

**AUDIT STANDARDS COMPARISON TO THE FDA PRODUCE SAFETY RULE**

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PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
<b>Subpart B—General Requirements</b>				
<b>§ 112.11 What general requirements apply to persons who are subject to this part?</b>				
You must take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act on account of such hazards.				
<b>§ 112.12 Are there any alternatives to the requirements established in this part? *</b>				
(a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.49, provided that you satisfy the requirements of paragraphs (b) and (c) of this section.				
(b) You may establish and use an alternative to any of the requirements specified in paragraph (a) of this section, provided you have adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part, and would not increase the likelihood that your covered produce will be adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act, in light of your covered produce, practices, and conditions.				
(c) Scientific data and information used to support an alternative to a requirement specified in paragraph (a) of this section may be developed by you, available in the scientific literature, or available to you through a third party. You must establish and maintain documentation of the scientific data and information on which you rely in				

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accordance with the requirements of subpart O of this part. You are not required to notify or seek prior approval from FDA regarding your decision to establish or use an alternative under this section.				
<b>Subpart C—Personnel Qualifications and Training</b>				
<b>§ 112.21 What requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces?</b>				
All of the following requirements apply regarding qualifications and training for personnel who handle (contact) covered produce or food contact surfaces:				
(a) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must receive adequate training, as appropriate to the person’s duties, upon hiring, and periodically thereafter, at least once annually.				
(b) All personnel (including temporary, part time, seasonal, and contracted personnel) who handle covered produce or food contact surfaces, or who are engaged in the supervision thereof, must have a combination of education, training, and experience necessary to perform the person’s assigned duties in a manner that ensures compliance with this part.				
(c) Training must be conducted in a manner that is easily understood by personnel being trained.				
(d) Training must be repeated as necessary and appropriate in light of observations or information indicating that personnel are not meeting standards established by FDA in subparts C through O of this part.				
<b>§ 112.22 What minimum requirements apply for training personnel who conduct a covered activity?</b>				
(a) At a minimum, all personnel who handle (contact) covered produce during covered activities or supervise the				

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conduct of such activities must receive training that includes all of the following:				
(1) Principles of food hygiene and food safety;				
(2) The importance of health and personal hygiene for all personnel and visitors, including recognizing symptoms of a health condition that is reasonably likely to result in contamination of covered produce or food contact surfaces with microorganisms of public health significance; and				
(3) The standards established by FDA in subparts C through O of this part that are applicable to the employee’s job responsibilities.				
(b) Persons who conduct harvest activities for covered produce must also receive training that includes all of the following:				
(1) Recognizing covered produce that must not be harvested, including covered produce that may be contaminated with known or reasonably foreseeable hazards;				
(2) Inspecting harvest containers and equipment to ensure that they are functioning properly, clean, and maintained so as not to become a source of contamination of covered produce with known or reasonably foreseeable hazards; and				
(3) Correcting problems with harvest containers or equipment, or reporting such problems to the supervisor (or other responsible party), as appropriate to the person’s job responsibilities.				
(c) At least one supervisor or responsible party for your farm must have successfully completed food safety training at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration.				
<b>§ 112.23 What requirements apply regarding supervisors?</b>				

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You must assign or identify personnel to supervise (or otherwise be responsible for) your operations to ensure compliance with the requirements of this part.				
<b>§ 112.30 Under this subpart, what requirements apply regarding records?</b>				
(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.				
(b) You must establish and keep records of training that document required training of personnel, including the date of training, topics covered, and the persons(s) trained.				
<b>Subpart D—Health and Hygiene</b>				
<b>§ 112.31 What measures must I take to prevent ill or infected persons from contaminating covered produce with microorganisms of public health significance?</b>				
(a) You must take measures to prevent contamination of covered produce and food contact surfaces with microorganisms of public health significance from any person with an applicable health condition (such as communicable illnesses that present a public health risk in the context of normal work duties, infection, open lesion, vomiting, or diarrhea).				
(b) The measures you must take to satisfy the requirements of paragraph (a) of this section must include all of the following measures:				
(1) Excluding any person from working in any operations that may result in contamination of covered produce or food contact surfaces with microorganisms of public health significance when the person (by medical examination, the person’s acknowledgement, or observation) is shown to have, or appears to have, an applicable health condition, until the person’s health condition no longer presents a risk to public health; and				

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(2) Instructing personnel to notify their supervisor(s) (or a responsible party) if they have, or if there is a reasonable possibility that they have an applicable health condition.				
<b>§ 112.32 What hygienic practices must personnel use?</b>				
(a) Personnel who work in an operation in which covered produce or food contact surfaces are at risk of contamination with known or reasonably foreseeable hazards must use hygienic practices while on duty to the extent necessary to protect against such contamination.				
(b) The hygienic practices that personnel use to satisfy the requirements of paragraph (a) of this section when handling (contacting) covered produce or food contact surfaces during a covered activity must include all of the following practices:				
(1) Maintaining adequate personal cleanliness to protect against contamination of covered produce and food contact surfaces;				
(2) Avoiding contact with animals other than working animals, and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals;				
(3) Washing hands thoroughly, including scrubbing with soap (or other effective surfactant) and running water that satisfies the requirements of § 112.44(a) (as applicable) for water used to wash hands, and drying hands thoroughly using single-service towels, sanitary towel service, electric hand dryers, or other adequate hand drying devices:				
(i) Before starting work;				
(ii) Before putting on gloves;				
(iii) After using the toilet;				
(iv) Upon return to the work station after any break or other absence from the work station;				
(v) As soon as practical after touching animals (including livestock and working animals), or any waste of animal origin; and				

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(vi) At any other time when the hands may have become contaminated in a manner that is reasonably likely to lead to contamination of covered produce with known or reasonably foreseeable hazards;				
(4) If you choose to use gloves in handling covered produce or food contact surfaces, maintaining gloves in an intact and sanitary condition and replacing such gloves when no longer able to do so;				
(5) Removing or covering hand jewelry that cannot be adequately cleaned and sanitized during periods in which covered produce is manipulated by hand; and				
(6) Not eating, chewing gum, or using tobacco products in an area used for a covered activity (however, drinking beverages is permitted in designated areas).				
<b>§ 112.33 What measures must I take to prevent visitors from contaminating covered produce and food contact surfaces with microorganisms of public health significance?</b>				
(a) You must make visitors aware of policies and procedures to protect covered produce and food contact surfaces from contamination by people and take all steps reasonably necessary to ensure that visitors comply with such policies and procedures.				
(b) You must make toilet and handwashing facilities accessible to visitors.				
<b>Subpart E—Agricultural Water *</b>				
<b>§ 112.41 What requirements apply to the quality of agricultural water?</b>				
All agricultural water must be safe and of adequate sanitary quality for its intended use.				
<b>§ 112.42 What requirements apply to my agricultural water sources, water distribution system, and pooling of water?</b>				
(a) At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your				

