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AGRICULTURAL WATER ASSESSMENT BUILDER, VERSION 1.0

PAPER-BASED TOOL

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Introduction:

Thank you for choosing to use the paper-based version of the Agricultural Water Assessment Builder. The online version of the builder can be accessed at https://agwaterassessment.fda.gov.

The Agricultural Water Assessment Builder v. 1.0 is a user-friendly tool designed to help farms understand the proposed requirements for an agricultural water assessment in the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water" proposed rule (agricultural water proposed rule). If finalized, the rule would replace the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) in the 2015 Produce Safety Final Rule with provisions for systems-based agricultural water assessments [1].

This paper-based version of the Agricultural Water Assessment Builder consists of various questions and prompts that are grouped based on topic (see Tables A through R) as covered in the proposed rule. Unless otherwise noted, proceed through the tables and questions in the order they're presented. Throughout this document, numbers in brackets are used to indicate where additional information is available. To view the additional information, click on the number in the bracket, which will take you to the appropriate location in the Appendix; or, users may go to the Appendix, find the relevant note number in the first column of Table S, and read through the corresponding text.

We welcome feedback on v1.0 of this optional resource, such as suggestions related to its functionality and useability. Feedback on this resource can be sent to agwaterbuilder@fda.hhs.gov or to Samir Assar, Director, Division of Produce Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-317) 5001 Campus Dr., College Park, MD 20740.

Use of this resource is not required by law (see legal disclaimer below) and would not be required. If the agricultural water proposed rule is finalized, FDA expects this resource to supplement and not replace other education, training, and experience that would be needed to understand and implement the requirements of the rule. This resource is being provided for illustrative purposes only because the requirements for agricultural water assessments under proposed § 112.43 have not been finalized.

Legal disclaimer: Use of the Agricultural Water Assessment Builder v. 1.0 does not constitute FDA approval of an agricultural water assessment or guarantee compliance with FDA's requirements, if finalized.

FDA has taken all reasonable precautions in creating the Agricultural Water Assessment Builder v. 1.0. However, FDA is not responsible for errors, omissions or deficiencies regarding the tool. The Agricultural Water Assessment Builder v. 1.0 is available "as is" and without warranties of any kind, either expressed or implied, including, but not limited to, warranties of performance, merchantability, and fitness for a particular purpose. FDA is not making a commitment in any way to regularly update the tool.

Responsibility for the interpretation and use of the Agricultural Water Assessment Builder v. 1.0 lies solely with the user.

Third parties' use of or acknowledgment of the tool does not in any way represent that FDA endorses such third parties or expresses any opinion with respect to their statements.

Table A: Optional user information

Identifier	Question or Prompt
A-1	Please provide your farm location.
A-2	Please provide your farm name.
A-3	Please provide your primary contact.

Table B. Applicability and exemptions

Identifier	Question or Prompt
B-1	Do you use agricultural water in the growing of covered produce (other than sprouts)? [2] *If YES, proceed to B-2 in this table.* *If NO, note that covered farms that do not use agricultural water in the growing of covered produce (other than sprouts) would not be required to prepare a written agricultural water assessment under proposed § 112.43(a), if finalized. You have reached the END of the Agricultural Water Assessment Builder.*
B-2	Can you demonstrate one of the following for the agricultural water you apply during growing activities for covered produce (other than sprouts)? [3] • Agricultural water meets the requirements in proposed § 112.44(a), including the microbial quality criterion of no detectable generic *E. coli* per 100 mL, and if untreated ground water, also meets the testing requirements in proposed §§ 112.44(b), 112.47, and 112.151. (This proposed exemption would not apply to untreated surface water, because proposed § 112.44(a) prohibits the use of untreated surface water for sprout irrigation or harvest or post-harvest application on covered produce); • Agricultural water meets the requirements in proposed § 112.44(c) for water from a Public Water System or public water supply; or • Agricultural water is treated in accordance with proposed § 112.46. *If YES, please explain and note that if one of these exemptions applies to a covered farm, it would not be required to prepare a written agricultural water assessment under proposed § 112.43(a), if finalized. You have reached the END of the Agricultural Water Assessment Builder.* *If NO, proceed to C-1 in the Table C for questions related to your agricultural water source.*

Elements of an agricultural water assessment

To begin, consider the components of the covered farm's agricultural water system. As a reminder, an agricultural water system means a source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities (see proposed § 112.3).

Table C. Agricultural water source

Identifier	Question or Prompt
C-1	Please provide a short name for your water source.
C-2	Provide a brief description of this source.
C-3	Where is this water source is located? [4]
C-4	Is this a ground water source or a surface water source? [5] *If GROUND WATER, proceed to C-5 through C-8 in this table.* *If SURFACE WATER, proceed to C-9 through C-12 in this table.*
C-5	To what extent is this ground water source under your control? [6]
C-6	To the extent that this ground water source is under your control, do you inspect it at the beginning of the growing season, as appropriate, but at least once annually, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces? Please provide a brief explanation of your practices. [7]
C-7	Consider the following factors in evaluating the degree of protection of this ground water source from known or reasonably foreseeable hazards. • Is this ground water source regularly monitored to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces? • Is this ground water source regularly monitored for significant deficiencies, which if observed, are corrected (such as control of cross-connections and repairs to well caps, well casings, sanitary seals, piping tanks, and treatment equipment)? • Is this ground water source and surrounding area kept free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances? • Do regular maintenance activities occur to prevent this ground water source from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity? • Are barriers such as earthen diversion berms or ditches present that may help minimize the influence of discharges or runoff from adjacent or nearby lands to this ground water source? • Is this ground water source subject to discharges or runoff from surrounding lands? • If this ground water source is a well, does it have a closed, tightly-fitting cap or sanitary seal to prevent potential contaminants from entering? • If this ground water source is a well, does it have an intact casing? If this ground water source is a well, does it have appropriate backflow prevention?
C-8	Based on this information, do you consider this ground water source to be protected from potential sources of known or reasonably foreseeable hazards? Please explain. *Proceed to D-1 in Table D for questions related to your agricultural water distribution system.*
C-9	To what extent is this surface water source under your control? [6]

Identifier	Question or Prompt
C-10	To the extent that this surface water source is under your control, do you inspect it at the beginning of the growing season, as appropriate, but at least once annually, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces? [7]
C-11	Consider the following factors in evaluating the degree of protection of this surface water source from known or reasonably foreseeable hazards. • Is this surface water source regularly monitored to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces? • Is this surface water source regularly monitored for significant deficiencies, which if observed, are corrected (such as control of cross-connections and repairs to treatment equipment)? • Do regular maintenance activities occur to prevent this surface water source from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity? • Is this surface water source and surrounding area kept free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances? • Are barriers such as earthen diversion berms or ditches present that may help minimize the influence of discharges or runoff from adjacent or nearby lands to this surface water source? • Is this surface water source subject to discharges or runoff from surrounding lands?
C-12	Based on this information, do you consider this surface water source to be protected from potential sources of known or reasonably foreseeable hazards? Please explain. *Proceed to D-1 in Table D for questions related to your agricultural water distribution system.*

