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supplements associated with those records.

(b) Records must be kept as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records.

(c) All electronic records must comply with part 11 of this chapter.

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(b) If you use reduction techniques, such as microfilming, you must make suitable reader and photocopying equipment readily available to FDA.

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

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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 (ex-

cept 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:

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(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?

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. 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 or-

ganic 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).

Agricultural water assessment means an evaluation of an agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) related to growing activities for covered produce (other than sprouts) to:

(1) Identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; and

(2) Determine whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with such known or reasonably foreseeable hazards.

Agricultural water system means a source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities.

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 117 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:

(1) *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:

(i) Pack or hold raw agricultural commodities;

(ii) 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 (1)(iii)(B)(I) of this definition; and

(iii) Manufacture/process food, provided that:

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

(B) 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);

(2) 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

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

(2) *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 as described in paragraphs (1)(ii) and (iii) 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, 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, eviscerating, 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 re-packing and activities performed incidental to packing or re-packing a food (*e.g.*, activities performed for the safe or effective packing or re-packing of that food (such as sorting, culling, grading, and weighing or conveying incidental to packing or re-packing)), 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.

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:

(1) In the same State or the same Indian reservation as the farm that produced the food; or

(2) 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).

Small business means a farm that 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 this section) the farm sold during the previous 3-year period is no more than \$500,000; and the farm is not a very small business as defined in this section.

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.

Very small business means a farm that 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 this section) the farm sold during the previous 3-year period is no more than \$250,000.

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.

[80 FR 74547, Nov. 27, 2015, as amended at 81 FR 26467, May 3, 2016; 89 FR 37514, May 6, 2024]

§ 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) 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.

[80 FR 74547, Nov. 27, 2015, as amended at 84 FR 12490, Apr. 2, 2019]

§ 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) the farm sold directly to qualified end-users (as defined in § 112.3) 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) 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.

[80 FR 74547, Nov. 27, 2015, as amended at 84 FR 12490, Apr. 2, 2019]

§ 112.6

§ 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 per-

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forming 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 § 112.45(b), 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.

[80 FR 74547, Nov. 27, 2015, as amended at 89 FR 37515, May 6, 2024]

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).

Subpart E—Agricultural Water

SOURCE: 89 FR 37515, May 6, 2024, unless otherwise noted.

§ 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.

§ 112.40 What requirements of this subpart apply to my covered farm?

This subpart applies to agricultural water used for, or intended for use in, growing, harvesting, packing, or holding covered produce. If you are using agricultural water for a covered activity listed in the first column, then you must meet the requirements in the second column. You also must meet the requirements in the third column, if applicable.

TABLE 1 TO § 112.40

If you use agricultural water for this covered activity	Then you must meet these requirements	If applicable, you also must meet these requirements
(a) Growing covered produce (other than sprouts).	§ 112.41 (quality standard).	§ 112.45 (measures).
	§ 112.42 (inspections and maintenance).	§ 112.46 (treatment).
	§ 112.43 (agricultural water assessment).	§ 112.47 (who may test).
	§ 112.50 (records)	§ 112.151 (test methods).
(b) Sprout irrigation water	§ 112.41 (quality standard).	§ 112.44(b) .. (testing untreated ground water).
	§ 112.42 (inspections and maintenance).	§ 112.45 (measures).
	§ 112.44(a) .. (microbial quality criterion).	§ 112.46 (treatment).
	§ 112.50 (records)	§ 112.47 (who may test).
	§ 112.151 (test methods).
(c) Harvesting, packing, or holding covered produce.	§ 112.41 (quality standard).	§ 112.44(b) .. (testing untreated ground water).
	§ 112.42 (inspections and maintenance).	§ 112.45 (measures).
	§ 112.44(a) .. (microbial quality criterion).	§ 112.46 (treatment).

TABLE 1 TO § 112.40—Continued

If you use agricultural water for this covered activity				
	§ 112.44(d) ..	(additional management and monitoring).	§ 112.47	(who may test).
	§ 112.50	(records)	§ 112.151	(test methods)

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

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

§ 112.42 What requirements apply to inspecting and maintaining my agricultural water systems?