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agricultural water systems, to the extent they are under your control (including water sources, water distribution systems, facilities, and equipment), to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces in light of your covered produce, practices, and conditions, including consideration of the following:				
(1) The nature of each agricultural water source (for example, ground water or surface water);				
(2) The extent of your control over each agricultural water source;				
(3) The degree of protection of each agricultural water source;				
(4) Use of adjacent and nearby land; and				
(5) The likelihood of introduction of known or reasonably foreseeable hazards to agricultural water by another user of agricultural water before the water reaches your covered farm.				
(b) You must adequately maintain all agricultural water distribution systems to the extent they are under your control as necessary and appropriate to prevent the water distribution system from being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system.				
(c) You must adequately maintain all agricultural water sources to the extent they are under your control (such as wells). Such maintenance includes regularly inspecting each source to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; correcting any significant deficiencies (e.g., repairs to well cap, well casing, sanitary seals, piping tanks				

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and treatment equipment, and control of cross-connections); and keeping the source free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances.				
(d) As necessary and appropriate, you must implement measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards as a result of contact of covered produce with pooled water. For example, such measures may include using protective barriers or staking to keep covered produce from touching the ground or using an alternative irrigation method.				
<b>§ 112.43 What requirements apply to treating agricultural water?</b>				
(a) When agricultural water is treated in accordance with § 112.45:				
(1) Any method you use to treat agricultural water (such as with physical treatment, including using a pesticide device as defined by the U.S. Environmental Protection Agency (EPA); EPA-registered antimicrobial pesticide product; or other suitable method) must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meet the relevant microbial quality criteria in § 112.44, as applicable.				
(2) You must deliver any treatment of agricultural water in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.				
(b) You must monitor any treatment of agricultural water at a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use and/or consistently meets the relevant microbial quality criteria in § 112.44, as applicable.				



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<b>§ 112.44 What specific microbial quality criteria apply to agricultural water used for certain intended uses?</b>				
(a) When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic <i>Escherichia coli</i> ( <i>E. coli</i> ) in 100 milliliters (mL) of agricultural water, and you must not use untreated surface water for any of these purposes:				
(1) Used as sprout irrigation water;				
(2) Applied in any manner that directly contacts covered produce during or after harvest activities (for example, water that is applied to covered produce for washing or cooling activities, and water that is applied to harvested crops to prevent dehydration before cooling), including when used to make ice that directly contacts covered produce during or after harvest activities;				
(3) Used to contact food contact surfaces, or to make ice that will contact food contact surfaces; and				
(4) Used for washing hands during and after harvest activities.				
(b) When you use agricultural water during growing activities for covered produce (other than sprouts) using a direct water application method, the following criteria apply (unless you establish and use alternative criteria in accordance with § 112.49):				
(1) A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic <i>E. coli</i> per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and				
(2) A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic <i>E. coli</i> per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90 <sup>th</sup> percentile using the lognormal distribution).				

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§ 112.45 What measures must I take if my agricultural water does not meet the requirements of § 112.41 or § 112.44?				
(a) If you have determined or have reason to believe that your agricultural water is not safe or of adequate sanitary quality for its intended use as required under § 112.41 and/or if your agricultural water does not meet the microbial quality criterion for the specified purposes as required under § 112.44(a), you must immediately discontinue that use(s), and before you may use the water source and/or distribution system again for the intended use(s), you must either:				
(1) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and, as applicable, adequately ensure that your agricultural water meets the microbial quality criterion in § 112.44(a); or				
(2) Treat the water in accordance with the requirements of § 112.43.				
(b) If you have determined that your agricultural water does not meet the microbial quality criteria (or any alternative microbial quality criteria, if applicable) required under § 112.44(b), as soon as practicable and no later than the following year, you must discontinue that use, unless you either:				
(1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:				
(i) Applying a time interval between last irrigation and harvest using either:				
(A) A microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of your geometric mean (GM)				

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and statistical threshold value (STV) to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), but no greater than a maximum time interval of 4 consecutive days; or				
(B) An alternative microbial die-off rate and any accompanying maximum time interval, in accordance with § 112.49; and/or				
(ii) Applying a time interval between harvest and end of storage using an appropriate microbial die-off rate between harvest and end of storage, and/or applying a (calculated) log reduction using appropriate microbial removal rates during activities such as commercial washing, to meet the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable), and any accompanying maximum time interval or log reduction, provided you have adequate supporting scientific data and information;				
(2) Re-inspect the entire affected agricultural water system to the extent it is under your control, identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, make necessary changes, and take adequate measures to determine if your changes were effective and adequately ensure that your agricultural water meets the microbial quality criteria in § 112.44(b) (or any alternative microbial criteria, if applicable); or				
(3) Treat the water in accordance with the requirements of § 112.43.				
<b>§ 112.46 How often must I test agricultural water that is subject to the requirements of § 112.44?</b>				
(a) There is no requirement to test any agricultural water that is subject to the requirements of § 112.44 when:				
(1) You receive water from a Public Water System, as defined under the Safe Drinking Water Act (SDWA)				

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regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (as defined in 40 CFR 141.2) approved to administer the SDWA public water supply program, and you have Public Water System results or certificates of compliance that demonstrate that the water meets that requirement;				
(2) You receive water from a public water supply that furnishes water that meets the microbial quality requirement described in § 112.44(a), and you have public water system results or certificates of compliance that demonstrate that the water meets that requirement; or				
(3) You treat water in accordance with the requirements of § 112.43.				
(b) Except as provided in paragraph (a) of this section, you must take the following steps for each source of water used for purposes that are subject to the requirements of § 112.44(b):				
(1) Conduct an initial survey to develop a microbial water quality profile of the agricultural water source.				
(i) The initial survey must be conducted:				
(A) For an untreated surface water source, by taking a minimum total of 20 samples of agricultural water (or an alternative testing frequency that you establish and use, in accordance with § 112.49) over a minimum period of 2 years, but not greater than 4 years.				
(B) For an untreated ground water source, by taking a minimum total of four samples of agricultural water during the growing season or over a period of 1 year.				
(ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest. The microbial water quality profile initially consists of the geometric mean (GM) and the statistical threshold value (STV) of generic <i>Escherichia coli</i> ( <i>E. coli</i> )				

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(colony forming units (CFU) per 100 milliliter (mL)) calculated using this data set. You must determine the appropriate way(s) in which the water may be used based on your microbial water quality profile in accordance with § 112.45(b).				
(iii) You must update the microbial water quality profile annually as required under paragraph (b)(2) of this section, and otherwise required under paragraph (b)(3) of this section.				
(2) Conduct an annual survey to update the microbial water quality profile of your agricultural water.				
(i) After the initial survey described in paragraph (b)(1)(i) of this section, you must test the water annually to update your existing microbial water quality profile to confirm that the way(s) in which the water is used continues to be appropriate. You must analyze:				
(A) For an untreated surface water source, a minimum number of five samples per year (or an alternative testing frequency that you establish and use, in accordance with § 112.49).				
(B) For an untreated ground water source, a minimum of one sample per year.				
(ii) The samples of agricultural water must be representative of your use of the water and must be collected as close in time as practicable to, but prior to, harvest.				
(iii) To update the microbial water quality profile, you must calculate revised GM and STV values using your current annual survey data, combined with your most recent initial or annual survey data from within the previous 4 years, to make up a rolling data set of:				
(A) At least 20 samples for untreated surface water sources; and				
(B) At least 4 samples for untreated ground water sources.				

