to read as follows:

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION**Subpart A—General Provisions**

Sec.

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Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

Subpart A—General Provisions**§ 112.1 What food is covered by this part?**

(a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:

(1) Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and unqi fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell

and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

§ 112.2 What produce is not covered by this part?

(a) The following produce is not covered by this part:

(1) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list: Asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.

(2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and

(3) Produce that is not a raw agricultural commodity.

(b) Produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (2), and (3) of this section) under the following conditions:

(1) The produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of part 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining, distilling, or otherwise manufacturing/processing produce into products such as sugar, oil, spirits, wine, beer or similar products; and

(2) You must disclose in documents accompanying the produce, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of

microorganisms of public health significance;” and

(3) You must either:

(i) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from the customer that performs the commercial processing described in paragraph (b)(1) of this section that the customer has established and is following procedures (identified in the written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(ii) Annually obtain written assurance, subject to the requirements of paragraph (b)(6) of this section, from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in paragraph (b)(1) of this section and that the customer:

(A) Will disclose in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(B) Will only sell to another entity that agrees, in writing, it will either:

(1) Follow procedures (identified in a written assurance) that adequately reduce the presence of microorganisms of public health significance; or

(2) Obtain a similar written assurance from its customer that the produce will receive commercial processing described in paragraph (b)(1) of this section, and that there will be disclosure in documents accompanying the food, in accordance with the practice of the trade, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and

(4) You must establish and maintain documentation of your compliance with applicable requirements in paragraphs (b)(2) and (3) in accordance with the requirements of subpart O of this part, including:

(i) Documents containing disclosures required under paragraph (b)(2) of this section; and

(ii) Annual written assurances obtained from customers required under paragraph (b)(3) of this section; and

(5) The requirements of this subpart and subpart Q of this part apply to such produce; and

(6) An entity that provides a written assurance under § 112.2(b)(3)(i) or (ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance.

§ 112.3 What definitions apply to this part?

(a) The definitions and interpretations of terms in section 201 of the Federal

Food, Drug, and Cosmetic Act apply to such terms when used in this part.

(b) For the purpose of this part, the following definitions of very small business and small business also apply:

(1) *Very small business.* For the purpose of this part, your farm is a very small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$250,000.

(2) *Small business.* For the purpose of this part, your farm is a small business if it is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in paragraph (c) of this section) you sold during the previous 3-year period is no more than \$500,000; and your farm is not a very small business as provided in paragraph (b)(1) of this section.

(c) For the purpose of this part, the following definitions also apply:

Adequate means that which is needed to accomplish the intended purpose in keeping with good public health practice.

Adequately reduce microorganisms of public health significance means reduce the presence of such microorganisms to an extent sufficient to prevent illness.

Agricultural tea means a water extract of biological materials (such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application. Agricultural teas are soil amendments for the purposes of this rule.

Agricultural tea additive means a nutrient source (such as molasses, yeast extract, or algal powder) added to agricultural tea to increase microbial biomass.

Agricultural water means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce).

Animal excreta means solid or liquid animal waste.

Application interval means the time interval between application of an agricultural input (such as a biological soil amendment of animal origin) to a growing area and harvest of covered produce from the growing area where the agricultural input was applied.

Biological soil amendment means any soil amendment containing biological materials such as stabilized compost, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea, or yard trimmings, alone or in combination.

Biological soil amendment of animal origin means a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term "biological soil amendment of animal origin" does not include any form of human waste.

Composting means a process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3 days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

Covered activity means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of "farm" as defined in this chapter. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in § 112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

Covered produce means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term "covered produce" refers to the harvestable or harvested part of the crop.

Curing means the final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may

or may not involve insulation, depending on environmental conditions.

Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water.

Farm means:

(i) *Primary Production Farm.* A

Primary Production Farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities. The term "farm" includes operations that, in addition to these activities:

(A) Pack or hold raw agricultural commodities;

(B) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (i)(C)(2)(i) of this definition; and

(C) Manufacture/process food, provided that:

(1) All food used in such activities is consumed on that farm or another farm under the same management; or

(2) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same management consists only of:

(i) Drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), and packaging and labeling such commodities, without additional manufacturing/processing (an example of additional manufacturing/processing is slicing);

(ii) Treatment to manipulate the ripening of raw agricultural commodities (such as by treating produce with ethylene gas), and packaging and labeling treated raw agricultural commodities, without additional manufacturing/processing; and

(iii) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing (an example of additional manufacturing/processing is irradiation); or

(ii) *Secondary Activities Farm.* A Secondary Activities Farm is an operation, not located on a Primary Production Farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the Primary

Production Farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the Secondary Activities Farm owns, or jointly owns, a majority interest in the Secondary Activities Farm. A Secondary Activities Farm may also conduct those additional activities allowed on a Primary Production Farm in paragraphs (i)(B) and (C) of this definition.

Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.

Food contact surfaces means those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operations. "Food contact surfaces" includes food contact surfaces of equipment and tools used during harvest, packing and holding.

Ground water means the supply of fresh water found beneath the Earth's surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water.

Growth media means material that acts as a substrate during the growth of covered produce (such as mushrooms and some sprouts) that contains, may contain, or consists of components that may include any animal waste (such as stabilized compost, manure, non-fecal animal byproducts or table waste).

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed on farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. Harvesting is limited to activities performed on raw agricultural commodities, or on processed foods created by drying/dehydrating a raw agricultural commodity without additional manufacturing/processing, on a farm. Harvesting does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Examples of harvesting include cutting (or otherwise separating) the edible portion of the raw agricultural commodity from the crop plant and removing or trimming part of the raw agricultural commodity (e.g., foliage, husks, roots or stems). Examples of harvesting also include cooling, field coring, filtering, gathering, hulling, removing stems and husks from, shelling, sifting, threshing, trimming of outer leaves of, and washing raw

agricultural commodities grown on a farm.

Hazard means any biological agent that has the potential to cause illness or injury in the absence of its control.

Holding means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa)). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Known or reasonably foreseeable hazard means a biological hazard that is known to be, or has the potential to be, associated with the farm or the food.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities include: Baking, boiling, bottling, canning, cooking, cooling, cutting, distilling, drying/dehydrating raw agricultural commodities to create a distinct commodity (such as drying/dehydrating grapes to produce raisins), evaporating, viscerating, extracting juice, formulating, freezing, grinding, homogenizing, labeling, milling, mixing, packaging (including modified atmosphere packaging), pasteurizing, peeling, rendering, treating to manipulate ripening, trimming, washing, or waxing. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Manure means animal excreta, alone or in combination with litter (such as straw and feathers used for animal bedding) for use as a soil amendment.

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term "undesirable microorganisms" includes those microorganisms that are of public health

significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Mixed-type facility means an establishment that engages in both activities that are exempt from registration under section 415 of the Federal Food, Drug, and Cosmetic Act and activities that require the establishment to be registered. An example of such a facility is a "farm mixed-type facility," which is an establishment that is a farm, but that also conducts activities outside the farm definition that require the establishment to be registered.

Monitor means to conduct a planned sequence of observations or measurements to assess whether a process, point or procedure is under control and, when required, to produce an accurate record of the observation or measurement.

Non-fecal animal byproduct means solid waste (other than manure) that is animal in origin (such as meat, fat, dairy products, eggs, carcasses, blood meal, bone meal, fish meal, shellfish waste (such as crab, shrimp, and lobster waste), fish emulsions, and offal) and is generated by commercial, institutional, or agricultural operations.

Packing means placing food into a container other than packaging the food and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or repacking)), but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

Pest means any objectionable animals or insects, including birds, rodents, flies, and larvae.

Pre-consumer vegetative waste means solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or

corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts, and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange, and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are primarily grown and processed for use as meal, flour, baked goods, cereals and oils rather than for direct consumption as small, hard fruits or seeds (including cereal grains, pseudo cereals, oilseeds and other plants used in the same fashion). Examples of food grains include barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g., cotton seed, flax seed, rapeseed, soybean, and sunflower seed).

Production batch of sprouts means all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

Qualified end-user, with respect to a food, means the consumer of the food (where the term consumer does not include a business); or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located:

- (i) In the same State or the same Indian reservation as the farm that produced the food; or
- (ii) Not more than 275 miles from such farm.

Raw agricultural commodity (RAC) means "raw agricultural commodity" as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.

Sanitize means to adequately treat cleaned surfaces by a process that is

effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Sewage sludge biosolids means the solid or semi-solid residue generated during the treatment of domestic sewage in a treatment works within the meaning of the definition of "sewage sludge" in 40 CFR 503.9(w).

Soil amendment means any chemical, biological, or physical material (such as elemental fertilizers, stabilized compost, manure, non-fecal animal byproducts, peat moss, perlite, pre-consumer vegetative waste, sewage sludge biosolids, table waste, agricultural tea and yard trimmings) intentionally added to the soil to improve the chemical or physical condition of soil in relation to plant growth or to improve the capacity of the soil to hold water. The term soil amendment also includes growth media that serve as the entire substrate during the growth of covered produce (such as mushrooms and some sprouts).

Spent sprout irrigation water means water that has been used in the growing of sprouts.

Stabilized compost means a stabilized (i.e., finished) biological soil amendment produced through a controlled composting process.

Static composting means a process to produce stabilized compost in which air is introduced into biological material (in a pile (or row) that may or may not be covered with insulating material, or in an enclosed vessel) by a mechanism that does not include turning. Examples of structural features for introducing air include embedded perforated pipes and a constructed permanent base that includes aeration slots. Examples of mechanisms for introducing air include passive diffusion and mechanical means (such as blowers that suction air from the composting material or blow air into the composting material using positive pressure).

Surface water means all water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water.

Table waste means any post-consumer food waste, irrespective of whether the source material is animal or vegetative in origin, derived from individuals, institutions, restaurants, retail operations, or other sources where the food has been served to a consumer.

Turned composting means a process to produce stabilized compost in which

air is introduced into biological material (in a pile, row, or enclosed vessel) by turning on a regular basis. Turning is the process of mechanically mixing biological material that is undergoing a composting process with the specific intention of moving the outer, cooler sections of the material being composted to the inner, hotter sections.

Visitor means any person (other than personnel) who enters your covered farm with your permission.

Water distribution system means a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings.

We means the U.S. Food and Drug Administration (FDA).

Yard trimmings means purely vegetative matter resulting from landscaping maintenance or land clearing operations, including materials such as tree and shrub trimmings, grass clippings, palm fronds, trees, tree stumps, untreated lumber, untreated wooden pallets, and associated rocks and soils.

You, for purposes of this part, means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of this part.

§ 112.4 Which farms are subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, a farm or farm mixed-type facility with an average annual monetary value of produce (as "produce" is defined in § 112.3(c)) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), adjusted for inflation using 2011 as the baseline year for calculating the adjustment, is a "covered farm" subject to this part. Covered farms subject to this part must comply with all applicable requirements of this part when conducting a covered activity on covered produce.

(b) A farm is not a covered farm if it satisfies the requirements in § 112.5 and we have not withdrawn the farm's exemption in accordance with the requirements of subpart R of this part.

§ 112.5 Which farms are eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?

(a) A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3(c)) the farm sold directly to qualified end-users

(as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food the farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3(c)) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.

(b) For the purpose of determining whether the average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

§ 112.6 What modified requirements apply to me if my farm is eligible for a qualified exemption in accordance with § 112.5?

(a) If your farm is eligible for a qualified exemption in accordance with § 112.5, you are subject to the requirements of:

- (1) This subpart (General Provisions);
- (2) Subpart O of this part (Records);
- (3) Subpart Q of this part (Compliance and Enforcement); and
- (4) Subpart R of this part (Withdrawal of Qualified Exemption).

(b) In addition, you are subject to the following modified requirements:

(1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.

(2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

(3) The complete business address that you must include in accordance with the requirements of paragraph (b)(1) or (2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

§ 112.7 What records must I establish and keep if my farm is eligible for a qualified exemption in accordance with § 112.5?

If your farm is eligible for a qualified exemption in accordance with § 112.5:

(a) You must establish and keep records required under this provision in accordance with the requirements of subpart O of this part, except that the requirement in § 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Such receipts must be dated as required under § 112.161(a)(4).

(b) You must establish and keep adequate records necessary to demonstrate that your farm satisfies the criteria for a qualified exemption that are described in § 112.5, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption.

Subpart B—General Requirements**§ 112.11 What general requirements apply to persons who are subject to this part?**

You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act on account of such hazards.

§ 112.12 Are there any alternatives to the requirements established in this part?

(a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.49, provided that you satisfy the requirements of paragraphs (b) and (c) of this section.

(b) You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions.

(c) Scientific data and information used to support an alternative to a requirement specified in paragraph (a)

of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in accordance with the requirements of subpart O of this part. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.

Subpart C—Personnel Qualifications and Training**§ 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?**

All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:

(a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually.

(b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a combination of education, training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part.

(c) Training must be conducted in a manner that is easily understood by personnel being trained.

(d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.

§ 112.22 What minimum requirements apply for training personnel who conduct a covered activity?

(a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the conduct of such activities must receive training that includes all of the following:

(1) Principles of food hygiene and food safety;

(2) The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is

reasonably likely to result in contamination of covered produce or food contact surfaces with microorganisms of public health significance; and

(3) The standards established by FDA in subparts C through O of this part that are applicable to the employee's job responsibilities.

(b) Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:

(1) Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;

(2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and

(3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person's job responsibilities.

(c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.

§ 112.23 What requirements apply regarding supervisors?

You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of this part.

§ 112.30 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.

Subpart D—Health and Hygiene**§ 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?**

(a) You must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an

applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).

(b) The measures you must take to satisfy the requirements of paragraph (a) of this section must include all of the following measures:

(1) Excluding any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person (by medical examination, the person's acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person's health condition no longer presents a risk to public health; and

(2) Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.

§ 112.32 What hygienic practices must personnel use?

(a) Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination.

(b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices:

(1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;

(2) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;

(3) Washing hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices:

- (i) Before starting work;
- (ii) Before putting on gloves;
- (iii) After using the toilet;

(iv) Upon return to the work station after any break or other absence from the work station;

(v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and

(vi) At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards;

(4) If you choose to use gloves in handling covered produce or food contact surfaces, maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so;

(5) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and

(6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas).

§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?

(a) You must make visitors aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures.

(b) You must make toilet and hand-washing facilities accessible to visitors.

Subpart E—Agricultural Water

§ 112.41 What requirements apply to the quality of agricultural water?

All agricultural water must be safe and of adequate sanitary quality for its intended use.

§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?

(a) At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:

(1) The nature of each agricultural water source (for example, ground water or surface water);

(2) The extent of your control over each agricultural water source;

(3) The degree of protection of each agricultural water source;

(4) Use of adjacent and nearby land; and

(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.

(b) You must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.

(c) You must adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

(d) As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.

§ 112.43 What requirements apply to treating agricultural water?

(a) When agricultural water is treated in accordance with § 112.45:

(1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet

the relevant microbial quality criteria in § 112.44, as applicable.

(2) You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.

(b) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.

§ 112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?

(a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:

(1) Used as sprout irrigation water;

(2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;

(3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and

(4) Used for washing hands during and after harvest activities.

(b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49):

(1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and

(2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic *E. coli* per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).

§ 112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?

(a) If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44(a), you must immediately discontinue that use(s), and before you may use the water source and/or distribution system again for the intended use(s), you must either:

(1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or

(2) Treat the water in accordance with the requirements of § 112.43.

(b) If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either:

(1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:

(i) Applying a time interval between last irrigation and harvest using either:

(A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your geometric mean (GM) and statistical threshold value (STV) to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of 4 consecutive days; or

(B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or

(ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate

supporting scientific data and information;

(2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or

(3) Treat the water in accordance with the requirements of § 112.43.

§ 112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?

(a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:

(1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR 141.2) approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;

(2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or

(3) You treat water in accordance with the requirements of § 112.43.

(b) Except as provided in paragraph (a) of this section, you must take the following steps for each source of water used for purposes that are subject to the requirements of § 112.44(b):

(1) Conduct an initial survey to develop a microbial water quality profile of the agricultural water source.

(i) The initial survey must be conducted:

(A) For an untreated surface water source, by taking a minimum total of 20 samples of agricultural water (or an alternative testing frequency that you establish and use, in accordance with § 112.49) over a minimum period of 2 years, but not greater than 4 years.

(B) For an untreated ground water source, by taking a minimum total of four samples of agricultural water during the growing season or over a period of 1 year.

(ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. The microbial water quality profile initially consists of the geometric mean (GM) and the statistical threshold value (STV) of generic *Escherichia coli* (*E. coli*) (colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. You must determine the appropriate way(s) in which the water may be used based on your microbial water quality profile in accordance with § 112.45(b).

(iii) You must update the microbial water quality profile annually as required under paragraph (b)(2) of this section, and otherwise required under paragraph (b)(3) of this section.

(2) Conduct an annual survey to update the microbial water quality profile of your agricultural water.

(i) After the initial survey described in paragraph (b)(1)(i) of this section, you must test the water annually to update your existing microbial water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze:

(A) For an untreated surface water source, a minimum number of five samples per year (or an alternative testing frequency that you establish and use, in accordance with § 112.49).

(B) For an untreated ground water source, a minimum of one sample per year.

(ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest.

(iii) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual survey data from within the previous 4 years, to make up a rolling data set of:

(A) At least 20 samples for untreated surface water sources; and

(B) At least 4 samples for untreated ground water sources.

(iv) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with § 112.45(b).

(3) If you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you must develop a new microbial water quality profile reflective of the time period at which

you believe your microbial water quality profile changed.

(i) To develop a new microbial water quality profile, you must calculate new GM and STV values using your current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of:

(A) At least 20 samples for untreated surface water sources; and

(B) At least 4 samples for untreated ground water sources.

(ii) You must modify your water use based on the new GM and STV values in your new microbial water quality profile in accordance with § 112.45(b).

(c) If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you must initially test the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected to be representative of the intended use(s). Based on these results, you must determine whether the water can be used for that purpose, in accordance with § 112.45(a). If your four initial sample results meet the microbial quality criteria of § 112.44(a), you may test once annually thereafter, using a minimum of one sample collected to be representative of the intended use(s). You must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criteria in § 112.44(a).

§ 112.47 Who must perform the tests required under § 112.46 and what methods must be used?

(a) You may meet the requirements related to agricultural water testing required under § 112.46 using:

(1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or

(2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.

(b) Agricultural water samples must be aseptically collected and tested using a method as set forth in § 112.151.

§ 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?

(a) You must manage the water as necessary, including by establishing and following water-change schedules for recirculated water, to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and

food contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).

(b) You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for buildup of organic material (such as soil and plant debris).

(c) You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

§ 112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

Provided you satisfy the requirements of § 112.12, you may establish and use one or more of the following alternatives:

(a) An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b);

(b) An alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i);

(c) An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A); and

(d) An alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A).

§ 112.50 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records:

(1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a);

(2) Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with this subpart;

(3) Scientific data or information you rely on to support the adequacy of a

method used to satisfy the requirements of § 112.43(a)(1) and (2);

(4) Documentation of the results of water treatment monitoring under § 112.43(b);

(5) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that you used to determine the time interval (in days) between harvest and end of storage, including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic *Escherichia coli* (*E. coli*), in accordance with § 112.45(b)(1)(ii);

(6) Documentation of actions you take in accordance with § 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (ii), such documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing;

(7) Annual documentation of the results or certificates of compliance from a public water system required under § 112.46(a)(1) or (2), if applicable;

(8) Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49; and

(9) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).

Subpart F—Biological Soil Amendments of Animal Origin and Human Waste

§ 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?

(a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable

generic *Escherichia coli* (*E. coli*) in 100 milliliters (mL) of water.

(b) A biological soil amendment of animal origin is untreated if it:

(1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic *E. coli* in 100 mL of water;

(2) Has become contaminated after treatment;

(3) Has been recombined with an untreated biological soil amendment of animal origin;

(4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or

(5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?

(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.

(b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.

(c) You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated.

§ 112.53 What prohibitions apply regarding use of human waste?

You may not use human waste for growing covered produce, except sewage sludge biosolids used in

accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.

§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?

Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:

(a) A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting), or a combination of scientifically valid controlled physical, chemical and/or biological processes that has been validated to satisfy the microbial standard in § 112.55(a) for *Listeria monocytogenes* (*L. monocytogenes*), *Salmonella* species, and *E. coli* O157:H7; or

(b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for *Salmonella* species and fecal coliforms. Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:

(1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and

(2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

§ 112.55 What microbial standards apply to the treatment processes in § 112.54?

The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.

(a) For *L. monocytogenes*, *Salmonella* species, and *E. coli* O157:H7, the relevant standards in the table in this paragraph (a); or

For the microorganism—	The microbial standard is—
(1) <i>L. monocytogenes</i>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.

For the microorganism—	The microbial standard is—
(2) <i>Salmonella</i> species	Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or milliliter, if liquid is being sampled) of total solids.
(3) <i>E. coli</i> O157:H7	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.

(b) *Salmonella* species are not detected using a method that can detect three MPN *Salmonella* species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?

(a) You must apply the biological soil amendments of animal origin specified in the first column of the table in this

paragraph (a) in accordance with the application requirements specified in the second column of the table in this paragraph (a) and the minimum application intervals specified in the third column of the table in this paragraph (a).

If the biological soil amendment of animal origin is—	Then the biological soil amendment of animal origin must be applied—	And then the minimum application interval is—
(1)(i) Untreated	In a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.	[Reserved].
(ii) Untreated	In a manner that does not contact covered produce during or after application.	0 days.
(2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b).	In a manner that minimizes the potential for contact with covered produce during and after application.	0 days.
(3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a).	In any manner (<i>i.e.</i> , no restrictions)	0 days.

(b) [Reserved]

§ 112.60 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:

(1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that:

(i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and

(ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and

(2) For a treated biological soil amendment of animal origin you

produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.

Subpart G–H [Reserved]

Subpart I—Domesticated and Wild Animals

§ 112.81 How do the requirements of this subpart apply to areas where covered activities take place?

(a) The requirements of this subpart apply when a covered activity takes place in an outdoor area or a partially-enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.

(b) The requirements of this subpart do not apply:

(1) When a covered activity takes place in a fully-enclosed building; or

(2) To fish used in aquaculture operations.

§ 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?

(a) You must take the steps set forth in paragraph (b) of this section if under

the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.

(b) You must:

(1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and

(2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.

§ 112.84 Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?

No. Nothing in this regulation authorizes the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531–1544) (*i.e.*, to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

Subpart J—[Reserved]

Subpart K—Growing, Harvesting, Packing, and Holding Activities

§ 112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?

If you grow, harvest, pack or hold produce that is not covered in this part (*i.e.*, excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:

(a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and

(b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.

§ 112.112 What measures must I take immediately prior to and during harvest activities?

You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the

growing area and all covered produce to be harvested, regardless of the harvest method used.

§ 112.113 How must I handle harvested covered produce during covered activities?

You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards—for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil.

