

Title 21 of the Code of Federal Regulations, Proposed Part 112 – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, Tracked changes compared to proposed part 112 issued on January 16, 2013

On September 29, 2014, the U.S. Food and Drug Administration (FDA or we) published a supplemental notice of proposed rulemaking proposing to amend certain specific provisions (79 FR 58434; referred to as “the supplemental proposed rule”) of the proposed rule, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, which was published on January 16, 2013 (78 FR 3504; referred to as “the 2013 proposed rule”). The 2013 proposed rule and the supplemental proposed rule, taken together, constitute the entirety of the proposed rule on “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.”

In the supplemental proposed rule, we are proposing to amend certain provisions and add certain new provisions to the previously proposed 21 CFR part 112. We listed each of the amended and new proposed provisions in that document. For the convenience of readers and ease of reference, we prepared this document to identify all of the changes and provide the complete proposed 21 CFR part 112, as proposed in the 2013 proposed rule and as amended in the supplemental proposed rule.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 112

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

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR Chapter I be amended to read as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

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

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

2. In §16.1:

- a. In paragraph (b)(1), add an entry in numerical order.
- b. In paragraph (b)(2), add an entry in numerical order.

The additions read as follows:

§ 16.1 Scope.

(b)***

(1)***

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

(2) ***

§§112.201 through 112.211, (part 112, subpart R), relating to withdrawal of a qualified exemption.

3. Add part 112 to read as follows:

PART 112--STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND
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Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

Subpart A--General Provisions

§ 112.1 What food is covered by this part?

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

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

(1) Fruits and vegetables such as almonds, apples, apricots, aprium, asian pear, avocados, babaco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and persian), mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, snow peas, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress, and watermelon; 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 – arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, brussels sprouts, chick-peas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams;

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

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

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

(1) The covered 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 parts 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 or distilling produce into products such as sugar, oil, spirits, or similar products;

(2) You must establish and keep documentation in accordance with the requirements of subpart O of this part, of the identity of the recipient of the covered produce that performs the commercial processing described in paragraph (b)(1) of this section; and

(3) The requirements of this subpart and subpart Q of this part apply to such produce.

§ 112.3 What definitions apply to this part?

(a) The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321) apply to such terms when used in this part.

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

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

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

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

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

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

Agricultural tea means a water extract of biological materials (such as humus, manure, non-fecal animal byproducts, peat moss, pre-consumer vegetative waste, table waste, or yard trimmings), excluding any form of human waste, produced to transfer microbial biomass, fine particulate

organic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application.

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

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

Animal excreta means solid or liquid animal waste.

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

Biological soil amendment means any soil amendment containing biological materials such as humus, 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, 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 humus 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, ~~provided that all covered produce used in covered packing or holding activities is grown, raised, or consumed on that farm or another farm under the same ownership on a farm.~~ Covered activity does not include manufacturing/processing within the meaning defined in this chapter.— 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. This part does not apply to activities of a facility that are subject to part 110 of this chapter.

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

Curing means the maturation 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.

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 ~~a facility (as defined in § 1.227 of this chapter)~~ an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both. The term “Farm” includes:

~~(i) Facilities that pack or hold food, provided that all food used in such activities that is grown, raised, or consumed on that farm or another farm under the same ownership;~~

~~(ii) Facilities that pack or hold food that is grown or raised on another farm whether or not under the same ownership; and~~

~~(iii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under same ownership.~~

The term "farm" includes establishments 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 ownership, or is processed food identified in paragraph (iii)(B)(1) 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 ownership; or

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

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and

(2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

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.

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 humus, manure, non-fecal animal byproducts or table waste).

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by 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 on ~~the a farm on which they were grown or raised, or another farm under the same ownership~~. Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm ~~or another farm under the same ownership~~ are examples of harvesting.

Hazard means any biological agent that is reasonably likely to cause illness or injury in the absence of its control.

Holding means storage of food. ~~Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage~~

~~of raw agricultural commodities grown or raised on the same farm or another farm under the same ownership, and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food and 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, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

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

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 are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. 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 (21 U.S.C. 350d) 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 grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities 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 applicable, to produce an accurate record of the observation or measurement.

Non-fecal animal byproduct means solid waste (other than excreta) 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.

Packaging (when used as a verb) means placing food into a container that directly contacts the food and that the consumer receives.

