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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
Small Entity Compliance Guide

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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[1]
Small Entity Compliance Guide

This guidance represents the current thinking of the Food and Drug Administration (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

The FDA Food Safety Modernization Act of 2011 (FSMA) directs the Food and Drug Administration (FDA) as the food regulatory agency of the U.S. Department of Health and Human Services to better protect public health by, among other things, adopting a modern, preventive, and risk-based approach to food safety. As a key element of the preventive approach to better protect public health, FDA published in the *Federal Register* the final rule entitled "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption" (the produce safety rule, or the rule) (80 FR 74354, November 27, 2015). The produce safety rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing and holding of fruits and vegetables grown for human consumption. The regulations are found at Title 21 of the Code of Federal Regulations part 112 (21 CFR part 112). The rule became effective on January 26, 2016, but compliance dates are staggered – see section II. F "When Do I Have to Comply with the Rule?"

We have prepared this Small Entity Compliance Guide in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. Law 104-121). This guidance

[1] This guidance has been prepared by the Office of Food Safety, Division of Produce Safety in the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration.

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

A. Key Requirements

The key requirements include:

- Personnel Qualifications and Training (21 CFR Part 112, subpart C)
- Health and Hygiene (21 CFR Part 112, subpart D
- Agricultural Water (21 CFR Part 112, subpart E)
- Biological Soil Amendments (21 CFR Part 112, subpart F)
- Domesticated and wild animals (21 CFR, Part 112, subpart I)
- Equipment, tools, and building (21 CFR, Part 112, subpart L)
- Sprouts (21 CFR, Part 112, subpart M)

B. Who Must Comply With The Rule?

Covered farms must comply with this rule. (21 CFR 112.4(a))

Farms or farm mixed-type facilities with an average annual monetary value of produce (as defined in 21 CFR 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, are considered "covered farms" and are subject to the applicable requirements of part 112 when conducting a covered activity on covered produce. (21 CFR 112.4(a))

A farm is not a covered farm if it meets the requirements for a qualified exemption (see section III of this guidance for additional detail). (21 CFR 112.4(b))

C. What Produce Is Covered Under The Rule?

Unless it is excluded under 21 CFR 112.2, food that is produce within the meaning of part 112 and that is a raw agricultural commodity (RAC) is covered by part 112. 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. (21 CFR 112.1(a)

Covered produce includes, but is not limited to, all of the following:

- **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))

- **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

Term	Definition
Agricultural Water	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).
Biological Soil Amendment	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.
Farm	**(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)(*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 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.
Produce	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).
Qualified Exemption	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.

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

Exemption	Conditions
Farms with limited sales are not covered by part 112	Farms with produce sales of ≤ $25,000 per year (during the previous 3 year period) are not

Exemption	Conditions
21 CFR 112.4(a)	covered by part 112.
Food grains are not produce and therefore are not covered by part 112 21 CFR 112.3	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).
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; figs; ginger; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts. 21 CFR 112.2(a)(1)	Not subject to the requirements of part 112. (If you grow, harvest, pack, or hold more than one produce commodity, you should consider this question separately for each one to determine whether that particular produce commodity is covered by the produce safety rule).
Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same management is not covered by part 112. 21 CFR 112.2(a)(2)	Not subject to the requirements of part 112. Farms where the produce is not for sale.
Produce that is not a "raw agricultural commodity" is not covered by part 112. 21 CFR 112.2(a)(3)	Not subject to the requirements of part 112.
Produce that receives commercial processing ("kill step" or other process) that adequately reduces the presence of microorganisms of public health significance is eligible for an exemption from part 112. 21 CFR 112.2(b)(1)	You must disclose in documents accompanying the produce in accordance with the practice of trade, that the food is "not processed to adequately reduce the presence of microorganisms of public health significance;" annually obtain written assurances from the customer; and document compliance with required disclosures and written assurances.