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(iv) You must modify your water use, as appropriate, based on the revised GM and STV values in your updated microbial water quality profile in accordance with § 112.45(b).				
(3) If you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you must develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed.				
(i) To develop a new microbial water quality profile, you must calculate new GM and STV values using your current annual survey data (if taken after the time of the change), combined with new data, to make up a data set of:				
(A) At least 20 samples for untreated surface water sources; and				
(B) At least 4 samples for untreated ground water sources.				
(ii) You must modify your water use based on the new GM and STV values in your new microbial water quality profile in accordance with § 112.45(b).				
(c) If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you must initially test the microbial quality of each source of the untreated ground water <u>at least four times</u> during the growing season or over a period of 1 year, using a <u>minimum total of four samples</u> collected to be representative of the intended use(s). Based on these results, you must determine whether the water can be used for that purpose, in accordance with § 112.45(a). If your four initial sample results meet the microbial quality criteria of § 112.44(a), you may test once annually thereafter, using a minimum of one sample collected to be representative of the intended use(s). You must resume				

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testing at least four times per growing season or year if any annual test fails to meet the microbial quality criteria in § 112.44(a).				
<b>§ 112.47 Who must perform the tests required under § 112.46 and what methods must be used?</b>				
(a) You may meet the requirements related to agricultural water testing required under § 112.46 using:				
(1) Test results from your agricultural water source(s) performed by you, or by a person or entity acting on your behalf; or				
(2) Data collected by a third party or parties, provided the water source(s) sampled by the third party or parties adequately represent your agricultural water source(s) and all other applicable requirements of this part are met.				
(b) Agricultural water samples must be aseptically collected and tested using a method as set forth in § 112.151.				
<b>§ 112.48 What measures must I take for water that I use during harvest, packing, and holding activities for covered produce?</b>				
(a) You must manage the water as necessary, including by establishing and following water-change schedules for recirculated water, to maintain its safety and adequate sanitary quality and minimize the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards (for example, hazards that may be introduced into the water from soil adhering to the covered produce).				
(b) You must visually monitor the quality of water that you use during harvest, packing, and holding activities for covered produce (for example, water used for washing covered produce in dump tanks, flumes, or wash tanks, and water used for cooling covered produce in hydrocoolers) for buildup of organic material (such as soil and plant debris).				

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(c) You must maintain and monitor the temperature of water at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.				
<b>§ 112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?</b>				
Provided you satisfy the requirements of § 112.12, you may establish and use one or more of the following alternatives:				
(a) An alternative microbial quality criterion (or criteria) using an appropriate indicator of fecal contamination, in lieu of the microbial quality criteria in § 112.44(b);				
(b) An alternative microbial die-off rate and an accompanying maximum time interval, in lieu of the microbial die-off rate and maximum time interval in § 112.45(b)(1)(i);				
(c) An alternative minimum number of samples used in the initial survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(1)(i)(A); and				
(d) An alternative minimum number of samples used in the annual survey for an untreated surface water source, in lieu of the minimum number of samples required under § 112.46(b)(2)(i)(A).				
<b>§ 112.50 Under this subpart, what requirements apply regarding records?</b>				
(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.				
(b) You must establish and keep the following records:				
(1) The findings of the inspection of your agricultural water system in accordance with the requirements of § 112.42(a);				



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(2) Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with this subpart;				
(3) Scientific data or information you rely on to support the adequacy of a method used to satisfy the requirements of § 112.43(a)(1) and (2);				
(4) Documentation of the results of water treatment monitoring under § 112.43(b);				
(5) Scientific data or information you rely on to support the microbial die-off or removal rate(s) that you used to determine the time interval (in days) between harvest and end of storage, including other activities such as commercial washing, as applicable, used to achieve the calculated log reduction of generic <i>Escherichia coli</i> ( <i>E. coli</i> ), in accordance with § 112.45(b)(1)(ii);				
(6) Documentation of actions you take in accordance with § 112.45. With respect to any time interval or (calculated) log reduction applied in accordance with § 112.45(b)(1)(i) and/or (ii), such documentation must include the specific time interval or log reduction applied, how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last irrigation and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing);				
(7) Annual documentation of the results or certificates of compliance from a public water system required under § 112.46(a)(1) or (2), if applicable;				
(8) Scientific data or information you rely on to support any alternative that you establish and use in accordance with § 112.49; and				
(9) Any analytical methods you use in lieu of the method that is incorporated by reference in § 112.151(a).				
<b>Subpart F—Biological Soil Amendments of Animal Origin and Human Waste</b>				

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<b>§ 112.51 What requirements apply for determining the status of a biological soil amendment of animal origin?</b>				
(a) A biological soil amendment of animal origin is treated if it has been processed to completion to adequately reduce microorganisms of public health significance in accordance with the requirements of § 112.54, or, in the case of an agricultural tea, the biological materials of animal origin used to make the tea have been so processed, the water used to make the tea is not untreated surface water, and the water used to make the tea has no detectable generic <i>Escherichia coli</i> ( <i>E. coli</i> ) in 100 milliliters (mL) of water.				
(b) A biological soil amendment of animal origin is untreated if it:				
(1) Has not been processed to completion in accordance with the requirements of § 112.54, or in the case of an agricultural tea, the biological materials of animal origin used to make the tea have not been so processed, or the water used to make the tea is untreated surface water, or the water used to make the tea has detectable generic <i>E. coli</i> in 100 mL of water;				
(2) Has become contaminated after treatment;				
(3) Has been recombined with an untreated biological soil amendment of animal origin;				
(4) Is or contains a component that is untreated waste that you know or have reason to believe is contaminated with a hazard or has been associated with foodborne illness; or				
(5) Is an agricultural tea made with biological materials of animal origin that contains an agricultural tea additive.				
<b>§ 112.52 How must I handle, convey, and store biological soil amendments of animal origin?</b>				
(a) You must handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of				

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contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments. Agricultural teas that are biological soil amendments of animal origin may be used in water distribution systems provided that all other requirements of this rule are met.				
(b) You must handle, convey and store any treated biological soil amendment of animal origin in a manner and location that minimizes the risk of it becoming contaminated by an untreated or in-process biological soil amendment of animal origin.				
(c) You must handle, convey, and store any biological soil amendment of animal origin that you know or have reason to believe may have become contaminated as if it was untreated.				
<b>§ 112.53 What prohibitions apply regarding use of human waste?</b>				
You may not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements.				
<b>§ 112.54 What treatment processes are acceptable for a biological soil amendment of animal origin that I apply in the growing of covered produce?</b>				
Each of the following treatment processes are acceptable for a biological soil amendment of animal origin that you apply in the growing of covered produce, provided that the resulting biological soil amendments are applied in accordance with the applicable requirements of § 112.56:				
(a) A scientifically valid controlled physical process (e.g., thermal), chemical process (e.g., high alkaline pH), biological process (e.g., composting), or a combination of scientifically valid controlled physical, chemical and/or biological processes that has been validated to satisfy the microbial standard in § 112.55(a) for <i>Listeria</i>				

