

# **Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: What You Need to Know About the FDA Regulation: Guidance for Industry Small Entity Compliance Guide**

*Additional copies are available from:  
Office of Food Safety  
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Food and Drug Administration  
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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition**

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**Standards for the Growing, Harvesting,  
Packing, and Holding of Produce for  
Human Consumption: What You Need to  
Know About the FDA Regulation:  
Guidance for Industry<sup>1</sup>  
Small Entity Compliance Guide**

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This guidance represents the

document is intended to assist small entities in complying with the rule set forth in 21 CFR Part 112 concerning Produce Safety. The rule is binding and has the full force and effect of law.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

## II. OVERVIEW OF THE RULE

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x **Fruits and vegetables such as:** almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees, macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams. (21 CFR 112.1(b)(1))

x **Mixes of intact fruits and vegetables,** such as fruit baskets. (21 CFR 112.1(b)(2))

This list of covered produce is not intended to be an exhaustive, exclusive nor a complete list and serves only as examples of produce covered by the rule.

**D. Key Terms**

The produce safety rule uses a substantial number of terms in very specific ways. A full list of these terms appears in this guidance in section XV “Definitions.” Table 1 lists some of the key terms used in this document.

Table 1 – Key Terms Used in Part 112

<b>Term</b>	<b>Definition</b>
Agricultural Water	





	<p>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).</p> <p>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 (<i>e.g.</i>, cotton seed, flax seed, rapeseed, soybean, and sunflower seed).</p>
Qualified Exemption	<p>A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:</p> <p>(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</p> <p>(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.</p>

**E. Which Commodities And Farms Are Exempt From The Requirements Of Part 112 Or Eligible For An Exemption?**

Table 2 identifies products and farms that are exempt or eligible for an exemption from part 112.

Table 2 – Commodities and Farms Exempt From the Requirements of Part 112 or Eligible for an Exemption

<b>Exemption</b>	<b>Conditions</b>
Farms with limited sales are not covered by part 112	Farms with produce sales of " S H year (during the previous 3 year period) are not

Exemption	Conditions
21 CFR 112.4(a)	covered by part 112.
<p>Food grains are not produce and therefore are not covered by part 112</p> <p>21 CFR 112.3</p>	<p>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).</p>

Produce that is rarely consumed raw is not covered by part 112

Produce identified as rarely consumed raw:

asparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets, (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; ggs; ginger; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkin

Exemption	Conditions
<p>A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if:</p> <p>(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food (as defined in 21 CFR 112.3) the farm sold directly to qualified end-users (as defined in 21 CFR 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</p> <p>(2) The average annual monetary value of all food (as defined in 21 CFR 112.3) the farm sold during the 3-year period preceding the applicable calendar year was less than \$500,000, adjusted for inflation.</p> <p>21 CFR 112.5</p>	<p>21 CFR 112.2(b)(2) through (b)(6)</p> <p>Farms eligible for qualified exemptions are subject to the requirements of:</p> <ol style="list-style-type: none"> <li>1. Subpart B (General Provisions)</li> <li>2. Subpart O (Records)</li> <li>3. Subpart Q (Compliance and Enforcement); and</li> <li>4. Subpart R (Withdrawal of Qualified Exemption)</li> </ol> <p>21 CFR 112.6(a)</p> <p>Farms eligible for qualified exemption are required to include the name and complete business address of the farm where the produce was grown on the food packaging label or display at the point of purchase, the name and complete business address of the farm where the produce was grown. 21 CFR 112.6(b)</p> <p>A farm’s qualified exemption may be withdrawn if there is an active investigation of an foodborne illness outbreak that is directly linked to the farm, or if FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conduct or conditions associated with the farm that are material to the safety of the food that would be covered by the produce safety rule. 21 CFR 112.201(a)</p>

**F. When Do I Have To Comply With The Rule?**

Table 3 describes the general compliance dates for requirements under part 112.

Table 3 –





**F. What Procedure Will FDA Use To Withdraw An Exemption?**

x The importance of health and employee hygiene (21 CFR 112.22(a)(2)).

### **B. What Additional Training Is Required For Persons Who Conduct Harvest Activities?**

Persons who conduct harvest activities for covered produce must also receive training on the following:

- x Recognizing produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards (21 CFR 112.22(b)(1));
- x Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so that they do not become a source of contamination (21 CFR 112.22(b)(2)); and
- x Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor, as appropriate to the person's job responsibilities (21 CFR 112.22(b)(3)).

### **C. After the Initial Training, Is There A Requirement For Continuing Education?**

Yes, all personnel must receive training upon hiring and then periodically thereafter, at least once annually. The 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 the rule. (21 CFR 112.21(a) and (d))

### **D. 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 part 112 (21 CFR 112.23). Supervisors must also be trained according to the requirements under 21 CFR 112.21 and 112.22.