Packing means placing food into a container other than packaging the food. ~~For farms and farm mixed-type facilities, packing also includes activities (which may include packaging) traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport, and also includes activities performed incidental to packing a food (e.g., activities performed for the safe or effective packing of that food (such as sorting, culling and grading)),~~ but does not include

activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act.

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

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

Produce means any fruit or vegetable (including mixes of intact fruits and vegetables) and includes mushrooms, sprouts (irrespective of seed source), peanuts, tree nuts and herbs. A fruit is the edible reproductive body of a seed plant or tree nut (such as apple, orange and almond) such that fruit means the harvestable or harvested part of a plant developed from a flower. A vegetable is the edible part of an herbaceous plant (such as cabbage or potato) or fleshy fruiting body of a fungus (such as white button or shiitake) grown for an edible part such that vegetable means the harvestable or harvested part of any plant or fungus whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts are used as food and includes mushrooms, sprouts, and herbs (such as basil or cilantro). Produce does not include food grains

meaning the small, hard fruits or seeds of arable crops, or the crops bearing these fruits or seeds, that are grown and processed for use as meal, flour, baked goods, cereals and oils rather than for fresh consumption (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, cotton seed, and soybeans.

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; or a restaurant or retail food establishment (as those terms are defined in § 1.227) that is located:

- (i) In the same State as the farm that produced the food; or
- (ii) Not more than 275 miles from such farm. The term “consumer” does not include a business.

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

Reasonably foreseeable hazard means a potential hazard that may be associated with the farm or the food.

Sanitize means to adequately treat cleaned food-contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

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

Soil amendment means any chemical, biological, or physical material (such as elemental fertilizers, humus, 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.

Static composting means a process to produce humus in which air is introduced into biological material (in a pile (or row) covered with at least 6 inches of 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 which is open to the atmosphere and subject to surface runoff, including water obtained from an underground aquifer that is held or conveyed in a manner that is open to the atmosphere, such as in canals, ponds, other surface containment or open conveyances.

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 humus 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.

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 means a person who is subject to some or all of the requirements in this part.

§ 112.4 Who is subject to the requirements of this part?

(a) Except as provided in paragraph (b) of this section, if you are a farm or farm mixed-type facility with an average annual monetary value of ~~food-produce~~ (as “~~produce~~food” is defined in § 112.3(c)) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), you are a “covered farm” subject to this part. If you are a covered farm subject to this

part, you must comply with all applicable requirements of this part when you conduct a covered activity on covered produce.

(b) You are not a covered farm if you satisfy the requirements in § 112.5 and we have not withdrawn your exemption in accordance with the requirements of subpart R of this part.

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

(a) You are eligible for a qualified exemption and associated modified requirements in a calendar year if:

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in § 112.3(c)) you sold directly to qualified end-users (as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food you sold to all other buyers during that period; and

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

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

§ 112.6 What modified requirements apply to me if I am eligible for a qualified exemption in accordance with § 112.5?

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

(1) This subpart A; and

(2) Subparts Q and R of this part.

(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 (b)(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.

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 (21 U.S.C. 342) on account of such hazards.

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

(a) You may establish alternatives to the following specific requirements of this part, provided that you satisfy the requirements of paragraphs (b) and (c) of this section:

(1) The requirements in § 112.44(c) for testing water, and taking action based on test results, when agricultural water is used during growing operations for covered produce (other than

sprouts) using a direct water application method, as provided in § 112.44(d); and

(2) Composting treatment processes established in § 112.54(c)(1) and (c)(2);

~~(3) The minimum application interval established in § 112.56(a)(1)(i) for an untreated biological soil amendment of animal origin that is reasonably likely to contact covered produce after application or for a compost agricultural tea that contains compost agricultural tea additives]; and~~

~~(4) The minimum application interval established in § 112.56(a)(4)(i) for a biological soil amendment of animal origin treated by a composting process that is reasonably likely to contact covered produce after application.~~

(b) You may establish and use an alternative to any of the requirements listed 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 (including meeting the same microbiological standards, where applicable), 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, including agro-ecological conditions and application interval.

(c) Scientific data and information used to support an alternative to a requirement listed 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.

Subpart C--Standards Directed to 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, at the beginning of each growing season (if applicable), and periodically thereafter.

(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 the training, in combination with education or experience 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 should 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 C 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--Standards Directed to 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 a 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 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, clean cloth towels, sanitary towel service 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; and
- (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.

§ 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) A visitor is any person (other than personnel) who enters your covered farm with your permission.
- (b) 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.
- (c) You must make toilet and hand-washing facilities accessible to visitors.