Table D. Agricultural water distribution system

Identifier	Question or Prompt
D-1	Please provide a short name for your water distribution system.
D-2	Provide a brief description of this distribution system (for example, unlined laterals, piped distribution system, etc.).
D-3	Where is this distribution system located? [4]
D-4	Is this an open or closed distribution system? [8] *If CLOSED DISTRIBUTION SYSTEM, proceed to D-5 through D-8 in this table.* *If OPEN DISTRIBUTION SYSTEM, proceed to D-9 through D-12 in this table.*
D-5	To what extent is this closed distribution system under your control? [6]
D-6	To the extent that this closed distribution system is under your control, do you inspect it at the beginning of the growing season, as appropriate, but at least once annually, to identify any conditions that are reasonably likely to introduce known or reasonably

Identifier	Question or Prompt
	foreseeable hazards into or onto covered produce or food contact surfaces? Please provide a brief explanation of your practices. [7]
D-7	Consider the following factors in evaluating the degree of protection of this closed distribution system from known or reasonably foreseeable hazards. • Is this closed distribution system regularly monitored to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces? • Is this closed distribution system regularly monitored for significant deficiencies, which if observed, are corrected (such as control of cross-connections and repairs to treatment equipment)? • Is this closed distribution system and surrounding area kept free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances? • Do regular maintenance activities occur to prevent this closed distribution system from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity? • Does this closed distribution system allow backflow from, or cross connections between, piping systems that discharge waste water or sewage and piping systems? • Are piping systems intact, properly constructed, and properly functioning?
D-8	Based on this information, do you consider this closed distribution system to be protected from potential sources of known or reasonably foreseeable hazards? Please explain. *Proceed to E-1 in Table E for questions pertaining to related equipment, buildings, and structures.*
D-9	To what extent is this open distribution system under your control? [6]
D-10	To the extent that this open distribution system is under your control, do you inspect it at the beginning of the growing season, as appropriate, but at least once annually, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces? Please provide a brief explanation of your practices. [7]
D-11	Consider the following factors in evaluating the degree of protection of this open distribution system from known or reasonably foreseeable hazards. • Is this open distribution system regularly monitored to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces? • Is this open distribution system regularly monitored for significant deficiencies, which if observed, are corrected? • Is this open distribution system and surrounding area kept free of debris, trash, domesticated animals, and other possible sources of contamination of covered produce to the extent practicable and appropriate under the circumstances? • Do regular maintenance activities occur to prevent this open distribution system from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity?

Identifier	Question or Prompt
	• Are barriers such as earthen diversion berms or ditches present that may help minimize the influence of discharges or runoff from adjacent or nearby lands to this open distribution system? • Is this open distribution system subject to discharges or runoff from surrounding lands?
D-12	Based on this information, do you consider this open distribution system to be protected from potential sources of known or reasonably foreseeable hazards? Please explain. *Proceed to E-1 in Table E for questions pertaining to related equipment, buildings, and structures.*

Table E. Related equipment, buildings, and structures

Identifier	Question or Prompt
E-1	Do you use any additional equipment (for example, drip tape, microjet sprinklers, lay flat irrigation hoses, siphon tubes, or sprayers) when applying preharvest agricultural water to covered produce? *If YES, proceed to E-2 through E-10 in this table.* *If NO, proceed to E-11 in this table.*
E-2	Please describe what water application equipment you use.
E-3	Is water application equipment inspected at the beginning of the growing season, as appropriate, but at least once annually, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces?
E-4	Is water application equipment regularly monitored to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces?
E-5	Is water application equipment stored in a way to prevent it from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity? (For example, is equipment stored in a way that protects it from debris, trash, domesticated animals or other possible sources of contamination?)
E-6	Are significant deficiencies with the water application equipment corrected (such as to repair cracks, corrosion, or other damage) if observed?
E-7	Does water application equipment result in pooling of water in the growing area? [9]
E-8	Do you take measures to reduce the potential for contamination of covered produce from pooled water (for example, through the use of protective barriers or through equipment adjustment)?
E-9	Do you perform any other maintenance on your water application equipment to prevent it from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity?
E-10	Based on this information, do you consider your water application equipment to be protected from potential sources of known or reasonably foreseeable hazards? Please explain.

Identifier	Question or Prompt
E-11	Does your agricultural water system include any buildings or structures, such as well houses, pump stations, storage sheds? *If YES, proceed to E-12 through E-15 in this table.* *If NO, proceed to F-1 in Table F for questions related to animal impacts and activities.*
E-12	Please describe what the buildings or structures are, and where they are located. [4]
E-13	Are these buildings and structures inspected at the beginning of the growing season, as appropriate, but at least once annually, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces?
E-14	Are these buildings and structures regularly monitored to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces?
E-15	Based on this information, do you consider these buildings or structures to protect your water sources, distribution systems, and related components (for example, application equipment) from potential sources of known or reasonably foreseeable hazards? Please explain.

Table F. Animal impacts and activities

Identifier	Question or Prompt
F-1	Are there any animal impacts or activities associated with your farm or with adjacent and nearby lands that may serve as a source of known or reasonably foreseeable hazards to your pre-harvest agricultural water systems? [10] *If YES, proceed to F-2 through F-10 in this table.* *If NO, proceed to G-1 in Table G for questions related to Biological Soil Amendments of Animal Origin (BSAAOs)*
F-2	Please provide a brief description of the animal activity.
F-3	Is this animal activity associated with your farm, with adjacent and nearby lands, or both? [11]
F-4	What type and approximate number of animals are associated with this activity?
F-5	Where do animals associated with this activity have access to? [12]
F-6	When do animals have access to these areas? [13]
F-7	What type of potential attractants and habitats (such as heavy vegetation, wooded areas, water sources, standing water, or pooled water) are present that might draw animals associated with this activity to your agricultural water sources or distribution systems, and where are they located? [14]
F-8	Consider the following for the areas that animals associated with this activity have access to: • Do these areas have fencing or other measures in place to prevent direct animal access to water sources or distribution systems? • Are these areas at a higher elevation than water sources or distribution systems?

Identifier	Question or Prompt
	• Do these areas allow for discharges or runoff into water sources or distribution systems? • Do these areas have physical barriers such as earthen diversion berms or ditches in place to help minimize discharges or runoff to water sources or distribution systems?
F-9	Are significant amounts of animal excreta observed that might impact the likelihood of hazards being introduced into your agricultural water sources or distribution systems? Please explain.
F-10	Based on this information, do you consider this animal activity to be reasonably likely to introduce known or reasonably foreseeable hazards into your agricultural water sources or distribution systems? Please explain. [15]

Table G. Biological soil amendments of animal origin (BSAAOs)

Identifier	Question or Prompt
G-1	Are there biological soil amendments of animal origin (BSAAOs) associated with your farm or with adjacent and nearby lands that may serve as a source of known or reasonably foreseeable hazards to your agricultural water sources or distribution systems? [16] *If YES, proceed to G-2 through G-9 in this table.* *If NO, proceed to H-1 in Table H for questions related to systems for the collection and disposal of human waste.*
G-2	Are these BSAAOs associated with your farm, with adjacent and nearby lands, or both? [11]
G-3	Where are the areas in which BSAAOs are applied to the land? [17]
G-4	When are BSAAOs applied to these areas? [18]
G-5	Are BSAAOs handled, conveyed, and stored in a manner and location so that they do not become a potential source of contamination to water sources and water distribution systems for pre-harvest agricultural water for non-sprout covered produce?
G-6	Are BSAAOs treated and applied in accordance with the produce safety regulation (such as where you or adjacent or nearby lands are covered farms subject to the produce safety regulation) or any other Federal, State, or international regulations, commendations, or guidelines for soil amendments?
G-7	Consider the following for areas to which BSAAOs are applied: • Are these areas at a higher elevation than water sources or distribution systems? • Do these areas allow for discharges or runoff into water sources or distribution systems? • Do these areas have physical barriers such as earthen diversion berms or ditches in place to help minimize discharges or runoff to water sources or distribution systems?
G-8	Are BSAAOs handled, conveyed, and stored in a manner and location so that they do not become a potential source of contamination to water sources and water distribution systems for pre-harvest agricultural water for non-sprout covered produce?