(a) *Inspection of your agricultural water systems.* 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, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, including consideration of the following:

- (1) The nature of each agricultural water source (for example, whether it is 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) *Maintenance of your agricultural water systems.* You must adequately maintain all agricultural water systems, to the extent they are under your control, as necessary and appropriate to prevent the systems from being a source of contamination to covered produce, food contact surfaces, or areas

used for a covered activity. Such maintenance includes:

- (1) Regularly monitoring each system to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces;
- (2) Correcting any significant deficiencies (such as control of cross-connections and repairs to well caps, well casings, sanitary seals, piping tanks, and treatment equipment);
- (3) Properly storing equipment and keeping the source and distribution system free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances; and
- (4) As necessary and appropriate, implementing measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards resulting from contact of covered produce with pooled water (for example, through use of protective barriers or through equipment adjustments).

§ 112.43 What requirements apply to assessing agricultural water used in growing covered produce (other than sprouts)?

(a) *Elements of an agricultural water assessment.* Based in part on the results of any inspections and maintenance you conducted under § 112.42, at the beginning of the growing season, as appropriate, but at least once annually, you must prepare a written agricultural water assessment for water that you apply to covered produce (other than sprouts) using a direct application method during growing activities. The

agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces, based on an evaluation of the following factors:

(1) Each agricultural water system you use for growing activities for the covered produce, including:

(i) The location and nature of the water source (for example, whether it is ground water or surface water);

(ii) The type of water distribution system (for example, open or closed conveyance); and

(iii) The degree of protection from possible sources of contamination, including by other water users; animal impacts; and adjacent and nearby land uses related to animal activity (for example, grazing or commercial animal feeding operations of any size), application of biological soil amendment(s) of animal origin, or presence of untreated or improperly treated human waste;

(2) Agricultural water practices associated with each agricultural water system, including the type of direct application method (such as foliar spray or drip irrigation of covered produce growing underground) and the time interval between the last direct application of agricultural water and harvest of the covered produce;

(3) Crop characteristics, including the susceptibility of the covered produce to surface adhesion or internalization of hazards;

(4) Environmental conditions, including the frequency of heavy rain or extreme weather events that may impact the agricultural water system (such as by stirring sediments) or covered produce (such as damage to edible leaves) during growing activities, air temperatures, and sun exposure; and

(5) Other relevant factors, including, if applicable, the results of any testing conducted pursuant to paragraph (d) of this section.

(b) *Exemptions.* You do not need to prepare a written agricultural water assessment for water that you directly apply during growing activities for covered produce (other than sprouts), if your water meets the criteria in paragraphs (b)(1) and (2) of this section.

(1) You can demonstrate that the water:

(i) Meets the requirements in §112.44(a), including the microbial quality criterion and the prohibition on the use of untreated surface water, and if untreated ground water, also meets the testing requirements in §§112.44(b), 112.47, and 112.151;

(ii) Meets the requirements in §112.44(c) for water from a public water system or public water supply; or

(iii) Is treated in accordance with §112.46.

(2) It is reasonably likely that the quality of water in paragraph (b)(1)(i), (ii), or (iii) of this section will not change prior to the water being used as agricultural water (for example, due to the manner in which the water is held, stored, or conveyed).

(c) *Outcomes.* Based on your evaluation under paragraph (a) of this section, you must determine whether measures under §112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water used in growing covered produce (other than sprouts). You must record your determination in the assessment, and you must take necessary and appropriate action, as follows:

(1) If your agricultural water is not safe or is not of adequate sanitary quality for its intended use(s), as required under §112.41, you must immediately discontinue use of the water and take corrective measures under §112.45(a) before resuming such use(s);

(2) If you have identified one or more conditions that are reasonably likely to introduce known or reasonably foreseeable hazards and are related to animal activity, application of a biological soil amendment of animal origin, or the presence of untreated or improperly treated human waste on adjacent or nearby lands, you must implement any mitigation measures under §112.45(b) promptly, and no later than the same growing season as the agricultural water assessment;

(3) If you have not identified any conditions that are reasonably likely to

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introduce a known or reasonably foreseeable hazard for which measures under §112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces, you must:

(i) Regularly inspect and adequately maintain your agricultural water system(s) under §112.42; and

(ii) Reassess your agricultural water annually and whenever a significant change occurs (such as a change in the manner or timing of water application) that increases the likelihood that a known or reasonably foreseeable hazard will be introduced into or onto covered produce or food contact surfaces; and

(4) If your agricultural water does not meet the criteria in paragraphs (c)(1), (2), or (3) of this section, you must either:

(i) Implement mitigation measures under §112.45(b) as soon as practicable and no later than 1 year after the date of the agricultural water assessment (as required by this section); or

(ii) Test the water pursuant to paragraph (d) of this section, consider the results as part of your assessment, and take appropriate action under paragraphs (c)(1), (2), or (3), or (c)(4)(i) of this section.

(d) *Testing as part of an assessment.* In conducting testing to be used as part of your assessment under paragraph (a)(5) of this section, you must use scientifically valid collection and testing methods and procedures, including:

(1) Any sampling conducted for purposes of paragraph (c)(4)(ii) of this section must be collected aseptically immediately prior to or during the growing season and must be representative of the water you use in growing covered produce (other than sprouts).

(2) The sample(s) must be tested for generic *Escherichia coli* (*E. coli*) as an indicator of fecal contamination (or for another scientifically valid indicator organism, index organism, or other analyte).

(3) The frequency of testing samples and any microbial criterion (or criteria) applied must be scientifically valid and appropriate to assist in determining, in conjunction with other data and information evaluated under para-

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graph (a) of this section, whether measures under §112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water used in growing covered produce (other than sprouts).

(e) *Reassessment.* You must conduct an agricultural water assessment and take appropriate action under paragraph (c) of this section:

(1) At least once annually when you apply agricultural water to covered produce (other than sprouts) during growing activities; and

(2) Whenever a significant change occurs in your agricultural water system(s) (including changes relating to animal activity, the application of biological soil amendments of animal origin, or the presence of untreated or improperly treated human waste associated with adjacent or nearby land uses), agricultural water practices, crop characteristics, environmental conditions, or other relevant factors that make it reasonably likely that a known or reasonably foreseeable hazard will be introduced into or onto covered produce (other than sprouts) or food contact surfaces through direct application of agricultural water during growing activities. Your reassessment must evaluate any factors and conditions that are affected by such change.

§ 112.44 What requirements apply to agricultural water used as sprout irrigation water and in harvesting, packing, and holding covered produce?

(a) *Microbial quality criterion.* When you use agricultural water for any one or more of the 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) Used during or after harvest activities in a manner that directly contacts covered produce (for example, water that is applied to covered produce for washing or cooling activities, water that is applied to harvested crops to prevent dehydration before

cooling, and water that is 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) *Untreated ground water.* You must test any untreated ground water used as sprout irrigation water or for harvesting, packing, or holding covered produce to determine if it meets the microbial quality criterion in paragraph (a) of this section, as follows:

(1) 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 aseptically and representative of the intended use(s). Based on these results, you must determine whether the water can be used for the intended purpose(s), in accordance with § 112.45(a).

(2) If your four initial sample results meet the microbial quality criterion, you may test once annually thereafter, using a minimum of one sample collected aseptically and representative of the intended use(s).

(3) If any annual test fails to meet the microbial quality criterion, you must:

(i) Immediately discontinue the use(s) and meet the requirements of § 112.45(a) before resuming such use(s); and

(ii) Resume testing at least four times per growing season or year, as required under paragraph (b)(1) of this section, until all of the survey results collected in a year meet the microbial quality criterion.

(4) You may meet these testing requirements using test results or data collected by a third party, as provided in § 112.47.

(c) *Exemptions.* There is no requirement to test agricultural water that is used as sprout irrigation water or for harvesting, packing, or holding covered produce when:

(1) You receive the 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 those microbial requirements;

(2) You receive the water from a public water supply that furnishes water that meets the microbial quality criterion in paragraph (a) of this section, 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 § 112.46.

(d) *Additional management and monitoring practices.* (1) You must manage water used in harvesting, packing, and holding covered produce as necessary, including by establishing and following water change schedules for non-single-pass water (including recirculated water or reused water) to maintain its safe 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).