Subpart E--Standards Directed to Agricultural Water

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

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

§ 112.42 What measures must I take with respect to my agricultural water sources, water distribution system, and pooling of water?

(a) At the beginning of a growing season, you must inspect the entire agricultural water system under your control (including water source, water distribution system, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food-contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:

- (1) The nature of each agricultural water source (for example, ground water or surface water);
- (2) The extent of your control over each agricultural water source;
- (3) The degree of protection of each agricultural water source;
- (4) Use of adjacent or nearby land; and
- (5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.

(b) You must adequately maintain all agricultural water sources that are under your control (such as wells) by regularly inspecting each source and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.

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

(d) You must immediately discontinue use of a source of agricultural water and/or its distribution system, and not use the water source and/or its distribution system when you have determined or have reason to believe that your agricultural water is not safe and of adequate sanitary quality for its intended use, until you either:

(1) Re-inspect the entire agricultural water system 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 test the water to determine if your changes were effective and to ensure that your agricultural water is safe and of adequate sanitary quality for its intended use; or

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

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

§ 112.43 What treatment of agricultural water is required, and what requirements apply to treating agricultural water?

(a) You must treat any agricultural water that you use (such as with an EPA-registered antimicrobial pesticide product) if you know or have reason to believe that the water is not safe and of adequate sanitary quality for its intended use.

(b) Any method you use to treat agricultural water to satisfy the requirement in paragraph (a) of this section must be effective to make the water safe and of adequate sanitary quality for its intended use.

(c)(1) You must deliver any treatment of agricultural water required by paragraph (a) of this section in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use.

(2) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use.

§ 112.44 What testing is required for agricultural water, and what must I do based on the test results?

(a) You must test the quality of agricultural water according to the requirements in § 112.45 using a quantitative, or presence-absence method of analysis provided in subpart N of this part to ensure there is no detectable generic Escherichia coli (E. coli) in 100 milliliters (mL) of agricultural water when it is:

(1) Used as sprout irrigation water;

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

(3) Used to make a treated agricultural tea;

(4) Used to contact food-contact surfaces, or to make ice that will contact food-contact surfaces; or

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

(b) If you find that there is any detectable generic E. coli in 100 mL of water, you must immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in paragraph (a) of this section. Before you may use the water source and/or distribution system again for the uses described in paragraph (a) of this section, you must either re-inspect the entire agricultural water system 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 retest the water to determine if your changes were effective and to ensure that the water meets the requirements of paragraph (a) of this section; or treat the water in accordance with the requirements of § 112.43.

(c) When agricultural water is used during growing activities for covered produce (other than sprouts) using a direct water application method you must test the quality of water in accordance with one of the appropriate analytical methods in subpart N to develop and verify the water quality profile of the water source as described in § 112.45(b)(1). If you find that there is more than 235 colony forming units (CFU) (or most probable number (MPN), as appropriate) generic *E. coli* per 100 mL for any single sample or a rolling geometric mean (n=5) of more than 126 CFU (or MPN, as appropriate) per 100 mL of water, you must

Using your water quality profile as described in § 112.45(b)(1), if you find that (when applicable) the estimate of the statistical threshold value (STV) of samples exceeds 410 colony forming units (CFU) of generic *E. coli* per 100 mL of water, or if you find that the geometric mean (GM) of samples exceeds 126 CFU of generic *E. coli* per 100 mL of water (or an alternative microbial standard consistent with paragraph (d)(1) of this section), you must either:

(1) Apply a time interval (in days) between last irrigation and harvest using a microbial die-off rate of 0.5 log per day (or an alternative microbial die-off rate consistent with paragraph (d)(2) of this section) to achieve a (calculated) log reduction of your geometric mean of generic *E. coli* level to 126 CFU or less per 100 mL and (when applicable) of your STV to 410 CFU or less per 100 mL, or an alternative microbial standard consistent with paragraph (d)(1) of this section;

(2) Apply a time interval (in days) between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage and/or appropriate

microbial removal rates during activities such as commercial washing to achieve a (calculated) log reduction of your geometric mean of generic E. coli level to 126 CFU or less per 100 mL and (when applicable) of your STV to 410 CFU or less per 100 mL (or an alternative microbial standard consistent with paragraph (d)(1) of this section), provided you have adequate supporting scientific data and information. You may apply this time interval in addition to the time interval in accordance with paragraph (c)(1) of this section; or

(3) If options (c)(1) or (c)(2) are not selected, immediately discontinue use of that source of agricultural water and/or its distribution system for the uses described in this paragraph. Before you may use the water source and/or distribution system again for the uses described in this paragraph, you must either re-inspect the entire agricultural water system 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 retest the water to determine if your changes were effective; or treat the water in accordance with the requirements of § 112.43.