Identifier	Question or Prompt
G-9	Based on this information, do you consider BSAAOs to be reasonably likely to introduce known or reasonably foreseeable hazards into your agricultural water sources or distribution systems? Please explain. [15]

Table H. Systems for the collection and/or disposal of human waste

Identifier	Question or Prompt
H-1	Are there systems for the collection and/or disposal of human waste associated with your farm or with adjacent and nearby lands that may serve as a source of known or reasonably foreseeable hazards to your pre-harvest agricultural water systems? [19] *If YES, proceed to H-2 through H-6 in this table.* *If NO, proceed to I-1 in Table I for questions related to application of human waste to land.*
H-2	Please provide a brief description of the system for the collection and/or disposal of human waste.
H-3	Is this system for the collection and/or disposal of human waste associated with your farm, with adjacent and nearby lands, or both? [11]
H-4	Is human waste treated to reduce microorganisms of public health significance, and to what extent?
H-5	Consider the following for this system for the collection and/or disposal of human waste: • Is this system in close proximity to water sources or distribution systems? • Does this system discharge human waste directly or indirectly (for example, via seepage) into water sources or distribution systems? • Is this system at a higher elevation than water sources or distribution systems? • Does this system allow for discharges or runoff into water sources or distribution systems? • Does this system have physical barriers such as earthen diversion berms or ditches in place to help minimize discharges or runoff to water sources or distribution systems? • May this system be negatively impacted by environmental conditions such as flooding and high winds that could result in it serving as a source of contamination to the environment (for example, the tipping over of a portable toilet in windy conditions)? • Is this system malfunctioning or otherwise not constructed or maintained to properly contain human waste?
H-6	Based on this information, do you consider this system for the collection and/or disposal of human waste to be reasonably likely to introduce known or reasonably foreseeable hazards into your agricultural water sources or distribution systems? Please explain. [15]

Table I. Application of human waste to land

Identifier	Question or Prompt
I-1	Is human waste applied on your farm or on adjacent and nearby lands that may serve as a source of known or reasonably foreseeable hazards to your agricultural water sources or distribution systems? [20] *If YES, proceed to I-2 through I-7 in this table.* *If NO, proceed to J-1 in Table J for questions related to other water users.*
I-2	Is this application of human waste associated with your farm, with adjacent and nearby lands, or both? [11]
I-3	Is human waste treated to control microorganisms of public health significance before being applied to land, and to what extent? [20]
I-4	Where is human waste applied to lands? [21]
I-5	When is human waste applied to these areas? [22]
I-6	Consider the following for areas to which human waste is applied: • Are these areas at a higher elevation than water sources or distribution systems? • May these areas allow for discharges or runoff into water sources or distribution systems? • Do these areas have physical barriers such as earthen diversion berms or ditches in place to help minimize discharges or runoff to water sources or distribution systems?
I-7	Based on this information, do you consider the application of human waste to land to be reasonably likely to introduce known or reasonably foreseeable hazards into your pre-harvest agricultural water systems? Please explain. [15]

Table J. Other water users

Identifier	Question or Prompt
J-1	Are there other water users not currently addressed above that are associated with your farm or with adjacent and nearby lands that may serve as a source of known or reasonably foreseeable hazards to your pre-harvest agricultural water systems? [23] *If YES, proceed to J-2 through J-8 in this table.* *If NO, proceed to K-1 in Table K for questions related to other potential sources of hazards.*
J-2	Please provide a brief description of the other water user(s), including how they use the water.
J-3	Are the other water user(s) associated with your farm, with adjacent and nearby lands, or both? [11]
J-4	Are the other water user(s) related to animal activity, application of a biological soil amendment of animal origin, or the presence of untreated or improperly treated human waste?
J-5	Where are the other water user(s) located? [24]
J-6	When do the other water user(s) use your agricultural water sources or distribution systems? [25]

Identifier	Question or Prompt
J-7	Are there any relevant factors that could impact whether the other water user(s) are likely to introduce known or reasonably foreseeable hazards into you water sources or distribution systems? Please describe. [26]
J-8	Based on this information, do you consider the other water user(s) to be reasonably likely to introduce known or reasonably foreseeable hazards into your agricultural water sources or distribution systems?

Table K. Other potential sources of known or reasonably foreseeable hazards

Identifier	Question or Prompt
K-1	Are there any other potential sources of known or reasonably foreseeable hazards that you haven't already addressed that are associated with your farm or with adjacent and nearby lands? [27] *If YES, proceed to K-2 through K-8 in this table.* *If NO, proceed to L-1 in Table L for questions related to crop characteristics.*
K-2	Please provide a brief description of this other factor.
K-3	Are the other potential sources of known or reasonably foreseeable hazards associated with your farm, adjacent and nearby lands, or both? [11]
K-4	Are these other potential sources of known or reasonably foreseeable hazards related to animal activity, application of a biological soil amendment of animal origin, or the presence of untreated or improperly treated human waste?
K-5	Where are these other potential sources of known or reasonably foreseeable hazards located? [28]
K-6	When might these other potential sources of known or reasonably foreseeable hazards affect the quality of water in your pre-harvest agricultural water systems? [29]
K-7	Are there any relevant factors that could impact whether the other factor is likely to introduce known or reasonably foreseeable hazards into you water sources or distribution systems? Please describe. [30]
K-8	Based on this information, do you consider these other potential sources as reasonably likely to introduce known or reasonably foreseeable hazards into your pre-harvest agricultural water systems? Please explain.

