

### § 112.3

### 21 CFR Ch. I (4–1–23 Edition)

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

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

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

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

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

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

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

#### § 112.3 What definitions apply to this part?

The definitions and interpretations of terms in section 201 of the Federal Food, Drug, and Cosmetic Act apply to such terms when used in this part. The following definitions also apply:

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

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

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

ganic matter, and soluble chemical components into an aqueous phase. Agricultural teas are held for longer than one hour before application. Agricultural teas are soil amendments for the purposes of this rule.

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

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

*Animal excreta* means solid or liquid animal waste.

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

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

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

*Composting* means a process to produce stabilized compost in which organic material is decomposed by the actions of microorganisms under thermophilic conditions for a designated period of time (for example, 3

days) at a designated temperature (for example, 131 °F (55 °C)), followed by a curing stage under cooler conditions.

*Covered activity* means growing, harvesting, packing, or holding covered produce on a farm. Covered activity includes manufacturing/processing of covered produce on a farm, but only to the extent that such activities are performed on raw agricultural commodities and only to the extent that such activities are within the meaning of “farm” as defined in this chapter. Providing, acting consistently with, and documenting actions taken in compliance with written assurances as described in §112.2(b) are also covered activities. This part does not apply to activities of a facility that are subject to part 117 of this chapter.

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

*Curing* means the final stage of composting, which is conducted after much of the readily metabolized biological material has been decomposed, at cooler temperatures than those in the thermophilic phase of composting, to further reduce pathogens, promote further decomposition of cellulose and lignin, and stabilize composition. Curing may or may not involve insulation, depending on environmental conditions.

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

*Farm* means:

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

- (i) Pack or hold raw agricultural commodities;
- (ii) Pack or hold processed food, provided that all processed food used in

such activities is either consumed on that farm or another farm under the same management, or is processed food identified in paragraph (1)(iii)(B)(I) of this definition; and

(iii) Manufacture/process food, provided that:

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

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

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

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

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

(2) *Secondary activities farm.* A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm. A secondary activities farm may also conduct those additional activities allowed on a primary production farm as described in paragraphs (1)(ii) and (iii) of this definition.

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

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

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

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

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

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

*Holding* means storage of food and also includes activities performed inci-

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

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

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

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

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

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

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

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

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

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

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

*Pre-consumer vegetative waste* means solid waste that is purely vegetative in origin, not considered yard trash, and derived from commercial, institutional, or agricultural operations without coming in contact with animal products, byproducts or manure or

with an end user (consumer). Pre-consumer vegetative waste includes material generated by farms, packing houses, canning operations, wholesale distribution centers and grocery stores; products that have been removed from their packaging (such as out-of-date juice, vegetables, condiments, and bread); and associated packaging that is vegetative in origin (such as paper or corn-starch based products). Pre-consumer vegetative waste does not include table waste, packaging that has come in contact with materials (such as meat) that are not vegetative in origin, or any waste generated by restaurants.

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

*Production batch of sprouts* means all sprouts that are started at the same time in a single growing unit (e.g., a single drum or bin, or a single rack of

trays that are connected to each other), whether or not the sprouts are grown from a single lot of seed (including, for example, when multiple types of seeds are grown in a single growing unit).

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

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

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

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

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

*Small business* means a farm that is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than \$500,000; and the farm is not a very small business as defined in this section.

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

substrate during the growth of covered produce (such as mushrooms and some sprouts).

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

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

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

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

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

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

*Very small business* means a farm that is subject to any of the requirements of this part and, on a rolling basis, the average annual monetary value of produce (as defined in this section) the farm sold during the previous 3-year period is no more than \$250,000.

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

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

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

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

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

[80 FR 74547, Nov. 27, 2015, as amended at 81 FR 26467, May 3, 2016]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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