§ 112.114 What requirements apply to dropped covered produce?

You must not distribute dropped covered produce. Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).

§ 112.115 What measures must I take when packaging covered produce?

You must package covered produce in a manner that prevents the formation of *Clostridium botulinum* toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).

§ 112.116 What measures must I take when using food-packing (including food packaging) material?

(a) You must use food-packing material that is adequate for its intended use, which includes being:

(1) Cleanable or designed for single use; and

(2) Unlikely to support growth or transfer of bacteria.

(b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.

Subpart L—Equipment, Tools, Buildings, and Sanitation

§ 112.121 What equipment and tools are subject to the requirements of this subpart?

Equipment and tools subject to the requirements of this subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance. Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment,

palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

§ 112.122 What buildings are subject to the requirements of this subpart?

Buildings subject to the requirements of this subpart include:

(a) Any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and

(b) Storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).

§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart?

All of the following requirements apply regarding equipment and tools subject to this subpart:

(a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and

(b) Equipment and tools must be:

(1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and

(2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.

(c) Seams on food contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.

(d)(1) You must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.

(2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.

(e) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must

do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards.

§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?

Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be:

- (a) Accurate and precise as necessary and appropriate in keeping with their purpose;
- (b) Adequately maintained; and
- (c) Adequate in number for their designated uses.

§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?

Equipment that is subject to this subpart that you use to transport covered produce must be:

- (a) Adequately clean before use in transporting covered produce; and
- (b) Adequate for use in transporting covered produce.

§ 112.126 What requirements apply to my buildings?

(a) All of the following requirements apply regarding buildings:

(1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must:

- (i) Provide sufficient space for placement of equipment and storage of materials;
- (ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and

(2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.

(b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in

your buildings, as appropriate, considering the potential for such contamination through:

- (1) Floors, walls, ceilings, fixtures, ducts, or pipes; and
- (2) Drip or condensate.

§ 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?

(a) You must take reasonable precautions to prevent contamination of covered produce, food contact surfaces, and food-packing materials in fully-enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:

- (1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed; or
- (2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.

(b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials.

§ 112.128 What requirements apply regarding pest control in buildings?

(a) You must take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.

(b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.

(c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).

§ 112.129 What requirements apply to toilet facilities?

All of the following requirements apply to toilet facilities:

(a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.

(b) Your toilet facilities must be designed, located, and maintained to:

- (1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;
- (2) Be directly accessible for servicing, be serviced and cleaned at a frequency

sufficient to ensure suitability of use, and be kept supplied with toilet paper; and

(3) Provide for the sanitary disposal of waste and toilet paper.

(c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.

§ 112.130 What requirements apply for hand-washing facilities?

All of the following requirements apply to hand-washing facilities:

(a) You must provide personnel with adequate, readily accessible hand-washing facilities during growing activities that take place in a fully-enclosed building, and during covered harvest, packing, or holding activities.

(b) Your hand-washing facilities must be furnished with:

- (1) Soap (or other effective surfactant);
- (2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and
- (3) Adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers).

(c) You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a hand-washing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(d) You may not use antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.

§ 112.131 What must I do to control and dispose of sewage?

All of the following requirements apply for the control and disposal of sewage:

(a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.

(b) You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of

covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

(d) After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

§ 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?

All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:

(a) You must convey, store, and dispose of trash, litter and waste to:

(1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and

(2) Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.

(b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.

§ 112.133 What requirements apply to plumbing?

The plumbing must be of an adequate size and design and be adequately installed and maintained to:

(a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for hand-washing and toilet facilities;

(b) Properly convey sewage and liquid disposable waste;

(c) Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources; and

(d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.

§ 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?

(a) If you have domesticated animals, to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must:

(1) Adequately control their excreta and litter; and

(2) Maintain a system for control of animal excreta and litter.

(b) [Reserved]

§ 112.140 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in:

(1) Growing operations for sprouts; and

(2) Covered harvesting, packing, or holding activities.

Subpart M—Sprouts

§ 112.141 What commodities are subject to this subpart?

The requirements of this subpart apply to growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots.

§ 112.142 What requirements apply to seeds or beans used to grow sprouts?

In addition to the requirements of this part, all of the following requirements apply to seeds or beans used to grow sprouts.

(a) You must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.

(b) Except as provided in paragraph (c) of this section, if you know or have reason to believe that a lot of seeds or beans may be contaminated with a pathogen (either because it has been associated with foodborne illness; or based on microbial test results, including a positive finding of a pathogen in tests required under § 112.144(b)), you must:

(1) Discontinue use of all seeds or beans from that lot for sprout production and ensure that sprouts grown from that lot of seeds or beans do not enter commerce; and

(2) Report the information (association with illness and/or findings of microbial testing) to the seed grower,

distributor, supplier, or other entity from whom you received the seeds or beans.

(c) If your reason to believe that a lot of seeds or beans may be contaminated was based only on microbial test results:

(1) You are not required to take the steps set forth in paragraph (b)(1) of this section if you treat your lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans; or

(2) You are not required to take the steps set forth in paragraphs (b)(1) and (2) of this section if you later reasonably determine, through appropriate followup actions, that the lot of seeds or beans is not the source of contamination (e.g., the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts).

(d) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards.

(e) You must either:

(1) Treat seeds or beans that will be used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance; or

(2) Rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment of the seeds or beans at the covered farm immediately before sprouting), provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that:

(i) The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and

(ii) The treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination.

§ 112.143 What measures must I take for growing, harvesting, packing, and holding sprouts?

You must take all of the following measures for growing, harvesting, packing, and holding sprouts:

(a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building.

(b) Any food contact surfaces you use to grow, harvest, pack, or hold sprouts must be cleaned and sanitized before

contact with sprouts or seeds or beans used to grow sprouts.

(c) You must conduct testing during growing, harvesting, packing, and holding sprouts, as specified in § 112.144.

(d) You must establish and implement a written environmental monitoring plan as specified in § 112.145.

(e) You must take certain actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment, as specified in § 112.146.

(f) You must establish and implement a written sampling plan to test spent sprout irrigation water or sprouts for pathogens as specified in § 112.147.

(g) You must take certain actions if the samples of spent sprout irrigation water or sprouts test positive for a pathogen as specified in § 112.148.

§ 112.144 What testing must I do during growing, harvesting, packing, and holding sprouts?

All of the following testing must be done during growing, harvesting, packing, and holding sprouts:

(a) You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* in accordance with the requirements of § 112.145.

(b) You must either:

(1) Test spent sprout irrigation water from each production batch of sprouts for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147; or

(2) If testing spent sprout irrigation water is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), test each production batch of sprouts at the in-process stage (*i.e.*, while sprouts are still growing) for *E. coli* O157:H7, *Salmonella* species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147.

(c) In addition to *E. coli* O157:H7 and *Salmonella* species, you must conduct tests as provided in paragraph (b) of this section for additional pathogens when the following conditions are met:

(1) Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and

(2) A scientifically valid test method for the pathogen is available to detect the pathogen in spent sprout irrigation water (or sprouts).

§ 112.145 What requirements apply to testing the environment for *Listeria* species or *L. monocytogenes*?

All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes*.

(a) You must establish and implement a written environmental monitoring plan that is designed to identify *L. monocytogenes* if it is present in the growing, harvesting, packing, or holding environment.

(b) Your written environmental monitoring plan must be directed to sampling and testing for either *Listeria* species or *L. monocytogenes*.

(c) Your written environmental monitoring plan must include a sampling plan that specifies:

(1) What you will test collected samples for (*i.e.*, *Listeria* species or *L. monocytogenes*);

(2) How often you will collect environmental samples, which must be no less than monthly, and at what point during production you will collect the samples; and

(3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment.

(d) You must aseptically collect environmental samples and test them for *Listeria* species or *L. monocytogenes* using a method as set forth in § 112.152.

(e) Your written environmental monitoring plan must include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*.

§ 112.146 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for *Listeria* species or *L. monocytogenes*?

You must, at a minimum, take the following actions if you detect *Listeria* species or *L. monocytogenes* in the growing, harvesting, packing, or holding environment:

(a) Conduct additional testing of surfaces and areas surrounding the area where *Listeria* species or *L. monocytogenes* was detected to evaluate the extent of the problem, including the potential for *Listeria* species or *L. monocytogenes* to have become established in a niche;

(b) Clean and sanitize the affected surfaces and surrounding areas;

(c) Conduct additional sampling and testing to determine whether the *Listeria* species or *L. monocytogenes* has been eliminated;

(d) Conduct finished product testing when appropriate;

(e) Perform any other actions necessary to prevent recurrence of the contamination; and

(f) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce.

§ 112.147 What must I do to collect and test samples of spent sprout irrigation water or sprouts for pathogens?

All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts for pathogens as required in § 112.144(b):

(a) You must establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination.

(b) In accordance with the written sampling plan required under paragraph (a) of this section, you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for pathogens using a method as set forth in § 112.153. You must not allow the production batch of sprouts to enter into commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for *E. coli* O157:H7, *Salmonella* species, and, if applicable, a pathogen meeting the criteria in § 112.144(c).

(c) Your written sampling plan must include a corrective action plan that at a minimum, requires you to take the actions in § 112.148, and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in § 112.144(c).

§ 112.148 What actions must I take if the samples of spent sprout irrigation water or sprouts test positive for a pathogen?

You must, at a minimum, take the following actions if the samples of spent sprout irrigation water or sprouts test positive for *E. coli* O157:H7, *Salmonella* species, or a pathogen meeting the criteria in § 112.144(c):

(a) Take appropriate action to prevent any food that is adulterated under

section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce;

(b) Take the steps required in § 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under § 112.142(c));

(c) Clean and sanitize the affected surfaces and surrounding areas; and

(d) Perform any other actions necessary to prevent reoccurrence of the contamination.

§ 112.150 Under this subpart, what requirements apply regarding records?

(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.

(b) You must establish and keep the following records:

(1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of § 112.142(e);

(2) Your written environmental monitoring plan in accordance with the requirements of § 112.145;

(3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of § 112.147(a) and (c);

(4) Documentation of the results of all analytical tests conducted for purposes of compliance with this subpart;

(5) Any analytical methods you use in lieu of the methods that are incorporated by reference in §§ 112.152 and 112.153; and

(6) Documentation of actions you take in accordance with §§ 112.142(b) and (c), 112.146, and 112.148.

Subpart N—Analytical Methods

§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46?

You must test the quality of water using:

(a) The method of analysis published by the U.S. Environmental Protection Agency (EPA), “Method 1603: *Escherichia coli* (*E. coli*) in Water by Membrane Filtration Using Modified membrane-Thermotolerant *Escherichia coli* Agar (Modified mTEC), EPA-821-R-09-007,” December, 2009. The Director of the Federal Register approves this incorporation by reference

in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from EPA, Office of Water (4303T), 1200 Pennsylvania Avenue NW., Washington, DC 20460. You may inspect a copy at FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html; or

(b)(1) A scientifically valid method that is at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity; or

(2) For any other indicator of fecal contamination you may test for pursuant to § 112.49(a), a scientifically valid method.

§ 112.152 What methods must I use to test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of § 112.144(a)?

You must test the growing, harvesting, packing, and holding environment for *Listeria* species or *L. monocytogenes* using:

(a) The method of analysis described in “Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples,” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039; <http://www.fda.gov/fsma>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(b) A scientifically valid method that is at least equivalent to the method of analysis in § 112.152(a) in accuracy, precision, and sensitivity.

§ 112.153 What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?

You must test spent sprout irrigation water (or sprouts) from each production batch for pathogens using:

(a) For *E. coli* O157:H7, *Salmonella* species:

(1) The method of analysis described in “Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts),” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1600; FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039; <http://www.fda.gov/fsma>; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(2) A scientifically valid method that is at least equivalent to the method of analysis in § 112.153(a)(1) in accuracy, precision, and sensitivity; and

(b) For any other pathogen(s) meeting the criteria in § 112.144(c), a scientifically valid method.

Subpart O—Records

§ 112.161 What general requirements apply to records required under this part?

(a) Except as otherwise specified, all records required under this part must:

(1) Include, as applicable:

(i) The name and location of your farm;

(ii) Actual values and observations obtained during monitoring;

(iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;

(iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and

(v) The date and time of the activity documented;

(2) Be created at the time an activity is performed or observed;

(3) Be accurate, legible, and indelible; and

(4) Be dated, and signed or initialed by the person who performed the activity documented.

(b) Records required under §§ 112.7(b), 112.30(b)(2), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

§ 112.162 Where must I store records?

(a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.

(b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.

§ 112.163 May I use existing records to satisfy the requirements of this part?

(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part.

(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.

§ 112.164 How long must I keep records?

(a)(1) You must keep records required by this part for at least 2 years past the date the record was created.

(2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year.

(b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.

§ 112.165 What formats are acceptable for the records I keep?

You must keep records as:

(a) Original records;

(b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or

(c) Electronic records. Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.

§ 112.166 What requirements apply for making records available and accessible to FDA?

(a) You must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.

(b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible.

(c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.

§ 112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?

Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.

Subpart P—Variances

§ 112.171 Who may request a variance from the requirements of this part?

A State, Federally-recognized tribe (or "tribe"), or a foreign country from which food is imported into the United States may request a variance from one or more requirements of this part, where the State, tribe, or foreign country determines that:

(a) The variance is necessary in light of local growing conditions; and

(b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure

that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.172 How may a State, tribe, or foreign country request a variance from one or more requirements of this part?

To request a variance from one or more requirements of this part, the competent authority (*i.e.*, the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition under § 10.30 of this chapter.

§ 112.173 What must be included in the Statement of Grounds in a petition requesting a variance?

In addition to the requirements set forth in § 10.30 of this chapter, the Statement of Grounds in a petition requesting a variance must:

(a) Provide a statement that the applicable State, tribe, or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part;

(b) Describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of this part to which the variance would apply;

(c) Present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.

§ 112.174 What information submitted in a petition requesting a variance or submitted in comments on such a petition are publicly available?

We will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with this request.

§ 112.175 Who responds to a petition requesting a variance?

The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director, Office of Compliance, CFSAN, responds to a request for a variance.

§ 112.176 What process applies to a petition requesting a variance?

(a) In general, the procedures set forth in § 10.30 of this chapter govern our response to a petition requesting a variance.

(b) Under § 10.30(h)(3) of this chapter, we will publish a notice in the **Federal Register**, requesting information and views on a filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (e.g., because their farm is covered by the petition or as a person similarly situated to persons covered by the petition).

(c) Under § 10.30(e)(3) of this chapter, we will respond to the petitioner in writing and will also make public a notice on FDA's Web site announcing our decision to either grant or deny the petition.

(1) If we grant the petition, either in whole or in part, we will specify the persons to whom the variance applies and the provision(s) of this part to which the variance applies.

(2) If we deny the petition (including partial denials), our written response to the petitioner and our public notice announcing our decision to deny the petition will explain the reason(s) for the denial.

(d) We will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied).

§ 112.177 Can an approved variance apply to any person other than those identified in the petition requesting that variance?

(a) A State, tribe, or a foreign country that believes that a variance requested by a petition submitted by another State, tribe, or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with § 10.30 of this chapter. These comments must include the information required in § 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State, tribe, or foreign country that submitted these comments that a separate request must be submitted in accordance with §§ 112.172 and 112.173.

(b) If we grant a petition requesting a variance, in whole or in part, we may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition.

(c) If we specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, we will inform the applicable State, tribe, or foreign country where the similarly situated persons are located of our decision in writing and will publish a notice on our Web site announcing our decision to apply the variance to similarly situated persons in that particular location.

§ 112.178 Under what circumstances may FDA deny a petition requesting a variance?

We may deny a variance request if it does not provide the information required under § 112.173 (including the requirements of § 10.30 of this chapter), or if we determine that the variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.179 When does a variance approved by FDA become effective?

A variance approved by FDA becomes effective on the date of our written decision on the petition.

§ 112.180 Under what circumstances may FDA modify or revoke an approved variance?

We may modify or revoke a variance if we determine that such variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act and to provide the same level of public health protection as the requirements of this part.

§ 112.181 What procedures apply if FDA determines that an approved variance should be modified or revoked?

(a) We will provide the following notifications:

(1) We will notify a State, tribe, or a foreign country directly, in writing at the address identified in its petition, if we determine that a variance granted in response to its petition should be modified or revoked. Our direct, written notification will provide the State, tribe, or foreign country with an opportunity to request an informal hearing under part 16 of this chapter.

(2) We will publish a notice of our determination that a variance should be modified or revoked in the **Federal Register**. This notice will establish a

public docket so that interested parties may submit written comments on our determination.

(3) When applicable, we will:

(i) Notify in writing any States, tribes, or foreign countries where a variance applies to similarly situated persons of our determination that the variance should be modified or revoked;

(ii) Provide those States, tribes, or foreign countries with an opportunity to request an informal hearing under part 16 of this chapter; and

(iii) Include in the **Federal Register** notice described in paragraph (a)(2) of this section public notification of our decision to modify or revoke the variance granted to States, tribes, or foreign countries in which similarly situated persons are located.

(b) We will consider submissions from affected States, tribes, or foreign countries and from other interested parties as follows:

(1) We will consider requests for hearings by affected States, tribes, or foreign countries under part 16 of this chapter.

(i) If FDA grants a hearing, we will provide the State, tribe, or foreign country with an opportunity to make an oral submission. We will provide notice on our Web site of the hearing, including the time, date, and place of the hearing.

(ii) If more than one State, tribe, or foreign country requests an informal hearing under part 16 of this chapter about our determination that a particular variance should be modified or revoked, we may consolidate such requests (for example, into a single hearing).

(2) We will consider written submissions submitted to the public docket from interested parties.

(c) We will provide notice of our final decision as follows:

(1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter.

(2) We will publish a notice of our decision in the **Federal Register**. The effective date of the decision will be the date of publication of the notice.

§ 112.182 What are the permissible types of variances that may be granted?

A variance(s) may be requested for one or more requirements in subparts A through O of this part. Examples of permissible types of variances include:

(a) Variance from the microbial quality criteria when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method, established in § 112.44(b);

(b) Variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in § 112.45(b)(1)(i); and

(c) Variance from the approach or frequency for testing water used for purposes that are subject to the requirements of § 112.44(b), established in § 112.46(b).

Subpart Q—Compliance and Enforcement

§ 112.192 What is the applicability and status of this part?

(a) The failure to comply with the requirements of this part, issued under section 419 of the Federal Food, Drug, and Cosmetic Act, is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act.

(b) The criteria and definitions in this part apply in determining whether a food is:

(1) Adulterated within the meaning of:

(i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or

(ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health;

or

(2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

§ 112.193 What are the provisions for coordination of education and enforcement?

Under section 419(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act, FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials by helping develop education, training, and enforcement approaches.

Subpart R—Withdrawal of Qualified Exemption

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

(a) We may withdraw your qualified exemption under § 112.5:

(1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or

(2) If we determine that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.

(b) Before FDA issues an order to withdraw your qualified exemption, FDA:

(1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction;

(2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and

(3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption.

§ 112.202 What procedure will FDA use to withdraw an exemption?

(a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued.

(b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with paragraph (a) of this section.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.

§ 112.203 What information must FDA include in an order to withdraw a qualified exemption?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 must include the following information:

(a) The date of the order;

(b) The name, address and location of the farm;

(c) A brief, general statement of the reasons for the order, including

information relevant to one or both of the following circumstances that leads FDA to issue the order:

(1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or

(2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm.

(d) A statement that the farm must either:

(1) Comply with subparts B through O of this part on the date that is 120 calendar days from the date of receipt of the order, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(2) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.

(e) A statement that a farm may request that FDA reinstate an exemption that was withdrawn by following the procedures in § 112.213;

(f) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act and of this subpart;

(g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 112.208;

(h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(i) The name and the title of the FDA representative who approved the order.

§ 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?

The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under § 112.5 must either:

(a) Comply with applicable requirements of this part within 120 calendar days of the date from receipt of the order or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a

timeframe that exceeds 120 calendar days from the date of receipt of the order; or

(b) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of § 112.206.

§ 112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?

(a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order:

(1) The owner, operator, or agent in charge of the farm must comply with applicable requirements of this part within 120 calendar days from the date of receipt of the order, or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and

(2) The owner, operator, or agent in charge of the farm is no longer subject to the modified requirements in §§ 112.6 and 112.7.

§ 112.206 What is the procedure for submitting an appeal?

(a) To appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must:

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 15 calendar days of the date of receipt of the order; and

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.207.

§ 112.207 What is the procedure for requesting an informal hearing?

(a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 15 calendar days of the date of receipt of the order.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial.

§ 112.208 What requirements are applicable to an informal hearing?

If the owner, operator, or agent in charge of the farm requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a) of this chapter, provides notice of the opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 112.209, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented

at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under a regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (2), (3), and (5) of this chapter and 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 112.209 Who is the presiding officer for an appeal and for an informal hearing?

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

§ 112.210 What is the timeframe for issuing a decision on an appeal?

(a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the

presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

§ 112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?

An order to withdraw a qualified exemption applicable to a farm under § 112.5 is revoked if:

(a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

(b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

(c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order

within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

(d) Confirmation of a withdrawal order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702.

§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

(a) If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that the farm has adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or at the request of a farm, reinstate the qualified exemption.

(b) You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of this subpart as follows:

(1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office

of Compliance in the Center for Food Safety and Applied Nutrition); and

(2) Present, in writing, data and information to demonstrate that you have adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

(c) If your qualified exemption was withdrawn under § 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under § 112.5, and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your qualified exemption was withdrawn under § 112.201(a)(1) and (2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of paragraph (b) of this section.