Table L. Crop characteristics

Identifier	Question or Prompt
L-1	Please identify the covered produce (other than sprouts) that you grow for which agricultural water is applied during growing activities. [31]
L-2	Are any of these commodities grown in a way that may make them vulnerable to contamination, including consideration for whether crops are grown near to the ground and/or in close proximity to pooled water? If so, please describe the relevant growth conditions for each commodity. [32]
L-3	Do any of these commodities have characteristics that make them vulnerable to contamination, including whether they are susceptible to surface adhesion of bacteria or

Identifier	Question or Prompt
	internalization of microbial hazards? If so, please describe the relevant characteristics for each commodity. [33]
L-3	Are any of these commodities subject to increased susceptibility to internalization of hazards due to physical damage from weather events? If so, please describe for each commodity. [34]

Table M. Agricultural water use practices

Identifier	Question or Prompt
M-1	For each type of covered produce (other than sprouts) for which agricultural water is applied during growing activities, please identify the direct water application methods that are used. [35]
M-2	For each type of covered produce (other than sprouts) for which agricultural water is applied during growing activities, please describe the interval between the last time agricultural water is applied to the covered produce and the date of harvest. [36]

Table N. Environmental conditions

Identifier	Question or Prompt
N-1	Are there weather events that are reasonably likely to introduce known or reasonably foreseeable hazards into your pre-harvest agricultural water systems? (Examples include heavy rain or flooding events that result in runoff or stirring up of sediments, and dry, windy conditions that may transfer pathogens to agricultural water sources or distribution systems.) [37] *If YES, proceed to N-2 through N-3 in this table.* *If NO, proceed to N-4 in this table.*
N-2	Please describe these weather events and their anticipated impact on agricultural water sources or distribution systems.
N-3	When do these weather events occur? [38]
N-4	Are there environmental conditions (such as high air temperatures or UV exposure) that have the potential to impact microbial survival on covered produce or in pre-harvest agricultural water systems? [39] *If YES, proceed to N-5 through N-6 in this table.* *If NO, proceed to O-1 in Table O for questions related to other relevant factors.*
N-5	Please describe these environmental conditions and their anticipated effect on covered produce or in agricultural water sources or distribution systems.
N-6	When do these environmental conditions occur? [40]

Table O. Other relevant factors

Identifier	Question or Prompt
O-1	Are there any other factors relevant to your agricultural water assessment that you wish to describe? (We note that covered farms that opt to test their agricultural water for purposes of proposed § 112.43(d) can find information about testing in the Outcomes section of the builder.) If so, please explain.

Outcomes

This section of the builder summarizes information about written determinations described in proposed § 112.45. As discussed in the proposed agricultural water rule, written determinations evaluate the following factors:

- The agricultural water system you use for growing activities for covered produce (other than sprouts), including the location and nature of the water source, the type of water distribution system, and the degree of protection from possible sources of contamination;
- Agricultural water practices, including the type of direct application and the time interval between the last direct application of agricultural water and harvest of the covered produce;
- Crop characteristics, including the susceptibility of the covered produce to surface adhesion or internalization of hazards;
- Environmental conditions, including the frequency of heavy rain or extreme weather events that may impact the agricultural water system or covered produce during growing activities, air temperatures, and sun exposure; and
- Other relevant factors, including, if applicable, the results of any testing conducted under proposed § 112.43(d). (We note that covered farms that opt to test their agricultural water for purposes of proposed § 112.43(d) can find information about testing further down in this section of the tool.)

Table P. Outcomes without testing

Identifier	Question or Prompt
P-1	Have you determined that there are any conditions that may result in pre-harvest agricultural water being not safe or not of adequate sanitary quality for its intended use? Please explain. (Note that indicating "Yes" would mean that pre-harvest agricultural water is not safe or is not of adequate sanitary quality for its intended use.) [41] *If YES, proceed to P-2 in this table.* *If NO, proceed to P-3 in this table.*
P-2	The proposed rule, if finalized, would require that if you determine that pre-harvest agricultural water is not safe or is not of adequate sanitary quality for its intended use(s), you would have to immediately discontinue such use(s). Before you could use the water

Identifier	Question or Prompt
	source and/or distribution system again for the intended use(s), you would be required to either: • 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; or • Treat the water in accordance with the requirements of proposed § 112.46. [42] In light of these proposed requirements, please identify which corrective measure you would choose and describe how and when you would plan to implement it. *Proceed to P-9 of this table.*
P-3	Is there a condition that is reasonably likely to introduce a known or reasonably foreseeable hazard that is 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? [15] *If YES, proceed to P-4 in this table.* *If NO, proceed to P-5 in this table.*
P-4	Based on the information you have provided, you have determined that there is a condition that is reasonably likely to introduce a known or reasonably foreseeable hazard and is 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. The proposed rule, if finalized, would require covered farms that make such a determination to implement any mitigation measures under proposed § 112.45(b) promptly, and no later than the same growing season as the assessment. Mitigation measures include: ▪ Making necessary changes (for example, repairs) to address any conditions that are reasonably likely to introduce such known or reasonably foreseeable hazards into or onto the covered produce or food contact surfaces; ▪ Increasing the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off (with a minimum interval of 4 days between application and harvest, except as supported by test results conducted under proposed § 112.43(d), or other scientifically valid data or information in accordance with proposed § 112.12); [43] ▪ Increasing the time interval between harvest and the end of storage using an appropriate microbial die-off rate, and/or conducting other activities, such as commercial washing to reduce pathogens using appropriate microbial removal rates, provided you have scientifically valid supporting data and information; [44] ▪ 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); [45] ▪ Treating the water in accordance with proposed § 112.46; [42] and

Identifier	Question or Prompt
	▪ Taking an alternative mitigation measure, provided that you satisfy the requirements of proposed § 112.12. In light of these proposed requirements, please identify which mitigation measure you would choose and describe how and when you would plan to implement it. [46] *Proceed to P-9 of this table.*
P-5	Are there other conditions that are reasonably likely to introduce known or reasonably foreseeable hazards for which measures would be necessary under the proposed rule, if finalized, to reduce potential for contamination of covered produce (other than sprouts) or food contact surfaces? *If NO, proceed to P-6 in this table.* *If YES, proceed to P-7 in this table.*
P-6	Based on the information you have provided, you have determined that there are not conditions that are reasonably likely to introduce known or reasonably foreseeable hazards for which measures under proposed § 112.45 would be necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces. The proposed rule, if finalized, would require that you: ▪ Regularly inspect and adequately maintain your agricultural water system(s) under § 112.42; and ▪ 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. [47] *You have reached the END of the Agricultural Water Assessment Builder.*
P-7	Based on the information you have provided in this section of the tool, you determined that there is a condition – not 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 – for which measures may be reasonably necessary under the proposed rule, if finalized, 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). The proposed rule, if finalized, would require that you either: ○ Implement mitigation measures as soon as practicable and no later than one year after the date of the agricultural water assessment; or ○ Test the water, consider the results as part of your assessment, and take appropriate action. Which of these actions would you plan to take? *If MITIGATION MEASURES, proceed to P-8 in this table.* *If TEST, proceed to Q-1 in Table Q for questions on agricultural water testing.*

Identifier	Question or Prompt
P-8	Based on the information you have provided, you have determined that there is a condition that is reasonably likely to introduce a known or reasonably foreseeable hazard and is not 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. The proposed rule, if finalized, would require that you implement any mitigation measures under proposed § 112.45(b) as soon as practicable and no later than the following year. Mitigation measures include: ▪ Making necessary changes (for example, repairs) to address any conditions that are reasonably likely to introduce such known or reasonably foreseeable hazards into or onto the covered produce or food contact surfaces; ▪ Increasing the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off (with a minimum interval of 4 days between application and harvest, except as supported by test results conducted under proposed § 112.43(d), or other scientifically valid data or information in accordance with proposed § 112.12); [43] ▪ Increasing the time interval between harvest and the end of storage using an appropriate microbial die-off rate, and/or conducting other activities, such as commercial washing to reduce pathogens using appropriate microbial removal rates, provided you have scientifically valid supporting data and information; [44] ▪ 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); [45] ▪ Treating the water in accordance with proposed § 112.46; [42] and ▪ Taking an alternative mitigation measure, provided that you satisfy the requirements of proposed § 112.12. In light of these proposed requirements, please identify which mitigation measure you would choose and describe how and when you would plan to implement it. [46] *Proceed to P-9 of this table.*
P-9	Thank you for using this tool. Please note that the proposed rule, if finalized, would require that covered farms conduct an agricultural water assessment and take appropriate action under proposed § 112.43(c): • At least once annually when you apply agricultural water to covered produce (other than sprouts) during growing activities; and • Whenever a significant change occurs in your agricultural water system(s), 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 would have to evaluate any factors and conditions that are affected by such change. [47] *You have reached the END of the Agricultural Water Assessment Builder.*