Exemption	Conditions
	21 CFR 112.2(b)(2) through (b)(6)
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 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 (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. 21 CFR 112.5	Farms eligible for qualified exemptions are subject to the requirements of: 1. Subpart B (General Provisions) 2. Subpart O (Records) 3. Subpart Q (Compliance and Enforcement); and 4. Subpart R (Withdrawal of Qualified Exemption) 21 CFR 112.6(a) 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) 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)

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

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

Table 3 – Compliance Dates for Part 112

Business Size	**Covered activities involving sprouts covered under subpart M (i.e., subject to all requirements of part 112**	**Covered activities involving all other covered produce (i.e. subject to part 112, except subpart M)**	
		Compliance date for certain specified agricultural water* requirements	**Compliance date for all other requirements**
Very Small Business	January 28, 2019	January 26, 2022	January 27, 2020
Small Business	January 26, 2018	January 26, 2021	January 28, 2019
All Other Businesses	January 26, 2017	January 27, 2020	January 26, 2018

* FDA has announced its intention to further extend the compliance dates for the agricultural water requirements. See https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm561844.htm.

III. INFORMATION FOR FARMS ELIGIBLE FOR QUALIFIED EXEMPTIONS

A. How Can I Tell If My Business Is Eligible For A Qualified Exemption?

A farm is eligible for a qualified exemption and associated modified requirements in a calendar year if (21 CFR 112.5(a)):

> (1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the food the farm sold directly to qualified end-users 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 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.

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. (21 CFR 112.5(b))

Qualified end-user means the consumer of the food (where "consumer" does not include a business); or a restaurant or retail food establishment located in the same state or Indian reservation as the farm, or located within 275 miles from the farm. (21 CFR 112.3)

B. What Records Must I Establish And Keep If My Farm Is Eligible For A Qualified Exemption?

If your farm is eligible for a qualified exemption, you must establish and keep records:

- Required in accordance with the requirements of subpart O of part 112, except that the requirement in 21 CFR 112.161(a)(4) for a signature or initial of the person performing

the activity is not required for sales receipts kept in the normal course of business. However, such receipts must be dated (21 CFR 112.7(a)); and

- Records necessary to demonstrate that your farm satisfied the criteria for a qualified exemption, including a written record reflecting that you have performed an annual review and verification of your farm's continued eligibility for the qualified exemption. (21 CFR 112.7(b))

C. What Modified Requirements Are Farms Eligible For Qualified Exemption Subject To?

If your farm is eligible for a qualified exemption, you are subject to the requirements of:

- Subpart A of part 112 (General Provisions),
- Subpart O of part 112 (Records),
- Subpart Q of part 112 (Compliance and Enforcement); and
- Subpart R of part 112 (Withdrawal of Qualified Exemption).

(21 CFR 112.6(a))

Subpart A establishes the eligibility criteria for a qualified exemption and the record keeping requirements for farms eligible for a qualified exemption.

Subpart O establishes the requirements for records required under part 112, including what documents satisfy the requirements, how documents must be stored, how records must be made available to FDA, and how long records must be kept.

Subpart Q establishes that failure to comply with the requirements of part 112 is a prohibited act and the criteria and definitions in part 112 apply in determining whether a food is adulterated (grown, harvested, packed or held in such conditions that it is unfit for food or food that has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health) or in violation of section 361 of the Public Health Service Act (42 U.S.C. 264). (21 CFR 112.192)

Subpart R outlines the circumstances and requirements for withdrawal of a qualified exemption.