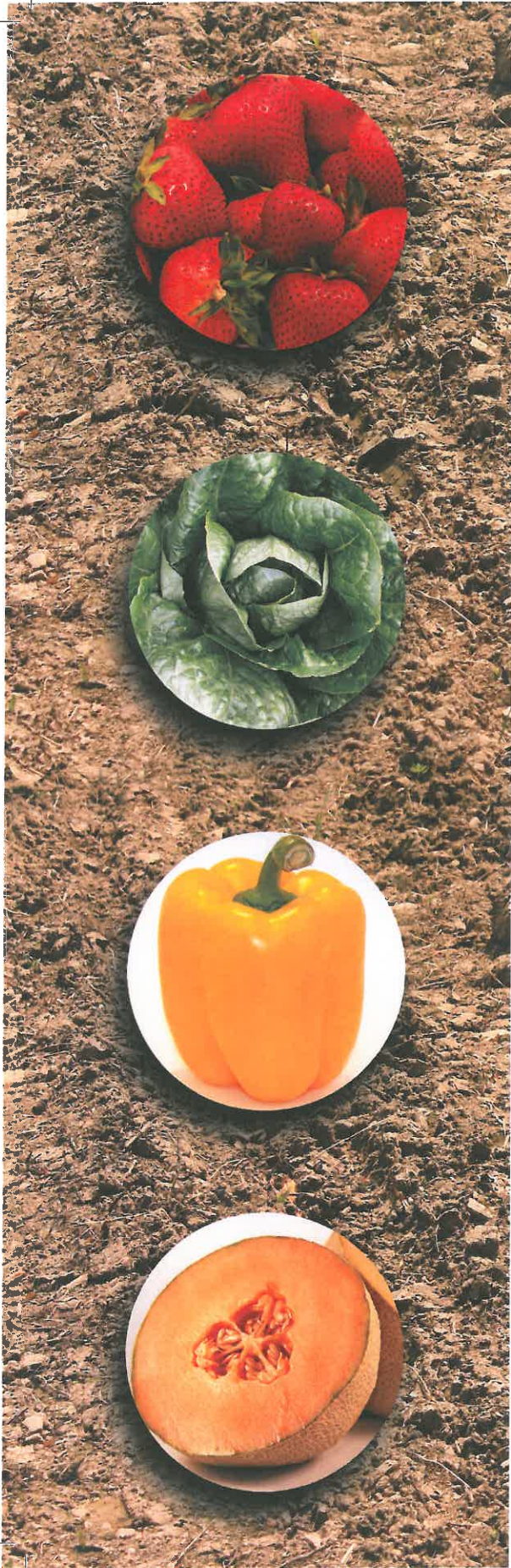
Dated: October 30, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-28159 Filed 11-13-15; 8:45 am]

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Produce Safety ALLIANCE

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FSMA Produce Safety Rule Regulatory Reference Table

Disclaimer

This educational tool was designed to provide produce growers and packers with an easy-to-use reference table that outlines the Food Safety Modernization Act (FSMA) Produce Safety Rule provisions. The regulatory requirements are summarized by subpart within this document, but this document does not represent the regulation in full. Using this tool does not guarantee compliance with the regulation but is meant to help navigate the regulation to quickly identify requirements. The complete *Title 21 of the Code of Federal Regulations, Part 112 – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (a.k.a., the Produce Safety Rule)* can be found at the FDA's website at: <http://www.gpo.gov/fdsys/pkg/FR-2015-11-27/pdf/2015-28159.pdf>. The codified section is included in the FSMA section of this manual.

Tool Design and Use

The first table shown in this tool, the **Summary Table**, provides a broad overview of what is included in each of the regulation's subparts, including their titles and section numbers.

After the Summary Table is a collection of **Subpart Tables** where subparts in the FSMA Produce Safety Rule are outlined with a general description of what they cover. While much of the language in these tables is verbatim from the FSMA Produce Safety Rule, there are instances where some sentences have been shortened for ease of use.

There are four primary columns in each **Subpart Table**.

- The first column denotes the subpart section in which the provision is located.
- The second column identifies the subpart number.
- The third column summarizes the language of the FSMA Produce Safety Rule provision.
- The last column denotes the PSA module where the information can be found. Subparts M, P, Q, and R do not contain references to the PSA modules. These subparts focus on regulatory areas beyond the scope of this curriculum. Subpart O also does not contain references to curriculum modules since this information (Records) applies to all curriculum modules.

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Summary Table

Subpart	Numbers	Section Description
A – General Provisions	112.1-112.7	Produce covered and not covered by regulation, definitions, who is subject to requirements, eligibility for qualified exemptions, modified requirements for exemptions, records kept for exemptions
B – General Requirements	112.11-112.12	General requirements, alternatives to requirements
C – Personnel Qualifications and Training	112.21-112.30	Training requirements for those who handle produce or food contact surfaces, supervisor requirements, training record requirements
D – Health and Hygiene	112.31-112.33	Measures to prevent contamination from ill or injured workers, hygienic practices, prevention of contamination from visitors
E – Agricultural Water	112.41-112.50	General water quality requirements, and criteria for certain intended uses, water source and water distribution system inspection, testing frequency, sampling and analysis requirements, corrective actions including treatment of agricultural water, measures to take during harvest, packing, and holding activities, permissible alternatives, recordkeeping requirements
F – Biological Soil Amendments of Animal Origin and Human Waste	112.51-112.60	Determining the status of a biological soil amendment of animal origin, handling, conveying, and storage of soil amendments, prohibitions for use of human waste, acceptable treatment processes, microbial standards, application requirements and intervals, recordkeeping requirements
G – Reserved		
H – Reserved		
I – Domesticated and Wild Animals	112.81-112.84	Requirements for working and domesticated animals, animal grazing in fields, threatened or endangered species protection, management of animal intrusion events
J – Reserved		
K – Growing, Harvesting, Packing, and Holding Activities	112.111-112.116	Measures to take if growing both covered and excluded produce, handling harvested produce, exclusion of dropped produce for fresh market, packaging activities and packing material requirements

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L – Equipment, Tools, Buildings, and Sanitation	112.121-112.140	Requirements for maintenance of equipment, tools, and buildings, requirements for calibration of instruments (e.g. thermometers), transportation of covered produce, pest control, toilet and handwashing facilities, sewage disposal, litter management, plumbing, domesticated animal excreta and litter
M – Sprouts	112.141-112.150	Requirements for growing, harvesting, and handling sprouts, testing requirements, management of sprout irrigation water, records required
N – Analytical Methods	112.151-112.153	Acceptable analytical methods for testing agricultural water quality for produce other than sprouts, for the sprout growing, harvesting, packing, and holding environments, and spent sprout irrigation water
O – Records	112.161-112.167	Record keeping requirements, storage, duration, accessibility, acceptable formats, disclosure of records outside FDA
P – Variances	112.171-112.182	Who may request variances, state, tribe and foreign country requests, data and information to submit, processing, approval, denial, modification, revocation of variance requests
Q – Compliance and Enforcement	112.192-112.193	Criteria and definitions as applicable to FD&C Act, failure to comply, coordination or education and enforcement
R – Withdrawal of Qualified Exemptions	112.201-112.213	FDA procedures and reasons for withdrawal of qualified exemptions, procedure for submitting appeals, requirements for requesting an informal hearing, timeframe for appeals, circumstances to reinstate a qualified exemption

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Subpart A – General Provisions

	Number	Requirement Description	Module #
A	112.1(a)	Outline of foods covered by the regulation, which in general covers produce (raw agricultural commodities) unless excluded by 112.2	1
A	112.1(b)	<p>Covered produce includes the following:</p> <p>1) almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops) citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guava, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapple, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, sourop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons and yams; and</p> <p>2) Mixes of intact fruits and vegetables (such as fruit baskets)</p>	1
A	112.2(a)	<p>Produce that is not covered by this part:</p> <p>1) 'Rarely consumed raw' produce: asparagus; beans, black; beans, great Northern; beans, kidney; beans, lima; beans, navy; beans, pinto; beets, garden (roots and tops); beets, sugar; cashews; cherries, sour; chickpeas, cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; squash, winter; sweet potatoes; and water chestnuts.</p> <p>2) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management; and</p> <p>3) Produce that is not a raw agricultural commodity</p>	1

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A	112.2(b)	<p>Produce is eligible for exemption under these conditions (except as noted in 112.2(b)(1), (2), and (3)):</p> <ol style="list-style-type: none"> 1) The produce receives commercial processing (including refining and distilling) that adequately reduces the presence of microorganisms of public health significance (e.g., processing of tomato paste or shelf stable tomatoes, processing produce into products such as sugar, oil, spirits, wines, and beer) 2) You must disclose in documents accompanying the produce, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and 3) You must either: <ol style="list-style-type: none"> i) Annually obtain written assurance, subject to the requirements of 112.2(b)(6), from the customer that performs the commercial processing described in 112.2(b)(1) that the customer has established and is following procedures that adequately reduce the presence of microorganisms of public health significance; or ii) Annually obtain written assurance, subject to the requirements of 112.2(b)(6), from your customer that an entity in the distribution chain subsequent to the customer will perform commercial processing described in 112.2(b)(1) and that the customer: <ol style="list-style-type: none"> A) Will disclose in documents accompanying the food that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and B) Will only sell to another entity that agrees, in writing, it will either: <ol style="list-style-type: none"> 1) Follow procedures that adequately reduce the presence of microorganisms of public health significance; or 2) Obtain similar written assurance from its customer that the produce will receive commercial processing described in 112.2(b)(1) and that there will be disclosure in documents accompanying the food, that the food is “not processed to adequately reduce the presence of microorganisms of public health significance”; and 4) You must establish and maintain documentation of your compliance with requirements in 112.2(b)(2) and (3) in accordance with the requirements of subpart O (Records), including: <ol style="list-style-type: none"> i) Documents containing disclosures required under 112.2(b)(2); and ii) Annual written assurances obtained from customers required under 112.2(b)(3); and 5) The requirements of subpart A (General Provisions) and subpart Q (Compliance and Enforcement) apply to such produce; and 6) An entity provides a written assurance under 112.2(b)(3)(i) or (ii) must act consistently with the assurance and document its actions taken to satisfy the written assurance 	1
A	112.3(a)	Definitions and interpretations of terms in section 201 of the FD&C Act (21 U.S.C. 321) apply to terms used in subpart A	

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A	112.3(b)	Definitions of very small and small businesses: 1) <u>Very small business</u> – if subject to subpart A and on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$250,000 2) <u>Small business</u> – if subject to this subpart A and on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than \$500,000, and your farm is not a very small business as described above	1
A	112.3(c)	Definitions which apply to the FSMA Produce Safety Rule – see curriculum glossary or 112.3(c) for full list of FSMA Produce Safety Rule definitions	Glossary
A	112.4(a-b)	Outlines who is subject to the regulation – a) A “covered farm” is any farm or farm mixed-type facility with an average annual monetary value of produce sold during the previous 3-year period of more than \$25,000 (on a rolling basis), use 2011 as the baseline year for calculating the adjustment for inflation b) A farm is not a covered farm if it satisfies the requirements in 112.5 and has not had exemptions withdrawn according to subpart R (Withdrawal of Qualified Exemptions)	1
A	112.5(a)	Qualified exemptions and modified requirements in a calendar year: 1) During the previous 3-year period, the average annual monetary value of food sold directly to qualified end users exceeded the average annual monetary value of food the farm sold to all other buyers (See definitions in 112.3(c)) AND 2) The average monetary value of all food the farm sold in the 3-year period was less than \$500,000, adjusted for inflation	1
A	112.5(b)	To determine whether the average monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than \$500,000, use 2011 as the baseline year for calculating the adjustment for inflation	1
A	112.6(a)	If your farm is eligible for a qualified exemption according to 112.5, you are subject to: 1) This subpart A (General Provisions); 2) Subpart O (Records); 3) Subpart Q (Compliance and Enforcement); and 4) Subpart R (Withdrawal of Qualified Exemptions)	1

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A	112.6(b)	<p>In addition to 112.6(a), you are subject to the following modified requirements:</p> <p>1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown</p> <p>2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice</p> <p>3) The complete business address must include the street address or PO box, city, state, and zip code for domestic farms, and a comparable full address for foreign farms</p>	1, 7
A	112.7(a-b)	<p>If your farm is eligible for a qualified exemption in 112.5:</p> <p>a) You must establish and keep records, according to subpart O (Records), except for in 112.161(a)(4) for a signature or initial of the person performing the activity is not required for sales receipts kept in the normal course of business. Receipts must be dated as required in 112.161(a)(4)</p> <p>b) You must establish and keep adequate records necessary to demonstrate that your farm satisfies criteria for a qualified exemption in 112.5, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for exemption</p>	1

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Subpart B – General Requirements

	Number	Requirement Description	Module #
B	112.11	You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act	1
B	112.12(a)	You may establish alternatives to certain specific requirements of subpart E (Agricultural Water), as specified in 112.49, provided you satisfy the requirements of 112.12(b) and (c)	5
B	112.12(b)	You may establish alternatives to the requirements in 112.12(a) provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection and not increase the likelihood that your covered produce would be adulterated under section 402 of the FD&C Act	5
B	112.12(c)	Scientific data and information used to support an alternative may come from available scientific literature, developed by you, or available from a third party. You must maintain documentation in accordance with subpart O (Records). You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.	5

Subpart C – Standards Directed to Personnel Qualifications and Training

	Number	Requirement Description	Module #
C	112.21(a)	All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are supervisors of said personnel, must receive adequate training per person's duties, upon hiring and periodically thereafter, at least once annually	2
C	112.21(b)	All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are supervisors of said personnel, must have a combination of education, training, and experience necessary to perform the person's duties	2
C	112.21(c)	Training must be conducted in a manner that is easily understood by personnel being trained.	2
C	112.21(d)	Training must be repeated, as necessary and appropriate in light of observations or information indicating personnel are not meeting standards in subparts C – O	2

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C	112.22(a)	Minimum training requirements for personnel who handle covered produce during covered activities or supervise the conduct of such activities must include: 1) The principles of food safety and hygiene 2) The importance of health and personal hygiene for visitors and all personnel, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food contact surfaces with microorganisms of public health significance 3) The standards in subparts C through O that apply to the employee's job responsibilities	2, 6
C	112.22(b)	Persons who conduct harvest activities must be trained on the following: 1) Recognizing when covered produce must not be harvested because of contamination risks 2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean and maintained so as not to become a source of contamination 3) Correcting and reporting any problems with harvest containers or equipment	2, 4, 6
C	112.22(c)	At least one supervisor from your farm must complete food safety training at least equivalent to the standardized curriculum recognized as adequate by the FDA	2, 7
C	112.23	You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance	2, 7
C	112.30(a)	You must keep records under this Subpart C (Personnel Qualifications and Training) in accordance with requirements in Subpart O (Records)	2
C	112.30(b)	You must keep records of training that document required training of personnel including: date of training, topics covered, person(s) trained	2, 4, 7

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Subpart D – Standards Directed to Health and Hygiene

	Number	Requirement Description	Module #
D	112.31(a)	Measures must be taken to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea)	2, 6
D	112.31(b)	The following measures must be taken to satisfy 112.31(a): 1) Exclude any person from working in any operations that may result in contamination of covered produce or food contact surfaces if they are shown to have or appear to have an applicable health condition 2) Instruct personnel to notify supervisors if they are ill or have an applicable health condition	2
D	112.32(a)	Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination	2, 6
D	112.32(b)	The following hygienic practices must be used to satisfy 112.32(a): 1) Maintain personal cleanliness to protect against contamination of covered produce and food contact surfaces 2) Avoid contact with animals other than working animals, and take action to minimize likelihood of contamination of covered produce 3) Wash hands thoroughly using soap (or other effective surfactant) and water (must satisfy requirements in 112.44(a)), dry hands thoroughly using single-service towels, sanitary towel service, electric hand dryers or other hand drying devices: i) Before starting work ii) Before putting on gloves iii) After using the toilet iv) Upon return to the work station after breaks v) As soon as practical after touching animals or animal waste vi) At any other time workers hands may become contaminated 4) If using gloves, maintain in an intact and sanitary manner and replace when necessary 5) Remove or cover hand jewelry that cannot be cleaned and sanitized when covered produce is manipulated by hand; and 6) Do not eat, chew gum, or use tobacco products in the area used for a covered activity (drinking beverages are permitted)	2, 4, 6
D	112.33(a)	Visitors must be made aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and steps must be taken to ensure visitors comply with such policies and procedures	2
D	112.33(b)	Toilet and handwashing facilities must be accessible to visitors	2

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Subpart E – Standards Directed to Agricultural Water

	Number	Requirement Description	Module #
E	112.41	All agricultural water must be safe and of adequate sanitary quality for its intended use	5
E	112.42(a)	At the beginning of the growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems, to the extent that they under your control, to identify food safety hazards including consideration of the following: 1) The nature of each agricultural water source (e.g., ground water or surface water) 2) The extent of your control over each agricultural water source 3) The degree of protection of each agricultural water source 4) Use of adjacent and nearby land; and 5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm	5
E	112.42(b)	All agricultural water distribution systems must be maintained, to the extent that they are under your control, as necessary to prevent the system from being a source of contamination, including regularly inspecting and adequately storing all equipment used in the system	5
E	112.42(c)	All agricultural water sources, to the extent that they are under your control, must be maintained by regularly inspecting each source, correcting any deficiencies, and keeping the source free of debris, trash, domesticated animals, and other sources of contamination to the extent practicable and appropriate	5
E	112.42(d)	As necessary and appropriate, measures must be implemented to reduce the potential for contamination of covered produce as a result of contact with pooled water (such as, using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method)	5
E	112.43(a)	When agricultural water is treated according to 112.45: 1) Any method used to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in 112.44, as applicable 2) Treatment of agricultural water must be delivered in a manner that ensures the treated water is consistently safe and of sanitary quality for its intended use and/or meets microbial quality criteria in 112.44, as applicable	5

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E	112.43(b)	Any treatment of agricultural water must be monitored at a frequency adequate to ensure the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets microbial quality criteria in 112.44, as applicable	5
E	112.44(a)	<p>You must ensure there is no detectable generic <i>Escherichia coli</i> (<i>E. coli</i>) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:</p> <ol style="list-style-type: none"> 1) Used as sprout irrigation water 2) Applied in any manner that directly contacts covered produce during or after harvest activities, including when used to make ice that contacts covered produce 3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces, and 4) Used for washing hands during and after harvest activities 	2, 5, 6
E	112.44(b)	<p>When agricultural water is used during growing activities for covered produce using direct water application method, the criteria in 112.44(b) (1) and (2) apply unless you use alternative criteria in accordance with 112.49</p> <ol style="list-style-type: none"> 1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic <i>E. coli</i> per 100 mL of water; and 2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic <i>E. coli</i> per 100 mL of water 	5
E	112.45(a)	<p>If you have determined or have reason to believe that your agricultural water does not meet the requirements of 112.41 or 112.44(a) you must immediately discontinue that use(s), and before you resume use of the water source and/or distribution system, you must either:</p> <ol style="list-style-type: none"> 1) Re-inspect the entire affected agricultural water system, to the extent that it is under your control, identify conditions that introduce foreseeable hazards to covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine effectiveness to ensure the criterion in 112.44(a) are met, as applicable; or 2) Treat the water in accordance with 112.43 	5

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E	112.45(b)	<p>If it is determined that the your agricultural water does not meet the microbial quality criteria required under 112.44(b) (or any alternative criteria, if applicable), you must discontinue use as soon as practicable and no later than the following year unless:</p> <p>1) A time interval (in days) and/or a calculated log reduction is applied by:</p> <ul style="list-style-type: none"> i) Applying a time interval between last irrigation and harvest using either: <ul style="list-style-type: none"> A) A microbial die-off rate of 0.5 log per day to achieve a calculated log reduction of the GM and STV to meet the microbial quality criteria in 112.44(b), for no more than 4 consecutive days; or B) An alternative microbial die-off rate and any accompanying maximum time interval according to 112.49; and/or ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate supporting scientific data <p>2) Re-inspect the entire affected agricultural water system under your control, identify conditions that introduce known or reasonably foreseeable hazards, make necessary changes, and take adequate measures to determine effectiveness to ensure criteria in 112.44(b) (or any alternative microbial criteria, if applicable) are met; or</p> <p>3) Treat the water in accordance with 112.43</p>	5
E	112.46(a)	<p>There is no requirement to test any agricultural water that is subject to the requirements of 112.44 when:</p> <p>1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA), that meets the microbial requirements under those regulations or those of a State approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;</p> <p>2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement described in 112.44(a), and you have public water system results or certificates of compliance; or</p> <p>3) You treat water in accordance with the requirements of 112.43</p>	5, 6
E	112.46(b)	<p>Except for agricultural water as provided in 112.46(a), you must take the following steps for each source of water that is subject to the requirements of 112.44(b) (those that relate to application during growing activities):</p>	5, 6

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14—FSMA Regulatory Reference Table

E	112.46(b)(1)	<p>Conduct an initial survey to develop a microbial water quality profile of the agricultural water source</p> <p>i) The initial survey must be conducted:</p> <p>A) For an untreated surface water source, by taking a minimum of 20 samples over a minimum period of 2 years, but not greater than 4 years</p> <p>B) For an untreated ground water source, by taking a minimum of 4 samples during the growing season or over a period of 1 year</p> <p>ii) The samples must be representative of your use and must be collected as close in time as practical to, but prior to, harvest. The microbial water quality profile (consisting of a GM and an STV) of generic <i>E. coli</i> per 100 mL is calculated using this data set. You must determine the appropriate way the water may be used based on your microbial water quality profile in accordance with 112.45(b)</p> <p>iii) You must update the microbial water quality profile annually as required by 112.46(b)(2) and (3)</p>	5
E	112.46(b)(2)	<p>Conduct an annual survey to update the microbial water quality profile of your agricultural water</p> <p>i) After the initial survey (described in 112.46(b)(1)(i), you must test the water annually to update your existing microbial water quality profile to confirm the appropriate use of the water. You must analyze:</p> <p>A) For an untreated surface water source, a minimum of 5 samples per year</p> <p>B) For an untreated ground water source, a minimum of 1 sample per year</p> <p>ii) The samples of agricultural water must be representative of your use and must be collected as close in time as practicable to, but prior to, harvest</p> <p>iii) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual water survey data from within the previous 4 years, to make up a rolling data set of:</p> <p>A) At least 20 samples for untreated surface water sources; and</p> <p>B) At least 4 samples for untreated ground water sources</p> <p>iv) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with 112.45(b)</p>	5

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E	112.46(b)(3)	<p>If you know or have reason to believe your microbial water quality profile no longer represents the quality of your water, you must develop a new microbial water quality profile reflective of the time period at which you believe the water quality profile changed (e.g. significant changes occur to adjacent land use likely to impact to the quality of the water source).</p> <p>i) To develop a new microbial water quality profile, you must calculate new GM and STV values using your current water survey (if taken after the time of change), combined with new data, to make up a data set of:</p> <p>A) At least 20 samples for untreated surface water sources; and</p> <p>B) At least 4 samples for untreated ground water sources</p> <p>ii) You must modify your water use based on the revised GM and STV values in your updated microbial water quality profile in accordance with 112.45(b)</p>	5
E	112.46(c)	<p>If you use untreated ground water for purposes that are subject to the requirements in 112.44(a), you must initially test the microbial quality of each water source at least 4 times per growing season or over a period of one year, collected to be representative of the intended use. Based on these results, you must determine whether the water can be used for that purpose, in accordance with 112.45(a). If the samples tested meet the microbial quality criterion of 112.44(a) (no detectable generic <i>E.coli</i> per 100 mL), you may test once annually thereafter, collecting one sample that is representative of your use. You must resume testing at least 4 times per growing season or year if any annual test fails to meet the applicable microbial quality criterion in 112.44(a).</p>	5
E	112.47(a)	<p>You may meet the requirements related to agricultural water testing in 112.46 using:</p> <p>1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or</p> <p>2) Data collected by a third party or parties, provided the water source(s) sampled adequately represent your agricultural water source(s) and all other applicable requirements of subpart E are met</p>	5
E	112.47(b)	Agricultural water samples must be aseptically collected and tested using a method as set forth in 112.151	5
E	112.48(a)	You must manage water used for harvesting, packing, and holding activities as necessary, including by establishing and following water-change schedules for re-circulated water to maintain safety and adequate sanitary quality (for example, from hazards that may be introduced into the water from soil adhering to the covered produce)	5, 6
E	112.48(b)	You must visually monitor the quality of water that you use during harvesting, packing, and holding activities (e.g. water used for washing or hydrocooling covered produce) for build-up of organic material (such as soil or plant debris)	5, 6