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<i>monocytogenes</i> ( <i>L. monocytogenes</i> ), <i>Salmonella</i> species, and <i>E. coli</i> O157:H7; or					
(b) A scientifically valid controlled physical, chemical, or biological process, or a combination of scientifically valid controlled physical, chemical, and/or biological processes, that has been validated to satisfy the microbial standard in § 112.55(b) for <i>Salmonella</i> species and fecal coliforms.					
Examples of scientifically valid controlled biological (e.g., composting) processes that meet the microbial standard in § 112.55(b) include:					
(1) Static composting that maintains aerobic (i.e., oxygenated) conditions at a minimum of 131 °F (55 °C) for 3 consecutive days and is followed by adequate curing; and					
(2) Turned composting that maintains aerobic conditions at a minimum of 131 °F (55 °C) for 15 days (which do not have to be consecutive), with a minimum of five turnings, and is followed by adequate curing.					
<b>§ 112.55 What microbial standards apply to the treatment processes in § 112.54?</b>					
The following microbial standards apply to the treatment processes in § 112.54 as set forth in that section.					
(a) For <i>L. monocytogenes</i> , <i>Salmonella</i> species, and <i>E. coli</i> O157:H7, the relevant standards in the table in this paragraph (a);					
For the microorganism-	The microbial standard is				
(1) <i>L. monocytogenes</i>	Not detected using a method that can detect one colony forming unit (CFU) per 5 gram (or milliliter, if liquid is being sampled) analytical portion.				
(2) <i>Salmonella</i> species	Not detected using a method that can detect three most probable numbers (MPN) per 4				

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	grams (or milliliter, if liquid is being sampled) of total solids.					
(3) <i>E. coli</i> O157:H7	Not detected using a method that can detect 0.3 MPN per 1 gram (or milliliter, if liquid is being sampled) analytical portion.					
or (b) <i>Salmonella</i> species are not detected using a method that can detect three MPN <i>Salmonella</i> species per 4 grams of total solids (dry weight basis); and less than 1,000 MPN fecal coliforms per gram of total solids (dry weight basis).						
<b>§ 112.56 What application requirements and minimum application intervals apply to biological soil amendments of animal origin?</b>						
(a) You must apply the biological soil amendments of animal origin specified in the first column of the table in this paragraph (a) in accordance with the application requirements specified in the second column of the table in this paragraph (a) and the minimum application intervals specified in the third column of the table in this paragraph (a).						
If the biological soil amendment of animal origin is—	Then the biological soil amendment of animal origin must be applied—	And then the minimum application interval is—				
(1)(i) Untreated	In a manner that does not contact covered produce during application and minimizes the potential for contact with	[Reserved].				

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	covered produce after application.				
(ii) Untreated	In a manner that does not contact covered produce during or after application.	0 days.			
(2) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled physical, chemical, and/or biological processes, in accordance with the requirements of § 112.54(b) to meet the microbial standard in § 112.55(b).	In a manner that minimizes the potential for contact with covered produce during and after application.	0 days.			
(3) Treated by a scientifically valid controlled physical, chemical, or biological process, or combination of scientifically valid controlled	In any manner ( <i>i.e.</i> , no restrictions.	0 days.			

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physical, chemical, or biological processes, in accordance with the requirements of § 112.54(a) to meet the microbial standard in § 112.55(a).						
<b>§ 112.60 Under this subpart, what requirements apply regarding records?</b>						
(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.						
(b) For any biological soil amendment of animal origin you use, you must establish and keep the following records:						
(1) For a treated biological soil amendment of animal origin you receive from a third party, documentation (such as a Certificate of Conformance) at least annually that:						
(i) The process used to treat the biological soil amendment of animal origin is a scientifically valid process that has been carried out with appropriate process monitoring; and						
(ii) The biological soil amendment of animal origin has been handled, conveyed and stored in a manner and location to minimize the risk of contamination by an untreated or in process biological soil amendment of animal origin; and						
(2) For a treated biological soil amendment of animal origin you produce for your own covered farm(s), documentation that process controls (for example, time, temperature, and turnings) were achieved.						
<b>Subpart I—Domesticated and Wild Animals</b>						
<b>§ 112.81 How do the requirements of this subpart apply to areas where covered activities take place?</b>						

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(a) The requirements of this subpart apply when a covered activity takes place in an outdoor area or a partially enclosed building and when, under the circumstances, there is a reasonable probability that animals will contaminate covered produce.				
(b) The requirements of this subpart do not apply:				
(1) When a covered activity takes place in a fully-enclosed building; or				
(2) To fish used in aquaculture operations.				
<b>§ 112.83 What requirements apply regarding grazing animals, working animals, and animal intrusion?</b>				
(a) You must take the steps set forth in paragraph (b) of this section if under the circumstances there is a reasonable probability that grazing animals, working animals, or animal intrusion will contaminate covered produce.				
(b) You must:				
(1) Assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce as needed during the growing season (based on your covered produce; your practices and conditions; and your observations and experience); and				
(2) If significant evidence of potential contamination is found (such as observation of animals, animal excreta or crop destruction), you must evaluate whether the covered produce can be harvested in accordance with the requirements of § 112.112 and take measures reasonably necessary during growing to assist you later during harvest when you must identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard.				
<b>§ 112.84 Does this regulation require covered farms to take actions that would constitute a “taking” of threatened or endangered species; to take measures to exclude animals from outdoor growing areas; or to</b>				



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<b>destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages?</b>				
No. Nothing in this regulation authorizes the “taking” of threatened or endangered species as that term is defined by the Endangered Species Act (16 U.S.C. 1531–1544) ( <i>i.e.</i> , to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct), in violation of the Endangered Species Act.				
This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.				
<b>Subpart K—Growing, Harvesting, Packing, and Holding Activities</b>				
<b>§ 112.111 What measures must I take if I grow, harvest, pack or hold both covered and excluded produce?</b>				
If you grow, harvest, pack or hold produce that is not covered in this part ( <i>i.e.</i> , excluded produce in accordance with § 112.2) and also conduct such activities on covered produce, and the excluded produce is not grown, harvested, packed or held in accordance with this part, you must take measures during these covered activities, as applicable, to:				
(a) Keep covered produce separate from excluded produce (except when covered produce and excluded produce are placed in the same container for distribution); and				
(b) Adequately clean and sanitize, as necessary, any food contact surfaces that contact excluded produce before using such food contact surfaces for covered activities on covered produce.				
<b>§ 112.112 What measures must I take immediately prior to and during harvest activities?</b>				
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				