Table Q. Agricultural water testing

Identifier	Question or Prompt
Q-1	At what frequency do you collect samples from this agricultural water source or distribution system? [48]
Q-2	When, with respect to your growing seasons, are samples from this agricultural water source or distribution system collected? [49]
Q-3	From where do you collect water samples for this agricultural water source or distribution system? [49]
Q-4	Are samples from this agricultural water source or distribution system collected aseptically? [50]
Q-4	What is the target organism for sampling of agricultural water from this source or distribution system? (Note that this could be generic *E. coli*, or other scientifically valid indicator organism, index organism, or other analyte.) [51]
Q-6	What microbial criterion or criteria do you use for agricultural water from this source or distribution system? [52]
Q-7	Please explain what your test results tell you in light of the other data and information evaluated under proposed § 112.43(a). [53]

Table R. Outcomes after testing

Identifier	Question or Prompt
R-1	In consideration of your test results, in conjunction with other data and information evaluated under proposed § 112.43(a), have you determined that there are any conditions that may result in your pre-harvest agricultural water being not safe or not of adequate sanitary quality for its intended use? Please explain. (Note that "Yes" would mean that your pre-harvest agricultural water is not safe or is not of adequate sanitary quality for its intended use.) [41] *If YES, proceed to R-2 in this table.* *If NO, proceed to R-3 in this table.*
R-2	The proposed rule, if finalized, would require that if you determine that pre-harvest agricultural water is not safe or is not of adequate sanitary quality for its intended use(s), you would have to immediately discontinue such use(s). Before you could use the water source and/or distribution system again for the intended use(s), you would be required to either: • 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; or • Treat the water in accordance with the requirements of proposed § 112.46. [42] In light of these proposed requirements, please identify which corrective measures you would choose and describe how and when you would plan to implement it.

Identifier	Question or Prompt
	Proceed to R-6 of this table.
R-3	Considering your test results, in conjunction with other data and information that you considered for the proposed agricultural water assessments, are there other conditions that are reasonably likely to introduce known or reasonably foreseeable hazards for which measures would be necessary under the proposed rule, if finalized, to reduce potential for contamination of covered produce (other than sprouts) or food contact surfaces? *If YES, proceed to R-4 in this table.* *If NO, proceed to R-5 in this table.*
R-4	Based on the information you have provided, you have determined that there is a condition that is reasonably likely to introduce a known or reasonably foreseeable hazard and is not 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. The proposed rule, if finalized, would require that you implement any mitigation measures under proposed § 112.45(b) as soon as practicable and no later than the following year. Mitigation measures include: • Making necessary changes (for example, repairs) to address any conditions that are reasonably likely to introduce such known or reasonably foreseeable hazards into or onto the covered produce or food contact surfaces; • Increasing the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off (with a minimum interval of 4 days between application and harvest, except as supported by test results conducted under § 112.43(d), or other scientifically valid data or information in accordance with § 112.12); [43] • Increasing the time interval between harvest and the end of storage using an appropriate microbial die-off rate, and/or conducting other activities, such as commercial washing to reduce pathogens using appropriate microbial removal rates, provided you have scientifically valid supporting data and information; [44] • 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); [45] • Treating the water in accordance with proposed § 112.46; [42] and • Taking an alternative mitigation measure, provided that you satisfy the requirements of proposed § 112.12. In light of these proposed requirements, please identify which mitigation measure you would choose and describe how and when you would plan to implement it. [46] *Proceed to R-6 of this table.*
R-5	Based on the information you have provided, you have determined that there are not conditions that are reasonably likely to introduce known or reasonably foreseeable hazards for which measures under proposed § 112.45 would be necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces. The proposed rule, if finalized, would require that you:

Identifier	Question or Prompt
	• Regularly inspect and adequately maintain your agricultural water system(s) under § 112.42; and • Reassess your agricultural water annually and whenever a significant change occurs (such as a change in the manner of 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. [47] *You have reached the END of the Agricultural Water Assessment Builder.*
R-6	Thank you for using this tool. Please note that the proposed rule, if finalized, would require that covered farms conduct an agricultural water assessment and take appropriate action under proposed § 112.43(c): • At least once annually when you apply agricultural water to covered produce (other than sprouts) during growing activities; and • Whenever a significant change occurs in your agricultural water system(s), 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 would have to evaluate any factors and conditions that are affected by such change. [47] *You have reached the END of the Agricultural Water Assessment Builder.*

Appendix

Numbers in brackets are used throughout this document to indicate where additional information is available. To view the additional information, find the relevant note number in the first column of Table S and read through the corresponding text.

Table S. Additional information

Note Number	Relevant information
1	**Agricultural water** means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce). (21 CFR 112.3) **Covered produce** means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term "covered produce" refers to the harvestable or harvested part of the crop. (21 CFR 112.3)

Note Number	Relevant information
	Direct water application method means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water. (21 CFR 112.3) **Agricultural water assessment** means an evaluation of an agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) related to growing activities for covered produce (other than sprouts) to: • (1) Identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; and • (2) Determine whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with such known or reasonably foreseeable hazards. (proposed addition to 21 CFR 112.3) **Agricultural water system** means a source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities. (proposed addition to 21 CFR 112.3) **Helpful resources:** • Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water (Agricultural Water Proposed Rule) (86 FR 69120). Dec. 6, 2021. • Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Final Rule (2015 Produce Safety Final Rule) (80 FR 74353). Nov. 27, 2015. • Final Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce (QAR). Nov. 2015. • Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (GAPs Guide). Oct. 1998.
2	**Agricultural water** means water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces, including water used in growing activities (including irrigation water applied using direct water application methods, water used for preparing crop sprays, and water used for growing sprouts) and in harvesting, packing, and holding activities (including water used for washing or cooling harvested produce and water used for preventing dehydration of covered produce). (21 CFR 112.3) **Covered produce** means produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. The term ‘‘covered produce’’ refers to the harvestable or harvested part of the crop. (21 CFR 112.3)