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16—FSMA Regulatory Reference Table

E	112.48(c)	You must monitor the temperature of water and maintain at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) to minimize the potential for contamination through infiltration of microorganisms into the produce	5, 6
E	112.49(a-d)	You may establish and use one or more of the following alternatives, provided you satisfy the requirements in 112.12: a) An alternative microbial quality criterion using an appropriate indicator of fecal contamination instead of the microbial quality criteria in 112.44(b) b) An alternative microbial die-off rate and an accompanying maximum time interval instead of those in 112.45(b)(1)(i) c) An alternative minimum number of samples used in the initial survey for an untreated surface water source instead of the minimum required in 112.46(b)(1)(i)(A) d) An alternative minimum number of samples used in the annual survey for an untreated surface water source instead of the minimum required in 112.46(b)(2)(i)(A)	5
E	112.50(a)	You must establish and keep records required under subpart E (Agricultural Water) in accordance with the requirements of subpart O (Records)	5
E	112.50(b)	You must establish and keep the following records: 1) The findings of your agricultural water system inspection as required by 112.42(a) 2) Documentation of the results of all analytical tests conducted on agricultural water for compliance with Subpart E (Agricultural Water) 3) Scientific data or information you rely on to support the adequacy of the methods used to satisfy 112.43(a)(1) and (2) 4) Documentation of the results of water treatment monitoring as required by 112.43(b) 5) Scientific data or information you rely on to support microbial die-off or removal rates that are used to determine the time interval (in days) between harvest and end of storage, including other activities, such as commercial washing, as applicable, used to achieve the calculated log reduction of generic <i>E.coli</i> in order to satisfy 112.45(b)(1)(ii) 6) Documentation of actions you take in accordance with 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with 112.45(b)(1)(i) and/or (ii), documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities (such as, dates of last irrigation and harvest, the dates of harvest and end of storage, and/or dates of activities such as commercial washing) 7) Annual documentation of the results or certificates of compliance from a public water system as outlined in 112.46(a)(1) or (a)(2), if applicable 8) Scientific data or information you rely on to support any alternative that you establish and use according to 112.49 9) Any analytical methods you use instead of the method that is referenced in 112.151(a)	5, 6, 7

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Subpart F – Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste

	Number	Requirement Description	Module #
F	112.51(a)	A biological soil amendment of animal origin is treated if it has been processed to completion to reduce microorganisms of public health significance in accordance with 112.54, or in the case of agricultural tea, the biological materials of animal origin have been processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable generic <i>E.coli</i> in 100 mL of water	3
F	112.51(b)	A biological soil amendment of animal origin is untreated if it: 1) Has not been processed to completion in accordance with 112.54, or in the case of agricultural tea, the biological materials of animal origin have not been processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic <i>E.coli</i> in 100 mL of water 2) Has become contaminated after treatment 3) Has been recombined with an untreated biological soil amendment of animal origin 4) Is or contains a component of untreated waste that you have reason to believe is contaminated or has been associated with foodborne illness 5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive	3
F	112.52(a)	You must handle, convey, and store any biological soil amendment of animal origin in a manner and location so that it does not become a potential source of contamination to covered produce, food contact surfaces, areas where produce packing or handling occur, water sources, water distribution systems, and other soil amendments	3, 4
F	112.52(b)	You must handle, convey, and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin	3, 4
F	112.52(c)	You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated	3
F	112.53	You may not use human waste for growing covered produce, except sewage sludge biosolids in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements	3
F	112.54	112.54(a)-(b) provide treatment processes acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce	3

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18—FSMA Regulatory Reference Table

F	112.54(a)	A scientifically valid controlled physical process (e.g. thermal), chemical process (e.g. high alkaline pH), biological process (e.g. composting), or a combination of scientifically valid controlled physical, chemical, and/or biological processes that has been validated to satisfy the microbial standard in 112.55(a) for <i>Listeria monocytogenes</i> , <i>Salmonella</i> species, and <i>E. coli</i> O157:H7; or	3
F	112.54(b)	A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in 112.55(b) for <i>Salmonella</i> and fecal coliforms. Scientifically valid controlled biological processes (e.g. composting) include: 1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131°F (55 °C) for 3 consecutive days and is followed by adequate curing; and 2) Turned composting that maintains aerobic conditions at a minimum of 131°F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing	3
F	112.55(a)	The following microbial standards apply to the treatment processes in 112.54. For <i>L. monocytogenes</i> , <i>Salmonella</i> species, and <i>E. coli</i> O157:H7, the relevant microbial standards are: 1) <i>L. monocytogenes</i> : Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or mL) analytical portion 2) <i>Salmonella</i> species: Not detected using a method that can detect three most probable numbers (MPN) per 4 grams (or mL) of total solids (dry weight basis) 3) <i>E. coli</i> O157:H7: Not detected using a method that can detect 0.3 MPN per 1 gram (or mL) analytical portion; or	3
F	112.55(b)	<i>Salmonella</i> species are not detected using a method that can detect three MPN <i>Salmonella</i> species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis)	3

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F	112.56(a-b)	<p>a) Requirements and minimum application intervals of biological soil amendments of animal origin that must be met:</p> <ol style="list-style-type: none"> 1) i) Untreated, applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application: [application interval is Reserved] ii) Untreated, applied in a manner that does not contact covered produce during or after application: 0 day application interval 2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of 112.54(b) to meet the microbial standard in 112.55(b), applied in any manner that minimizes the potential for contact with covered produce during and after application: 0 day application interval 3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, or biological processes, in accordance with the requirements of 112.54(a) to meet the microbial standard in 112.55(a), applied any manner (no restrictions): 0 day application interval <p>b) [Reserved]</p>	3
F	112.60(a)	You must establish and keep records required under subpart F (Biological Soil Amendments and Human Waste) in accordance with the requirements of subpart O (Records)	3
F	112.60(b)	<p>For any biological soil amendment of animal origin you use, you must establish and keep records for:</p> <ol style="list-style-type: none"> 1) A treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that: <ol style="list-style-type: none"> i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and 2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature and turnings) were achieved 	3, 7

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Subpart I – Standards Directed to Domesticated and Wild Animals

	Number	Requirement Description	Module #
I	112.81(a)	The requirements of subpart I (Domesticated and Wild Animals) apply when covered activities take place in an outdoor area or a partially-enclosed building and when there is a reasonable probability that animals will contaminate covered produce	4
I	112.81(b)	The requirements of subpart I do not apply: 1) When a covered activity takes place in a fully-enclosed building; or 2) To fish used in aquaculture operations	4
I	112.83(a)	You must take steps listed in 112.83(b) if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce	4
I	112.83(b)	You must: 1) Assess relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and 2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta, or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of 112.112 and take reasonable measures during growing to assist you during harvest when you must identify, and not harvest, covered produce that is likely to be contaminated with a known or reasonably foreseeable hazard	4
I	112.84	This regulation does not authorize the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531-1544) (i.e., to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act. This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages	4

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Subpart K – Standards Directed to Growing, Harvesting, Packing, and Holding Activities

	Number	Requirement Description	Module #
K	112.111(a-b)	If you grow, harvest, pack or hold produce that is not covered in subpart K (i.e., excluded produce in accordance with 112.2) and also conduct activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with subpart K, you must take measures during these covered activities to: a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce	6
K	112.112	You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta	2, 4, 6
K	112.113	You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards (e.g., by avoiding contact of cut surfaces of harvested produce with soil)	2, 6
K	112.114	You must not distribute covered produce that drops to the ground before or during harvest (dropped covered produce). Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds)	2, 6
K	112.115	You must package covered produce in a manner that prevents the formation of <i>Clostridium botulinum</i> toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms)	6
K	112.116(a-b)	a) You must use food-packing material that is adequate for its intended use, which includes being: 1) Cleanable or designed for single use; and 2) Unlikely to support growth or transfer of bacteria b) If you reuse food-packing material, you must take steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or by using a clean liner	6

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Subpart L – Standards Directed to Equipment, Tools, Buildings, and Sanitation

	Number	Requirement Description	Module #
L	112.121	Equipment and tools that are subject to the requirements of Subpart L (Equipment, Tools, Buildings and Sanitation) are those that are intended to, or likely to, contact covered produce and any instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance	6
L	112.122(a-b)	Buildings subject to the requirements of subpart L include: a) Fully and partially enclosed buildings used for covered activities, including those that have a roof but no walls b) Storage sheds, buildings, and other structures used to store food contact surfaces (such as harvest containers and food-packing materials)	6
L	112.123(a)	You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and	6
L	112.123(b)	Tools and equipment must be: 1) Installed and maintained to facilitate cleaning of equipment and of all adjacent spaces; and 2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests	3, 6
L	112.123(c)	Seams on food contact surfaces of equipment and tools must be smoothly bonded or maintained to minimize the accumulation of dirt, filth, food particles, and organic material, therefore minimizing the opportunity for the harboring or growth of microorganisms	6
L	112.123(d)	1) You must inspect, maintain, clean, and sanitize when necessary and appropriate, all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce 2) You must maintain and clean all non-food contact surfaces of equipment and tools used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce	3, 6
L	112.123(e)	Pallets, forklifts, tractors, and other vehicles that are intended to or likely to contact covered produce must be used in a manner that minimizes the potential for contamination of covered produce or food contact surfaces	3, 6
L	112.124(a-c)	Instruments used to measure, regulate, or record temperatures, pH, sanitizer efficacy, or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be: a) Accurate and precise; b) Adequately maintained; and c) Adequate in number for their designated uses	6

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L	112.125(a-b)	Equipment used to transport covered produce must: a) Be adequately cleaned prior to transporting covered produce b) Adequate for use in transporting covered produce	6
L	112.126(a)	All of the following requirements apply regarding buildings: 1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination. Buildings must: i) Provide sufficient space for equipment and storage of materials ii) Permit proper precautions to be taken to reduce the potential for contamination through separation of operations by location, time, partition, enclosed systems, or other effective means; and 2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building	6
L	112.126(b)	You must implement measures to prevent contamination of covered produce and food contact surfaces in your buildings from: 1) Floors, walls, ceilings, fixtures, ducts, or pipes; and 2) Drip or condensate	6
L	112.127(a)	Reasonable precautions must be taken to prevent contamination by: 1) Excluding domesticated animals from fully-enclosed buildings where covered produce is stored, food contact surfaces or food-packing materials are exposed; or 2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted by location, time or partition	4, 6
L	112.127(b)	Guard or guide dogs may be allowed in some areas of fully enclosed buildings as long as they are not likely to contaminate produce, food contact surfaces, or food-packing materials	4
L	112.128(a-c)	Requirements regarding pest control in buildings: a) Measures must be taken as reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established (such as by use of screens) or by monitoring for the presence of pests and removing them when present	4, 6
L	112.129(a)	Adequate, readily accessible toilet facilities, must be provided to personnel, including toilet facilities readily accessible to growing areas during harvesting activities	2

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24—FSMA Regulatory Reference Table

L	112.129(b)	Toilet facilities must be designed, located, and maintained to: 1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distributions systems with human waste 2) Be directly accessible for servicing and be cleaned and stocked on a sufficient schedule to ensure suitability of use 3) Provide for the sanitary disposal of waste and toilet paper	2, 6
L	112.129(c)	During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a handwashing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands	2
L	112.130(a)	Handwashing facilities must be provided to personnel during growing activities that take place in a full-enclosed building and during covered harvest, packing, or holding activities	2
L	112.130(b)	Handwashing facilities must have: 1) Soap or other effective surfactant 2) Running water that satisfies 112.44(a) 3) Drying devices, such as, single use towels, sanitary towel service, or electric hand dryers	2
L	112.130(c)	You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a handwashing facility and take appropriate measures to prevent waste water from a handwashing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards	2
L	112.130(d)	Antiseptic hand rubs may not be used as a replacement for washing hands with soap and water	2
L	112.131(a)	Sewage must be disposed of into an adequate sewage or septic system or through other adequate means	4, 6
L	112.131(b)	You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards	4, 6
L	112.131(c)	You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems	2, 4, 6

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L	112.131(d)	After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems	2, 5
L	112.132(a-b)	Requirements for the control and disposal of trash, litter, and waste: a) You must convey, store, and dispose of trash, litter and waste to: 1) Minimize attracting or harboring pests 2) Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and water distribution systems b) You must adequately operate systems for waste management and disposal so they are not a potential source of contamination	5, 6
L	112.133(a-d)	Plumbing must be of adequate size and design, and be adequately installed and maintained to: a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or handwashing and toilet facilities b) Properly convey sewage and liquid disposable waste c) Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources d) Not allow backflow from or cross-connections between piping systems that discharge waste water or carry water for a covered activity, for sanitary operations, or for use in handwashing facilities	5, 6
L	112.134(a-b)	a) Animal excreta and litter from domesticated animals must: 1) Be adequately controlled to prevent contamination 2) Have a system to maintain control of litter and excreta b) [Reserved]	3, 4, 5
L	112.140(a-b)	Records for Subpart L (Equipment, Tools, Buildings, and Sanitation) must: a) Be established and kept in accordance with Subpart O (Records) b) Be established and kept to document the date and method of cleaning and sanitizing equipment subject to subpart L used in: 1) Growing operations for sprouts; and 2) Covered harvesting, packing, or holding activities	2, 6

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Subpart M – Standards Directed to Sprouts

	Number	Requirement Description
M	112.141	The requirements of subpart M apply to growing, harvesting, packing, and holding of all sprouts, except soil or substrate-grown sprouts harvested without their roots
M	112.142(a-e)	<p>In addition to requirements in subpart M, all the following requirements apply to seeds or beans used to grow sprouts:</p> <p>a) You must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.</p> <p>b) If you know or have reason to believe that a lot of seeds or beans may have been contaminated with a pathogen (either because it has been associated with foodborne illness or based on microbial test results, including positive results from tests required in 112.144(b), you must:</p> <ol style="list-style-type: none"> 1) Discontinue use of all seeds or beans from that lot for sprout production and ensure that sprouts grown from that lot of seeds or beans do not enter the market; and 2) Report the information associated with illness and/or findings of microbial testing to the seed grower, distributor, supplier, or other entity from whom you received the seeds or beans <p>c) If contamination of seeds or beans is based only on microbial test results:</p> <ol style="list-style-type: none"> 1) You are not required to discontinue use of all seeds or beans (112.142(b)(1)) if you treat your lot of seeds or beans with a process that is reasonably certain to achieve destruction or elimination of the most resistant microorganisms of public health significance; or 2) You are not required to discontinue use of all seeds or beans (112.142(b)(1)) or report the information (112.142(b)(2)) if you later reasonably determine, through followup actions, that the lot of seeds or beans is not the source of contamination (e.g. the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts) <p>d) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards</p> <p>e) You must either:</p> <ol style="list-style-type: none"> 1) Treat seeds or beans that will be used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance; or 2) Rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of seeds or beans, provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that: <ol style="list-style-type: none"> i) The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and ii) The treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination

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M	112.143(a-g)	<p>You must take all of the following measures for growing, harvesting, packing, and holding sprouts:</p> <ul style="list-style-type: none"> a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building b) Any food contact surfaces you use to grow, harvest, pack, and hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts c) You must test the growing, harvesting, packing, and holding environment as specified in 112.144 d) You must establish and implement a written environmental monitoring plan as specified in 112.145 e) You must take certain actions if you detect <i>Listeria</i> species or <i>L. monocytogenes</i> in the growing, harvesting, packing, and holding environment as specified in 112.146 f) You must establish and implement a written sampling plan to test spent sprout irrigation water or sprouts for pathogens as specified in 112.147 g) You must take certain actions if the samples of spent sprout irrigation water or sprouts test positive for a pathogen as specified in 112.148
M	112.144(a-c)	<p>All of the following testing must be done during growing, harvesting, packing, and holding sprouts:</p> <ul style="list-style-type: none"> a) You must test the growing, harvesting, packing, and holding environment for <i>Listeria</i> species or <i>L. monocytogenes</i> in accordance with the requirements of 112.145 b) You must either: <ul style="list-style-type: none"> 1) Test spent sprout irrigation water from each production batch of sprouts for <i>E. coli</i> O157:H7, <i>Salmonella</i> species and any pathogens meeting the criteria in 112.144(c) in accordance with the requirements of 112.147; or 2) If testing spent sprout irrigation water is not practicable (for example, for soil-grown sprouts or hydroponically grown sprouts), test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) for <i>E. coli</i> O157:H7, <i>Salmonella</i> species and any pathogens meeting the criteria in 112.144(c) in accordance with the requirements of 112.147 c) In addition to <i>E. coli</i> O157:H7 and <i>Salmonella</i> species, you must conduct tests provided in 112.144(b) for additional pathogens when the following conditions are met: <ul style="list-style-type: none"> 1) Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and 2) A scientifically valid test method for the pathogen is available to detect the pathogen in spent sprout irrigation water (or sprouts)

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M	112.145(a-e)	<p>All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for <i>Listeria</i> species or <i>L. monocytogenes</i></p> <p>a) You must establish and implement a written environmental monitoring plan that is designed to identify <i>L. monocytogenes</i> if it is present in the growing, harvesting, packing, or holding environment</p> <p>b) Your written environmental monitoring plan must be directed to sampling and testing for either <i>Listeria</i> species or <i>L. monocytogenes</i></p> <p>c) Your written environmental monitoring plan must include a sampling plan that specifies:</p> <ol style="list-style-type: none"> 1) What you will test collected samples for (i.e., <i>Listeria</i> species or <i>L. monocytogenes</i>); 2) How often you will collect environmental samples, which must be no less than monthly and at what point during production you will collect the samples; and 3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment <p>d) You must aseptically collect environmental samples and test them for <i>Listeria</i> species or <i>L. monocytogenes</i> according to the method in 112.152</p> <p>e) Your written environmental monitoring plan must include a corrective action plan that at a minimum, requires you to take the actions in 112.146 and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for <i>Listeria</i> species or <i>L. monocytogenes</i></p>
M	112.146(a-f)	<p>You must take the following actions if you detect <i>Listeria</i> species or <i>L. monocytogenes</i> in the growing, harvesting, packing, or holding environment:</p> <p>a) Conduct additional testing of surfaces and areas surrounding the area where <i>Listeria</i> species or <i>L. monocytogenes</i> was detected to evaluate the extent of the problem, including the potential for <i>Listeria</i> species or <i>L. monocytogenes</i> to have become established in a niche;</p> <p>b) Clean and sanitize the affected surfaces and surrounding areas;</p> <p>c) Conduct additional sampling and testing to determine whether the <i>Listeria</i> species or <i>L. monocytogenes</i> has been eliminated;</p> <p>d) Conduct finished product testing when appropriate;</p> <p>e) Perform any other actions necessary to prevent reoccurrence of the contamination; and</p> <p>f) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into the market</p>

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M	112.147(a-c)	<p>All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts for pathogens as required in 112.144(b):</p> <p>a) You must establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination.</p> <p>b) In accordance with the written sampling plan required in 112.147(a), you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for pathogens using the method in 112.153. You must not allow the production batch of sprouts to enter into the market unless the results of the testing of spent sprout irrigation water or sprouts are negative for <i>E. coli</i> O157:H7, <i>Salmonella</i> species or a pathogen meeting the criteria in 112.144(c)</p> <p>c) Your written sampling plan must include a corrective action plan that at a minimum, requires you to take the actions in 112.148 and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for <i>E. coli</i> O157:H7, <i>Salmonella</i> species or a pathogen meeting the criteria in 112.144(c)</p>
M	112.148(a-d)	<p>You must take the following actions if samples of spent sprout irrigation water or sprouts test positive for <i>E. coli</i> O157:H7, <i>Salmonella</i> species or a pathogen meeting the criteria in 112.144(c):</p> <p>a) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into the market;</p> <p>b) Take steps required in 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under 112.142(c);</p> <p>c) Clean and sanitize the affected surfaces and surrounding areas; and</p> <p>d) Perform any other actions necessary to prevent reoccurrence of the contamination</p>

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M	112.150(a-b)	<p>a) You must establish and keep records required under subpart M (Sprouts) in accordance with the requirements of subpart O (Records)</p> <p>b) You must establish and keep the following records:</p> <ol style="list-style-type: none"> 1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment according to the requirements in 112.142(e); 2) Your written environmental monitoring plan in accordance with the requirements of 112.145; 3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of 112.147(a) and (c); 4) Documentation of the results of all analytical testing conducted for the purposes of compliance with subpart M (Sprouts) 5) Any analytical methods you use instead of the methods that are referenced in 112.152 and 112.153; and 6) Documentation of actions you take in accordance with 112.142(b) and (c), 112.146, and 112.148
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Subpart N – Analytical Methods

	Number	Requirement Description	Module #
N	112.151(a-b)	<p>You must test the quality of water using a method of analysis:</p> <p>a) As published by the EPA "Method 1603: <i>Escherichia coli</i> (<i>E. coli</i>) in Water by Membrane Filtration Using Modified membrane-Thermotolerant <i>Escherichia coli</i> Agar (Modified mTEC), EPA-821-R-09-007," December, 2009, which is available from U.S. EPA or at http://www.epa.gov/cwa-methods/approved-cwa-microbiological-test-methods; or</p> <p>b) 1) A scientifically valid method that is at least equivalent to the method of analysis in 112.151(a) in accuracy, precision, and sensitivity; or</p> <p>2) For any other indicator of fecal contamination you may test for pursuant to 112.49(a), a scientifically valid method</p>	5
N	112.152(a-b)	<p>You must test the growing, harvesting, packing, and holding environment for <i>Listeria</i> species or <i>L. monocytogenes</i> using:</p> <p>a) The method of analysis described in "Testing Methodology for <i>Listeria</i> species or <i>L. monocytogenes</i> in Environmental Samples," Version 1, October 2015, U.S. Food and Drug Administration; or</p> <p>b) A scientifically valid method that is at least equivalent to the method of analysis in 112.152(a) in accuracy, precision, and sensitivity</p>	Refer to Sprout Safety Alliance

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N	112.153(a-b)	<p>You must test spent sprout irrigation water (or sprouts) from each production batch for pathogens using:</p> <p>a) For <i>E. coli</i> O157:H7, <i>Salmonella</i> species:</p> <ol style="list-style-type: none"> 1) The method of analysis described in "Testing Methodologies for <i>E. coli</i> O157:H7 and <i>Salmonella</i> species in Spent Sprout Irrigation Water (or Sprouts)," Version 1, October 2015, U.S. Food and Drug Administration; or 2) A scientifically valid method that is at least equivalent to the method of analysis in 112.153(a)(1) in accuracy, precision, and sensitivity; and <p>b) For any other pathogen(s) meeting the criteria in 112.144(c), a scientifically valid method</p>	Refer to Sprout Safety Alliance
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Subpart O – Requirements Applying to Records That You Must Establish and Keep

