

**Changes to Subpart E Made by FDA on 05/06/24**

\*all highlighted parts are new and added changes  
 \*all strikethrough parts are removed from the PSR

Subpart E—Agricultural Water

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

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

**§112.40** What requirements of this subpart apply to my covered farm?

This subpart applies to agricultural water used for, or intended for use in, growing, harvesting, packing, or holding covered produce. If you are using agricultural water for a covered activity listed in the first column, then you must meet the requirements in the second column. You also must meet the requirements in the third column, if applicable.

**Table 1 to §112.40**

If you use agricultural water for this covered activity	Then you must meet these requirements	If applicable, you also must meet these requirements
(a) Growing covered produce (other than sprouts)	§112.41 (quality standard) §112.42 (inspections and maintenance) §112.43 (agricultural water assessment) §112.50 (records)	§112.45 (measures) §112.46 (treatment) §112.47 (who may test) §112.151 (test methods)
(b) Sprout irrigation water	§112.41 (quality standards) §112.42 (inspections and maintenance) §112.44(a) (microbial quality criterion) §112.50 (records)	§112.44(b) testing untreated ground water §112.45 (measures) §112.46 (treatment) §112.47 (who may test) §112.151 (test methods)
(c) Harvesting, packing, or holding covered produce	§112.41 (quality standard) §112.42 (inspections and maintenance) §112.44(a) (microbial quality and criterion) §112.44(d) (additional management and monitoring) §112.50 (records)	§112.44(b) (testing untreated ground water) §112.45 (measures) §112.46 (treatment) §112.47 (who may test) §112.151 (test methods)

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

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

~~§112.42—What requirements apply to my agricultural water sources, water distribution system, and pooling of water?~~ What requirements apply to inspecting and maintaining my agricultural water systems?

(a) **Inspection of your agricultural water systems.** At the beginning of a growing season, as appropriate, but at least once annually, you must inspect all of your 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, whether it is 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) **Maintenance of your agricultural water systems.** 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 systems from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity, or water sources, including by regularly inspecting and adequately storing all equipment used in the system. **Such maintenance includes:**

- (1) Regularly monitoring each system to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces;
- (2) Correcting any significant deficiencies (such as control of cross connections and repairs to well caps, well castings, sanitary seals, piping tanks, and treatment equipment);
- (3) Properly storing equipment and keeping the source and distribution system free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances; and
- (4) As necessary and appropriate, implementing measures reasonably necessary to reduce the potential for contamination of covered produce with known or reasonably foreseeable hazards resulting from contact of covered produce with pooled water (for example, through use of protective barriers or through equipment adjustments).

~~(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 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.~~

§112.43 **What requirements apply to treating agricultural water? What requirements apply to assessing agricultural water used in growing covered produce (other than sprouts)**

~~(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.~~

**(a)** Elements of an agricultural water assessment. Based in part on the results of any inspections and maintenance you conducted under §112.42, at the beginning of the growing season, as appropriate, but at least once annually, you must prepare a written agricultural water assessment for water that you apply to covered produce (other than sprouts) using a direct application method during growing activities. The agricultural water assessment must identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered producedur (other than sprouts) or food contact surfaces, based on evaluation of the following factors:

**(1)** Each agricultural water system you use for growing activities for the covered produce, including:

**(i)** The location and nature of the water source (for example, whether it is ground water or surface water);

**(ii)** The type of water distribution system (for example, open or closed conveyance); and

**(iii)** The degree of protection from possible sources of contamination, including by other water users; animal impacts; and adjacent and nearby land uses related to animal activity (for example, grazing or commercial animal feeding operations of any size), application of biological soil amendment(s) of animal origin, or presence of untreated or improperly treated human waste;

**(2)** Agricultural water practices associated with each agricultural water system, including the type of direct application method (such as foliar spray or drip irrigation of covered produce growing underground) and the time interval between the last direct application of agricultural water and harvest of the covered produce;

**(3)** Crop characteristics, including the susceptibility of the covered produce to surface adhesion or internalization of hazards;

**(4)** Environmental conditions, including the frequency of heavy rain or extreme weather events that may impact the agricultural water system (such as stirring sediments) or covered produce (such as damage to edible leaves) during growth activities, air temperatures, and sun exposure; and

(5) Other relevant factors, including, if applicable, the results of any testing conducted pursuant to paragraph (d) of this section.