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reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta. At a minimum, identifying and not harvesting covered produce that is reasonably likely to be contaminated with animal excreta or that is visibly contaminated with animal excreta requires a visual assessment of the growing area and all covered produce to be harvested, regardless of the harvest method used.				
<b>§ 112.113 How must I handle harvested covered produce during covered activities?</b>				
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.				
<b>§ 112.114 What requirements apply to dropped covered produce?</b>				
You must not distribute dropped covered produce. Dropped covered produce is covered produce that drops to the ground before harvest. Dropped covered produce does not include root crops that grow underground (such as carrots), crops that grow on the ground (such as cantaloupe), or produce that is intentionally dropped to the ground as part of harvesting (such as almonds).				
<b>§ 112.115 What measures must I take when packaging covered produce?</b>				
You must package covered produce in a manner that prevents the formation of <i>Clostridium botulinum</i> toxin if such toxin is a known or reasonably foreseeable hazard (such as for mushrooms).				
<b>§ 112.116 What measures must I take when using food-packing (including food packaging) material?</b>				

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(a) You must use food-packing material that is adequate for its intended use, which includes being:				
(1) Cleanable or designed for single use; and				
(2) Unlikely to support growth or transfer of bacteria.				
(b) If you reuse food-packing material, you must take adequate steps to ensure that food contact surfaces are clean, such as by cleaning food-packing containers or using a clean liner.				
<b>Subpart L—Equipment, Tools, Buildings, and Sanitation</b>				
<b>§ 112.121 What equipment and tools are subject to the requirements of this subpart?</b>				
Equipment and tools subject to the requirements of this subpart are those that are intended to, or likely to, contact covered produce; and those instruments or controls used to measure, regulate, or record conditions to control or prevent the growth of microorganisms of public health significance. Examples include knives, implements, mechanical harvesters, waxing machinery, cooling equipment (including hydrocoolers), grading belts, sizing equipment, palletizing equipment, and equipment used to store or convey harvested covered produce (such as containers, bins, food-packing material, dump tanks, flumes, and vehicles or other equipment used for transport that are intended to, or likely to, contact covered produce).				
<b>§ 112.122 What buildings are subject to the requirements of this subpart?</b>				
Buildings subject to the requirements of this subpart include:				
(a) Any fully- or partially-enclosed building used for covered activities, including minimal structures that have a roof but do not have any walls; and				
(b) Storage sheds, buildings, or other structures used to store food contact surfaces (such as harvest containers and food-packing materials).				

**AUDIT STANDARDS COMPARISON TO THE FDA PRODUCE SAFETY RULE**

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§ 112.123 What general requirements apply regarding equipment and tools subject to this subpart?				
All of the following requirements apply regarding equipment and tools subject to this subpart:				
(a) You must use equipment and tools that are of adequate design, construction, and workmanship to enable them to be adequately cleaned and properly maintained; and				
(b) Equipment and tools must be:				
(1) Installed and maintained as to facilitate cleaning of the equipment and of all adjacent spaces; and				
(2) Stored and maintained to protect covered produce from being contaminated with known or reasonably foreseeable hazards and to prevent the equipment and tools from attracting and harboring pests.				
(c) Seams on food contact surfaces of equipment and tools that you use must be either smoothly bonded, or maintained to minimize accumulation of dirt, filth, food particles, and organic material and thus minimize the opportunity for harborage or growth of microorganisms.				
(d)(1) You must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.				
(2) You must maintain and clean all non-food-contact surfaces of equipment and tools subject to this subpart used during harvesting, packing, and holding as frequently as reasonably necessary to protect against contamination of covered produce.				
(e) If you use equipment such as pallets, forklifts, tractors, and vehicles such that they are intended to, or likely to, contact covered produce, you must do so in a manner that minimizes the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards.				

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<b>§ 112.124 What requirements apply to instruments and controls used to measure, regulate, or record?</b>				
Instruments or controls you use to measure, regulate, or record temperatures, hydrogen-ion concentration (pH), sanitizer efficacy or other conditions, in order to control or prevent the growth of microorganisms of public health significance, must be:				
(a) Accurate and precise as necessary and appropriate in keeping with their purpose;				
(b) Adequately maintained; and				
(c) Adequate in number for their designated uses.				
<b>§ 112.125 What requirements apply to equipment that is subject to this subpart used in the transport of covered produce?</b>				
Equipment that is subject to this subpart that you use to transport covered produce must be:				
(a) Adequately clean before use in transporting covered produce; and				
(b) Adequate for use in transporting covered produce.				
<b>§ 112.126 What requirements apply to my buildings?</b>				
(a) All of the following requirements apply regarding buildings:				
(1) Buildings must be suitable in size, construction, and design to facilitate maintenance and sanitary operations for covered activities to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. Buildings must:				
(i) Provide sufficient space for placement of equipment and storage of materials;				
(ii) Permit proper precautions to be taken to reduce the potential for contamination of covered produce, food contact surfaces, or packing materials with known or reasonably foreseeable hazards. The potential for contamination must be reduced by effective design				

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including the separation of operations in which contamination is likely to occur, by one or more of the following means: Location, time, partition, enclosed systems, or other effective means; and				
(2) You must provide adequate drainage in all areas where normal operations release or discharge water or other liquid waste on the ground or floor of the building.				
(b) You must implement measures to prevent contamination of your covered produce and food contact surfaces in your buildings, as appropriate, considering the potential for such contamination through:				
(1) Floors, walls, ceilings, fixtures, ducts, or pipes; and				
(2) Drip or condensate.				
<b>§ 112.127 What requirements apply regarding domesticated animals in and around a fully-enclosed building?</b>				
(a) You must take reasonable precautions to prevent contamination of covered produce, food contact surfaces, and food-packing materials in fully enclosed buildings with known or reasonably foreseeable hazards from domesticated animals by:				
(1) Excluding domesticated animals from fully-enclosed buildings where covered produce, food contact surfaces, or food-packing material is exposed; or				
(2) Separating domesticated animals in a fully enclosed building from an area where a covered activity is conducted on covered produce by location, time, or partition.				
(b) Guard or guide dogs may be allowed in some areas of a fully enclosed building if the presence of the dogs is unlikely to result in contamination of produce, food contact surfaces, or food-packing materials.				
<b>§ 112.128 What requirements apply regarding pest control in buildings?</b>				

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(a) You must take those measures reasonably necessary to protect covered produce, food contact surfaces, and food-packing materials from contamination by pests in buildings, including routine monitoring for pests as necessary and appropriate.				
(b) For fully-enclosed buildings, you must take measures to exclude pests from your buildings.				
(c) For partially-enclosed buildings, you must take measures to prevent pests from becoming established in your buildings (such as by use of screens or by monitoring for the presence of pests and removing them when present).				
<b>§ 112.129 What requirements apply to toilet facilities?</b>				
All of the following requirements apply to toilet facilities:				
(a) You must provide personnel with adequate, readily accessible toilet facilities, including toilet facilities readily accessible to growing areas during harvesting activities.				
(b) Your toilet facilities must be designed, located, and maintained to:				
(1) Prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, water sources, and water distribution systems with human waste;				
(2) Be directly accessible for servicing, be serviced and cleaned at a frequency sufficient to ensure suitability of use, and be kept supplied with toilet paper; and				
(3) Provide for the sanitary disposal of waste and toilet paper.				
(c) During growing activities that take place in a fully-enclosed building, and during covered harvesting, packing, or holding activities, you must provide a hand-washing station in sufficiently close proximity to toilet facilities to make it practical for persons who use the toilet facility to wash their hands.				