(d) You may establish and use alternatives to the following requirements ~~established in paragraph (c) of this section~~, provided you satisfy the requirements of § 112.12:

- (1) Microbial quality standard established in paragraph (c) of this section; and
- (2) Microbial die-off rate established in paragraph (c)(1) of this section that is used to determine the time interval between last irrigation and harvest.

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

~~(a) You must test any agricultural water that is subject to the requirements of § 112.44 at the beginning of each growing season, and every three months thereafter during the growing season, except that There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 water when:~~

- (1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;
- (2) You receive water from a public water supply that furnishes water that meets the microbial requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or
- (3) You treat water in accordance with the requirements of § 112.43.

~~(b) If you use untreated surface water for purposes that are subject to the requirements of § 112.44, you must test the water as specified in the table in this paragraph.~~

If the untreated surface water is:	Then you must test the untreated surface water:
(1) From any source where a significant quantity of runoff is likely to drain into the source (for example, a river or natural lake) ...	At least every 7 days during the growing season
(2) From any source where underground aquifer water is transferred to a surface water containment constructed and maintained in a manner that minimizes runoff drainage into the containment (for example, an on-farm man-made water reservoir) ...	At least once each month during the growing season

~~(b) If you use untreated surface water for purposes that are subject to the requirements of § 112.44(c), you must take the following steps for each source of the untreated surface water:~~

- ~~(1) Conduct a baseline survey to develop a water quality profile of the agricultural water source.~~

(i) You must conduct a baseline survey in order to initially develop the water quality profile of your water source. You must determine the appropriate way(s) in which the water may be used based on your water quality profile in accordance with § 112.44(c)(1) through (3).

(ii) The baseline survey must be conducted over a minimum period of 2 years by calculating the geometric mean (GM) and the statistical threshold value (STV) of generic Escherichia coli (E. coli) (colony forming units (CFU) per 100 mL) using a minimum total of 20 samples, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest. The water quality profile initially consists of the GM and STV of generic E. coli calculated using this data set.

(iii) You must develop a new water quality profile:

(A) At least once every 10 years by recalculating the GM and STV values using a minimum total of 20 samples collected during your most recent annual surveys (which are required under paragraph (b)(2) of this section); and

(B) When required under paragraphs (b)(2) and (b)(3) of this section.

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

(i) After the baseline survey described in paragraphs (b)(1)(i) and (b)(1)(ii) of this section, you must test the water annually to verify your existing water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze a minimum number of five samples per year, consisting of samples of agricultural water as it is used during growing activities using a direct water application method, collected during a time period(s) as close as practical to harvest.

(ii) If the GM and/or STV values of the annual survey samples do not support your water quality profile and therefore your existing water use as specified in § 112.44(c), you must develop a new water quality profile and, as appropriate, modify your water use based on the new water quality profile in accordance with § 112.44(c)(1) through (3) as soon as practical and no later than the following year. To develop a new water quality profile, you must calculate new GM and STV values using either:

(A) Your current annual survey data, combined with your most recent baseline or annual survey data from prior years, to make up a data set of at least 20 samples; or

(B) Your current annual survey data, combined with new data, to make up a dataset of at least 20 samples; and

(3) If you know or have reason to believe that your water quality profile no longer represents the quality of your water for reasons other than those in paragraph (b)(2) of this section (for example, if there are significant changes in adjacent land use, erosion, or other impacts to water outside your control that are reasonably likely to adversely affect the quality of your water source), you must develop a new water quality profile. To develop a new water quality profile, you must calculate new GM and STV values using your current annual survey data, combined with new data, to make up a data set of at least 20 samples. Then, as required by § 112.44(c)(1) through (3), you must modify your water use based on the new water quality profile as soon as practical and no later than the following year.

(c) If you use untreated ground water for purposes that are subject to the requirements of § 112.44, you must test the quality of each source of the water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected during a time period(s) as close as practical to harvest. If the samples tested meet the applicable

microbial standard of § 112.44 (i.e., no detectable generic E. coli per 100 mL under 112.44(a) or a geometric mean of generic E. coli of 126 CFU or less per 100 mL under 112.44(c), as applicable), you may test once annually thereafter, using a minimum of one sample collected during a time period as close as practical to harvest. You must resume testing at least four times per growing season or year if any annual test fails to meet the applicable microbial standard in § 112.44.