(b) Exemptions. You do not need to prepare a written agricultural water assessment for water that you directly apply during growing activities for covered produce (other than sprouts), if your water meets the criteria in paragraphs (b)(1) and (2) of this section.

(1) You can demonstrate that the water:

(i) Meets the requirements in §112.44(a), including the microbial quality criterion and the prohibition on the use of untreated surface water, and if untreated ground water, also meets the testing requirements in §§112.44(b), 112.47, and 112.151;

(ii) Meets the requirements in §112.44(c) for water from a public water system or public water supply; or

(iii) Is treated in accordance with §112.46.

(2) It is reasonably likely that the quality of water in paragraph (b)(1)(i), (ii), (iii) of this section will not change prior to the water being used as agricultural water (for example, due to the manner in which the water is held, stored, or conveyed).

(c) Outcomes. Based on your evaluation under paragraph (a) of this section, you must determine whether measures under §112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water used in growing covered produce (other than sprouts). You must record your determination in the assessment, and you must take necessary and appropriate action, as follows:

(1) If your agricultural water is not safe or is not of adequate sanitary quality for its intended use(s), as required under §112.41, you must immediately discontinue use of the water and take corrective measures under §112.45(a) before resuming such use(s);

(2) If you have identified one or more conditions that are reasonably likely to introduce known or reasonably foreseeable hazards and are related to animal activity, application of a biological soil amendment of animal origin, or the presence of untreated or improperly treated human waste on adjacent or nearby lands, you must implement any mitigation measures under §112.45(b) promptly, and no later than the same growing season as the agricultural water assessment;

(3) If you have not identified any conditions that are reasonably likely to introduce a known or reasonably foreseeable hazard for which measures under §112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces, you must:

(i) Regularly inspect and adequately maintain your agricultural water system(s) under §112.42; and

(ii) Reassess your agricultural water annually and whenever a significant change occurs (such as a change in the manner or timing of water application) that increases the likelihood that a known or reasonably foreseeable hazard will be introduced into or onto covered produce or food contact surfaces; and

(4) If your agricultural water does not meet the criteria in paragraphs (c) (1), (2), or (3) of this section, you must either:

(i) Implement mitigation measures under §112.45(b) as soon as practicable and no later than 1 year after the date of the agricultural water assessment (as required by this section); or

(ii) Test the water pursuant to paragraph (d) of this section, consider the results as part of your assessment, and take appropriate action under paragraphs (c)(1), (2), or (3), or (c)(4)(i) of this section.

(d) Testing as part of an assessment. In conducting testing to be used as part of your assessment under paragraph (a)(5) of this section, you must use scientifically valid collection and testing methods and procedures, including:

(1) Any sampling conducted for purposes of paragraph (c)(4)(ii) of this section must be collected aseptically immediately prior to or during the growing season and must be representative of the water you use in growing covered produce (other than sprouts).

(2) The sample(s) must be tested for generic *Escherichia coli* (*E. coli*) as an indicator of fecal contamination (or for another scientifically valid indicator organism, index organism, or other analyte).

(3) The frequency of testing samples and any microbial criterion (or criteria) applied must be scientifically valid and appropriate to assist in determining, in conjunction with other data and information evaluated under paragraph (a) of this section, whether measures under §112.45 are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water used in growing covered produce (other than sprouts).

(e) Reassessment. You must conduct an agricultural water assessment and take appropriate action under paragraph (c) of this section:

(1) At least once annually when you apply agricultural water to covered produce (other than sprouts) during growing activities; and

(2) Whenever a significant change occurs in your agricultural water system(s) (including changes relating to animal activity, the application of biological soil amendments of animal origin, or the presence of untreated or improperly treated human waste associated with adjacent or nearby land uses), agricultural water practices, crop characteristics, environmental conditions, or other relevant factors that make it reasonably likely that a known or reasonably foreseeable hazard will be introduced into or onto covered produce (other than sprouts) or food contact surfaces through direct application of agricultural water during growing activities. Your reassessment must evaluate any factors and conditions that are affected by such change.