(2) You must visually monitor the quality of water that you use during harvesting, 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).

(3) You must maintain and monitor the temperature of water that you use during harvesting, packing, and holding activities for covered produce at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and that is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

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§ 112.45 What measures must I take for agricultural water to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards?

(a) *Discontinue use(s)*. 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(s) in growing, harvesting, packing, or holding covered produce as required under § 112.41, and/or if your agricultural water used as sprout irrigation water or for harvesting, packing, or holding activities does not meet the requirements in § 112.44(a) (including the microbial quality criterion), you must immediately discontinue such use(s). 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 § 112.46.

(b) *Implement mitigation measures*. (1) You must implement any mitigation measures that are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water. Such measures must be implemented as soon as practicable and no later than 1 year after the date of your agricultural water assessment or reassessment (as required by § 112.43), except that mitigation measures for known or reasonably foreseeable hazards related to animal activity, the application of biological soil amendments of animal origin, or the presence of untreated or improperly treated human waste on adjacent or nearby lands must be implemented

promptly, and no later than the same growing season as such assessment or reassessment. Mitigation measures include:

(i) Making necessary changes (for example, repairs) to address any conditions that are reasonably likely to introduce such known or reasonably foreseeable hazards into or onto the covered produce or food contact surfaces;

(ii) Increasing the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off, provided you have scientifically valid supporting data and information;

(iii) Increasing the time interval between harvest and the end of storage to allow for microbial die-off, and/or conducting other activities during or after harvest to allow for microbial die-off or removal, provided you have scientifically valid supporting data and information;

(iv) Changing the method of water application to reduce the likelihood of contamination of the covered produce (such as by changing from overhead spray to subsurface drip irrigation of certain crops);

(v) Treating the water in accordance with § 112.46; and

(vi) Taking an alternative mitigation measure, provided that you satisfy the requirements of § 112.12.

(2) If you fail to implement appropriate mitigation measures in accordance with paragraph (b)(1) of this section, or if you determine that your mitigation measures were not effective to reduce the potential for contamination of the covered produce or food contact surfaces with known or reasonably foreseeable hazards, you must discontinue use of the agricultural water until you have implemented mitigation measures adequate to reduce the potential for such contamination, consistent with § 112.41.

§ 112.46 What requirements apply to treating agricultural water?

(a) 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(s) and/or meet the microbial quality criterion in § 112.44(a), as applicable;

(b) 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(s) and, if applicable, also meets the microbial quality criterion in § 112.44(a); and

(c) You must monitor any treatment of agricultural water using an adequate method and frequency to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use(s) and, if applicable, also meets the microbial quality criterion in § 112.44(a).

(d) Treatment may be conducted by you or by a person or entity acting on your behalf.

§ 112.47 Who must perform the tests required under this subpart?

(a) You may meet the requirements related to agricultural water testing required under §§ 112.43(c)(4)(ii) and 112.44 using:

(1) Results from agricultural water testing 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 sampled by the third party or parties adequately represents 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 methods as set forth in § 112.151, as applicable.

§§ 112.48–112.49 [Reserved]

§ 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, as applicable:

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

(2) Your written agricultural water assessments, including descriptions of factors evaluated and written determinations, in accordance with § 112.43;

(3) Scientific data or information that you rely on to support the use of an index organism, indicator organism, or other analyte, other than testing for generic *E.coli* for purposes of § 112.43(c)(4)(ii);

(4) Scientific data or information that you rely on to support the frequency of testing and any microbial criterion (or criteria) you applied for purposes of § 112.43(c)(4)(ii), if applicable;

(5) Documentation of the results of all analytical tests for purposes of compliance with this subpart, including any testing conducted under §§ 112.43 and 112.44;

(6) Annual documentation of the results or certificates of compliance from a public water system required under § 112.44(c)(1) or (2), if applicable;

(7) Documentation of actions you take in accordance with § 112.45;

(8) Scientific data or information you rely on to support the time interval between last direct application of agricultural water and harvest in § 112.45(b)(1)(ii), and/or the time interval between harvest and end of storage and/or use of other activities during or after harvest in § 112.45(b)(1)(iii);

(9) Scientific data or information you rely on to support an alternative mitigation measure that you establish and use in accordance with § 112.45(b)(1)(vi).