Note Number	Relevant information
	If you use agricultural water in growing covered produce (other than sprouts), then you would be required to meet the requirements in proposed § 112.43 for agricultural water assessments, if finalized. If you use agricultural water as sprout irrigation water, or for harvesting, packing, or holding of covered produce, you would not be required to meet the requirements in § 112.43 for agricultural water assessments, if finalized.
3	Under proposed § 112.43(b)(1), if finalized, a covered farm would be exempt from the requirement to conduct an assessment for pre-harvest agricultural water if the farm can demonstrate that the agricultural water meets the requirements of proposed § 112.44(a), which is applicable to agricultural water used for sprout irrigation or for harvest or post-harvest uses--i.e., untreated ground water that meets the microbial water quality criterion of no detectable generic *E. coli*, based on testing requirements in proposed §§ 112.44(b), 112.47, and 112.151. The exclusion in proposed § 112.43(b)(1) would not apply to untreated surface water, because proposed § 112.44(a) prohibits the use of untreated surface water for sprout irrigation or harvest or post-harvest application on covered produce. Proposed § 112.43(b)(2) would exempt a covered farm from the requirement to conduct an agricultural water assessment for pre-harvest agricultural water for non-sprout covered produce that a covered farm receives from a public water system that the covered farm can demonstrate: meets the microbial requirements of EPA Safe Drinking Water Act (SDWA) regulations in 40 CFR part 141 (or the regulations of a State approved to administer the SDWA program) through public water system results or certificates of compliance or meets the microbial quality criterion in § 112.44(a) through public water system results or certificates of compliance. (See also proposed § 112.44(c)). Proposed § 112.43(b)(3) would exempt a covered farm from the requirement to conduct an agricultural water assessment for pre-harvest agricultural water for non-sprout covered produce that is treated in accordance with proposed § 112.46 (such as through application of an EPA-registered antimicrobial pesticide product).
4	For example, location information could include a general description of its location, such as 'Northeast corner of my farm, near the intersection of Road X and Y', GPS coordinates, or other location descriptors. (See 21 CFR 112.161 and proposed revisions to § 112.50)
5	**Ground water** means the supply of fresh water found beneath the Earth's surface, usually in aquifers, which supply wells and springs. Ground water does not include any water that meets the definition of surface water. (21 CFR 112.3). **Surface water** means all water open to the atmosphere (rivers, lakes, reservoirs, streams, impoundments, seas, estuaries, etc.) and all springs, wells, or other collectors that are directly influenced by surface water. (21 CFR 112.3).

Note Number	Relevant information
6	We recognize that not all aspects of a water source or system may be under your control. For example, you may have more control over a ground water source such as a well if the well is under your control and you are able to protect it from the influence of surface activities. You may have greater access to and control of on-farm surface water sources such as impoundments, catches, and ponds, than you would for flowing surface waters that only course through but do not originate on your land. While you may not have control over the factors assessed under proposed § 112.43(a), they are no less important to consider when determining the safe use of agricultural water on covered produce.
7	Per proposed § 112.42(a), 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, to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, including consideration of the following: • The nature of each agricultural water source (for example, whether it is ground water or surface water); • The extent of your control over each agricultural water source; • The degree of protection of each agricultural water source; • Use of adjacent and nearby land; and • 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.
8	Some water used for growing activities is conveyed through open distribution systems of canals and laterals that can be subject to the introduction of hazards such as via runoff, animal intrusion, direct discharge, or seepage. Other water is distributed through closed distribution systems, such as through piping that conveys water from the source to the field. Covered farms with open and closed components in their agricultural water distribution systems would consider the individual properties and characteristics of each component when conducting a pre-harvest agricultural water assessment under proposed § 112.43(a)(1).
9	We acknowledge the potential for small pools of water to temporarily form in field areas or at the base of plants after irrigation. Small amounts of water of this nature are temporary and occur in the normal course of irrigation practices. We are not suggesting that it will always be possible to eliminate pooling. However, pooled water that remains for extended periods of time can be a source of contamination and pooled water in close proximity to the crop may serve as an attractant for pests and other animals, which may in turn introduce hazards into the pooled water that may contaminate produce.
10	Animals – such as wildlife, domesticated companion animals, working animals, grazing animals, livestock and poultry – can serve as sources of human pathogens. FDA acknowledges the longstanding co-location of animals and plant food production systems

Note Number	Relevant information
	in agriculture. This proposed rule would not prohibit the presence of animals (such as grazing animals or working animals) on a covered farm, nor would it require the destruction of wildlife habitat or the clearing of farm borders. Rather, the proposed rule would require a covered farm to evaluate and take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto non-sprout covered produce or food contact surfaces by pre-harvest agricultural water.
11	By ''adjacent'' land we are referring to land sharing a common border with the water source or distribution system. By ''nearby'' land we are referring to a broader category of land, including land that does not adjoin the water source or distribution system but has the potential to affect the covered farm's agricultural water source or distribution system based on the land's location.
12	Consider areas in which animals might be in close proximity to pre-harvest agricultural water systems, whether animals have direct access to pre-harvest agricultural water systems for loafing and drinking, and whether runoff or tailwater returns from certain areas is likely to be introduced into pre-harvest agricultural water systems. Consider also whether there are any animal or traffic patterns that have the potential to spread contaminants to pre-harvest agricultural water systems.
13	Consider whether animals have access to these areas at times when agricultural water is being applied to covered produce using a direct water application method.
14	Some covered farms will be aware of potential animal impacts from grazing animals, working animals, or animal intrusion through assessments done under subpart I (§§ 112.81-112.84) of the produce safety regulation-which, under certain circumstances, requires a covered farm to assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce (such as observation of significant quantities of animals, significant amounts of animal excreta, or significant crop destruction). (See 80 FR 74354 at 74478-74485.) The covered farm could consider findings from this assessment for example, whether significant amounts of animal excreta are observed-when evaluating the likelihood of hazards being introduced into their pre-harvest agricultural water sources. Additionally, a covered farm would be aware of potential animal impacts on agricultural water systems through inspections and maintenance performed on agricultural water sources and agricultural water systems it controls under proposed § 112.42. For example, pooled water in close proximity to the crop may serve as an attractant for pests and other animals which may in turn introduce hazards into pooled water that may contaminate produce. (See 80 FR 74354 at 74434).
15	We recognize that farms may face uncertainty in evaluating the potential effect of adjacent and nearby land uses when they are unable to obtain the relevant information, such as if adjacent or nearby land users are not willing to share information. Due to the nature of the risks associated with animal activity, application of a biological soil

Note Number	Relevant information
	amendment of animal origin, or the presence of untreated or improperly treated human waste on adjacent or nearby lands, in these instances, farms should consider accounting for the increased likelihood of hazard introduction to the water systems from adjacent or nearby lands when making decisions around the safe use of their water.
16	**Biological soil amendment of animal origin** means a biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term ‘‘biological soil amendment of animal origin’’ does not include any form of human waste. (21 CFR 112.3).
17	Consider areas that BSAAOs are applied to that are in close proximity to pre-harvest agricultural water systems, or areas from which runoff or tailwater returns may be introduced into pre-harvest agricultural water systems.
18	Consider whether BSAAOs are applied to the land during times when agricultural water is being applied to covered produce using a direct water application method.
19	In assessing systems for the collection and/or disposal of human waste in this section, consider systems such as the following: • Toilet facilities (such as portable toilets, outhouses, and fixed toilet facilities) • Sewage disposal systems (such as sewers, piped sewage systems, septic tanks, drain fields, and septic leach fields) • Wastewater treatment plants • Any other human waste systems
20	Application of human waste on agricultural land is subject to regulation by EPA under 40 CFR part 503. Sewage sludge that is to be applied to land or placed in or on a surface disposal site must meet EPA and state requirements for the control of pathogenic microorganisms and vectors. Covered farms subject to the Produce Safety Rule must not use human waste for growing covered produce, except sewage sludge biosolids used in accordance with requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements. (§ 112.53).
21	Consider areas of land that human waste is applied to that are in close proximity to pre-harvest agricultural water systems, or areas from which runoff or tailwater returns may be introduced into pre-harvest agricultural water systems.
22	Consider whether human waste is applied to the land during times when agricultural water is being applied to covered produce using a direct water application method.
23	This could include other user(s) of your pre-harvest agricultural water systems that are not currently captured above. For example, this might include whether water is used for recreational purposes (for example, swimming), or whether tailwater is returned to the agricultural water system by another user upstream of you.