**§112.44** ~~What specific microbial quality criteria apply to agricultural water used for certain intended uses?~~ What requirements apply to agricultural water used as sprout irrigation water and in harvesting, packing, and holding covered produce?

(a) **Microbial quality criterion.** When you use agricultural water for any one or more of these following purposes, you must ensure there is no detectable generic *Escherichia coli* (*E. coli*) 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 **Used during or after harvest activities** in a 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, **and water that is used to make ice that directly contacts covered produce during or after harvest activities**); ~~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):~~

Untreated ground water. You must test any untreated ground water used as sprout irrigation water or for harvesting, packing, or holding covered produce to determine if it meets the microbial quality criterion in paragraph (a) of this section, as follows:

**(1)** ~~A geometric mean (GM) of your agricultural water samples of 126 or less colony forming units (CFU) of generic E. coli per 100 mL of water (GM is a measure of the central tendency of your water quality distribution); and~~

You must initially test the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected aseptically and representative of the intended use(s). Based on these results, you must determine whether the water can be used for the intended purpose(s), in accordance with §112.45(a).

**(2)** ~~A statistical threshold value (STV) of your agricultural water samples of 410 or less CFU of generic E. coli per 100 mL of water (STV is a measure of variability of your water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution).~~

If your four initial sample results meet the microbial quality criterion, you may test once annually thereafter, using a minimum of one sample collected aseptically and representative of the intended use(s).

**(3)** If any annual test fails to meet the microbial quality criterion, you must:

**(i)** Immediately discontinue the use(s) and meet the requirements of §112.45(a) before resuming such use(s); and

**(ii)** Resume testing at least four times per growing season or year, as required under paragraph (b)(1) of this section, until all of the survey results collected in a year meet the microbial quality criterion.

**(4)** You may meet these testing requirements using test results or data collected by a third party, as provided in §112.47.

(c) Exemptions. There is no requirement to test agricultural water that is used as sprout irrigation water or for harvesting, packing, or holding covered produce when:

(1) You receive the water from a public water system, as defined under the Safe Drinking Water Act (SDWA) regulations, 40 CFR part 141, that furnishes water that meets the microbial requirements under those regulations or under the regulations of a State (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 those microbial requirements;

(2) You receive the water from a public water supply that furnishes water that meets the microbial quality criterion in paragraph (a) of this section, 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 §112.46.

(d) Additional management and monitoring practices. (1) You must manage water used in harvesting, packing, and holding covered produce as necessary, including by establishing and following water change schedules for non-single-pass water (including recirculated water or reused water) to maintain its safe 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).

(2) You must visually monitor the quality of water that you use during harvesting, 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).

(3) You must maintain and monitor the temperature of water that you use during harvesting, packing, and holding activities for covered produce at a temperature that is appropriate for the commodity and operation (considering the time and depth of submersion) and that is adequate to minimize the potential for infiltration of microorganisms of public health significance into covered produce.

**§112.45** What measures must I take if my agricultural water does not meet the requirements of §112.41 or §112.44? for agricultural water to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards?

(a) **Discontinued use(s)** 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 **in growing, harvesting, packing, or holding covered produce** as required under §112.41 and/or if your agricultural water used as sprout irrigation water or for harvesting, packing, or holding activities does not meet the requirements in §112.44(a) (including the microbial quality criterion) ~~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~~. **§112.46**

~~(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: — Implement mitigation measures.~~

~~(1) Apply a time interval(s) (in days) and/or a (calculated) log reduction by:~~

You must implement any mitigation measures that are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with your agricultural water. Such measures must be implemented as soon as practicable and no later than 1 year after the date of your agricultural water assessment or reassessment (as required by §112.43), except that mitigation measures for known or reasonably foreseeable hazards related to animal activity, the application of biological soil amendments of animal origin, or the presence of untreated or improperly treated human waste on adjacent or nearby lands must be implemented promptly, and no later than the same growing season as such assessment or reassessment. Mitigation measures include:

**(i)** Making necessary changes (for example, repairs) to address any conditions that are reasonably likely to introduce such known or reasonably likely to introduce such known or reasonably foreseeable hazards into or onto the covered produce or food contact surfaces;