In addition, if your farm is eligible for a qualified exemption you are subject to the following modified requirements:

- When a food packaging label is required on food that would otherwise be covered produce under the FD&C Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address (street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms) of the farm where the produce was grown. (21 CFR 112.6(b)(1) and (3))

- When a food packaging label is not required on food that would otherwise be covered produce under the FD&C Act, you must prominently and conspicuously display, at the

point of purchase, the name and complete business address (street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms) 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. (21 CFR 112.6(b)(2) and (3))

D. When Must Farms Eligible For A Qualified Exemption Comply With Part 112?

Table 4 – Compliance Dates for Part 112 for Farms Eligible for a Qualified Exemption

Business Size	**Farm Eligible for a Qualified Exemption (if applicable)**			
	Compliance Date for Retention of Records Supporting Eligibility in 21 CFR 112.7(b)	**Compliance date for modified requirements in 21 CFR 112.6(b)(1)**	**Compliance date for all other requirements in 21 CFR 112.6 and 112.7 for farms producing sprouts**	**Compliance date for all other requirements in 21 CFR 112.6 and 112.7 for farms not producing sprouts**
Very Small Business	January 26, 2016	January 1, 2020	January 28, 2019	January 27, 2020
Small Business			January 26, 2018	January 28, 2019
All other Businesses			N/A	N/A

E. Can A Farm's Qualified Exemption Be Withdrawn?

Yes, a farm's qualified exemption can be withdrawn in the event of an active investigation of an outbreak that is directly linked to the farm, or if FDA determines it is necessary to protect public health based on conduct or conditions on the farm that may pose a risk to public health. (21 CFR 112.201(a))

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

- May consider other actions to protect the public health and prevent or mitigate a foodborne illness outbreak, including a warning letter, recall, administrative detention, refusal or food offered for import, seizure, and injunction;
- Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 15 calendar days of the date of receipt of the notification, to FDA's notification; and
- Must consider the actions taken by the farm to address the circumstance that may lead FDA to withdraw the exemption.

(21 CFR 112.201(b))

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

FDA will issue an order to withdraw the exemption in writing to the owner, operator, or agent in charge of the farm. The order must be in writing, and signed and dated by the officer or qualified employee of FDA who is issuing the order. (21 CFR 112.202)

G. If My Qualified Exemption is Withdrawn, Under What Circumstances Would FDA Reinstate My Qualified Exemption?

If FDA determines that your farm has adequately resolved any problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, FDA will, on its own initiative or at your request, reinstate the qualified exemption. (21 CFR 112.213(a))

You may ask FDA to reinstate a qualified exemption that has been withdrawn by submitting a request in writing and presenting data and information to demonstrate that you have adequately responded to any problems with the conduct and conditions that are material to the safety of the food produced and harvested at your farm. (21 CFR 112.213(b))

If your qualified exemption was withdrawn because of an active foodborne illness outbreak directly linked to your farm 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 and will notify you in writing that your exempt status has been reinstated. (21 CFR 112.213(c))

IV. PERSONNEL QUALIFICATIONS AND TRAINING – SUBPART C

All personnel (including temporary, part time, seasonal, and contracted personnel) who handle (contact) covered produce or food contact surfaces, or who are engaged in the supervision thereof are required to:

- Receive adequate training, as appropriate to the person's duties, upon hiring, and periodically thereafter, at least once annually. (21 CFR 112.21(a))
- Have a combination of education training, and experience necessary to perform the person's assigned duties in a manner that ensures compliance with this part. (21 CFR 112.21(b))

A. What Are The Specific Requirements For Training Personnel?

The training must be appropriate to the person's duties and conducted in a manner that is easily understood by personnel being trained to ensure compliance with the rule (21 CFR 112.21(c) and 112.22(a)(3)). Personnel must be trained on certain topics, including:

- The principles of food hygiene and food safety (21 CFR 112.22(a)(1)); and

- 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:

- 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));

- 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

- 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)):

- Maintain adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;
- 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;
- 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:
    - Before starting work;
    - Before putting on gloves;
    - After using the toilet;
    - Upon return to the work station after any break or other absence from the work station;
    - As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and
    - At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of produce with known or reasonably foreseeable hazards.
- Remove or cover hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and
- Not eat, chew gum, or use tobacco products in an area used for an activity covered by the rule. However, drinking beverages is permitted in designated areas).
- If personnel use gloves when handling covered produce or food contact surfaces, the gloves must be changed often to ensure they are maintained in an intact and sanitary condition.