(d) If you use untreated surface water for purposes that are subject to the requirements of § 112.44(a), you must test the quality of each source of the water with an adequate frequency to provide reasonable assurances that the water meets the required microbial standard. You must have adequate scientific data or information to support your testing frequency.

(e) You may meet the requirements related to agricultural water testing required under paragraphs (b), (c), and (d) of this section using:

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

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

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

(a) You must manage the water as necessary, including by establishing and following water-change schedules for re-circulated water, to maintain adequate sanitary quality and

minimize the potential for contamination of covered produce and food-contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce);

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

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

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

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

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

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

(2) Documentation of the results of any analytical tests conducted to determine whether agricultural water is safe and of adequate sanitary quality for its intended use;

(3) Scientific data or information you rely on to support the adequacy of a method used to satisfy the requirements of § 112.43(b) and (c)(1);

(4) Documentation of the results of water treatment monitoring under § 112.43(c)(2);

(5) Documentation of the results of water testing you perform to satisfy the requirements of §112.44; ~~and~~

(6) Scientific data or information you rely on to support any alternative to the requirements established in § 112.44(c) for agricultural water used during growing activities using a direct water application method in accordance with the requirements of § 112.44(d);~~;~~

(7) Annual documentation of the results or certificates of compliance from a public water system under 112.45(a)(1) or (a)(2), if applicable;~~;~~

(8) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that is used to determine the time interval (in days) between harvest and end of storage and/or other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic E.coli in accordance with the provision in § 112.44(c)(2); and

(9) Scientific data or information you rely on to support your testing frequency for untreated surface water used for purposes that are subject to the requirements of § 112.44(a).

Subpart F--Standards Directed to 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 used to make the tea have been so processed and the water used to make the tea satisfies the requirements of 112.44(a).

(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 used to make the tea have not been so processed or the water used to make the tea does not satisfy the requirements of 112.44(a);
- (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 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, and water distribution systems.

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

(b) A scientifically valid controlled physical process, chemical process, or combination of scientifically valid controlled physical and chemical processes, that has been demonstrated to satisfy the microbial standard in § 112.55(b) for Salmonella and fecal coliforms; or

(c) A scientifically valid controlled composting process that has been demonstrated to satisfy the microbial standard in § 112.55(b) for Salmonella and fecal coliforms. Scientifically valid controlled composting processes include:

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

(2) Turned composting that maintains aerobic conditions at a minimum of 131°F (55 °C) for 15 days, with a minimum of five turnings, and is followed by adequate curing, which includes proper insulation; or

(3) Other scientifically valid, controlled composting processes, provided you satisfy the requirements of § 112.12, including that the alternative process has been demonstrated to satisfy the microbial standard in §112.55(b).

§ 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 or;

For the microorganism:	The microbial standard is:
(1) <u>L. monocytogenes</u>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram analytical portion
(2) <u>Salmonella</u> species	Less than three most probable numbers (MPN) per 4 grams of total solids (dry weight basis)
(3) <u>E. coli</u> O157:H7	Less than 0.3 MPN per 1 gram analytical portion

(b) Less than three MPN Salmonella species per four grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).

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

(a) Except as provided in paragraph (b) of this section, you must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph in accordance with the application requirements specified in the second column of the table in this paragraph and the minimum application intervals specified in the third column of the table in this paragraph.

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 ...	9 months [Reserved]

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:
(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 or chemical process, or combination of scientifically valid controlled physical and chemical processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a) ...	In any manner (i.e., no restrictions) ...	0 days
(3) Treated by a scientifically valid controlled physical or chemical process, or combination of scientifically valid controlled physical and chemical 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
(4)(i) Treated by a composting process in accordance with the requirements of § 112.54(c) 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 ...	45 days 0 days
(ii) Treated by a composting process in accordance with the requirements of § 112.54(c) to meet the microbial standard in § 112.55(b) ...	In a manner that does not contact covered produce during or after application ...	0 days

~~(b) You may establish and use alternatives to the minimum application intervals established in paragraphs (a)(1)(i) and (a)(4)(i) of this section, provided you satisfy the requirements of § 112.12.~~