**(ii)** Increasing the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off, provided you have scientifically valid supporting data and information;

**(iii)** Increasing the time interval between harvest and the end of storage to allow for microbial die-off, and/or conducting other activities during or after harvest to allow for microbial die-off or removal, provided you have scientifically valid supporting data and information;

**(iv)** Changing the method of water application to reduce the likelihood of contamination of the covered produce (such as by changing from overhead spray to subsurface drip irrigation of certain crops);

**(v)** Treating the water in accordance with §112.46; and

**(vi)** Taking an alternative mitigation measure, provided that you satisfy the requirements of §112.12.

**(2)** If you fail to implement appropriate mitigation measures in accordance with paragraph (b)(1) of this section, or if you determine that your mitigation measures were not effective to reduce the potential for contamination of the covered produce or food contact surfaces with known or reasonably foreseeable hazards, you must discontinue use of the agricultural water until you



have implemented mitigation measures adequate to reduce the potential for such contamination, consistent with §112.41.

~~(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) 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.~~

~~§112.46 How often must I test agricultural water that is subject to the requirements of §112.44?~~

**§112.46** What requirements apply to treating agricultural water?

**(a)** 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(s) and/or meet the microbial quality criterion in §112.44(a), as applicable;

**(b)** 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(s) and, if applicable, also meets the microbial quality criterion in §112.44(a); and

(c) You must monitor any treatment of agricultural water using an adequate method and frequency to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use(s) and, if applicable, also meets the microbial quality criterion in §112.44(a).

(d) Treatment may be conducted by you or by a person or entity acting on your behalf.

(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) 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 *Escherichia coli* (*E. coli*) (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.~~

~~(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 at least four times during the growing season or over a period of 1 year, using a minimum total of four samples 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 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).~~

§112.47 Who must perform the tests required under §112.46 and what methods must be used this subpart?

(a) You may meet the requirements related to agricultural water testing required under §112.46 using: §§112.43(c)(4)(ii) and 112.44 using:

(1) Test Results from your agricultural water source(s) testing 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 represents 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, as applicable

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

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

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

§112.49 What alternatives may I establish and use in lieu of the requirements of this subpart?

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).

**§112.48-112.49 Reserved**

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

(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, **as applicable**:

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

~~(2) Documentation of the results of all analytical tests conducted on agricultural water for purposes of compliance with this subpart;~~ Your written agricultural water assessments, including descriptions of factors evaluated and written determinations, in accordance with §112.43;

(3) Scientific data or information that you rely on to support the ~~adequacy of a method used to satisfy the requirements of §112.43(a)(1) and (2);~~ **use of an index organism, indicator organism, or other analyte, other than testing for generic E. coli for the purposes of §112.43(c)(4)(ii);**

~~(4) Documentation of the results of water treatment monitoring under §112.43(b);~~ Scientific data or information that you rely on to support the frequency of testing and any microbial criterion (or criteria) you applied for purposes of §112.43(c)(4)(ii), if applicable;

~~(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 Escherichia coli (E. coli), in accordance with §112.45(b)(1)(ii);~~ Documentation of the results of all analytical tests for purposes of compliance with this subpart, including any testing conducted under §§112.43 and 112.44;

~~(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);~~—Annual documentation of the results or certificates of compliance from a public water system required under §112.44(c)(1) or (2), if applicable;

~~(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;~~ Documentation of actions you take in accordance with §112.45;

(8) Scientific data or information you rely on to support ~~any alternative that you establish and use in accordance with §112.49; and~~ **the time interval between last direct application of agricultural water and harvest in §112.45(b)(1)(ii), and/or the time interval between harvest and end of storage and/or use of other activities during or after harvest in §112.45(b)(1)(iii);**

~~(9) Any analytical methods you use in lieu of the method that is incorporated by reference in §112.151(a)– Scientific data or information you rely on to support an alternative mitigation measure that you establish and use in accordance with §112.45(b)(1)(vi)~~

(10) Scientific data or information you rely on to support the adequacy of a treatment method used to satisfy the requirements of §112.46(a) and (b);

(11) Documentation of the results of water treatment monitoring under §112.46(c); and

(12) Any analytical methods you use in lieu of the method that is incorporated by reference in §112.151(a).