B. Are There Any Requirements To Restrict Ill Personnel?

Yes. You must exclude 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. Ill or infected personnel must not be allowed to return to work until his/her health condition no longer presents a risk to public health. (21 CFR 112.31)

VI. AGRICULTURAL WATER – SUBPART E

Subpart E establishes requirements to ensure that all agricultural water is safe and of adequate sanitary quality for its intended use. (21 CFR 112.41) Please note that FDA has announced its

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):

- Nature of each agricultural water source;
- Extent of your control over each agricultural water source;
- Degree of protection of each agricultural water source;
- Use of adjacent and nearby land; and
- Likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before it reaches the covered farm.

B. What Is The Microbial Water Quality Profile?

The microbial water quality profile consists of two numerical values of generic *E. coli* in the water, the GM and the STV.

1. What is the GM?

The GM is an average, and therefore represents what is called the central tendency of the water quality (essentially, the average amount of generic *E.coli* in a water source).

2. What is the STV?

The STV reflects the amount of variation in water quality during the sampling timeframe. The STV value is a representation of the 90th percentile of the total population size of generic *E. coli* in the sampled agricultural water.

3. Is there an online tool to help calculate the GM and STV?

The FDA is exploring the development of an online tool that farms can use to input their water sample data and calculate these values. (See 80 FR 74443 (Comment 213) for further explanation.)

4. What about the variability of these values?

These criteria account for variability in the data and allow for occasional high readings of generic *E. coli* in appropriate context, making it much less likely (as compared to the originally proposed criteria for this water use) that a farm will have to discontinue use of its water source due to small fluctuations in water quality. These criteria are intended as a water management

tool for use in 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:

- No detectable generic *E. coli* are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact. Examples include water used for washing hands during and after harvest, water used on food contact surfaces, water used to directly contact produce (including to make ice) during or after harvest, and water used for sprout irrigation. You must not use untreated surface water for any of these purposes. (21 CFR 112.44(a))

- The second set of numerical criteria is for agricultural water that is directly applied to growing produce (other than sprouts). The criteria are based on two values, the geometric mean (GM) and the statistical threshold value (STV). (21 CFR 112.45(b))

    - The GM of samples is 126 or less colony forming units (CFU) of generic *E. coli* per 100 mL of water (21 CFR 112.44(b)(1)); and

    - STV of samples is 410 CFU or less of generic *E. coli* in 100 mL of water (21 CFR 112.44(b)(2)).

D. What If The CFU's Exceed The Established Numerical Criteria?

If the water does not meet the microbial criteria for growing produce other than sprouts, corrective actions are required as soon as is practicable, but no later than the following year. The rule provides farmers with additional flexibility by which they can meet the criteria and then be able to use the water on their crops. (21 CFR 112.45(b)) These options include:

- Allowing time for potentially dangerous microbes to die off on the field by using a standardized microbial die-off rate of 0.5 log per day between last irrigation and harvest, but this rate can be utilized for no more than four consecutive days. The rule also allows for an alternative die-off rate (with accompanying maximum time interval), in accordance with 21 CFR 112.49. (21 CFR 112.45(b)(1)(i))

- Allowing time for potentially dangerous microbes to die off between harvest and end of storage, and/or to be removed during commercial activities, such as washing, within appropriate limits, and provided you have adequate scientific support. (21 CFR 112.45(b)(1)(ii))

- Re-inspecting the affected agricultural water system to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards, make necessary

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

- 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:

- Sourced from a Public Water System that meets certain requirements (21 CFR 112.46(a)(1)),
- Sourced from a public water supply that meets the microbial quality requirement (21 CFR 112.46(a)(2)), or
- 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:

- **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))
- **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))

1. What requirements does the produce rule establish for testing public water?

There is no requirement to test agricultural water that is received from public water systems or supplies that meet requirements established in the rule (provided that the farm has Public Water System results or certificates of compliance demonstrating that the water meets relevant requirements), or if the water is treated in compliance with the rule's treatment requirements. (21 CFR 112.46(a))