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<b>§ 112.130 What requirements apply for hand-washing facilities?</b>				
All of the following requirements apply to hand-washing facilities:				
(a) You must provide personnel with adequate, readily accessible handwashing facilities during growing activities that take place in a fully enclosed building, and during covered harvest, packing, or holding activities.				
(b) Your hand-washing facilities must be furnished with:				
(1) Soap (or other effective surfactant);				
(2) Running water that satisfies the requirements of § 112.44(a) for water used to wash hands; and				
(3) Adequate drying devices (such as single service towels, sanitary towel service, or electric hand dryers).				
(c) You must provide for appropriate disposal of waste (for example, waste water and used single-service towels) associated with a hand-washing facility and take appropriate measures to prevent waste water from a handwashing facility from contaminating covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.				
(d) You may not use antiseptic hand rubs as a substitute for soap (or other effective surfactant) and water.				
<b>§ 112.131 What must I do to control and dispose of sewage?</b>				
All of the following requirements apply for the control and disposal of sewage:				
(a) You must dispose of sewage into an adequate sewage or septic system or through other adequate means.				
(b) You must maintain sewage and septic systems in a manner that prevents contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water				



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distribution systems with known or reasonably foreseeable hazards.				
(c) You must manage and dispose of leakages or spills of human waste in a manner that prevents contamination of covered produce, and prevents or minimizes contamination of food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.				
(d) After a significant event (such as flooding or an earthquake) that could negatively impact a sewage or septic system, you must take appropriate steps to ensure that sewage and septic systems continue to operate in a manner that does not contaminate covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems.				
<b>§ 112.132 What must I do to control and dispose of trash, litter, and waste in areas used for covered activities?</b>				
All of the following requirements apply to the control and disposal of trash, litter, and waste in areas used for covered activities:				
(a) You must convey, store, and dispose of trash, litter and waste to:				
(1) Minimize the potential for trash, litter, or waste to attract or harbor pests; and				
(2) Protect against contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems with known or reasonably foreseeable hazards.				
(b) You must adequately operate systems for waste treatment and disposal so that they do not constitute a potential source of contamination in areas used for a covered activity.				
<b>§ 112.133 What requirements apply to plumbing?</b>				

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The plumbing must be of an adequate size and design and be adequately installed and maintained to:				
(a) Distribute water under pressure as needed, in sufficient quantities, in all areas where used for covered activities, for sanitary operations, or for handwashing and toilet facilities;				
(b) Properly convey sewage and liquid disposable waste;				
(c) Avoid being a source of contamination to covered produce, food contact surfaces, areas used for a covered activity, or agricultural water sources; and				
(d) Not allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for a covered activity, for sanitary operations, or for use in hand-washing facilities.				
<b>§ 112.134 What must I do to control animal excreta and litter from domesticated animals that are under my control?</b>				
(a) If you have domesticated animals, to prevent contamination of covered produce, food contact surfaces, areas used for a covered activity, agricultural water sources, or agricultural water distribution systems with animal waste, you must:				
(1) Adequately control their excreta and litter; and				
(2) Maintain a system for control of animal excreta and litter.				
(b) [Reserved]				
<b>§ 112.140 Under this subpart, what requirements apply regarding records?</b>				
(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.				
(b) You must establish and keep documentation of the date and method of cleaning and sanitizing of equipment subject to this subpart used in:				

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(1) Growing operations for sprouts; and				
(2) Covered harvesting, packing, or holding activities.				
<b>Subpart M—Sprouts</b>				
<b>§ 112.141 What commodities are subject to this subpart?</b>				
The requirements of this subpart apply to growing, harvesting, packing, and holding of all sprouts, except soil or substrate-grown sprouts harvested without their roots.				
<b>§ 112.142 What requirements apply to seeds or beans used to grow sprouts?</b>				
In addition to the requirements of this part, all of the following requirements apply to seeds or beans used to grow sprouts.				
(a) You must take measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into or onto seeds or beans that you will use for sprouting.				
(b) Except as provided in paragraph (c) of this section, if you know or have reason to believe that a lot of seeds or beans may be contaminated with a pathogen (either because it has been associated with foodborne illness; or based on microbial test results, including a positive finding of a pathogen in tests required under § 112.144(b)), you must:				
(1) Discontinue use of all seeds or beans from that lot for sprout production and ensure that sprouts grown from that lot of seeds or beans do not enter commerce; and				
(2) Report the information (association with illness and/or findings of microbial testing) to the seed grower, distributor, supplier, or other entity from whom you received the seeds or beans.				
(c) If your reason to believe that a lot of seeds or beans may be contaminated was based only on microbial test results:				
(1) You are not required to take the steps set forth in paragraph (b)(1) of this section if you treat your lot of				

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seeds or beans with a process that is reasonably certain to achieve destruction or elimination in the seeds or beans of the most resistant microorganisms of public health significance that are likely to occur in the seeds or beans; or				
(2) You are not required to take the steps set forth in paragraphs (b)(1) and (2) of this section if you later reasonably determine, through appropriate follow-up actions, that the lot of seeds or beans is not the source of contamination (e.g., the lot of seeds or beans is not the source of a pathogen found in spent sprout irrigation water or sprouts).				
(d) You must visually examine seeds and beans, and packaging used to ship seeds or beans, for signs of potential contamination with known or reasonably foreseeable hazards.				
(e) You must either:				
(1) Treat seeds or beans that will be used to grow sprouts using a scientifically valid method to reduce microorganisms of public health significance; or				
(2) Rely on prior treatment of seeds or beans conducted by a grower, distributor, or supplier of the seeds or beans (whether to fulfill this requirement completely or for the purpose of considering such prior treatment when applying appropriate additional treatment of the seeds or beans at the covered farm immediately before sprouting), provided that you obtain documentation (such as a Certificate of Conformance) from the grower, distributor, or supplier that:				
(i) The prior treatment was conducted using a scientifically valid method to reduce microorganisms of public health significance; and				
(ii) The treated seeds or beans were handled and packaged following the treatment in a manner that minimizes the potential for contamination.				