	Number	Requirement Description
○	112.161(a)	<ol style="list-style-type: none"> 1) All records required under subpart O (Records) must include, as applicable: <ol style="list-style-type: none"> i) Name and location of your farm; ii) Actual values and observations obtained during monitoring; iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record; iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and v) The date and time of the activity documented; 2) Be created at the time an activity is performed or observed; 3) Be accurate, legible, and indelible; and 4) Be dated, and signed or initialed by the person who performed the activity documented
○	112.161(b)	Records required under 112.7(b), 112.30(b), 112.50(b)(2), (4), and (6), 112.60(b)(2), 112.140(b)(1) and (2), and 112.150(b)(1), (4), and (6), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party
○	112.162(a-b)	<p>Record Storage:</p> <ol style="list-style-type: none"> a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm
○	112.163(a-b)	<ol style="list-style-type: none"> a) Existing records kept for compliance with other regulations do not need to be duplicated if they contain all the information required by subpart O b) The information required by subpart O does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by subpart O, may be kept separately or combined with the existing records

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32—FSMA Regulatory Reference Table

○	112.164(a-b)	<p>Record Storage Duration:</p> <p>a) 1) You must keep records required by subpart ○ for at least 2 years past the date the record was created</p> <p>2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year</p> <p>b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued</p>
○	112.165(a-c)	<p>You must keep records as:</p> <p>a) Original records;</p> <p>b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or</p> <p>c) Electronic records, in compliance with part 11 of this chapter</p>
○	112.166(a-c)	<p>a) You must have all records required under subpart ○ (Records) readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying</p> <p>b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible</p> <p>c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request</p>
○	112.167	Records required by subpart ○ are subject to the disclosure requirements under part 20 of this chapter

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Subpart P – Variances

	Number	Requirement Description
P	112.171(a-b)	<p>A State, Federally-recognized tribe (or “tribe”), or a foreign country from which food is imported into the United States may request a variance from one or more requirements of subpart P (Variances), where the State, tribe, or foreign country determines that:</p> <p>a) The variance is necessary in light of local growing conditions; and</p> <p>b) The procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P</p>
P	112.172	To request a variance from one or more requirements of subpart P, the competent authority (i.e., the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition under 10.30 of this chapter
P	112.173(a-c)	<p>In addition to the requirements set forth in 10.30 of this chapter, the Statement of Grounds in a petition requesting a variance must:</p> <p>a) Provide a statement that the applicable State, tribe, or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P;</p> <p>b) Describe with particularity the variance requested, including the persons to whom the variance would apply and the provision(s) of subpart P to which the variance would apply;</p> <p>c) Present information demonstrating that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P</p>
P	112.174	FDA will presume that information submitted in a petition requesting a variance and comments submitted on such a petition, including a request that a variance be applied to its similarly situated persons, does not contain information exempt from public disclosure under part 20 of this chapter and will be made public as part of the docket associated with this request
P	112.175	The Director or Deputy Directors of the Center for Food Safety and Applied Nutrition (CFSAN), or the Director, Office of Compliance, CFSAN, responds to a request for a variance

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34—FSMA Regulatory Reference Table

P	112.176(a-d)	<p>Process applicable to a petition requesting variance:</p> <p>a) In general, the procedures set forth in 10.30 of this chapter govern FDA's response to a petition requesting a variance</p> <p>b) Under 10.30(h)(3) of this chapter, FDA will publish a notice in the Federal Register, requesting information and views on a filed petition, including information and views from persons who could be affected by the variance if the petition were to be granted (e.g., either because their farm is covered by the petition or as a person similarly situated to persons covered by the petition)</p> <p>c) Under 10.30(e)(3) of this chapter, FDA will respond to the petitioner in writing and will also make public a notice on FDA's website announcing their decision to either grant or deny the petition</p> <p>1) If FDA grants the petition, either in whole or in part, FDA will specify the persons to whom the variance applies and the provision(s) of subpart P to which the variance applies</p> <p>2) If FDA denies the petition (including partial denials), their written response to the petitioner and their public notice announcing their decision to deny the petition will explain the reason(s) for the denial</p> <p>d) FDA will make readily accessible to the public, and periodically update, a list of filed petitions requesting variances, including the status of each petition (for example, pending, granted, or denied)</p>
P	112.177(a-c)	<p>a) A State, tribe, or a foreign country that believes that a variance requested by a petition submitted by another State, tribe, or foreign country should also apply to similarly situated persons in its jurisdiction may request that the variance be applied to its similarly situated persons by submitting comments in accordance with 10.30 of this chapter. These comments must include the information required in 112.173. If FDA determines that these comments should instead be treated as a separate request for a variance, FDA will notify the State, tribe, or foreign country that submitted these comments that a separate request must be submitted in accordance with 112.172 and 112.173</p> <p>b) If FDA grants a petition requesting a variance, in whole or in part, FDA may specify that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition</p> <p>c) If FDA specifies that the variance also applies to persons in a specific location who are similarly situated to those identified in the petition, FDA will inform the applicable State, tribe, or foreign country where the similarly situated persons are located of their decision in writing and will publish a notice on their website announcing their decision to apply the variance to similarly situated persons in that particular location</p>
P	112.178	<p>FDA may deny a variance request if it does not provide the information required under 112.173 (including the requirements of 10.30 of this chapter), or if FDA determines that the variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P</p>

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P	112.179	A variance approved by FDA becomes effective the date of their written decision on the petition
P	112.180	FDA may modify or revoke a variance if they determine that such variance is not reasonably likely to ensure that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of subpart P
P	112.181(a)	<p>a) FDA will provide the following notifications:</p> <ol style="list-style-type: none"> 1) FDA will notify a State, tribe, or a foreign country directly, in writing at the address identified in its petition, if they determine that a variance granted in response to its petition should be modified or revoked. FDA's direct, written notification will provide the State, tribe, or foreign country with an opportunity to request an informal hearing under part 16 of this chapter 2) FDA will publish a notice of their determination that a variance should be modified or revoked in the Federal Register. This notice will establish a public docket so that interested parties may submit written comments on FDA's determination 3) When applicable, FDA will: <ol style="list-style-type: none"> i) Notify in writing any States, tribes, or foreign countries where a variance applies to similarly situated persons of their determination that the variance should be modified or revoked; ii) Provide those States, tribes, or foreign countries with an opportunity to request an informal hearing under part 16 of this chapter; and iii) Include in the Federal Register notice, as described in 112.181(a)(2), public notification of their decision to modify or revoke the variance granted to States, tribes, or foreign countries in which similarly situated persons are located
P	112.181(b)	<p>FDA will consider submissions from affected States, tribes, or foreign countries and from other interested parties as follows:</p> <ol style="list-style-type: none"> 1) FDA will consider requests for hearings by affected States, tribes, or foreign countries under part 16 of this chapter <ol style="list-style-type: none"> i) If FDA grants a hearing, they will provide the State, tribes, or foreign country with an opportunity to make an oral submission. FDA will provide notice on their website of the hearing, including the time, date, and place of the hearing ii) If more than one State, tribe, or foreign country requests an informal hearing under part 16 of this chapter about their determination that a particular variance should be modified or revoked, FDA may consolidate such requests (for example, into a single hearing) 2) FDA will consider written submissions submitted to the public docket from interested parties
P	112.181(c)	<p>FDA will provide notice of their final decision as follows:</p> <ol style="list-style-type: none"> 1) On the basis of the administrative record, FDA will issue a written decision, as provided for under part 16 of this chapter 2) FDA will publish a notice of their decision in the Federal Register. The effective date of the decision will be the date of publication of the notice

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P	112.182(a-c)	<p>Examples of permissible types of variances include:</p> <p>a) Variance from the microbial quality criteria, established in 112.44(b), when agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method;</p> <p>b) Variance from the microbial die-off rate that is used to determine the time interval between last irrigation and harvest, and/or the accompanying maximum time interval, established in 112.45(b)(1)(i); and</p> <p>c) Variance from the approach or frequency for testing water used for purposes that are subject to the requirements of 112.44(b), established in 112.46(b)</p>
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Subpart Q – Compliance and Enforcement

	Number	Requirement Description
Q	112.192(a-b)	<p>a) The failure to comply with the requirements of subpart Q (Compliance and Enforcement), issued under section 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h), is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(vv))</p> <p>b) The criteria and definitions in subpart Q apply in determining whether a food is:</p> <ol style="list-style-type: none"> 1) Adulterated within the meaning of: <ol style="list-style-type: none"> i) Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)) in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or ii) Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or 2) In violation of section 361 of the Public Health Service Act (42 U.S.C. 264)
Q	112.193	Under Section 419(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h(b)(2)(A)), FDA coordinates education and enforcement activities by State, territorial, tribal, and local officials by helping develop education, training, and enforcement approaches

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Subpart R – Withdrawal of Qualified Exemption

	Number	Requirement Description
R	112.201(a)	FDA may withdraw your qualified exemption under 112.5: 1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or 2) If FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm
R	112.201(b)	Before FDA issues an order to withdraw your qualified exemption, FDA: 1) May consider one or more other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction; 2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and 3) Must consider the actions taken by the farm to address the circumstances that may lead FDA to withdraw the exemption
R	112.202(a-d)	a) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to either such Director, must approve an order to withdraw the exemption before the order is issued b) Any officer or qualified employee of FDA may issue an order to withdraw the exemption after it has been approved in accordance with 112.202(a) c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order

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R	112.203(a-i)	<p>An order to withdraw a qualified exemption applicable to a farm under 112.5 must include the following information:</p> <ul style="list-style-type: none"> a) The date of the order; b) The name, address and location of the farm; c) A brief, general statement of the reasons for the order, including information relevant to one or both of the following circumstances that leads FDA to issue the order: <ul style="list-style-type: none"> 1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or 2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm d) A statement that the farm must either: <ul style="list-style-type: none"> 1) Comply with subparts B through O of subpart R on the date that is 120 calendar days from the date of receipt of the order; or 2) Appeal the order within 15 calendar days of the receipt of the order in accordance with the requirements of 112.206 e) A statement that a farm may request that FDA reinstate an exemption that was withdrawn by following the procedures in 112.213; f) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350(f)) and of subpart R; g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in 112.208; h) The mailing address, telephone number, email address, and facsimile number of the FDA district office and the name of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and i) The name and the title of the FDA representative who approved the order
R	112.204(a-b)	<p>The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under 112.5 must either:</p> <ul style="list-style-type: none"> a) Comply with applicable requirements of this part within 120 calendar days of the date from receipt of the order or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; or b) Appeal the order within 15 calendar days of the date of receipt of the order in accordance with the requirements of 112.206

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R	112.205(a-b)	<p>a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.</p> <p>b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order:</p> <ol style="list-style-type: none"> 1) The owner, operator, or agent in charge of the farm must comply with applicable requirements of subpart R within 120 calendar days of the date of receipt of the order, or, if operations have ceased and will not resume within 120 calendar days, before the beginning of operations in the next growing season, or within a reasonable timeframe, agreed to by FDA, based on a written justification, submitted to FDA, for a timeframe that exceeds 120 calendar days from the date of receipt of the order; and 2) The owner, operator, or agent in charge of the farm is no longer subject to the modified requirements in 112.6 and 112.7
R	112.206(a-b)	<p>a) To appeal an order to withdraw a qualified exemption applicable to a farm under 112.5, the owner, operator, or agent in charge of the farm must:</p> <ol style="list-style-type: none"> 1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, e-mail address, or facsimile number identified in the order within 15 calendar days of the date of receipt of the order; and 2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies <p>b) In a written appeal of the order withdrawing an exemption provided under 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in 112.207</p>
R	112.207(a-b)	<p>a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm:</p> <ol style="list-style-type: none"> 1) May request an informal hearing; and 2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with 112.206 within 15 calendar days of the date of receipt of the order <p>b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the material submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial</p>

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R	112.208(a-b)	If the owner, operator or agent in charge of the farm requests an informal hearing, and FDA grants the request: a) The hearing will be held within 15 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA b) The presiding officer may require that a hearing conducted under subpart R be completed within 1 calendar day, as appropriate
R	112.208(c)	FDA must conduct the hearing in accordance with part 16 of this chapter. <i>* 112.208(c)(1-7) are not included on this table for brevity, please see page Please see page 74567 in the codified section.</i>
R	112.209	The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director
R	112.210(a-b)	a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed b) If the owner, operator, or agent in charge of a farm appeals the order and requests an informal hearing: 1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or 2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed
R	112.211(a-d)	An order to withdraw a qualified exemption applicable to a farm under 112.5 is revoked if: a) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time d) Confirmation of a withdrawal order by the presiding officer is considered a final Agency action for purposes of 5 U.S.C. 702

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R	112.213(a)	If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) determines that the farm has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) will, on his own initiative or at the request of a farm, reinstate the qualified exemption
R	112.213(b)	You may ask FDA to reinstate a qualified exemption that has been withdrawn under the procedures of subpart R as follows: 1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and 2) Present, in writing, data and information to demonstrate that you have adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm, such that continued withdrawal of the exemption is not necessary to protect the public health and prevent or mitigate a foodborne illness outbreak
R	112.213(c)	If your qualified exemption was withdrawn under 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will reinstate your qualified exemption under 112.5, and FDA will notify you in writing that your exempt status has been reinstated.
R	112.213(d)	If your qualified exemption was withdrawn under 112.201(a)(1) and (a)(2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under 112.5, in accordance with the requirements of 112.213(b)

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Produce Safety, Audits, and Regulations: A Few Short Question and Answers to Help Fruit and Vegetable Growers

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Q. Why should fruit and vegetable growers know something about food safety?

A. Many fruits and vegetables are eaten raw, with no cooking step to kill microorganisms that could be present. Since farmers grow food people eat, they should know something about how to keep fruits and vegetables safe during production and packing. Produce safety is also important for maintaining market access. Many buyers require fresh produce suppliers to be certified by a third party audit organization to verify food safety practices, such as Good Agricultural Practices, are being used on the farms. In addition, the Food Safety Modernization Act (FSMA) Produce Safety Rule will require food safety practices on farms that are subject to the regulation.

Good Agricultural Practices (GAPs)

Any agricultural management practice or operational procedure that reduces microbial risks or prevents contamination of fruits and vegetables on the farm or in the packing areas.

Third-Party Audit Organizations

An independent organization hired by the farmer (or in some cases, the buyer) to audit their food safety practices. This requires the farm to have a written Farm Food Safety Plan and for a person from the audit company to visit the farm to conduct the audit. Prices for the audit vary and there are many organizations that offer audits (e.g. USDA-AMS, Global GAP, PrimusLabs).

Food Safety Modernization Act – Produce Safety Rule

“The FDA Food Safety Modernization Act (FSMA) enables FDA to better protect public health by strengthening the food safety system. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. As a key element of this preventive approach, FDA was mandated under FSMA to establish science-based, minimum standards for the safe growing, harvesting, packing, and holding of produce on farms to minimize contamination that could cause serious adverse health consequences or death.”

(<http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>)

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Q. Why would buyers require third-party audits?

A. Third-party audit certification is meant to provide verification to the buyer that the produce they purchase is grown and packed under conditions that result in safe, wholesome fresh produce. Safe food is important for many reasons, primary among them being the health of consumers. Many institutions, such as hospitals, daycare centers and nursing homes, feed individuals who are immunocompromised due to illness or age. It is also important from a liability standpoint to have standards that help assure the produce they buy is safe.

Q. Do all buyers require third-party audits?

A. No. Buyer requirements for food safety practices vary widely. Some have no requirements, some require that growers have food safety training, some require a written Farm Food Safety Plan, and some require a third-party audit.

Q. If I pass an audit, does it mean my produce is 100% microbiologically safe?

A. No. Since fresh produce is not cooked or treated in any way that eliminates all food safety risks, there is no way to guarantee safety. This is why it is important that all fresh produce growers understand food safety risks that exist on the farm and take steps to reduce food safety risks.

Q. Who pays for the third-party audit?

A. Usually the grower. In some cases, buyers will pay for the audit or provide partial reimbursement of expenses associated with being audited. Sometimes there are grants available through state departments of agriculture, non-profit organizations, or grower groups to reduce costs.

Q. What do I need to do to have a third-party audit?

A. First, you need to have a written Farm Food Safety Plan. The plan needs to be implemented on your farm with recordkeeping in place to document your practices. Second, you need to contact the audit organization to schedule an audit. It is extremely helpful to conduct your own self-audit prior to having an audit. The audit questions are available, so no audit question should ever be a surprise.

Q. How do I know what audit company to contact?

A. That depends. Some buyers require a specific third-party audit, so they will specify which audit organization is acceptable. If the buyer accepts any third-party audit, growers tend to select the audit that is most affordable and easiest to understand.

Q. If I pass an audit, does that mean I meet the regulatory requirements outlined in the FSMA Produce Safety Rule?

A. No. First, the FSMA Produce Safety Rule became final on November 27, 2015 so most audits are not yet aligned with the requirements in the audit. It is anticipated that some audit companies may modify their audit checklists to incorporate the final FSMA Produce Safety Rule requirements. If you have passed an audit, it is likely you have many necessary practices in place, but not a guarantee of full compliance.

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Q. Will there be farm inspections as part of the FSMA Produce Safety Rule?

A. It is anticipated that farm inspections will be a part of the FSMA Produce Safety Rule, but currently there is no information on how and when these might occur.

Q. What should growers do right now?

A. Every grower should learn about GAPs and understand how produce safety impacts their farm. It does not matter if you have a small farm or a large farm. If you are growing fresh produce that you sell to others, you need to know about produce safety since it impacts the safety and marketability of the crops you grow. All growers also should become familiar with the FSMA Produce Safety Rule, determine if they are subject to the rule, and how it might impact their farm.

Q. How do growers get started and learn more about produce safety and third party audits?

A. There are many ways to get started. There are in-person trainings, online trainings, and this fall there will be Produce Safety Alliance trainings available nationally. In addition, there are consultants, third-party audit organizations, and other Land-Grant Universities that offer educational materials and training courses about both GAPs and third party audits. Visit producesafetyalliance.cornell.edu to join the listserv to be notified about upcoming trainings and to find collaborators in your state.

Summary

The key point is that growers should realize that understanding and implementing produce safety practices are important to the safety of the fruits and vegetables they grow and to the viability of their farm business. Produce safety practices may be required by many buyers, as well as by federal regulation if the farm is subject to the FSMA Produce Safety Rule. The good news is that there are resources available to help growers. Please visit the National GAPs Program (gaps.cornell.edu) and the Produce Safety Alliance (producesafetyalliance.cornell.edu) websites for more information.

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Food Safety Plan Writing Resources

University & Land Grant Resources

1. Cornell University – National GAPs Program

<http://www.gaps.cornell.edu>

Farm Food Safety Decision Trees:

<http://gaps.cornell.edu/educational-materials/decision-trees>

2. University of California – Food Safety

<http://ucfoodsafety.ucdavis.edu/>

UC Small Farm Program – Food Safety:

http://sfp.ucdavis.edu/food_safety/

3. Colorado State University – Farm to Table Food Safety

<http://farmtotable.colostate.edu/>

Template Food Safety Plan:

<http://farmtotable.colostate.edu/grow-files/2012-ColoradoFarmPlanFillableForm.pdf>

4. Michigan State University – Agrifood Safety

<http://www.gaps.msue.msu.edu/index.html>

5. University of Minnesota – Food Safety Plan for You

<http://safety.cfans.umn.edu/fsp4u/>

Template Food Safety Plan:

<http://safety.cfans.umn.edu/files/2013/07/Farm-Food-Safety-Plan-Template.pdf>

6. North Carolina State University – NC Fresh Produce Safety

<https://ncfreshproducesafety.ces.ncsu.edu/ncfreshproducesafety-gaps-food-safety-plans/>

7. Penn State University – How to Write a Food Safety Plan

<http://extension.psu.edu/food/safety/farm/how-do-i-write-a-food-safety-plan>

Template USDA Harmonized Food Safety Plan:

<http://extension.psu.edu/food/safety/farm/how-do-i-write-a-food-safety-plan/template-harmonized-food-safety-plan/view>

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8. Rutgers – Developing a Plan for a Third-Party Audit

<http://njveg.rutgers.edu/html/mf-food-safety.html>

On Farm Food Safety Publications:

<http://plant-pest-advisory.rutgers.edu/food-safety-publications/>

Commodity Specific / Industry

9. Arizona Leafy Greens Marketing Agreement

<http://www.arizonaleafygreens.org/>

10. California Leafy Greens Marketing Agreement

<http://www.lgma.ca.gov/food-safety-program/food-safety-practices/>

11. California Strawberry Commission

<http://calstrawberry.com/>

12. Family Farmed – On Farm Food Safety Project

<http://onfarmfoodsafety.org/>

13. Mushroom GAPs

<https://sites.google.com/a/mgap.org/mgap/>

Penn State MGAP Resources:

<http://extension.psu.edu/food/safety/farm/mushrooms>

14. University of Maine Cooperative Extension

<http://umaine.edu/potatoes/gap-self-audits-and-documentation/>

15. Tomato GAPs

United Fresh Tomato Guidelines:

<http://www.unitedfresh.org/food-safety/fresh-tomato-supply-chain-auditing-protocols/>

16. University of Vermont – Center for Sustainable Agriculture

<http://www.uvm.edu/~susagctr/?Page=whatwedo/producesafety/gapresources.html>

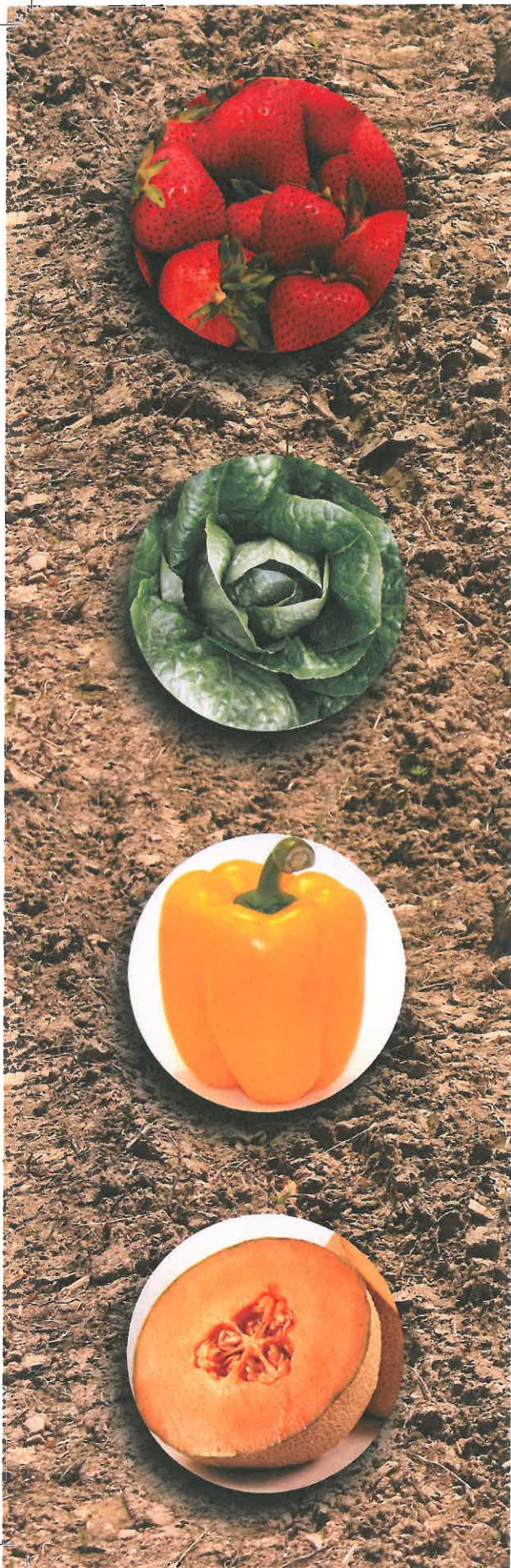
17. Washington State Department of Agriculture – Bridging the GAPs

<http://agr.wa.gov/Inspection/GAPGHP/Guide.aspx>

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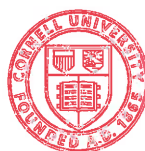
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FDA/USDA Resources

FDA/USDA Resources



Cornell University

KEY REQUIREMENTS: Final Rule on Produce Safety



The FDA Food Safety Modernization Act (FSMA) Produce Safety rule is now final, and the earliest compliance dates for some farms begin one year after the effective date of the final rule (see “Compliance Dates” below). The rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.