(10) Scientific data or information you rely on to support the adequacy of a treatment method used to satisfy the requirements of § 112.46(a) and (b);

(11) Documentation of the results of water treatment monitoring under § 112.46(c); and

(12) 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*

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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.
(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 (or milliliter, if liquid is being sampled) of total solids; and less than 1,000 MPN fecal coliforms per gram (or milliliter, if liquid is being sampled) of total solids.

§ 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).

[80 FR 74547, Nov. 27, 2015, as amended at 81 FR 26468, May 3, 2016]

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.

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(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,

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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 nec-

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essary 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, in-

cluding 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 sufficient 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:

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(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.

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§ 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

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(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,

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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

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(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 subpart E of this part?

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

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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, index organism, or other analyte you may test for pursuant to § 112.43(d), a scientifically valid method.

[80 FR 74547, Nov. 27, 2015, as amended at 89 FR 37518, May 6, 2024]

§ 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, 5001 Campus Dr., 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_regulations/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, 5001 Campus Dr., 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_regulations/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); 112.50(b)(2), (5), (7), and (11); 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.

[80 FR 74547, Nov. 27, 2015, as amended at 84 FR 12491, Apr. 2, 2019; 89 FR 37519, May 6, 2024]

§ 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

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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,

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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.

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(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 re-

quirements 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

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(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 Division Director in whose division 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

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employee of FDA who is issuing the order.

[80 FR 74547, Nov. 27, 2015, as amended at 85 FR 16552, Mar. 24, 2020]

§ 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, fax number, and name of the FDA Division Director in whose division 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.

[80 FR 74547, Nov. 27, 2015, as amended at 85 FR 16552, Mar. 24, 2020]

§ 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 sea-

son, 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 Division Director in whose division 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 fax 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.

[80 FR 74547, Nov. 27, 2015, as amended at 85 FR 16552, Mar. 24, 2020]

§ 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

§ 112.208

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 Division 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 mate-

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rial 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.

[80 FR 74547, Nov. 27, 2015, as amended at 85 FR 16552, Mar. 24, 2020]

§ 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 Office of Regulatory Affairs Program Director or another FDA official senior to an FDA Division Director.

[85 FR 16552, Mar. 24, 2020]

§ 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 Division Director in whose division 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 Division Director in whose division 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 or her 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 Division Director in whose division 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.

[80 FR 74547, Nov. 27, 2015, as amended at 85 FR 16552, Mar. 24, 2020]

PART 113—THERMALLY PROCESSED LOW-ACID FOODS PACKAGED IN HERMETICALLY SEALED CONTAINERS

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AUTHORITY: 21 U.S.C. 342, 371, 374; 42 U.S.C. 264.

SOURCE: 44 FR 16215, Mar. 16, 1979, unless otherwise noted.

Subpart A—General Provisions

§ 113.3 Definitions.

For the purposes of this part, the following definitions apply:

(a) *Aseptic processing and packaging* means the filling of a commercially sterilized cooled product into

presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.

(b) *Bleeders* means openings used to remove air that enters with steam from retorts and steam chambers and to promote circulation of steam in such retorts and steam chambers. Bleeders may serve as a means of removing condensate.

(c) *Come-up-time* means the time which elapses between the introduction of steam into the closed retort and the time when the retort reaches the required processing temperature.

(d) *Commercial processor* includes any person engaged in commercial, custom, or institutional (church, school, penal, or other organization) processing of food, including pet food. Persons engaged in the production of foods that are to be used in market or consumer tests are also included.

(e) *Commercial sterility*: (1) “Commercial sterility” of thermally processed food means the condition achieved—

(i) By the application of heat which renders the food free of—

(a) Microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution; and

(b) Viable microorganisms (including spores) of public health significance; or

(ii) By the control of water activity and the application of heat, which renders the food free of microorganisms capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(2) “Commercial sterility” of equipment and containers used for aseptic processing and packaging of food means the condition achieved by application of heat, chemical sterilant(s), or other appropriate treatment that renders the equipment and containers free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(f) *Critical factor* means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and