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<b>§ 112.143 What measures must I take for growing, harvesting, packing, and holding sprouts?</b>				
You must take all of the following measures for growing, harvesting, packing, and holding sprouts:				
(a) You must grow, harvest, pack, and hold sprouts in a fully-enclosed building.				
(b) Any food contact surfaces you use to grow, harvest, pack, or hold sprouts must be cleaned and sanitized before contact with sprouts or seeds or beans used to grow sprouts.				
(c) You must conduct testing during growing, harvesting, packing, and holding sprouts, as specified in § 112.144.				
(d) You must establish and implement a written environmental monitoring plan as specified in § 112.145.				
(e) You must take certain actions if you detect <i>Listeria</i> species or <i>L. monocytogenes</i> in the growing, harvesting, packing, or holding environment, as specified in § 112.146.				
(f) You must establish and implement a written sampling plan to test spent sprout irrigation water or sprouts for pathogens as specified in § 112.147.				
(g) You must take certain actions if the samples of spent sprout irrigation water or sprouts test positive for a pathogen as specified in § 112.148.				
<b>§ 112.144 What testing must I do during growing, harvesting, packing, and holding sprouts?</b>				
All of the following testing must be done during growing, harvesting, packing, and holding sprouts:				
(a) You must test the growing, harvesting, packing, and holding environment for <i>Listeria</i> species or <i>L. monocytogenes</i> in accordance with the requirements of § 112.145.				
(b) You must either:				
(1) Test spent sprout irrigation water from each production batch of sprouts for <i>E. coli</i> O157:H7, <i>Salmonella</i> species, and any pathogens meeting the criteria in paragraph (c) of				

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this section, in accordance with the requirements of § 112.147; or				
(2) If testing spent sprout irrigation water is not practicable (for example, soil-grown sprouts harvested with roots or for hydroponically grown sprouts that use very little water), test each production batch of sprouts at the in process stage ( <i>i.e.</i> , while sprouts are still growing) for <i>E. coli</i> O157:H7, <i>Salmonella</i> species, and any pathogens meeting the criteria in paragraph (c) of this section, in accordance with the requirements of § 112.147.				
(c) In addition to <i>E. coli</i> O157:H7 and <i>Salmonella</i> species, you must conduct tests as provided in paragraph (b) of this section for additional pathogens when the following conditions are met:				
(1) Testing for the pathogen is reasonably necessary to minimize the risk of serious adverse health consequences or death from use of, or exposure to, sprouts; and				
(2) A scientifically valid test method for the pathogen is available to detect the pathogen in spent sprout irrigation water (or sprouts).				
<b>§ 112.145 What requirements apply to testing the environment for <i>Listeria</i> species or <i>L. monocytogenes</i>?</b>				
All of the following testing requirements apply for the growing, harvesting, packing, and holding environment for <i>Listeria</i> species or <i>L. monocytogenes</i> .				
(a) You must establish and implement a written environmental monitoring plan that is designed to identify <i>L. monocytogenes</i> if it is present in the growing, harvesting, packing, or holding environment.				
(b) Your written environmental monitoring plan must be directed to sampling and testing for either <i>Listeria</i> species or <i>L. monocytogenes</i> .				
(c) Your written environmental monitoring plan must include a sampling plan that specifies:				

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(1) What you will test collected samples for ( <i>i.e.</i> , <i>Listeria</i> species or <i>L. monocytogenes</i> );				
(2) How often you will collect environmental samples, which must be no less than monthly, and at what point during production you will collect the samples; and				
(3) Sample collection sites; the number and location of sampling sites must be sufficient to determine whether measures are effective and must include appropriate food contact surfaces and non-food-contact surfaces of equipment, and other surfaces within the growing, harvesting, packing, and holding environment.				
(d) You must aseptically collect environmental samples and test them for <i>Listeria</i> species or <i>L. monocytogenes</i> using a method as set forth in § 112.152.				
(e) Your written environmental monitoring plan must include a corrective action plan that, at a minimum, requires you to take the actions in § 112.146, and details when and how you will accomplish those actions, if the growing, harvesting, packing, or holding environment tests positive for <i>Listeria</i> species or <i>L. monocytogenes</i> .				
<b>§ 112.146 What actions must I take if the growing, harvesting, packing, or holding environment tests positive for <i>Listeria</i> species or <i>L. monocytogenes</i>?</b>				
You must, at a minimum, take the following actions if you detect <i>Listeria</i> species or <i>L. monocytogenes</i> in the growing, harvesting, packing, or holding environment:				
(a) Conduct additional testing of surfaces and areas surrounding the area where <i>Listeria</i> species or <i>L. monocytogenes</i> was detected to evaluate the extent of the problem, including the potential for <i>Listeria</i> species or <i>L. monocytogenes</i> to have become established in a niche;				
(b) Clean and sanitize the affected surfaces and surrounding areas;				

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(c) Conduct additional sampling and testing to determine whether the <i>Listeria</i> species or <i>L. monocytogenes</i> has been eliminated;				
(d) Conduct finished product testing when appropriate;				
(e) Perform any other actions necessary to prevent recurrence of the contamination; and (f) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce.				
<b>§ 112.147 What must I do to collect and test samples of spent sprout irrigation water or sprouts for pathogens?</b>				
All of the following requirements apply for collecting and testing samples of spent sprout irrigation water or sprouts for pathogens as required in § 112.144(b):				
(a) You must establish and implement a written sampling plan that identifies the number and location of samples (of spent sprout irrigation water or sprouts) to be collected for each production batch of sprouts to ensure that the collected samples are representative of the production batch when testing for contamination.				
(b) In accordance with the written sampling plan required under paragraph (a) of this section, you must aseptically collect samples of spent sprout irrigation water or sprouts, and test the collected samples for pathogens using a method as set forth in § 112.153. You must not allow the production batch of sprouts to enter into commerce unless the results of the testing of spent sprout irrigation water or sprouts are negative for <i>E. coli</i> O157:H7, <i>Salmonella</i> species, and, if applicable, a pathogen meeting the criteria in § 112.144(c).				
(c) Your written sampling plan must include a corrective action plan that at a minimum, requires you to take the actions in § 112.148, and details when and how you will accomplish those actions, if the samples of spent sprout irrigation water or sprouts test positive for <i>E. coli</i> O157:H7,				



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PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION	Audit Standard Language	Analysis of Alignment of Audit Standard	Description of Gaps and Actions to Align	Additional Comments
<i>Salmonella</i> species, or a pathogen meeting the criteria in § 112.144(c).				
<b>§ 112.148 What actions must I take if the samples of spent sprout irrigation water or sprouts test positive for a pathogen?</b>				
You must, at a minimum, take the following actions if the samples of spent sprout irrigation water or sprouts test positive for <i>E. coli</i> O157:H7, <i>Salmonella</i> species, or a pathogen meeting the criteria in § 112.144(c):				
(a) Take appropriate action to prevent any food that is adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act from entering into commerce;				
(b) Take the steps required in § 112.142(b) with respect to the lot of seeds or beans used to grow the affected production batch of sprouts (except as allowed under § 112.142(c));				
(c) Clean and sanitize the affected surfaces and surrounding areas; and				
(d) Perform any other actions necessary to prevent reoccurrence of the contamination.				
<b>§ 112.150 Under this subpart, what requirements apply regarding records?</b>				
(a) You must establish and keep records required under this subpart in accordance with the requirements of subpart O of this part.				
(b) You must establish and keep the following records:				
(1) Documentation of your treatment of seeds or beans to reduce microorganisms of public health significance in the seeds or beans, at your farm; or alternatively, documentation (such as a Certificate of Conformance) from your seed supplier that seeds or beans are treated to reduce microorganisms of public health significance and are appropriately handled and packaged following the treatment, in accordance with the requirements of § 112.142(e);				