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 directly applied to growing produce (other than sprouts) has been conducted, annual testing of a minimum of five samples per year is required to update the calculations of GM and STV. The five new samples, plus a minimum of the previous most recent 15 samples, create a rolling dataset of at least 20 samples for use in confirming that that the water is still used appropriately by recalculating the GM and STV. (21 CFR 112.46 (b)(2)(i)(B))

3. Does the produce rule require annual testing of untreated ground water?

Yes, after the initial water quality profile for untreated ground water that is directly applied to growing produce (other than sprouts) has been conducted, an annual survey of a minimum of one sample per year is required to update the calculations of GM and STV. The new samples, plus a minimum of the previous most recent three samples, create a rolling dataset of at least four samples for use in confirming that the water may still be used by updating the GM and STV. (21 CFR 112.46(b)(2)(i)(A))

For untreated ground water that is used for the purposes listed in 21 CFR 112.44(a) for which no detectable generic *E. coli* is allowed, FDA requires farms to initially test the untreated ground water at least four times during the growing season or over a period of one year. Farms must determine whether the water can be used for the intended purpose based on these results.

- If the four initial sample results meet the no detectable generic *E. coli* criterion, testing can be done once annually thereafter, using a minimum of one sample.
- If any annual test fails to meet the microbial quality criterion, farms must resume testing at least four times per growing season or year.

(21 CFR 112.46(c))

F. Are There Alternatives To The Quality And Testing Requirements For Agricultural Water?

You may establish alternatives to certain specific requirements of subpart E, 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. (21 CFR 112.49)

Examples of alternative requirements may include:

- Alternatives to the microbial quality criteria using an appropriate indicator of fecal contamination;
- Alternative microbial die-off rate and accompanying maximum allowed time interval; or
- Alternative number of samples used in the initial survey and subsequent annual survey for untreated surface water sources.

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 establish and maintain documentation of the scientific data and information on which you rely. (21 CFR 112.12(c))

2. Must I notify FDA of my decision to use an alternative?

No. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative (21 CFR 112.12(c)).

VII. BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN AND HUMAN WASTE – SUBPART F

Subpart F of part 112 establishes requirements for the use of biological soil amendments of animal origin (BSAAO) and human waste. A soil amendment is a material, including manure that is intentionally added to the soil to improve its chemical or physical condition for growing plants or to improve its capacity to hold water.

A. How Do You Determine The Status Of A BSAAO?

A BSAAO is considered treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the standards set by 21 CFR 112.54. (21 CFR 112.51(a))

A BSAAO is considered untreated in several circumstances including if it:

- Has not been processed to completion in accordance with 21 CFR 112.54;
- Has become contaminated after treatment;
- Has been recombined with an untreated BSAAO;
- Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard that has been associated with foodborne illness; or
- It is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.

(21 CFR 112.51(b))

B. What Are The Requirements For Untreated BSAAO?

FDA is conducting a risk assessment and extensive research on the number of days needed between the applications of untreated BSAAO (e.g., raw manure) and harvesting to minimize the risk of contamination.

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 includes two examples of scientifically valid composting methods, 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:

- Static composting that maintains aerobic (i.e. oxygenated) conditions at a minimum of 131^{o}F (55^{o}C) for 3 consecutive days and is followed by adequate curing; and

- Turned composting that maintains aerobic conditions at a minimum of 131^{o}F (55^{o}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?

If significant evidence of potential contamination by animals is found (e.g. significant amounts of excreta or crop destruction), you must identify and not harvest such contaminated crops. You must also take measures which might include, for example, placing flags outlining the affected area to identify, and not harvest, produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard. (21 CFR 112.112 and 112.83(b)(2)).

B. What If My Farm Allows Grazing Between Harvests?

Although the produce rule does not require establishing waiting periods between grazing and harvest, the FDA encourages farmers to voluntarily consider applying such intervals as appropriate for the farm's commodities and practices.