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

(a) You must establish and keep records required under this subpart F 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) Documentation of the date of application of any untreated biological soil amendment of animal origin (including raw manure) or any biological soil amendment of animal origin treated~~

~~by composting to a growing area and the date of harvest of covered produce from that growing area, except when covered produce does not contact the soil during or after application of the soil amendment;~~

~~(12)~~ For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) 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;

(ii) The applicable treatment process is periodically verified through testing using a scientifically valid analytical method on an adequately representative sample to demonstrate that the process satisfies the applicable microbial standard in § 112.55, including the results of such periodic testing; and

(iii) 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;

~~(23)~~ 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; and

~~(34)~~ Scientific data or information you rely on to support any alternative composting process used to treat a biological soil amendment of animal origin in accordance with the requirements of

§ 112.54(c)(3); and

~~(5) Scientific data or information you rely on to support any alternative minimum application interval in accordance with the requirements of § 112.56(b).~~

Subpart G—[Reserved]

Subpart H—[Reserved]

Subpart I--Standards Directed to 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 when a covered activity takes place in a fully-enclosed building.

§ 112.82 What requirements apply regarding domesticated animals that I allow to graze in fields or use as working animals where I grow covered produce?

At a minimum, if you allow animals to graze or use them as working animals in fields where covered produce is grown, and under the circumstances there is a reasonable probability that grazing or working animals will contaminate covered produce, you must take the following measures:

(a) An adequate waiting period between grazing and harvesting for covered produce in any growing area that was grazed to ensure the safety of the harvested crop; and

(b) If working animals are used in a growing area where a crop has been planted, measures to prevent the introduction of known or reasonably foreseeable hazards into or onto covered produce.

§ 112.83 What requirements apply regarding animal intrusion?

(a) If under the circumstances there is a reasonable probability that animal intrusion will contaminate covered produce, you must monitor those areas that are used for a covered activity for evidence of animal intrusion:

(1) As needed during the growing season based on:

(i) Your covered produce; and

(ii) Your observations and experience; and

(2) Immediately prior to harvest.

(b) If animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction via grazing, occurs, you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112.

§ 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--Standards Directed to 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; 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 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.

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

You must handle harvested covered produce in a manner that protects against contamination with known or reasonably foreseeable hazards – for example, by avoiding contact of cut surfaces of harvested produce with soil.

§ 112.114 What requirements apply to dropped covered produce?

You must not distribute covered produce that drops to the ground before harvest (dropped covered produce) unless it is exempt under § 112.2(b). Dropped covered produce does not

include root crops (such as carrots) that grow underground or crops (such as cantaloupe) that grow on the ground.

§ 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.

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

Subpart L--Standards Directed to 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 undesirable microorganisms or other contamination. Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).

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

Buildings subject to the requirements of this subpart include:

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

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

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

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

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

(b) Equipment and tools must be:

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

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

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

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

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

(e) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must do so in a manner that minimizes the potential for contamination of covered produce or food-contact surfaces with known or reasonably foreseeable hazards.

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

Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of undesirable microorganisms or other contamination, 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 design and construction requirements apply to my buildings?

All of the following design and construction requirements apply regarding buildings.

(a) 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:

- (1) Provide sufficient space for placement of equipment and storage of materials;
- (2) 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
- (3) Be constructed in such a manner that floors, walls, ceilings, fixtures, ducts and pipes can be adequately cleaned and kept in good repair, and that drip or condensate does not contaminate covered produce, food-contact surfaces, or packing materials.

(b) 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.

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

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

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

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

§ 112.128 What requirements apply regarding pest control in buildings?

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

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

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

§ 112.129 What requirements apply to toilet facilities?

All of the following requirements apply to toilet facilities:

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

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

(1) Prevent contamination of covered produce, food-contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;

(2) Be directly accessible for servicing, be serviced and cleaned on a schedule sufficient to ensure suitability of use, and be kept supplied with toilet paper; and

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

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

§ 112.130 What requirements apply for hand-washing facilities?

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

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

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

(1) Soap (or other effective surfactant);

(2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands;
and

(3) Adequate drying devices (such as single service towels, clean cloth towels or sanitary towel service).

(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 hand antiseptic/sanitizer or wipes as a substitute for soap and water.

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

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

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

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

(c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food-contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.

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

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

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

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

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

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

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

§ 112.133 What requirements apply to plumbing?