### **E. Is There A Requirement To Maintain Records For Training?**

Yes. You must establish and keep records that document required training of personnel, including the date of training, topics covered, and the person(s) trained in accordance with subpart O (records). (21 CFR 112.30(b))

## **V. HEALTH AND HYGIENE – SUBPART D**

### **A. What Hygienic Practices Must Personnel Use?**

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. (21 CFR 112.31(a))

When handling or contacting covered produce or food contact surfaces, personnel must (21 CFR 112.31(b)):



- x Maintain adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;
- x Avoid contact with animals, other than working animals, and take appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;
- x Wash hands thoroughly, including scrubbing with soap (or other effective cleanser) and running water that meets the requirements of rule for water used to wash hands, as well as drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices. Hands must be washed:
  - o Before starting work;
  - o Before putting on gloves;
  - o After using the toilet;
  - o Upon return to the work station after any break or other absence from the work station;
  - o As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and
  - o At any other time when the hands may be contaminated by animal contact.

intention to explore ways to simplify the agricultural water standards in March 2017. See <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm546089.htm>.

**A. What Requirements Apply To Agricultural Water Sources, Water Distribution Systems, And Pooling Of Water?**

At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your agricultural water systems to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces. The following should be taken into consideration during such an inspection (21 CFR 112.42):

- x Nature of each agricultural water source;

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tool for use in better understanding the microbial quality of agricultural water over time in order to determine a long-term strategy for use of water sources during growing produce other than sprouts.

### **C. What Are The Requirements For Water Quality?**

Part 112 establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination:

- x No detectable generic *E. coli* are allowed for certain uses of agricultural water in which it is reasonably likely that

changes, and take adequate measures to determine if changes were effective. (21 CFR 112.45(b)(2))

x Treating the water. (21 CFR 112.45(b)(3))

If generic E. coli is detected, such water must be immediately discontinued and corrective actions taken before re-use for any purposes in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. (21 CFR 112.45(a))

### **E. What Are The Testing Requirements For Agricultural Water?**

You must develop a water quality profile in accordance with 21 CFR 112.46 unless your agricultural water is:

- x Sourced from a Public Water System that meets certain requirements (21 CFR 112.46(a)(1)),
- x Sourced from a public water supply that meets the microbial quality requirement (21 CFR 112.46(a)(2)), or
- x Treated in accordance with the requirements in 21 CFR 112.43 (21 CFR 112.46(a)(3)).

The testing frequency required for a water quality profile is based on the type of water source (i.e., surface or ground water) and the use of the water:

- x **Untreated surface water** directly applied to growing produce (other than sprouts): A minimum of 20 samples, representative of the agricultural water that is used for production and under your control must be collected as close as practicable (but prior) to harvest over the course of two to four years. These initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria. (21 CFR 112.46 (b)(1)(i)(A))
- x **Untreated ground water** directly applied to growing produce (other than sprouts): A minimum of four samples, collected as close as is practicable (but prior) to harvest, during the growing season or over a period of one year. These initial survey findings are used to calculate the GM and STV and determine if the water meets the required microbial quality criteria. (21 CFR 112.46 (b)(1)(i)(B))

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2. Does the produce rule require annual testing of untreated surface water?

Yes, after your initial water quality profile for untreated surface water that is directl(a)-10(ce w)( )Tj E( )Tj EL

1. What type of data or information can I rely on?

Scientific data and information used to support an alternative to a requirement may be developed by you, available in scientific literature, or available to you through a third party. You must

At this time, FDA does not object to farmers complying with the United States Department of Agriculture (USDA) National Organic Program Standards related to raw manure use, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for the crops not in contact with the soil.

Untreated BSAAO, such as raw manure, must be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with produce after application. (21 CFR 112.56(a)(1))

### **C. What Are The Requirements For Treated BSAAO?**

Part 112 establishes microbial standards that set limits on detectable amounts of bacteria (including *Listeria monocytogenes*, *Salmonella* species, fecal coliforms, and *E. coli* O157:H7) for processes used to treat BSAAO, including manure.

#### **1. Are there microbial testing requirements for BSAAO?**

No. The produce safety rule has established microbial standards only to validate treatment processes. If the scientifically valid treatment processes listed in 21 CFR 112.54 (e.g., physical, chemical, biological, or in combination) have been documented to meet the respective microbial standards in 21 CFR 112.55, then the application requirements and minimum application intervals in 21 CFR 112.56(a) apply to the BSAAO in question.