C. Are Animals Required To Be Excluded From The Growing Areas?

No. Farms are not required to exclude animals from outdoor growing areas, destroy animal habitat, or clear borders around growing or drainage areas. Nothing in the rule should be interpreted as requiring or encouraging such actions. (21 CFR 112.84)

IX. GROWING, HARVESTING, PACKING, AND HOLDING ACTIVITIES – SUBPART K

A. 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 21 CFR112.2) and also conduct activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with the regulations, you must take measures to:

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

- 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 contamination of covered produce and food contact surfaces including, for example, appropriate storage, maintenance and cleaning of equipment, tools, instruments (including transport equipment) and building structures. (21 CFR 112.123)

Equipment and tools include those that are intended to, or likely to, contact covered produce. Examples include knives, mechanical harvesters, cooling equipment, grading belts, dump tanks, and vehicles or other equipment for transport. (21 CFR 112.121)

B. What Are the Requirements for Buildings Used for Covered Activities?

The produce safety rule covers any fully or partially-enclosed buildings that are used for covered activities, as well as storage sheds, buildings or other structures used to store food contact surfaces (such as harvest containers and food packing materials. (21 CFR 112.122)

Buildings must be suitable in size, construction, and design to facilitate maintenance and proper sanitation to reduce the potential for contamination from, for example, condensate, domesticated animals, and pests. (21 CFR 112.126 – 112.128)

Adequate and readily accessible toilet and hand washing facilities are required. (21 CFR 112.129 and 112.130)

And proper disposal of sewage and other trash, litter, and waste in areas used for covered activities is also required. (21 CFR 112.131 – 112.132)

XI. SPROUTS – SUBPART M

Subpart M of Part 112 includes requirements to help prevent the contamination of sprouts. The requirements of subpart M apply to the growing, harvesting, packing, and holding of all sprouts, except soil- or substrate-grown sprouts harvested without their roots. (21 CFR 112.141)

A. Why Are There Different Requirements For Sprouts?

Sprouts have been frequently associated with foodborne illness outbreaks and are especially vulnerable to dangerous microbes because of the warm, moist and nutrient-rich conditions needed to grow them.

B. What Requirements Apply to Seeds or Beans Used To Grow Sprouts?

Requirements that apply to seeds or beans used to grow sprouts include:

- Taking measures to prevent the introduction of dangerous microbes into or onto seeds or beans used for sprouting, and

- Treating seeds or beans that will be used for sprouting (or relying on prior treatment by the seed/bean grower, distributor, or supplier with appropriate documentation) to reduce microorganisms of public health significance.

(21 CFR 112.142)

C. What Requirements Apply To The Growing, Harvesting, Packing and Holding Of Sprouts?

Requirements that apply to the growing, harvesting, packing, and holding of sprouts include:

- Sprouts must be grown, harvested, and packed in fully enclosed buildings and have established written and implemented sampling plans to test water or sprouts for pathogens, as well as corrective actions if pathogens are detected. (21 CFR 112.143)
- Using a valid testing method to test of spent sprout irrigation water from each production batch of sprouts, or in-process sprouts from each production batch (if testing water is not practical), for *E.coli* O157:H7, *Salmonella* species and any other pathogen meeting the criteria in 21 CFR 112.144(c). (21 CFR 112.44)
    - Validated testing methods for the growing, harvesting, packing, and holding environments and spent sprout irrigation water (or sprouts) can be found in 21 CFR 112.152 and 112.153.
- Testing the growing, harvesting, packing, and holding environment for the presence of *Listeria* species or *L. monocytogenes*. (21 CFR 112.44)
- Taking corrective actions if spent sprout irrigation water, sprouts, and/or an environmental sample tests positive. (21 CFR 112.146 and 112.148)

D. When Must I Comply With The Requirements for Sprouts?

Sprout operations will have less time to come into compliance with the rule than farms growing other produce. They will have one to three years to comply based on the size of their operation, with no additional time to meet the water requirements. See section II.F "When Do I Have To Comply With The Rule?"