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

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

(b) Properly convey sewage and liquid disposable waste;

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

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

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

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

(1) Adequately control their excreta and litter; and

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

(b) [Reserved]

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

(a) You must establish and keep records required under this subpart L 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--Standards Directed to Sprouts

§ 112.141 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) If your farm grows seeds or beans for use to grow sprouts, 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) If you know or have reason to believe that a lot of seeds or beans have been associated with foodborne illness, you must not use that lot of seeds or beans to produce sprouts.

(c) 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.

§ 112.142 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, and hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts.

(c) You must treat seeds or beans that will be used to grow sprouts using a scientifically valid method immediately before sprouting to reduce microorganisms of public health significance. Prior treatment conducted by a grower, handler, or distributor of seeds or beans does not eliminate your responsibility to treat seeds or beans immediately before sprouting at your covered farm.

§ 112.143 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 § 112.144.

(b) You must either:

(1) Test spent sprout irrigation water from each production batch of sprouts for E. coli O157:H7 and Salmonella species in accordance with the requirements of § 112.146; or

(2) If testing spent sprout irrigation water is not practicable (for example, for soil-grown sprouts), test each production batch of sprouts at the in-process stage (i.e., while sprouts are still growing) for E. coli O157:H7 and Salmonella species in accordance with the requirements of § 112.146.

§ 112.144 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

(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 collect environmental samples and test them for Listeria species or L. monocytogenes according to the method in § 112.152.

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

You must 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 microbial sampling and testing to determine whether the Listeria species or L. monocytogenes has been eliminated;

(d) Conduct finished product testing when appropriate; and

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

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

All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts:

(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 E. coli O157:H7 and Salmonella species using a method that has been validated for its intended use (testing spent sprout irrigation water or sprouts) to ensure that the testing is accurate, precise, and sensitive in detecting these pathogens.

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

(a) You must establish and keep records required under this subpart M 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;

- (2) Your written environmental monitoring plan in accordance with the requirements of § 112.144;
- (3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of § 112.146(a);
- (4) The results of all testing conducted in accordance with the requirements of §§ 112.143 and 112.144;
- (5) Any analytical methods you use in lieu of the methods that are incorporated by reference in §§ 112.152; and
- (6) The testing method you use in accordance with the requirements of § 112.146(b).

Subpart N--Analytical Methods

§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.45?

(a) You must test the quality of water using a method of analysis:

(1) As published in the “Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC) International” (18th ed., revision 4, 2011) which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the AOAC International, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, 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) As published in the Standards Methods for the Examination of Water and Wastewater (21st ed., 2005), American Public Health Association (APHA), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from

the APHA, 800 I St. NW., Washington, DC 20001, 202-777-2742. You may inspect a copy at the Center for Food Safety and Applied Nutrition's Library, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-2163, 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

(3) As prescribed in Chapter 4 of the FDA Bacteriological Analytical Manual (BAM) (Edition 8, Revision A, 1998), as updated in June 2011. The Director of the Federal Register approves the incorporation by reference of FDA's BAM, Chapter 4 (Edition 8, Revision A, 1998), as updated in June 2011, in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy of the method from Office of Regulatory Science, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1990, or you may examine a copy at CFSAN's Library, 5100 Paint Branch Pkwy., College Park, MD, 240-402-2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html; or

(4) That is at least equivalent to the appropriate method of analysis in §§112.151(a)(1), (a)(2) or (a)(3) in accuracy, precision, and sensitivity.

§ 112.152 What methods must I use to test the growing environment for *Listeria* species or *L. monocytogenes* to satisfy the requirements of § 112.143(a) and § 112.144?

You must test the growing environment by testing for the presence of *Listeria* species or *L. monocytogenes* in environmental samples using the methods and procedures described in Chapter 10 of FDA's Bacteriological Analytical Manual (BAM) April 2011, Edition (Edition 8,

Revision A, 1998), or a method that is at least equivalent in accuracy, precision, and sensitivity. The Director of the Federal Register approves the incorporation by reference of FDA's BAM, Chapter 10--"Listeria monocytogenes, Detection and Enumeration of Listeria monocytogenes in Foods," April 2011, in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy of the method from Office of Regulatory Science, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1990, or you may examine a copy at CFSAN's Library, 5100 Paint Branch Pkwy., College Park, MD, 240-402-2163, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html.

Subpart O--Requirements Applying to Records That You Must Establish and Keep

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

(a) 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) When records are required to be established and kept in subparts C, E, F, L, and M of this part (§§ 112.30, 112.50, 112.60, 112.140, and 112.150), you must establish and keep documentation of actions you take when a standard in those subparts is not met.