Note Number	Relevant information
24	Consider whether other water user(s) are in close proximity to your water system, and whether they have direct access to the water and where.
25	Consider whether other user(s) use the water during times when agricultural water is being applied to covered produce using a direct water application method.
26	Depending on the nature of the other water user(s), this could include consideration for the proximity of other users to agricultural water systems, the likelihood of discharges or runoff from other users to agricultural water systems, whether other users discharge known or reasonably foreseeable hazards into agricultural water system directly or indirectly, whether other water users treat potential sources of known or reasonably foreseeable hazards to reduce microorganisms of public health significance, etc.
27	This could include potential sources of known or reasonably foreseeable hazards to your pre-harvest agricultural water systems that are not currently captured above.
28	Consider whether the other factor is in close proximity to your agricultural water system, or if it is in an area from which discharges or runoff into agricultural water systems may occur.
29	Consider whether the other factor may introduce known or reasonably foreseeable hazards to your agricultural water during times when agricultural water is being applied to covered produce using a direct water application method.
30	Depending on the nature of the other factor, this could include consideration for the proximity of the other factor to agricultural water systems, the likelihood of discharges or runoff from the other factor into agricultural water systems, whether the other factor discharges known or reasonably foreseeable hazards into agricultural water systems directly or indirectly, whether potential sources of known or reasonably foreseeable hazards are treated to reduce microorganisms of public health significance, etc.
31	Per 21 CFR 112.1(b), for the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following: • Fruits and vegetables such as almonds, apples, apricots, apriums, Artichokes-globe-type, Asian pears, avocados, babacos, bananas, Belgian endive, blackberries, blueberries, boysenberries, brazil nuts, broad beans, broccoli, Brussels sprouts, burdock, cabbages, Chinese cabbages (Bok Choy, mustard, and Napa), cantaloupes, carambolas, carrots, cauliflower, celeriac, celery, chayote fruit, cherries (sweet), chestnuts, chicory (roots and tops), citrus (such as clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cowpea beans, cress-garden, cucumbers, curly endive, currants, dandelion leaves, fennel-Florence, garlic, genip, gooseberries, grapes, green beans, guavas, herbs (such as basil, chives, cilantro, oregano, and parsley), honeydew, huckleberries, Jerusalem artichokes, kale, kiwifruit, kohlrabi, kumquats, leek, lettuce, lychees,

Note Number	Relevant information
	macadamia nuts, mangos, other melons (such as Canary, Crenshaw and Persian), mulberries, mushrooms, mustard greens, nectarines, onions, papayas, parsnips, passion fruit, peaches, pears, peas, peas-pigeon, peppers (such as bell and hot), pine nuts, pineapples, plantains, plums, plumcots, quince, radishes, raspberries, rhubarb, rutabagas, scallions, shallots, snow peas, soursop, spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), sweetsop, Swiss chard, taro, tomatoes, turmeric, turnips (roots and tops), walnuts, watercress, watermelons, and yams; and • Mixes of intact fruits and vegetables (such as fruit baskets). This list of commodities is not meant to be an exhaustive list.
32	The growth characteristics of a crop (for example, near to the ground) and surface properties (for example, porosity) affect the probability and degree of contamination. The possibility of splash dispersal may also become problematic during periods of rainfall, especially when increased levels of pathogens are transported to growing areas. Additionally, pooled water that remains for extended periods of time can be a source of contamination. Pooled water in close proximity to the crop may serve as an attractant for pests and other animals, which may in turn introduce hazards into the pooled water that may contaminate produce.
33	This could include consideration for produce that has a large surface area (such as leafy vegetables) and topographical features (such as netted rinds or rough surfaces) that may foster attachment or entrapment or pathogens. This could also include consideration for biological damage that may occur to the produce, such as from phytopathogens, that may make a commodity more susceptible to the persistence and growth of human pathogens.
34	This could include damage to edible leaves, freezing of an epidermal peel, or hail damage from weather events that may result in increased susceptibility to internalization of hazards.
35	As a reminder, **direct water application method** means using agricultural water in a manner whereby the water is intended to, or is likely to, contact covered produce or food contact surfaces during use of the water (21 CFR 112.3). In responding to this question, consider whether you use the following application methods to apply agricultural water to covered produce (other than sprouts) during growing activities and whether the water is intended to or likely to contact the covered produce or food contact surfaces: • Overhead or sprinkler irrigation. • Microirrigation (sometimes referred to as microjet or microspray irrigation) • Seepage irrigation (sometimes referred to as subirrigation) • Drip irrigation • Furrow or flood irrigation • Crop sprays (for example, for chemical applications, frost protection, evaporative cooling, or fertigation) • Other application method

Note Number	Relevant information
	The Final Qualitative Assessment of Risk explains that different irrigation methods present different risks based on the extent to which the irrigation water is directly applied to the harvestable portion of the crop. The location of the harvestable portion of a plant in relation to irrigation water has been shown to play a significant role in contamination in studies of lettuce, cantaloupe, and bell pepper. The likelihood of produce contamination may be reduced if irrigation water is delivered by subsurface drip irrigation as compared to using the same water to irrigate by overhead spray.
36	As explained in the Final Qualitative Assessment of Risk, the timing of water application is an important factor in determining the likelihood of contamination, because pathogens die off over time on the surface of produce. Generally, bacteria or pathogens in water that is applied early in the growing cycle are subject to die-off from several environmental forces, such as UV exposure, temperature, humidity, and the presence of competitive organisms. In contrast, pathogens present in agricultural water that is applied shortly before harvest may not be exposed to the same environmental conditions for sufficient time to provide a similar magnitude of die-off.
37	Precipitation and its effects (for example, discharge and flow rate), along with temperature, are common factors reported to affect the microbial quality of watersheds with agricultural land inputs. Seasonal changes in rainfall--particularly heavy rainfall and flooding events--can greatly affect surface water quality and may result in sediments, which can serve as reservoirs for pathogens, being dispersed within the water column. Additionally, airborne transmission may also result in contamination of the environment--such as agricultural water and growing areas--particularly when dry, windy conditions are present.
38	Consider the frequency of these events, and whether they are likely to occur at times when agricultural water is being applied to covered produce using a direct water application method.
39	Survival of pathogens and other microorganisms on produce commodities prior to harvest is dependent upon several environmental factors, including sunlight (UV) intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate. Generally, pathogens and other microbes die-off or are inactivated relatively rapidly under hot, dry, and sunny conditions compared to inactivation rates observed under cloudy, cool and wet conditions Additionally, changes in temperature and seasonality are expected to impact persistence of foodborne pathogens in the environment. In general, the survival of pathogens in water sources decreases with increasing temperatures. However, exceptions may be observed in certain geographic areas and/or on certain farm environments due to factors that confound the effects of temperature, such as nutrient levels and humidity.
40	Consider whether these weather events occur at times when agricultural water is being applied to covered produce using a direct water application method.