This rule was first proposed in January 2013. In response to input received during the comment period and during numerous public engagements that included public meetings, webinars, listening sessions, and visits to farms across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective.

The final rule is a combination of the original proposal and revisions outlined in the supplemental proposal, with additional changes as appropriate. The definition of “farm” and related terms were revised in the final Preventive Controls for Human Food rule, and the same definitions of those terms are used in this rule to establish produce safety standards. Operations whose only activities are within the farm definition are not required to register with FDA as food facilities and thus are not subject to the preventive controls regulations.

Below are summaries of some key requirements, compliance dates, and other information.

1. AGRICULTURAL WATER:

- **Water quality:** The final rule adopts the general approach to water quality proposed in the supplemental rule, with some changes. The final rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination.
 - No detectable generic *E. coli* are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. Examples include water used for washing hands during and after harvest, water used on food-contact surfaces, water used to directly contact produce (including to make ice) during or after harvest, and water used for sprout irrigation. The rule establishes that such water use must be immediately discontinued and corrective actions taken before re-use for any of these purposes if generic *E. coli* is detected. The rule prohibits use of untreated surface water for any of these purposes.
 - The second set of numerical criteria is for agricultural water that is directly applied to growing produce (other than sprouts). The criteria are based on two values, the geometric mean (GM) and the statistical threshold (STV). The GM of samples is 126 or less CFU of generic *E. coli* per 100 mL of water and the STV of samples is 410 CFU or less of generic *E. coli* in 100 mL of water.
 - The GM is an average, and therefore represents what is called the central tendency of the water quality (essentially, the average amount of generic *E. coli* in a water source).
 - STV reflects the amount of variability in the water quality (indicating *E. coli* levels when adverse conditions come into play—like rainfall or a high river stage that can wash waste into rivers and canals). Although this is an over simplification, it can be described as the level at which 90 percent of the samples are below the value.

- The FDA is exploring the development of an online tool that farms can use to input their water sample data and calculate these values.
- These criteria account for variability in the data and allow for occasional high readings of generic *E. coli* in appropriate context, making it much less likely (as compared to the originally proposed criteria for this water use) that a farm will have to discontinue use of its water source due to small fluctuations in water quality.
- These criteria are intended as a water management tool for use in understanding the microbial quality of agricultural water over time and determining a long-term strategy for use of water sources during growing produce other than sprouts.
- If the water does not meet these criteria, corrective actions are required as soon as is practicable, but no later than the following year. Farmers with agricultural water that does not initially meet the microbial criteria have additional flexibility by which they can meet the criteria and then be able to use the water on their crops. These options include, for example:
 - Allowing time for potentially dangerous microbes to die off on the field by using a certain time interval between last irrigation and harvest, but no more than four consecutive days.
 - Allowing time for potentially dangerous microbes to die off between harvest and end of storage, or to be removed during commercial activities such as washing, within appropriate limits.
 - Treating the water.
- **Testing:** The final rule adopts the general approach to testing untreated water used for certain purposes proposed in the supplemental notice, with some changes. The rule still bases testing frequency on the type of water source (i.e. surface or ground water).
 - In testing untreated surface water—considered the most vulnerable to external influences—that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of 20 samples, collected as close as is practicable to harvest over the course of two to four years. The initial survey findings are used to calculate the GM and STV (these two figures are referred to as the “microbial water quality profile”) and determine if the water meets the required microbial quality criteria.
 - After the initial survey has been conducted, an annual survey of a minimum of five samples per year is required to update the calculations of GM and STV.
 - The five new samples, plus the previous most recent 15 samples, create a rolling dataset of 20 samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.
 - For untreated ground water that is directly applied to growing produce (other than sprouts), the FDA requires farms to do an initial survey, using a minimum of four samples, collected as close as is practicable to harvest, during the growing season or over a period of one year. The initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria.
 - After the initial survey has been conducted, an annual survey of a minimum of one sample per year is required to update the calculations of GM and STV.
 - The new sample, plus the previous most recent three samples, create a rolling dataset of four samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV.
 - For untreated ground water that is used for the purposes for which no detectable generic *E. coli* is allowed, the FDA requires farms to initially test the untreated ground water at least four times during the growing season or over a period of one year. Farms must determine whether the water can be used for that purpose based on these results.
 - If the four initial sample results meet the no detectable generic *E. coli* criterion, testing can be done once annually thereafter, using a minimum of one sample. Farms must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criterion.
 - There is no requirement to test agricultural water that is received from public water systems or supplies that meet requirements

established in the rule (provided that the farm has Public Water System results or certificates of compliance demonstrating that the water meets relevant requirements), or if the water is treated in compliance with the rule's treatment requirements.

2. BIOLOGICAL SOIL AMENDMENTS:

■ **Raw Manure:** The FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of raw manure as a soil amendment and harvesting to minimize the risk of contamination. (A soil amendment is a material, including manure, that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water.)

- At this time, the FDA does not object to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil. The agency considers adherence to these standards a prudent step toward minimizing the likelihood of contamination while its risk assessment and research is ongoing.
- The final rule requires that untreated biological soil amendments of animal origin, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application.

■ **Stabilized Compost:** Microbial standards that set limits on detectable amounts of bacteria (including *Listeria monocytogenes*, *Salmonella* spp., fecal coliforms, and *E. coli* 0157:H7) have been established for processes used to treat biological soil amendments, including manure. The rule includes two examples of scientifically valid composting methods that meet those standards. Stabilized compost prepared using either of these methods must be applied in a manner that minimizes the potential for contact with produce during and after application.

3. SPROUTS

- The final rule includes new requirements to help prevent the contamination of sprouts, which have been frequently associated with foodborne illness outbreaks. Sprouts are especially vulnerable to dangerous microbes because of the warm, moist and nutrient-rich conditions needed to grow them.
 - Between 1996 and 2014, there were 43 outbreaks, 2,405 illnesses, and 171 hospitalizations, and 3 deaths associated with sprouts, including the first documented outbreak of *Listeria monocytogenes* associated with sprouts in the United States.
- Requirements specific to sprouts include, for example:
 - Taking measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, in addition to treating seeds or beans that will be used for sprouting (or relying on prior treatment by the seed/bean grower, distributor, or supplier with appropriate documentation).
 - Testing of spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch, for certain pathogens. Sprouts cannot be allowed to enter commerce until it is ascertained that these required pathogen test results are negative.
 - Testing the growing, harvesting, packing and holding environment for the presence of *Listeria* species or *Listeria monocytogenes*.
 - Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive.
- Sprout operations will have less time to come into compliance with the rule than farms growing other produce. They will have one to three years to comply based on the size of their operation, with no additional time to meet the water requirements.

4. DOMESTICATED AND WILD ANIMALS

- The rule addresses concerns about the feasibility of compliance for farms that rely on grazing animals (such as livestock) or working animals for various purposes. It establishes the same standards for these animals as it does for intrusion by wild animals (such as deer or feral swine). Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated.
 - At a minimum, this requires all covered farms to visually examine the growing area and all covered produce to be harvested, regardless of the harvest method used.
 - In addition, under certain circumstances the rule requires farms to do additional assessment during the growing season, and if significant evidence of potential contamination by animals is found, to take measures reasonably necessary to assist later during harvest. Such measures might include, for example, placing flags outlining the affected area.
- Although the final rule does not require establishing waiting periods between grazing and harvest, the FDA encourages farmers to voluntarily consider applying such intervals as appropriate for the farm's commodities and practices. The agency will consider providing guidance on this practice in the future, as needed.
- As was stated in the supplemental notice, farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas. Nothing in the rule should be interpreted as requiring or encouraging such actions.

5. WORKER TRAINING AND HEALTH AND HYGIENE

- Requirements for health and hygiene include:
 - Taking measures to prevent contamination of produce and food-contact surfaces by ill or infected persons, for example, instructing personnel to notify their supervisors if they may have a health condition that may result in contamination of covered produce or food contact surfaces.

- Using hygienic practices when handling (contacting) covered produce or food-contact surfaces, for example, washing and drying hands thoroughly at certain times such as after using the toilet.
- Taking measures to prevent visitors from contaminating covered produce and/or food-contact surfaces, for example, by making toilet and hand-washing facilities accessible to visitors.

- Farm workers who handle covered produce and/or food-contact surfaces, and their supervisors, must be trained on certain topics, including the importance of health and hygiene.
- Farm workers who handle covered produce and/or food contact surfaces, and their supervisors, are also required to have a combination of training, education and experience necessary to perform their assigned responsibilities. This could include training (such as training provided on the job), in combination with education, or experience (e.g., work experience related to current assigned duties).

6. EQUIPMENT, TOOLS AND BUILDINGS

- The rule establishes standards related to equipment, tools and buildings to prevent these sources, and inadequate sanitation, from contaminating produce. This section of the rule covers, for example, greenhouses, germination chambers, and other such structures, as well as toilet and hand-washing facilities.
 - Required measures to prevent contamination of covered produce and food contact surfaces include, for example, appropriate storage, maintenance and cleaning of equipment and tools.

EXEMPTIONS

The rule does not apply to:

- Produce that is not a raw agricultural commodity. (A raw agricultural commodity is any food in its raw or natural state)
- The following produce commodities that FDA has identified as rarely consumed raw: asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets

(roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts

- Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed)
- Produce that is used for personal or on-farm consumption.
- Farms that have an average annual value of produce sold during the previous three-year period of \$25,000 or less.

The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions.

The rule also provides a qualified exemption and modified requirements for certain farms.

- To be eligible for a qualified exemption, the farm must meet two requirements:
 - The farm must have food sales averaging less than \$500,000 per year during the previous three years; and
 - The farm's sales to qualified end-users must exceed sales to all others combined during the previous three years. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away.
- A farm with the qualified exemption must still meet certain modified requirements, including disclosing the name and the complete business address of the farm where the produce was grown either on the label of the produce or at the point of purchase. These farms are also required to establish and keep certain documentation.

- A farm's qualified exemption may be withdrawn as follows:

- If there is an active investigation of an outbreak of foodborne illness that is directly linked to the farm, or
- If FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the farm's produce that would be covered by the rule.

- Before FDA issues an order to withdraw a qualified exemption, the agency:

- May consider one or more other actions to protect public health, including a warning letter, recall, administrative detention, refusal of food offered for import, seizure and injunction.
- Must notify the owner, operator, or agent in charge of the farm, in writing, of the circumstances that may lead FDA to withdraw the exemption, provide an opportunity for response within 15 calendar days of receipt of the notification, and consider actions taken by the farm to address the issues raised by the agency.

- A withdrawn exemption may be reinstated if (as applicable):

- The FDA determines that the outbreak was not directly linked to the farm, and/or
- The FDA determines that the problems with conduct or conditions material to the safety of the food produced or harvested at the farm have been adequately resolved, and continued withdrawal of the exemption is not necessary to protect public health or prevent or mitigate an outbreak of foodborne illness.

VARIANCES

The rule also permits states, tribes, or foreign countries from which food is imported into the U.S. to submit a petition, along with supporting information, to FDA requesting a variance(s) from one or more of the requirements of this rule.

- The rule enables a state, tribe, or country, if it concludes that meeting one or more of the rule's requirements would be problematic in light of local growing conditions, to request variances to those

requirements. The state, tribe, or foreign country must demonstrate that the requested variance is reasonably likely to ensure that the produce is not adulterated and provides the same level of public health protection as the corresponding requirement(s) in the rule.

- The final rule makes it clear that federally recognized tribes may submit a variance petition.
- The request for a variance must be submitted by a competent authority, meaning a person or organization that is the regulatory authority for food safety for the state, tribe, or foreign country.
- A foreign government does not need to have a systems recognition arrangement or equivalence agreement with the FDA to obtain a variance.
- The variance request must include relevant and scientifically valid information specific to the produce or activity. Information could relate to crops, climate, soil, geography or environment, as well as the practices of that particular region.
- Examples of types of variances that may be granted include a variance from the agricultural water microbial quality criteria for water used during growing covered produce (other than sprouts) using a direct water application method, a variance from the microbial die-off rate used to determine the time interval between the last irrigation and harvest and/or the accompanying maximum time interval; and a variance from the approach or frequency for water testing for water uses subject to the rule's microbial quality criteria.

COMPLIANCE DATES

Compliance dates for covered activities, except for those involving sprouts, after the effective date of the final rule are:

- Very small businesses, those with more than \$25,000 but no more than \$250,000 in average annual produce sales during the previous three year period: four years.

- Small businesses, those with more than \$250,000 but no more than \$500,000 in average annual produce sales during the previous three year period: three years.
- All other farms: two years.
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each of these compliance dates for the rest of the final rule.

Compliance dates for modified requirements for farms eligible for a qualified exemption are:

- For labeling requirement (if applicable): January 1, 2020.
- For retention of records supporting eligibility for a qualified exemption: Effective date of the final rule.
- For all other modified requirements:
 - Very small businesses, four years after the effective date of the final rule.
 - Small businesses, three years after the effective date of the final rule.

Compliance dates for covered activities involving sprouts after the effective date of the final rule are:

- Very small businesses: three years
- Small businesses: two years
- All other farms: one year

ENVIRONMENTAL IMPACT STATEMENT

The FDA has also released the Final Environmental Impact Statement (EIS), which places the Produce Safety rule in the context of its likely impact on the environment, including human health and socioeconomic effects. The Draft EIS was published in January 2015. The FDA considered public comments submitted in the two months that followed in drafting the Final EIS. The FDA considered the findings of the Final EIS in finalizing the produce rule.

- The EIS evaluated actions that FDA proposed in the original and supplemental rules, as well as a number of alternative actions for each of the provisions identified as having the potential to result in significant environmental impacts. The provisions of the final rule represent FDA's preferred alternatives, which are detailed in a Record of Decision (ROD). The ROD addresses how the EIS findings were incorporated into decisions about the final rule. The agency's preferred alternatives are those that the FDA believes best fulfill the agency's statutory mission and responsibility, giving consideration to economic, environmental, technical and other factors.
- A significant beneficial impact on public health is expected due to the anticipated decrease in the number of illnesses tied to produce contamination.
- As in the Draft EIS, the Final EIS notes that any produce regulation that causes a farmer to use ground water instead of surface water could exacerbate existing groundwater shortages, although added flexibility in the water provisions make such a management decision unlikely.
- The Final EIS also concludes that Native American farmers may be disproportionately affected by any increases in operating costs necessitated by the produce rule since their average income is 30 percent less than that of other farmers.
- Establishing the FDA FSMA Food Safety Technical Assistance Network, already operational, to provide a central source of information to support industry understanding and implementation of FSMA.
- The FDA is developing a comprehensive training strategy that includes collaboration with:
 - The Produce Safety Alliance;
 - The Sprout Safety Alliance;
 - The National Institute of Food and Agriculture in the U.S. Department of Agriculture (to administer a grant program to provide food safety training, education and technical assistance to small and mid-size farms and small food processors, beginning farmers, socially disadvantaged farmers, and small produce merchant wholesalers); and
 - Cooperative agreement partners (to develop training programs for sustainable agriculture and tribal operations).
- The FDA also plans to work with cooperative extension units, land grant universities, trade associations, foreign partners, the Joint Institute for Food Safety and Applied Nutrition (JIFSAN), and other stakeholders to develop a network of institutions that can provide technical assistance to the farming community, especially small and very small farms.

ASSISTANCE TO INDUSTRY

The FDA is developing several guidance documents on subjects that include:

- General guidance on implementation and compliance
- A Small Entity Compliance Guide that explains the actions a small or very small business must take to comply with the rule.
- Other documents, including guidance on sprouts, are being considered and prioritized.

Plans for training and technical assistance are well under way. They include:

- FDA has entered into a cooperative agreement with National Association of State Departments of Agriculture (NASDA) to help with the implementation of the produce safety regulations.

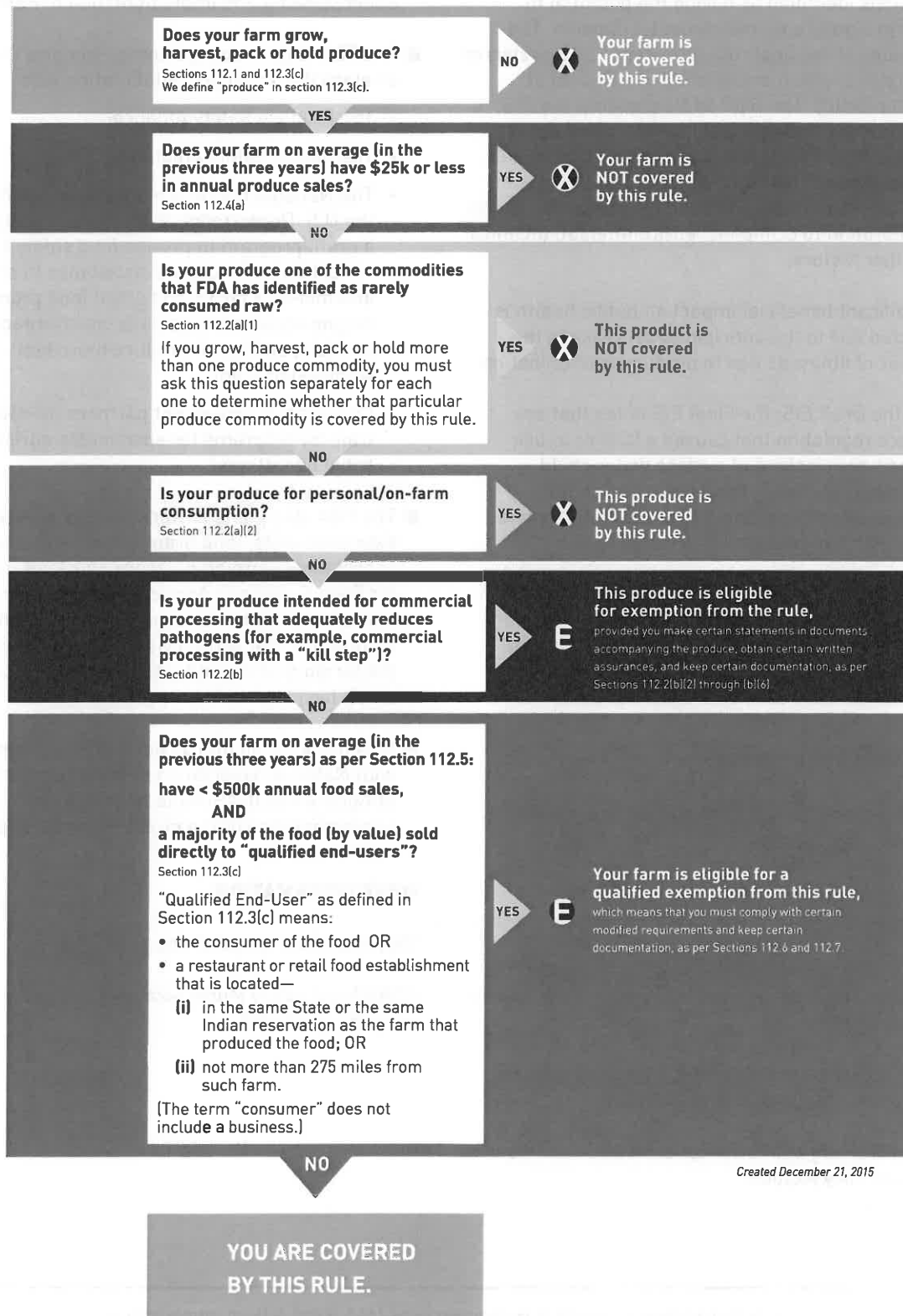
MORE INFORMATION

Visit <http://www.regulations.gov/>

FDA's Food Safety Modernization Act page at www.fda.gov/FSMA

STANDARDS FOR PRODUCE SAFETY Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.



FSMA Technical Assistance Network

At-a-Glance

The FDA Food Safety Modernization Act (FSMA) Technical Assistance Network (TAN) is now operational and providing technical assistance to industry, regulators, academia, consumers and others regarding FSMA implementation. The TAN will address questions related to the FSMA rules, FSMA programs, and implementation strategies after the rules are final. We encourage stakeholders to first visit FDA's FSMA webpage at www.fda.gov/fsma, which contains detailed information on all aspects of FSMA, including implementation. The webpage includes Frequently Asked Questions about FSMA by topic area. FDA is implementing the TAN in two phases:

- Phase 1 addresses inquiries related to the publication of FSMA rules and is operational.
- Phase 2 will provide technical assistance to FDA and State staff performing inspections and supporting compliance activities; it will be implemented by 2017 when preventive controls inspections are targeted to begin.

Below are the key features of the TAN:

- Inquiries may be submitted through a web form. The web form can be accessed at www.fda.gov/fsma. Go to **Contact Us** and then **How to Contact FDA on FSMA**.
- Inquiries may also be submitted by mail if the Internet is not available at the following address:

Food and Drug Administration
5100 Paint Branch Pkwy
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

Note: the FSMA related mailboxes
(e.g. FSMA@fda.hhs.gov and FSMAfaqs@fda.hhs.gov)
are no longer active.