(c) Records required under §§ 112.50(b)(4), 112.50(b)(5), 112.60(b)(1), 112.60(b)(3), 112.140, 112.150(b)(1), 112.150(b)(4), and 112.161(b), must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

§ 112.162 Where must I store records?

(a) Offsite storage of records is permitted after 6 months following the date the record was made 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?

Yes. The regulations in this part do not require duplication of existing records if those records contain all of the information required by this part.

§ 112.164 How long must I keep records?

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

(b) Records that relate to the general adequacy of the equipment or processes being used by a farm, including the results of scientific studies and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes 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, in compliance with 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 FDA?

Records required by 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 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 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 (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of this part.

§ 112.172 How may a State 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 (e.g., the regulatory authority for food safety) for a State 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 or foreign country has determined that the variance is necessary in light of local growing conditions and that the procedures, processes, and practices to be followed under the variance are reasonably likely to ensure that the produce is

not adulterated under section 402 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 342) and to provide the same level of public health protection as the requirements of 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 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 would 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 (either 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 website 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 or a foreign country that believes that a variance requested by a petition submitted by another State 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 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 or foreign country where the similarly situated persons are located of our decision in writing and will publish a notice on our website 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 (21 U.S.C. 342) 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 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 (21 U.S.C. 342) 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 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 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 submissions on our determination.

(3) When applicable, we will:

(i) Notify in writing any States 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 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 or foreign countries in which similarly situated persons are located.

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

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

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

(ii) If more than one State 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?

Examples of permissible types of variances include:

(a) Variance from the requirements, established in § 112.44(c), when agricultural water is used during growing operations for covered produce (other than sprouts) using a direct water

application method;

(b) Variance from the process conditions, established in § 112.54(c)(1), for static

composting; and

(c) Variance from the process conditions, established in § 112.54(c)(2), for turned composting;

~~(d) Variance from the minimum application interval, established in § 112.56(a)(1), for an untreated biological soil amendment of animal origin; and~~

~~(e) Variance from the minimum application interval, established in § 112.56(a)(4), for a biological soil amendment of animal origin treated by a composting process in accordance with the requirements of § 112.54(e).~~

Subpart Q--Compliance and Enforcement

§ 112.191 How do the criteria and definitions in this part apply?

The criteria and definitions in this part apply in determining whether a food is adulterated:

(a) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)) in that the food has been grown, harvested, packed, or held under such conditions that it is unfit for food; or

(b) Within the meaning of 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.

The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. 264).

§ 112.192 What is the result of a failure to comply with this part?

The failure to comply with the requirements of this part, issued under section 419 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350h), is a prohibited act under section 301(vv) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(vv)).

§ 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 (21 U.S.C. 350h(b)(2)(A)), FDA coordinates education and enforcement activities by State, Territorial, tribal, and local officials.

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:

(a1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or

(2b) 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, import alert, 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 10 calendar days of the date 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) If, after considering other regulatory and/or administrative actions, as appropriate, FDA determines that a qualified exemption applicable to a farm under § 112.5 should be withdrawn, any officer or qualified employee of FDA may issue an order to withdraw the exemption.~~

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

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

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

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

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

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

(a) The date of the order;

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

(c) A brief, general statement of the reasons for the order, including information relevant to:

(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 comply with subparts B through O of this part on the date that is 60 calendar days after the date of the order;

(e) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350(f)) and of this subpart;

(f) 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;

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

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

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

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

(a) Comply with applicable requirements of this part within 60 calendar days of the date of the order or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season; or

(b) Appeal the order within 10 calendar days of the date 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, the owner, operator, or agent in charge of the farm must comply with applicable requirements of this part within 60 calendar days of the date of the order, or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season.

§ 112.206 What is the procedure for submitting an appeal?

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

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, e-mail address, or facsimile number identified in the order within 10 calendar days of the date of the order; and

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

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

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

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

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 10 calendar days of the date of the order.

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

§ 112.208 What requirements are applicable to an informal hearing?

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

(a) The hearing will be held within 10 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 opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

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

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

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

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

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

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under 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), (a)(2), (a)(3), and (a)(5), and § 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

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

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

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

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

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

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

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

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

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

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

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

(c) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

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

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

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

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

(1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

(2) Present, in writing, data and information to demonstrate that you have adequately resolved the problems with the conduct or 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 (a)(2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of paragraph (b) of this section.