Note Number	Relevant information
41	We are maintaining the requirements for corrective measures in § 112.45(a), as explained and supported by the 2015 produce safety final rule (80 FR 74354 at 74429-74431, 74440-74441), including the requirement that if a covered farm determines or has reason to believe that their agricultural water is not safe or of adequate sanitary quality for its intended use, then they must immediately discontinue such use. For example, if in performing their agricultural water assessment a covered farm finds that there is a dead and decaying sheep in the canal upstream and at a close distance from where they draw water, they would have reason to believe that their agricultural water is not safe or of adequate sanitary quality for its intended use because the water is reasonably likely to contain human pathogens transferred by the dead and decaying sheep.
42	Proposed § 112.46, if finalized, would require that: • 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, as applicable; • 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; and • 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. • Treatment may be conducted by you or by a person or entity acting on your behalf. The proposed requirements, if finalized, would not require covered farms to consider treating agricultural water as an immediate first step, and we believe some of the other options are likely to be more feasible than the options available for farms to use to treat water. Moreover, it is important to note that proposed § 112.46, if finalized, would not specifically require the use of an EPA-registered antimicrobial pesticide product. Instead, proposed § 112.46(a) would require that any method you use to treat agricultural water must be effective to make the water safe and of adequate sanitary quality for its intended use and/or meets the microbial quality criterion in § 112.44.
43	**Time Interval without Testing Data** If a covered farm does not test its pre-harvest agricultural water as part of an agricultural water assessment under proposed § 112.43(d) but determines that the application of a time interval prior to harvest would be an appropriate mitigation measure, the farm could

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	use a time interval between last direct application of agricultural water and harvest of at least 4 days. Lacking quantitative test data, the covered farm could not use less than 4 days as a time interval between last direct application and harvest under proposed § 112.45(b)(1)(ii), unless the farm had scientifically valid data or information to support use of a die-off rate of 0.5 log per day for less than 4 days in accordance with proposed § 112.12. **Time Interval with Testing Data** If a covered farm tests its pre-harvest agricultural water as part of an agricultural water assessment under proposed § 112.43(d) and determines that the application of a time interval prior to harvest is an appropriate mitigation measure, the farm could choose to use a microbial die-off rate of 0.5 log per day, for potentially less than 4 days between last direct water application and harvest, to achieve a (calculated) log reduction to meet the criteria the farm would establish per proposed § 112.43(d)(3). (Alternately, the covered farm could choose to use a different time interval (and accompanying die-off rate) if the farm has scientifically valid data or information in accordance with proposed § 112.12.) We expect that scientific data and information used to support a pre-harvest time interval would be relevant to conditions on the covered farm (such as the region, crop, and environment), and be characterized in a manner that addresses the likely biphasic nature of microbial die-off (i.e., the two different decay constants of a rapid short-term die-off and a gradual long-term die-off).
44	We are not proposing to establish a specific microbial die-off rate(s) between harvest and end of storage or specific microbial removal rate(s) during postharvest activities such as commercial washing. We do not have sufficient information to support the derivation of appropriate, broadly-applicable microbial die-off or removal rate(s) for this purpose. We are proposing to provide this option so that a covered farm may account for microbial die-off or removal during post-harvest activities (i.e., between harvest and end of storage, and during activities such as commercial washing), provided the farm has adequate scientific data or information to support the conclusions in accordance with proposed § 112.12.
45	The Final Qualitative Assessment of Risk explains that different irrigation methods present different risks based on the extent to which the irrigation water is directly applied to the harvestable portion of the crop. The location of the harvestable portion of a plant in relation to irrigation water plays a significant role in contamination in studies of lettuce, cantaloupe, and bell pepper. The likelihood of produce contamination may be reduced if irrigation water is delivered by subsurface drip irrigation as compared to using the same water to irrigate by overhead spray.
46	We note that proposed § 112.45(b)(2), if finalized, would provide that if you failed to implement appropriate mitigation measures, or if you determined that the measures were not effective to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with any known or reasonably foreseeable hazards, you would be required to discontinue use of the pre-harvest agricultural water until you have

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	implemented mitigation measures adequate to reduce the potential for such contamination, consistent with § 112.41.
47	Potential significant changes that occur in your agricultural water systems could include 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. Additionally, a change from an untreated ground water source to an untreated surface water source would be a significant change that would require a reassessment under proposed § 112.43(e). The reassessment would evaluate the impacts of those changes on the factors in proposed § 112.43(a)(1) through (5), any new hazards identified, and the outcome and determination under proposed § 112.43(c).
48	A covered farm that opts to test pre-harvest agricultural water under § 112.43(d), if finalized, could choose to use sampling frequencies in the 2015 produce safety final rule. For untreated surface water, this would include initially collecting at least 20 samples over a 2-4-year period, with at least 5 samples collected annually thereafter; and for untreated ground water, this would include initially collecting at least 4 samples over a growing season or year, with at least 1 sample collected annually thereafter. However, farms would have the flexibility under the proposed rule, if finalized, to use any sampling frequency when testing under proposed § 112.43(d)(3), provided that it is scientifically valid and adequate to assist in determining, in conjunction with other data and information evaluated under § 112.43(a), whether measures are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water for non-sprout covered produce.
49	Proposed § 112.43(d)(1) would require, in part, that samples of pre-harvest agricultural water tested as part of an agricultural water assessment be representative of the water used in growing non-sprout covered produce. This rule is not prescriptive about the exact point of collection of water samples when testing is required, but it requires that all water samples must be representative of your use of the water.
50	Aseptic sampling, often used for product and environmental samples, is a sampling technique used to assure that the microbial load of a sample is not affected by the sampling method and/or the sample collector does not contaminate the source from which the sample is collected. The use of sterile sampling implements and containers and a prescribed sampling method defines aseptic sampling. Collecting and delivering samples to the laboratory using an aseptic technique also helps assure the microbiological findings accurately reflect the agricultural water at the time of sampling.
51	A covered farm that opts to test pre-harvest agricultural water under proposed § 112.43(d), if finalized, would be required to test its agricultural water for generic *E. coli* as an indicator of fecal contamination, but also may test for another scientifically valid indicator organism, index organism, or other analyte.

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	We use the term ''scientifically valid'' to mean an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, textbooks, or proprietary research.
52	A covered farm that opts to test pre-harvest agricultural water under § 112.43(d), if finalized, could choose to use the microbial water quality criteria for water used during growing activities (for non-sprout covered produce) in the 2015 produce safety final rule, which consist of a geometric mean (GM) of 126 or less CFU generic *E. coli* per 100 mL and a statistical threshold value (STV) or 410 or less CFU generic *E. coli* per 100 mL. However, farms would have the flexibility to apply any microbial criterion or criteria that would be scientifically valid and appropriate to assist in determining, in conjunction with other data and information evaluated under proposed § 112.43(a), whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water.
53	In addition to considering how results compare to any microbial criterion or criteria they have established, covered farms could consider water quality data collected over time – whether historical data, new data, or both – that can assist in analyzing trends. For example, this approach could be useful in situations in which potential hazards are introduced into a water system intermittently, such that a covered farm is able to compare data to further refine its assessments of whether measures under proposed § 112.45 are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water.