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(2) Your written environmental monitoring plan in accordance with the requirements of § 112.145;				
(3) Your written sampling plan for each production batch of sprouts in accordance with the requirements of § 112.147(a) and (c);				
(4) Documentation of the results of all analytical tests conducted for purposes of compliance with this subpart;				
(5) Any analytical methods you use in lieu of the methods that are incorporated by reference in §§ 112.152 and 112.153; and				
(6) Documentation of actions you take in accordance with §§ 112.142(b) and				
(c), 112.146, and 112.148.				
<b>Subpart N—Analytical Methods *</b>				
<b>§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of § 112.46?</b>				
You must test the quality of water using:				
(a) The method of analysis published by the U.S. Environmental Protection Agency (EPA), “Method 1603: <i>Escherichia coli</i> ( <i>E. coli</i> ) in Water by Membrane Filtration Using Modified membrane-Thermo-tolerant <i>Escherichia coli</i> Agar (Modified mTEC), EPA-821-R-09-007,” December, 2009. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from EPA, Office of Water (4303T), 1200 Pennsylvania Avenue NW., Washington, DC 20460. You may inspect a copy at FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301-796-2039, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <a href="http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html">http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html</a> ; or				

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(b)(1) A scientifically valid method that is at least equivalent to the method of analysis in § 112.151(a) in accuracy, precision, and sensitivity; or				
(2) For any other indicator of fecal contamination you may test for pursuant to § 112.49(a), a scientifically valid method.				
<b>§ 112.152 What methods must I use to test the growing, harvesting, packing, and holding environment for <i>Listeria</i> species or <i>L. monocytogenes</i> to satisfy the requirements of § 112.144(a)?</b>				
You must test the growing, harvesting, packing, and holding environment for <i>Listeria</i> species or <i>L. monocytogenes</i> using:				
(a) The method of analysis described in “Testing Methodology for <i>Listeria</i> species or <i>L. monocytogenes</i> in Environmental Samples,” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1600; FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039; <a href="http://www.fda.gov/fsma">http://www.fda.gov/fsma</a> ; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: <a href="http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html">http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html</a> ; or				
(b) A scientifically valid method that is at least equivalent to the method of analysis in § 112.152(a) in accuracy, precision, and sensitivity.				

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<b>§ 112.153 What methods must I use to test spent sprout irrigation water (or sprouts) from each production batch of sprouts for pathogens to satisfy the requirements of § 112.144(b) and (c)?</b>				
You must test spent sprout irrigation water (or sprouts) from each production batch for pathogens using:				
(a) For <i>E. coli</i> O157:H7, <i>Salmonella</i> species:				
(1) The method of analysis described in “Testing Methodologies for <i>E. coli</i> O157:H7 and <i>Salmonella</i> species in Spent Sprout Irrigation Water (or Sprouts),” Version 1, October 2015, U.S. Food and Drug Administration. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 5. You may obtain a copy from, and/or inspect a copy at, the Division of Produce Safety, Center for Food Safety and Applied Nutrition (CFSAN), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1600; FDA’s Main Library, 10903 New Hampshire Ave., Bldg. 2, Third Floor, Silver Spring, MD 20993, 301–796–2039; <a href="http://www.fda.gov/fsma">http://www.fda.gov/fsma</a> ; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: <a href="http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html">http://www.archives.gov/federal_register/code_of_federal_regulation/ibr_locations.html</a> ; or				
(2) A scientifically valid method that is at least equivalent to the method of analysis in § 112.153(a)(1) in accuracy, precision, and sensitivity; and				
(b) For any other pathogen(s) meeting the criteria in § 112.144(c), a scientifically valid method.				
<b>Subpart O—Records</b>				
<b>§ 112.161 What general requirements apply to records required under this part?</b>				

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(a) Except as otherwise specified, all records required under this part must:				
(1) Include, as applicable:				
(i) The name and location of your farm;				
(ii) Actual values and observations obtained during monitoring;				
(iii) An adequate description (such as the commodity name, or the specific variety or brand name of a commodity, and, when available, any lot number or other identifier) of covered produce applicable to the record;				
(iv) The location of a growing area (for example, a specific field) or other area (for example, a specific packing shed) applicable to the record; and				
(v) The date and time of the activity documented;				
(2) Be created at the time an activity is performed or observed;				
(3) Be accurate, legible, and indelible; and				
(4) Be dated, and signed or initialed by the person who performed the activity documented.				
(b) Records required under §§				
112.7(b)				
112.30(b)				
112.50(b)(2), (4), and (6),				
112.60(b)(2),				
112.140(b)(1) and (2), and				
112.150(b)(1), (4), and (6),				
...must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.				
<b>§ 112.162 Where must I store records?</b>				
(a) Offsite storage of records is permitted if such records can be retrieved and provided onsite within 24 hours of request for official review.				

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(b) Electronic records are considered to be onsite at your farm if they are accessible from an onsite location at your farm.				
<b>§ 112.163 May I use existing records to satisfy the requirements of this part?</b>				
(a) Existing records (e.g., records that are kept to comply with other Federal, State, or local regulations, or for any other reason) do not need to be duplicated if they contain all of the required information and satisfy the requirements of this part. Existing records may be supplemented as necessary to include all of the required information and satisfy the requirements of this part.				
(b) The information required by this part does not need to be kept in one set of records. If existing records contain some of the required information, any new information required by this part may be kept either separately or combined with the existing records.				
<b>§ 112.164 How long must I keep records?</b>				
(a)(1) You must keep records required by this part for at least 2 years past the date the record was created.				
(2) Records that a farm relies on during the 3-year period preceding the applicable calendar year to satisfy the criteria for a qualified exemption, in accordance with §§ 112.5 and 112.7, must be retained as long as necessary to support the farm’s status during the applicable calendar year.				
(b) Records that relate to the general adequacy of the equipment or processes or records that relate to analyses, sampling, or action plans being used by a farm, including the results of scientific studies, tests, and evaluations, must be retained at the farm for at least 2 years after the use of such equipment or processes, or records related to analyses, sampling, or action plans, is discontinued.				
<b>§ 112.165 What formats are acceptable for the records I keep?</b>				

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You must keep records as: (a) Original records;				
b) True copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records); or				
(c) Electronic records. Records that are established or maintained to satisfy the requirements of this part and that meet the definition of electronic records in § 11.3(b)(6) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this part, but that also are required under other applicable statutory provisions or regulations, remain subject to part 11 of this chapter.				
<b>§ 112.166 What requirements apply for making records available and accessible to FDA?</b>				
(a) You must have all records required under this part readily available and accessible during the retention period for inspection and copying by FDA upon oral or written request, except that you have 24 hours to obtain records you keep offsite and make them available and accessible to FDA for inspection and copying.				
(b) If you use electronic techniques to keep records, or to keep true copies of records, or if you use reduction techniques such as microfilm to keep true copies of records, you must provide the records to FDA in a format in which they are accessible and legible.				
(c) If your farm is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but must be returned to your farm within 24 hours for official review upon request.				
<b>§ 112.167 Can records that I provide to FDA be disclosed to persons outside of FDA?</b>				
Records obtained by FDA in accordance with this part are subject to the disclosure requirements under part 20 of this chapter.				