#### **2. What regulations apply to stabilized compost?**

The produce safety rule (21 CFR 112.54(b)(1) and (b)(2)), that meet the microbial standard in 21 CFR 112.55(b). Growers that prepare their own stabilized compost only need to document the process controls (e.g. time/temperature and turnings). If the stabilized compost was purchased from a third party supplier, annual documentation would also be required that a valid process was used to treat the compost as well as documentation that the product was handled, conveyed and stored in a manner and location to minimize the risk of re-contamination (21 CFR 112.60(b)(1)(i) and (b)(1)(ii)). Stabilized compost that meets treatment requirements of 21 CFR 112.54(b) to meet the microbial standard in 21 CFR 112.55(b) may be applied with a zero day application interval, but must be applied in a manner that minimizes the potential for contact with produce during and after application. (21 CFR 112.56(a)(2))

Examples of scientifically valid composting methods include:

- x Static composting that maintains aerobic (i.e. oxygenated) conditions at a minimum of 131°F (55°C) for 3 consecutive days and is followed by adequate curing; and
- x Turned composting that maintains aerobic conditions at a minimum of 131°F (55°C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.

(21 CFR 112.54)

#### **D. Can I Use Human Waste?**

No. You may not use human waste for growing covered produce, except sewage sludge biosolids used in compliance with U.S. Environmental Protection Agency (EPA) regulations (40 CFR part 503) or equivalent regulatory requirements. (21 CFR 112.53)

### **VIII. DOMESTICATED AND WILD ANIMALS – SUBPART I**

Subpart I of Part 112 addresses concerns about the feasibility of compliance for farms that rely on grazing animals (such as livestock) or working animals for various purposes. It establishes the same standards for these animals as it does for intrusion by wild animals (such as deer or feral swine). Farmers are required to take all measures reasonably necessary to identify and not harvest produce that is likely to be contaminated. (21 CFR 112.83)

#### **A. What Must I Do When Contaminated Produce Is Identified?**



x Adequately clean and sanitize, as needed, any food contact surfaces that contact excluded produce before using the surface for covered activities on covered produce.

(21 CFR 112.111)

### **B. What Measures Must I Take Immediately Prior To And During Harvest Activities?**

You must take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. (21 CFR 112.112)

### **C. How Must I Handle Harvested Covered Produce During Covered Activities?**

You must handle harvested covered produce during covered activities in a manner that protects against contamination with known or reasonably foreseeable hazards, for example, by avoiding, to the degree practicable, contact of cut surfaces of harvested produce with soil. (21 CFR 112.113)

### **D. What Requirements Apply To Dropped Covered Produce?**

You must not distribute dropped covered produce that has fallen to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds). (21 CFR 112.114)

### **E. Are There Any Packaging Requirements?**

Yes. 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 mushrooms). (21 CFR 112.115)

### **F. Are There Any Requirements For Food-Packing Material?**

Yes. You must use food-packing material that is adequate for its intended use, is cleanable or designed for single use and is unlikely to support the growth or transfer of bacteria. (21 CFR 112.116 (a))

### **G. Can I Reuse Food-Packing Material?**

Yes. If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner. (21 CFR 112.116 (b))

## **X. EQUIPMENT, TOOLS, AND BUILDING – SUBPART L**

Subpart L of part 112 establishes standards related to equipment, tools, and buildings to prevent these sources, and inadequate sanitation, from contaminating produce.

### **A. What Are the Requirements for Equipment and Tools?**

You must ensure that appropriate measures are taken to use equipment and tools that are of adequate design and construction to enable adequate cleaning and maintenance and prevent

x Treating seeds or beans that will be used for sprouting (or relying on prior treatment by

- x A scientifically valid method that is at least equivalent to the method of analysis in 21 CFR 112.151(a) in accuracy, precision, and sensitivity; or
- x For any other indicator of fecal contamination you may test for pursuant to 21 CFR 112.49(a), a scientifically valid method.

(21 CFR 112.151)

**B. What Methods Must I Use To Test The Growing, Harvesting, Packing, and Holding Environment for *Listeria* species or *L. monocytogenes* for 21 CFR 112.144(a)?**

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

- x The method of analysis described in “Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples,” FDA, or
- x A scientifically valid method that is at least equivalent.

(21 CFR 112.152)

**C. What Methods Must I Use To Test The Growing, Harvesting, Packing, and Holding Environment for *Listeria* species or *L. monocytogenes* for 21 CFR 112.144(b) and (c)?**

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

- x The method of analysis described in “Testing Methodologies for *E. coli* O157:H7 and *Salmonella* species in Spent Sprout Irrigation Water (or Sprouts), Version 1, October 2015, FDA, or
- x A scientifically valid method that is at least equivalent





**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 part 112 in accordance with 21 CFR Part 112.1 and 112.2. The term “covered produce” refers to the harvestable or harvested part of the crop.

**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) Th add A Pahe)(B)ghetion i(fi)(B)gwater.

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



cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer

**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-

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

Stabilized compost