- Inquiries are answered by FDA Information Specialists or Subject Matter Experts, based on the complexity of the question. Complicated questions may require more time for a response. FDA will respond to inquiries received as soon as possible. However, response times may vary, due to complexity of question and the volume of inquiries we receive.
- Once a question is submitted, the inquirer will receive notification of receipt and a case number to be referenced in future correspondence.
- Questions will be tracked and trended using a Knowledge Management System (KMS) to assist FDA in prioritizing, in part, FSMA policy, guidance, and training. Additionally, repeat questions will be addressed in Frequently Asked Question or guidance documents posted on FDA's website.
- Routine communication and data-sharing protocols with external TANs, e.g. Alliances (such as the Food Safety Preventive Controls Alliance), are vital for coordination and success.

FDA's Strategy for FSMA Training: Who Will Provide Training for the Food Industry? Public and Private Partners Working Together

Executive Summary

The FDA Food Safety Modernization Act (FSMA) will transform the nation's food safety system into one that is based on the prevention of foodborne illnesses. It will be a system in which the food industry systematically puts in place measures proven effective in preventing contamination.

Keeping food safe to eat is paramount, no matter where it is produced, whether conventional or organic, whether the operation is small, medium or large, whether it's produce or processed foods.

The FDA has finalized the seven foundational rules that will implement FSMA. These include the two Preventive Controls rules for Human and Animal Food, the Produce Safety rule, and the Foreign Supplier Verification Programs (FSVP) rule. There will be extensive outreach to industry to help ensure that everyone who seeks to comply with these rules, whether legally required to or not, understands the new requirements.

Food industry training will be an important component of successful implementation. The Produce Safety Rule and the Preventive Controls rules all have training components, although they are not the same for each rule. There will be ample time for farmers and food producers to come into compliance with the FSMA rules. Compliance dates for the rules are staggered according to the size of the business and other factors.

While members of the food industry are ultimately responsible for getting the training they need to comply with the FSMA rules, the FDA recognizes the importance of its role in facilitating that training. For the agency, this means joining with public and private partners in state, federal, tribal and international governments, industry, and academia in the development and delivery of training.

One size doesn't fit all. The most important goal that the FDA expects of any training program is the outcome—that it advances knowledge among the food industry to meet FSMA requirements. There is more than one way to get there and there will be a variety of training options and delivery formats:

- The vision of FSMA training began in 2010-2012 with the creation of public-private Alliances funded primarily by the FDA as a resource for industry and to facilitate widespread understanding of the new standards to support compliance. Training through the Alliances will be available shortly after the rules have been finalized.

- Recognizing the great diversity among members of the food industry, the FDA is building on that investment by funding cooperative agreements that will develop training options for local food production systems and tribal operations.
- The FDA is partnering with the U.S. Department of Agriculture's National Institute of Food and Agriculture (NIFA) to provide grants to fund a National Coordination Center (NCC) and four Regional Centers (RCs) to provide training opportunities for owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers.

FSMA training will encompass various members of the food industry, including domestic and foreign food producers and domestic importers. The FDA will work with partners around the world—including the Alliances, regulatory counterparts, and multinational organizations—to promote training to the global community of food suppliers. Participants will likely receive documentation of completion for any of the above mentioned training options.

The following is a description of the evolving training strategy. There is a glossary of frequently used terms and a listing of some of the FDA's training partners at the end of this document.

Summary of the Major Components of the Training Strategy

The FDA is striving for transparency as this multi-faceted training plan for the food industry, outlined below, takes shape.

Crafting the FSMA Alliance Curricula

The Produce Safety Alliance (PSA), Food Safety Preventive Controls Alliance (FSPCA), and Sprout Safety Alliance (SSA) are developing training programs to help domestic and foreign food businesses—including small and very small farms and facilities—understand the requirements of the preventive controls regulations and the Produce Safety rule. The Alliances are composed of representatives from the government, including FDA, USDA, and state regulatory agencies, the food industry, and academia.

The Alliances initially conducted extensive outreach to gain an understanding of training needs, including a consideration of food safety training available prior to FSMA. Since then, the Alliances have actively engaged over the past several years with hundreds of stakeholders—including food processors, the farming community, academia, cooperative extension, and regulators—to develop industry training curricula. Numerous working groups assessed course content needs, established learning objectives, and defined critical elements for the curricula. The Alliances also conducted pilot sessions with these partners to review training materials.

The curricula developed through the Alliances will focus on the FSMA rules and the foundational

reasons for the rules' existence to foster an understanding of both what is required and why it is required. They will be designed to be model curricula with training modules that can be added to meet unique needs.

The Alliances are working to ensure that training opportunities available to international food businesses are consistent with those being provided domestically. FSPCA—working with PSA, as well as representatives of importers and foreign governments, and others—has established an International Subcommittee to address the training, education and technical assistance needs of global stakeholders.

More on the individual Alliances:

- The most longstanding is the **Produce Safety Alliance (PSA)**, a partnership created between Cornell University, the U.S. Department of Agriculture (USDA) and FDA in 2010. PSA's role includes developing:
 - Standardized training and education curriculum to assist the domestic and foreign produce industry, including but not limited to small and very small farms, as well as regulatory personnel, with the implementation of FDA's Produce Safety rule.
 - A Train-the-Trainer (TTT) course to develop certified trainers and an interview process for developing certified lead trainers who are qualified to use the curriculum to train farms. The TTT course will include information on Good Agricultural Practices (GAPs), concepts of adult learning, and the forthcoming FSMA Produce Safety standards.
 - A website at www.producesafetyalliance.cornell.edu
 - A network of trainers to support the produce industry and the dissemination of produce safety trainings
- The **Food Safety Preventive Controls Alliance (FSPCA)**, initiated in 2011 and coordinated by Illinois Institute of Technology's Institute for Food Safety and Health, is developing a standardized training and education program and technical information network to help the domestic and foreign food industry, including certain mixed-type facilities on farms, comply with the requirements of the Preventive Controls rules for human and animal food, as well as the rule on Foreign Supplier Verification Programs (FSVP). This work includes developing:
 - Two separate standardized hazard analysis and preventive controls training courses and distance education modules—one for human food industry and regulatory personnel and another for animal food industry and regulatory personnel.

- A training curriculum that addresses:
 - resources for and preliminary steps in developing a food safety plan,
 - types of hazards, conducting a hazard analysis, preventive controls for hazards,
 - monitoring preventive controls, verification and validation, and corrective actions/corrections,
 - recordkeeping, and
 - regulatory requirements.
- A website at <http://www.iit.edu/ifsh/alliance/>
- Two separate Train-the-Trainer courses for those interested in helping to train food facilities—one course for human food and another for animal food.
- A module on the FSVP rule for processors who import foods, and a full FSVP course for non-processor importers. The Alliance is also encouraging all importers to take the complete Preventive Controls training.
- The **Sprout Safety Alliance (SSA)**, initiated in 2012 and coordinated by Illinois Institute of Technology's Institute for Food Safety and Health, is serving as a network hub and resource for the sprout industry, and federal and state regulatory agencies. SSA is developing:
 - Training materials that will provide techniques to enhance the safe production of sprouts, and facilitate implementation of relevant requirements in the Produce Safety rule.
 - A Train-the-Trainer course for those interested in helping to train farms on safe sprout production.
 - A website at http://www.iit.edu/ifsh/sprout_safety/

The Alliance-developed materials will be publically available for use in training activities and as benchmarks for others developing equivalent curricula.

Alternate Training Options

The FDA will be issuing guidance that details the core criteria, learning objectives, and elements recommended for FSMA training programs.

The three FDA-funded Alliances (Produce Safety, Food Safety Preventive Controls, and Sprout Safety) are developing model, standardized curricula that are intended to meet the needs of, and be used by, the majority of those affected by the FSMA rules.

By the same token, the FDA recognizes that traditional training activities may not work for all groups,

and there are certain instances in which alternate curricula and training delivery may be appropriate.

The FDA intends to fund the development of certain alternate training programs for specific target audiences through cooperative agreements, as discussed further below. The agency will work closely with the participants in those agreements and expects to recognize the training programs that are developed through these collaborations.

The agency intends that the standardized curricula being developed by the Alliances and the alternate curricula to be developed through cooperative agreements are the only ones that will be officially recognized by the FDA. The agency encourages those developing other training courses to work with the Alliances, the NCC and the RCs to ensure consistency and completeness of training. The agency plans to provide additional information regarding how such training programs will be evaluated.

Cooperative Agreements

FDA-funded cooperative agreements encompass a range of actions to support implementation of the FSMA rules.

- The agency has entered into a five-year cooperative agreement with the **National Association of State Departments of Agriculture (NASDA)** that brings together a range of state partners to collaboratively plan implementation of the Produce Safety rule.
 - Experts from FDA and NASDA are working together to develop a set of best practices for implementation of the produce rule. A coalition of states with strong interest in leading this implementation is actively participating in the development of these practices.
 - NASDA will help facilitate industry training and will also play a role in the delivery of training to state regulators.
- To accommodate alternate approaches to FSMA readiness, the FDA plans to fund development of several specific training programs through cooperative agreements. The agency's goal is to work with groups that understand the special needs of and have direct access to businesses that face unique circumstances and challenges in implementing FSMA. These training programs would include providing an awareness of the underlying reasons for the new standards and would ensure that training addresses the unique needs of the target audiences.

Specifically, cooperative agreements are planned to support curricula development and dissemination among two such communities: local food producers, including those engaged in direct marketing (see glossary below for more information), and tribes.

- The agency plans to allocate Fiscal Year 2016 funds for the development of training curricula and delivery, in addition to education and outreach, with a focus on small and mid-

size businesses involved in local food production, including those that engage in sustainable and organic farming.

- The FDA anticipates funding a similar cooperative agreement for the development of training curricula and dissemination in tribal communities.
- The FDA will be involved in facilitating communications between the Alliances and the participants in the new cooperative agreements to maximize use of materials that are already developed, when appropriate.

Establishing the National Coordination and Regional Centers to Support Training Delivery

In January 2015, the FDA announced that it had joined with USDA's National Institute of Food and Agriculture (NIFA) in a collaborative partnership to establish the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program, as mandated in Section 209 of FSMA.

As mandated in FSMA, this competitive grant program will provide food safety training, education, extension, outreach, and technical assistance to owners and operators of farms, small food processors, and small fruit and vegetable merchant wholesalers.

Grants issued through this program will fund a **National Coordination Center (NCC)** and four **Regional Centers (RCs)**, which will be involved in both key components of training—primarily facilitating training delivery but also, in certain situations, facilitating curricula development targeted to specific audiences.

- FDA has awarded the **International Food Protection Training Institute** (<http://www.ifpti.org>) a grant of up to \$600,000 over three years to establish the NCC, which will lead coordination of curriculum development and delivery to those food businesses covered by the FSMA Section 209 mandate for implementation of FSMA.
- The NCC will coordinate and support the delivery of standardized and/or alternate training curricula through the RCs.
- The RCs will be charged with understanding and communicating the landscape of training opportunities available to target businesses in their region. They will identify any need to develop or tailor curricula to meet specific unmet regional needs and/or to target a specific audience. Training programs may differ to meet those needs. The NCC will facilitate communication between the RCs, the Alliances and other partnering groups about the development of such region- and/or audience-specific materials.

- The regional centers will be established with separate grant money in the Southern, Western, North Central and Northeast regions of the country. These centers will work with representatives from non-governmental and community-based organizations, as well as representatives from cooperative extension services, food hubs, local farm cooperatives and other entities that can address specific needs of the communities they serve.
- Those eligible to receive a grant to establish a regional center included federal, state, or local government agencies, state cooperative extension services, non-profit community-based or non-governmental organizations, institutions of higher education, tribal organizations and tribal stakeholders, or a collaboration of two or more eligible entities.

Work has already begun on the establishment of the regional centers. In October 2015, NIFA issued grants for the Southern and Western regional centers to the University of Florida and Oregon State University. In February 2016, the FDA issued grants for the North Central and Northeast centers to Iowa State University and the University of Vermont and State Agricultural College.

Delivering the Training

Communication between organizations involved in curriculum development and delivery will strengthen the delivery of training and will involve coordination between the Alliances, NCC, RCs, and other training providers. Other organizations have had key roles in the development and/or delivery of training, as well as training certificates.

- The three Alliances—**Produce Safety Alliance (PSA)**, **Food Safety Preventive Controls Alliance (FSPCA)**, and **Sprout Safety Alliance (SSA)**—are developing Train-the-Trainer programs to ensure that lead trainers are familiar with, and prepared to deliver, the curricula and that they understand the requirements of the FSMA rules.
 - Lead trainers—selected based on their education, work experience and training experience—who complete Train-the-Trainer programs will, in turn, deliver training to industry through an established process in which a certificate of completion of the PSA, FSPCA or SSA training is issued to participants.
- The FDA intends that funding of organizations and tribes through **cooperative agreements** will finance both the development of training curricula and the delivery of that training.
 - Training delivery for industry—and possibly trainers—will be coordinated through the cooperative agreement and these organizations will interact with the NCC, RCs,

Alliances, Extension and other partners to increase awareness of recognized training programs.

- These programs may also provide a certificate of completion to food industry participants.
- An important partner in the delivery of the recognized training programs will be the well-established network of cooperative extension offices affiliated with land-grant universities. This key group will support training efforts based on both the standardized and alternate curricula recognized by FDA.
- Other key partners on training delivery include:
 - PSA's four **Regional Extension Associates**, which will deliver training curricula developed by PSA.
 - NASDA and other state regulatory stakeholder associations, including the **Association of Food and Drug Officials**, the **Association of Public Health Laboratories**, the **Association of American Feed Control Officials**, and the **Association of State and Territorial Health Officials**. These state stakeholder groups participate in the Alliances and will help facilitate FDA-recognized industry training, as well as the training of state regulators.
 - The **Joint Institute for Food Safety and Applied Nutrition (JIFSAN)** for international training programs. JIFSAN is a partnership between the FDA and the University of Maryland.
 - Other training entities, such as government agencies, cooperative extension, universities, trade associations, nonprofit and community-based organizations, and consultants, who will deliver both the standardized and alternate curricula recognized by FDA.
- The NCC will coordinate training delivery to food businesses covered by the FSMA Section 209 mandate through the RCs and will ensure the involvement of partners during the development of and dissemination of training.
 - The RCs will coordinate and facilitate the delivery of curricula.
 - The RCs may also coordinate with multiple training entities to deliver the curricula in the most effective way for a target audience.

FSMA Collaborative Training Forum

The FDA intends to establish an informal **FSMA Collaborative Training Forum**, co-chaired by the FDA and USDA, to provide an opportunity for dialogue between the agencies, centers, associations and

others involved in this training.

- It will be a chance for representatives of these groups to come together, share information about their programs, provide updates about the work, and discuss issues of common concern. The purpose is not to come to a consensus on issues but to have an open dialogue about them and, to the greatest extent possible, eliminate duplication and maximize the use of limited resources.
- Participants will represent the FDA, USDA, the Alliances, the NCC, JIFSAN, NASDA, and the organizations who have received cooperative agreements. Others may be invited to join where appropriate.
- It is anticipated that meetings will be held on a quarterly basis.

Conclusion

FDA is on a path to working with public and private partners globally to ensure that training programs meet the needs of those who must comply with the new FSMA standards, no matter their size, nature or location.

It will take time and effort to make this work, and to get it right. FDA is committed to making sure that everyone involved in the food supply chain knows what training and education resources are available, and how to gain access to them.

Glossary of Terms Often Used in FSMA Training Documents

- **Standardized training curriculum:** A structured program in which the training materials will be recognized by the FDA as meeting the training standards and requirements in the Produce Safety rule (as proposed) and the Preventive Controls rules. The three FDA-funded Alliances (Produce Safety, Food Safety Preventive Controls, and Sprout Safety) are developing model, standardized curricula designed to meet the needs of, and be used by, the majority of stakeholders who must comply with the FSMA rules.
- **Alternate curriculum:** FDA-recognized training programs to be developed through cooperative agreements. The agreements currently planned will support curricula development and dissemination among local food producers and tribes. The agency plans to provide additional information regarding how training programs developed by other entities (including universities, trade associations, and non-profit organizations) will be evaluated.
- **Train-the-Trainer:** Programs offered to those interested in becoming trainers and providing training for others on the FSMA regulations. The lead trainers would be schooled in

foundational food safety principles, the applicable FSMA regulations, the content of the training curriculum and how to deliver it, conducting working group exercises (as appropriate), and the principles of adult education. These are being developed by the Alliances and may also be part of alternative training programs.

- **Training delivery:** The dissemination of training curricula. (The approach may vary as appropriate for the target audience.)
- **Regional needs:** Regions may have unique needs based on target audiences and the nature of their food operations. This could include environmental differences, cultural considerations, the type of product, and marketing strategies. Examples include dry-climate farming practices, organic products, and direct-marketing channels.
- **Cooperative agreements:** An FDA cooperative agreement is a grant funding mechanism that involves significant FDA participation during the performance of the work. These usually involve FDA-funded partnerships with entities in the public or private sector, or both, that are designed, in this case, to lay the groundwork for FSMA implementation.
- **Local food production:** Food marketing channels that focus on providing food to a community or region directly or through intermediated markets. The farms and food enterprises that utilize these market channels include diversified, sustainable, organic, and identity-preserved agricultural operations; owner-operated and family farms; beginning and socially disadvantaged farmers; value-added farm businesses and small-scale processors; and direct and intermediated supply chain participants.

Setting the Stage for FSMA Implementation

The following organizations working in partnership with FDA have important roles in providing training to the food industry in preparation for implementation of FSMA:

Produce Safety Alliance (PSA): This Alliance was created by FDA and USDA, in cooperation with Cornell University, to develop a standardized training and education program to increase produce safety knowledge and prepare the produce industry and associated groups for FSMA implementation.

Food Safety Preventive Controls Alliance (FSPCA): This Alliance was created by a grant from FDA to the Illinois Institute of Technology's Institute for Food Safety and Health, to develop a standardized training and education program that will help industry comply with the Preventive Controls rules for human and animal food for animals under FSMA.

Sprout Safety Alliance (SSA): This Alliance was created by FDA, in cooperation with the Illinois Institute of Technology's Institute for Food Safety and Health, to develop a standardized training and education

program and help sprout producers identify and implement best practices in the safe production of sprouts and prepare for FSMA implementation.

National Institute of Food and Agriculture (NIFA): Part of the U.S. Department of Agriculture, NIFA is partnering with the FDA to provide grants to fund food safety training, education, extension, outreach, and technical assistance to owners and operators of farms; small food processors; and small fruit and vegetable merchant wholesalers.

National Coordination Center (NCC): This center, funded by the FDA, will lead the coordination of training delivery, outreach, education and technical assistance to reach small and medium-size farms, beginning and socially disadvantaged farmers, small processors, and small fruit and vegetable merchant wholesalers.

Regional Centers (RCs): These regional centers will work with the NCC to increase the understanding and adoption of established food safety standards, guidance, and protocols. They will identify region and audience-specific training, education, outreach and technical assistance needs and deliver training to food producers covered by the FSMA Section 209 mandate, in addition to ensuring the availability of informed trainers.

International Food Protection Training Institute (IFPTI): Established in 2009, IFPTI is a public-private partnership that addresses public health needs and collaborates with industry, federal, state and international governments, and other organizations. IFPTI, which builds training and certification systems for food safety professionals, has been awarded the contract to establish the NCC described above.

Cooperative Extension and Land-Grant Universities: More than 100 land-grant colleges and universities have extension programs through which they bring science-based information to agricultural producers and small business owners, among others. Members of the Cooperative Extension System will have key roles in the delivery of FSMA training.

Cooperative Agreement Partners: The recipients of FDA funding to support curricula training and delivery to local food producers, including sustainable and organic farms, and tribes.

National Association of State Departments of Agriculture (NASDA): This association of state officials is in partnership with the FDA to collaboratively plan implementation of the produce safety rule under FSMA. NASDA will help facilitate industry training and will also play a role in the delivery of training to state regulators.

Additional Organizations: These state stakeholder organizations will also have roles in facilitating regulatory and industry training:

- **Association of Food and Drug Officials**, whose members include state and local officials involved in critical food safety issues;
- **Association of Public Health Laboratories**, which works to strengthen laboratories serving public health;
- **Association of American Feed Control Officials**, whose members include state, local and federal officials involved in the safety of animal feed, and
- **Association of State and Territorial Health Officials**, which represents public health agencies and professionals.

Joint Institute for Food Safety and Applied Nutrition (JIFSAN): This partnership between the FDA and the University of Maryland strives to increase global knowledge of effective food safety practices.

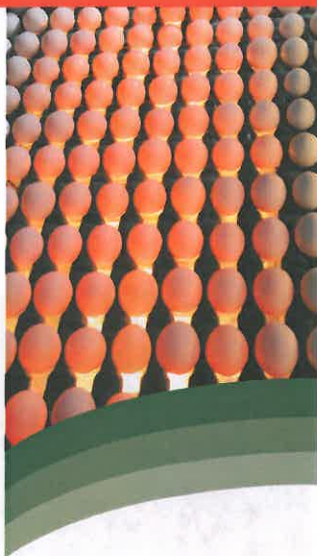
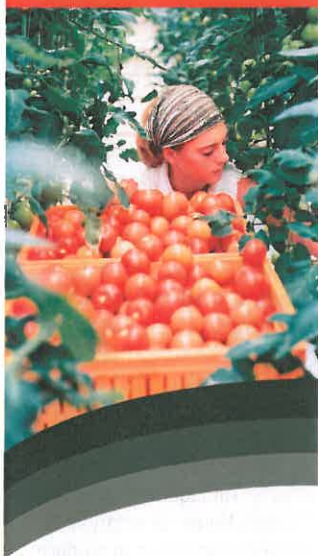
FSMA Collaborative Training Forum: Co-chaired by the FDA and USDA, this forum will facilitate communication and coordination between the groups involved in FSMA training and give the groups an opportunity to share information about their programs and address common concerns. In addition to the two agencies, represented groups will include the Alliances, the NCC, JIFSAN, NASDA, and the organizations that have received cooperative agreements with FDA. Other stakeholder groups may also be included.



United States Department of Agriculture

Agricultural Marketing Service

Creating Opportunities for American Farmers and Businesses



The U.S. Department of Agriculture's Agricultural Marketing Service (AMS) provides the agriculture industry with valuable tools and services that help create marketing opportunities. AMS ensures the quality and availability of wholesome food and agricultural products for consumers in domestic and export markets.

American agriculture is extremely diverse and includes urban and rural operations of every size. It supports 1 in 12 U.S. jobs and provides safe, affordable food to consumers across the globe. The last 4 years represent the strongest in U.S. history, with U.S. agricultural product exports exceeding \$478 billion.

Nearly 4,000 AMS professionals work every day to support agriculture, from individual farmers to international businesses, helping American agriculture remain competitive in a global marketplace. AMS' services and grant investments also create opportunities by supporting economic development in small towns and rural communities that stand as the backbone of American values.

Marketing Agreements and Orders

Marketing agreements and orders are initiated by industry to help provide stable markets for dairy products, fruits, vegetables, and specialty crops. They help maintain the quality of produce being marketed; standardize packages/containers; and authorize advertising, research, and market development. Each order and agreement is tailored to the needs of local market conditions for producing and selling.