XII. ANALYTICAL METHODS – SUPBART N

A. What Methods Must I Use To Test The Quality of Water For 21 CFR 112.46?

You must test the quality of water using:

- The method of analysis published by the U.S. Environmental Protection Agency (EPA), or

- 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

- 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:

- The method of analysis described in "Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples," FDA, or

- 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:

- 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

- A scientifically valid method that is at least equivalent

(21 CFR 112.153)

XIII. RECORDS – SUBPART O

A. What Are The General Records Requirements For The Produce Rule?

All records under part 112 must be created at the time an activity is performed or observed; be accurate, legible, and indelible; be dated, and signed or initialed by the person who performed the activity documented; and include the following, as applicable:

- The name and location of your farm,

- Actual values and observations obtained during monitoring,

- 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, and

- The date and time of the activity documented.

(21 CFR 112.161(a))

B. Must I Store My Records Onsite?

No. Offsite storage of records is permitted if the records can be retrieved and provided onsite within 24 hours of a request for official review. (21 CFR 112.162(a))

C. Are Electronic Records Acceptable?

Yes. Electronic records are acceptable and are considered to be onsite at your farm if they are accessible from an onsite location at your farm. (21 CFR 112.162(b))

D. How Long Must I Keep Records?

You must keep records required by this part for at least 2 years past the date the record was created. (21 CFR 112.164(a)(1))

Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued. (21 CFR 112.164(b))

E. Does The 2 Year Period Also Apply to Records Used To Be Eligible For A Qualified Exemption?

No. Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with 21 CFR 112.5 and 112.7, must be retained as long as necessary to support the farm's status during the applicable calendar year. (21 CFR 112.164(a)(2))

XIV. VARIANCES – SUBPART P

A. Can A Farm Apply For A Variance?

No. The produce rule permits States, tribes, or foreign countries to submit a petition, along with supporting information, to FDA requesting a variance(s) from the requirements of the produce rule.

B. Who May Request a Variance?

States, tribes, or foreign countries from which food is imported into the United States may submit a petition, along with supporting information, to FDA requesting a variance(s) from one or more of the requirements under the produce rule if the state, tribe, or country concludes that meeting one or more of the requirements would be problematic in light of local growing

conditions. The state, tribe, or foreign country must demonstrate that the requested variance is reasonably likely to ensure that the produce is not adulterated and provides the same level of public health protection as the corresponding requirement(s) in the produce rule. (21 CFR 112.171)

C. How May a Variance Be Requested?

To request a variance from one or more requirements of this rule, the competent authority (i.e., the regulatory authority for food safety) for a State, tribe, or a foreign country must submit a petition under 21 CFR 10.30. (21 CFR 112.172)

In addition to the requirements of 21 CFR 10.30, a Statement of Grounds must be included in a petition for a variance. (21 CFR 112.173)

D. When Does a Variance Approved by FDA Become Effective?

A variance approved by FDA becomes effective on the date of FDA's written decision on the petition. (21 CFR 112.179)

E. Under What Circumstances May FDA Modify or Revoke an Approved Variance?

FDA may modify or revoke a variance if it is determined that the variance is not reasonably likely to ensure that the produce is not adulterated under section 401 of the FD&C Act and to provide the same level of public health protection as the requirements of this rule. (21 CFR 112.180)

XV. DEFINITIONS (21 CFR 112.3)

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 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 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)(*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 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.

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

cooling, field coring, filtering, gathering, hulling, shelling, sifting, threshing, trimming of outer leaves of, and washing raw agricultural commodities grown on a farm.

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

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

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

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

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

Microorganisms means yeasts, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species having public health significance. The term “undesirable microorganisms” includes those microorganisms that are of public health significance, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

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

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

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

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

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).

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.

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.

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).

You, for purposes of part 112, means the owner, operator, or agent in charge of a covered farm that is subject to some or all of the requirements of part 112.