Commodity Procurement

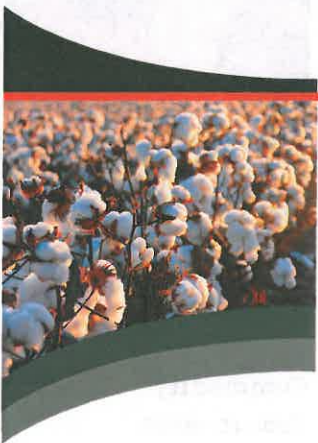
AMS purchases a variety of food products in support of USDA's National School Lunch Program and other food assistance programs. These purchases also help to stabilize prices in agricultural commodity markets. The purchases include around 250 different items, such as fresh fruits, vegetables, beef, and poultry. Each year, AMS issues over 2,000 contracts to purchase about 1.5 billion pounds of food, with about half of the contracts supporting U.S. small businesses.

AMS awards more than \$60 million each year through its Organic Cost Share programs, the Farmers Market Promotion Program, Specialty Crop Block Grant Program, and Federal-State Marketing Improvement Program.

www.ams.usda.gov

Quality Standards, Grading, Certification, Auditing, and Inspection

AMS quality standards, grading, certification, auditing, and inspection are voluntary tools and services that industry can use to help promote and communicate quality and wholesomeness to consumers. These services assist businesses in differentiating themselves from their competition. Examples of USDA grades include USDA Prime, USDA Grade A, and U.S. No. 1. Annually, AMS grades, audits, certifies and/or inspects over \$150 billion worth of agricultural products, ensuring the quality of domestic goods and helping American farms and businesses export goods to over 100 different countries.

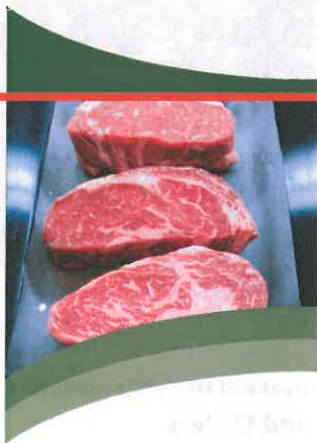


Research and Promotion

Research and Promotion programs, authorized by Congress, are industry-driven and industry-funded. AMS oversees over 20 research and promotion boards that empower farmers, ranchers, and agricultural businesses. The programs establish a framework to pool resources to develop new markets, strengthen existing markets, and conduct important research and promotion activities. AMS provides oversight, ensuring fiscal responsibility, program efficiency, and fair treatment of participating stakeholders.

USDA Market News

For 100 years, AMS has provided free, unbiased price and sales information to assist in the marketing and distribution of farm commodities. Each year, Market News issues thousands of reports providing the industry with key wholesale, retail, and shipping data. The reports give farmers, producers, and other agricultural businesses the information they need to evaluate market conditions, identify trends, make purchasing decisions, monitor price patterns, evaluate transportation equipment needs, and accurately assess movement. The information captures data for cotton, fruits, vegetables and specialty crops, livestock, meats, poultry, eggs, grain and hay, milk and dairy, and tobacco.



Seed Regulatory and Testing Services

AMS helps support the \$12 billion U.S. seed industry by educating and training analysts from State governments, industry organizations, and private companies on Federal or State seed laws, changes in industry rules, and both common and advanced testing and, identification techniques with the goal of promoting uniformity in seed testing throughout the United States. This support helps seed companies remain competitive both domestically and abroad.

National Organic Program

Organic certification verifies that farms and handling facilities comply with the USDA organic regulations and allow farmers and businesses to sell, label, and represent their products as organic. The program protects the integrity of organic products through auditing certifiers, investigating complaints, and enforcement. The program also helps American farmers and processors tap into the growing international organic market through trade partnerships with several countries. Today, the industry encompasses over 17,000 organic businesses and has grown to \$35 billion in annual U.S. retail sales.



Laboratory Approval and Testing Services

AMS National Science Laboratories (NSL) is a full-service testing facility that provides analyses on raw and processed agricultural commodities. NSL provides chemical, microbiological, biomolecular, and physical testing services in support of grading, commodity purchases, research, and domestic and export marketing. Also, AMS administers laboratory approval programs to enhance market access for U.S. commodities, domestically and internationally. This service verifies that products meet various customers' or countries' testing requirements.

Plant Variety Protection (PVP)

The PVP office grants certificates of intellectual property protection (similar to patents) to developers of new varieties of plants which are reproduced sexually by seed or are tuber propagated. This protection enables a breeder to market the variety exclusively for 20 years (25 years for trees and vines), which creates an incentive for the development of new varieties. The PVP office has issued more than 8,700 certificates of protection since 1970.

Farmers Markets and Local Food

AMS works to improve marketing opportunities for producers through the combination of research, technical services, and grants. Each year, AMS helps hundreds of agricultural food businesses, including farmers markets, food hubs, wholesale markets, retailers, State agencies, community planning organizations, and other agri-food focused groups, enhance their local food marketing efforts. Through the National Farmers Market Directory, AMS connects consumers to producers at over 8,000 farmers markets, providing location and operation information.

Perishable Agricultural Commodities Act (PACA)

PACA was enacted at the request of the fruit and vegetable industry to promote fair trade in the industry. The PACA protects businesses dealing in fresh and frozen fruits and vegetables by establishing and enforcing a code of fair business practices and by helping companies resolve business disputes.

Front page photos: girl picking tomatoes and hillside with dairy cows courtesy Gunnar Magnusson.

Photos on this page: cotton field courtesy Kimberly Vardeman; San Francisco Farmers Market courtesy Gary Yost



United States Department of Agriculture

Agricultural Marketing Service



GOOD AGRICULTURAL PRACTICES (GAPs)

The USDA Agricultural Marketing Service's Specialty Crops Inspection (SCI) Division is a team of professionals who provide quality assurance reviews, inspections, and food safety audits, and develop national standards for both fresh and processed fruits and vegetables, and related products, to support the global specialty crops market.

WHAT ARE GAPs

GAPs are principles and practices applied at the farm level to reduce the risk of microbial contamination of fruits and vegetables during production, harvest, and packaging. The principles are based on the Food and Drug Administration's *"Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables."* SCI's GAPs audits verify that your operation follows and maintains the processes and practices you have put in place to minimize potential food safety risks. GAPs audits cover:

- Farm/Greenhouse
- Harvest
- Packing house and cooler/cold storage
- Storage and distribution
- Transportation
- Traceability

BENEFITS OF GAPs CERTIFICATION

- Broadens your market opportunities by satisfying buyers' demands for suppliers to be GAPs certified.
- Reduces your risk of not complying with national and international regulations, standards, and guidelines.
- Reduces the risk of your product introducing food-borne illnesses into the supply chain.

SCI — YOUR AUDIT PROVIDER

A few reasons to choose SCI as your GAPs audit provider:

- Nationwide team of experts that provides fast, cost-effective services.
- Proven record of buyer acceptance of our customers' product.
- Effective way to communicate to your customers your commitment to food safety and adherence to best practices.
- USDA auditors receive robust training, and are constantly evaluated to ensure their performance.
- Ongoing verification of your continued compliance and performance.

FOR MORE INFORMATION

USDA Specialty Crops Inspection Division
1400 Independence Avenue, SW
Room 1536-S, Stop 0240
Washington, DC 20250-0240

Email: SCI@ams.usda.gov
Phone: 202-720-5870
www.ams.usda.gov



GOOD AGRICULTURAL PRACTICES - HARMONIZED GAPs

WHAT IS HARMONIZED GAPs

Developed under the leadership of the United Fresh Food Safety & Technology Council to drive harmonization of several GAP standards, and to reduce audit fatigue by suppliers, and allow operations to focus their food safety resources on achieving food safety.

- The Produce GAPs Harmonization Initiative, was an all-industry effort including growers, shippers, produce buyers, government agencies, audit organizations and other stakeholders.
- The result is Good Agricultural Practices standards and audit checklists for pre and post-harvest operations, applicable to all fresh produce commodities, and all sizes of on-farm operations and all regions in the U.S.

THE BENEFITS OF HARMONIZED GAPs

- Brings together many audit schemes
- Developed and recognized by major institutional buyers and sellers and minimizes "audit creep"
- Are risk-based, science based, attainable, auditable and verifiable
- Takes into account regional food safety needs
- Not commodity specific -- allowing for adaptability to generally all commodity groups
- Harmonized audits reduce the number of multiple audits for the same operations.
- Evaluates and measures a Grower Risk Assessment
- Includes an evaluation and assessment of worker health and hygiene
- USDA acceptance criteria includes a section for "Global Markets Program" -- an added step to meet international requirements. Including:
 - * Farm supplies are traced and reviewed
 - * Chemical storage and chemical origination
 - * Food Defense

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Last updated May 2014



United States Department of Agriculture

Agricultural Marketing Service

Innovative GroupGAP Food Safety Program

Unique Verification Program Opens Doors for Produce Industry

Along with a number of programs and services that facilitate marketing, the United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) helps create opportunities for growers and buyers through its Good Agricultural Practices (GAP) and Good Handling Practices (GHP) Audit Programs, which verify that operations follow industry-recognized food safety practices and recommendations from the Food and Drug Administration (FDA).

After 3 years of field testing, AMS is launching GroupGAP, a new food safety certification option that will increase opportunities for the entire industry to supply and buy GAP-certified produce.

Benefits to Buyers and Retailers

The GroupGAP Program is an innovative solution that helps retailers and buyers meet the increasing consumer demand for local food while maintaining strong food safety standards.

- USDA-AMS certifies that the grower groups are following industry-recognized food safety practices.
- More small and mid-sized farmers can demonstrate that they have met retailer food safety requirements for "buy local" programs.



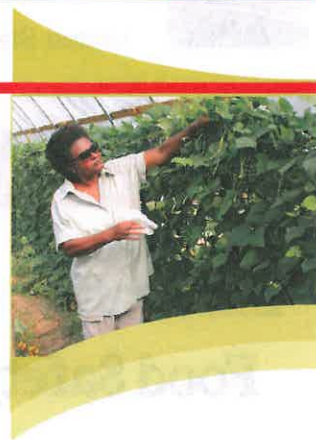
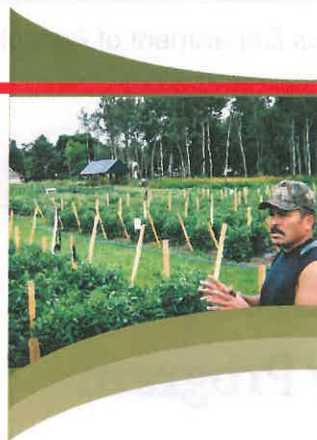
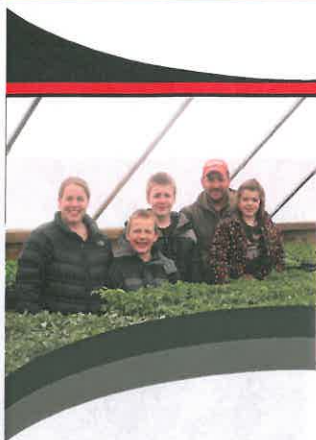
- These new suppliers help stores build an inventory of local food from growers who previously couldn't access mainstream retail markets.
- GroupGAP efficiencies allow buyers and retailers to broaden their base of suppliers, so they are more resilient in the face of supply challenges or disruptions.
- Diverse product offerings are available from a group of growers rather than a single grower, and
- Importantly, GroupGAP will comply with upcoming FDA requirements under the Food Safety Modernization Act.

Paving a New Path for Small Growers To Reach the Retail Market

At the same time that retailers need assurances that vendors are complying with food safety guidelines, demand for local food is expanding beyond farmers markets into grocery stores, restaurants, schools, and other institutions. As more and more retailers require these types of audits, demand for AMS services has increased, with the agency performing over 3,800 GAP/GHP audits in 2014.

(continued on back)

www.ams.usda.gov



How it Works

Many small and mid-sized farmers currently face challenges paying for the food safety certification needed to participate in these larger markets. The GroupGAP Audit Program makes it easier for growers and cooperatives, particularly small growers, to afford GAP certification. Under the program, an entire group of growers can be certified, potentially saving money and time by leveraging economies of scale in the marketplace. GroupGAP helps smaller operations comply with food safety requirements. Members of a group can:

- Fully leverage existing resources and share certification costs.
- Develop and implement their own quality management systems and food safety programs.

- Reduce individual documentation and maintenance requirements, and
- Maintain compliance via internal audits by a single, shared USDA-trained food safety manager, with verification by USDA-licensed auditors.

Partnerships at Work

AMS is working with its long-time partner, the Wallace Center at Winrock International, to implement GroupGAP. Moving forward, GroupGAP will partner with State extension agencies and other organizations that support small and mid-sized growers through outreach to buyers, retailers, and food hubs.

Visit www.ams.usda.gov/gapghp for information about GroupGAP certification. You can also contact the Specialty Crops Inspection Division at: (202) 720-5870.

Visit www.ams.usda.gov/services/local-regional for information about AMS' support of the local food sector. You can also contact the Transportation and Marketing Program at: (202) 720-8326.

Additional Resources

www.ams.usda.gov/about-ams/programs-offices/specialty-crops-program

www.ams.usda.gov/about-ams/programs-offices/transportation-marketing-program

www.ams.usda.gov/about-ams/programs-offices/outreach

www.wallacecenter.org

www.fda.gov

www.grants.gov





GroupGAP helps small and mid-sized farmers comply with the food safety requirements needed to supply larger markets.


October 2015

www.ams.usda.gov

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Second page photos from the far left and second to left courtesy of the Upper Peninsula Food Exchange.

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 <p>USDA Agricultural Marketing Service</p>	<p>Specialty Crops Program</p>	<p>Main line: (202) 720-4722 FVInfo@usda.gov</p>
<p>Program and Division</p> <p>AMS Specialty Crops Program</p> <p>Office of the</p> <p>Deputy Administrator</p> <p>www.ams.usda.gov/fv</p>	<p>Services</p> <p>USDA AMS Specialty Crops Program (SCP) provides customized solutions to enhance the competitive, efficient, and transparent marketing of all specialty crops. We offer a full range of quality assurance and audit verification services providing our clients and their customers with confidence that products are grown, processed, and distributed under the most favorable conditions. Our range of services include:</p> <ul style="list-style-type: none"> • Commodity Standards Development • Grading, Inspection, Certification and Audit-based Verification Services • Commodity and other technical training programs • Domestic and International Commodity Market News • Marketing Order and Agreements administration • Research and Promotion program administration • Economic Analysis • Perishable Agricultural Commodities Act (PACA) enforcement 	<p>Contacts</p> <p>Charles Parrott, Deputy Administrator (202) 720-4722 charles.parrott@ams.usda.gov</p> <p>Christopher Purdy, Associate Deputy Administrator, (202) 720-3209 christopher.purdy@ams.usda.gov</p> <p>Melissa Bailey, Associate Deputy Administrator (202) 720-6394 melissa.bailey@ams.usda.gov</p> <p>Jeffrey Davis, Business Development (202) 260-9519 jeffrey.davis4@ams.usda.gov</p>
<p>Specialty Crops Inspection Division</p>   <p>www.ams.usda.gov/scihome</p>	<p>Serving the fresh, processed and fresh-cut fruit and vegetable and specialty crops industry with:</p> <ul style="list-style-type: none"> • Fresh and processed produce quality/condition inspection and grading services. • Audit-based solutions to enhance food safety practices, including Good Agricultural Practices (GAP) for growers, Good Handling Practices (GHP) for packers, shippers, and distributors, and Good Manufacturing Practices (GMP) for processor's and fresh-cut operations. • Quality Monitoring Program (QMP) to verify supplier contract compliance. • Identity Preservation Program for clients with unique, value-added products. • Food Defense Surveys to verify a farm, packinghouse or processor food defense program. • Qualified through Verification (QTV) program to assist food processors enhance their hazard analysis critical control point (HACCP) plan. • U.S. Grade Standards. • Industry training. 	<p>Lorenzo Tribbett, Director (202) 720-2011 lorenzo.tribbett@ams.usda.gov</p> <p>Randle Macon, Associate Director (202) 720-4693 randle.macon@ams.usda.gov</p> <p>Nathaniel "Chip" Taylor, Associate Director (202) 720-2333 nathaniel.taylor@ams.usda.gov</p> <p>John Lund, Business Development (202) 690-4938 john.lund@ams.usda.gov</p>
<p>Market News Division</p>  <p>www.marketnews.usda.gov/portal/fv</p>	<p>Collects and disseminates detailed information on market conditions for hundreds of agricultural commodities at major domestic and international wholesale markets, production areas, and ports of entry. Price and movement data and related services.</p>	<p>Terry Long, Director (202) 720-2175 terry.long@ams.usda.gov</p> <p>John Okoniewski, Deputy Director (202) 720-9932 john.okoniewski@ams.usda.gov</p>

 <p>USDA Agricultural Marketing Service</p>	<h2 style="text-align: center;">Specialty Crops Program</h2>	<p>Main line: (202) 720-4722 FVInfo@usda.gov</p>
<p>Program and Division</p> <p>Perishable Agricultural Commodities Act (PACA) Division</p> <p>www.ams.usda.gov/paca</p>	<p style="text-align: center;">Services</p> <p>Proactively works for the fruit and vegetable industry promoting interstate and foreign commerce through dispute resolution, mediation, arbitration, licensing, and outreach programs facilitating fair trade practices. The PACA enforces federal regulations outside the civil court system by upholding contract requirements, mandating full and prompt payment, by removing unscrupulous individuals from the trade when needed, and providing advice on trust protection.</p>	<p style="text-align: center;">Contacts</p> <p>Judith Rudman, Director (202) 720-4180 judithw.rodman@ams.usda.gov</p> <p>Gary Neffendorf, Deputy Director (202) 720-2272 gary.neffendorf@ams.usda.gov</p> <p>John Koller, Business Development (703) 720-1442 john.koller@ams.usda.gov</p>
<p>Marketing Order and Agreement Division</p> <p>www.ams.usda.gov/moab</p>	<p>Helps fruit, vegetable and specialty crop producers and handlers achieve marketing success through industry driven programs. Marketing orders and agreements improve returns to producers by:</p> <ul style="list-style-type: none"> • Targeting domestic and foreign markets with industry funded promotion, advertising, publicity, production and marketing research, and market information programs; • Maintaining a consistently high quality of produce on the market; • Standardizing packages and containers; • Regulating the flow of product to market. 	<p>Michael Durando, Director (202) 720-2491 michael.durando@ams.usda.gov</p> <p>Candice Spalding, Deputy Director (202) 720-9914 candice.spalding@ams.usda.gov</p> <p>Richard Lower, Assistant to the Director (202) 720-2020 richard.lower@ams.usda.gov</p>
<p>Promotion and Economics Division</p> <p>www.ams.usda.gov/fvpromotion</p>	<p>Administration of nationwide research and promotion programs for the fresh fruit and vegetable industry. Authorized by federal legislation, Research and Promotion Programs are designed to strengthen the position of the industry in the marketplace and to maintain and expand domestic and foreign markets. The programs are all fully funded by industry assessments. Analysis of economic information and programs related to federal food purchase and other programs.</p>	<p>Heather Pichelmann, Director (202) 720-9915 heather.pichelmann@ams.usda.gov</p> <p>Patricia Petrella, Deputy Director (202) 260-9496 patricia.petrella@ams.usda.gov</p>
<p>AMS Commodity Procurement Division</p> <p>www.ams.usda.gov/fvprocurement</p>	<p>Purchase of fresh and processed products from approved vendors for school lunch and other government food programs.</p>	<p>David Tuckwiller, Director (202) 720-2784 david.tuckwiller@ams.usda.gov</p> <p>Ron Ulibarri, Branch Chief, (202) 720-8764 ronald.ulibarri2@ams.usda.gov</p> <p>Dianna Price, Small Business Coordinator (202) 720-4237, dianna.price@ams.usda.gov</p> <p>Sara Hernandez, Business Development (202) 680-4734, sara.hernandez@ams.usda.gov</p>



U. S. Department Of Agriculture
Natural Resources Conservation Service

Support for Produce Farmers

The U.S. Department of Agriculture's Natural Resources Conservation Service (NRCS) partners with farmers to support conservation on their farms. Both conservation of natural resources and assuring a safe food supply are essential for produce farmers. NRCS Conservation Planners identify and address resource concerns related to soil, water, air, plants, animals, and energy, as well as social and economic factors.



Many NRCS conservation practices address pathogen movement in the environment. For example, by slowing and filtering runoff, filter strips and riparian vegetation protect surface water from pathogen contamination. Other conservation practices assist farmers in managing animal waste or wildlife movement patterns. NRCS Conservation Planners recognize that their central mission of supporting farmers' conservation stewardship may intersect with food safety management activities.

When a farmer expresses concerns about the design, installation or management of a conservation practice for any reason, NRCS staff strive to include farmers' considerations of complex production, market and regulatory factors in the planning process, and seek ways to best support conservation while allowing farmers to make other management decisions necessary in their farm and ranching operations.

Once a conservation plan is completed, NRCS Conservation Practice Standards (CPS) and other supporting documents are used to ensure that the best possible science and technology are used to guide site-specific implementation of a conservation plan. Typically, a conservation plan includes a suite of practices individually tailored to the unique needs of the setting, and the landowner's interest and ability to implement the plan.

NRCS Certified Conservation Planners provide producers with technical assistance for their farm and help to determine if they are eligible for NRCS financial assistance to address their conservation goals. A conservation plan, developed through the planning process may qualify the producer for various Farm Bill conservation financial assistance programs.



Resources to co-manage conservation and food safety

Research scientists and extension specialists, working together with food safety and conservation professionals, have created a series of educational and training resources to support produce farmers as they make food safety sensitive conservation management decisions. These resources can be found here: http://ucfoodsafety.ucdavis.edu/Preharvest/Co-Management_of_Food_Safety_and_Sustainability/

These include:

- An on-line training course for food safety professionals with USDA-Agricultural Marketing Service (AMS) Good Agricultural Practices (GAPs) auditor training CEUs offered;
- A series of resource sheets for food safety auditors that describe conservation practices commonly used in agriculture's production environment; and
- Educational materials for produce growers, buyers and food safety professionals.

General information about pathogens available from NRCS

Nutrient Management Technical Note No. 9 March 2012

Introduction to Waterborne Pathogens in Agricultural Watersheds

Provides general information about pathogens. See here:

<http://directives.sc.egov.usda.gov/OpenNonWebContent.aspx?content=32935.wba>

**Introduction to Waterborne
Pathogens in Agricultural
Watersheds**



Information from FDA about Produce Safety Rule

Information about the Produce Safety Rule can be found at the U.S. Food and Drug Administration (FDA) website: <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334114.htm>

A Printer Friendly Fact Sheet on the main provisions of the rule is available here:

<http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM472887.pdf>

**For detailed information about NRCS services in your area,
please contact your local Field Office.**

<http://www.nrcs.usda.gov/wps/portal/nrcs/main/national/about/>



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