

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 112

[Docket No. FDA-2021-N-0471]

RIN 0910-AI49

Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Food and Drug Administration ~~(FDA, the Agency, or we)~~ is issuing a final rule to amend the agricultural water provisions of the produce safety regulation. This rule replaces the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) with a regulatory approach that incorporates recent science and FDA outbreak investigation findings to achieve improved public health protections as compared to the earlier requirements. The rule requires systems-based assessments, with required testing in certain circumstances, that focus on key risk factors for contamination by pre-harvest agricultural water and will enable farms to implement effective preventive measures. The rule requires farms to take timely action based on risk and includes a new requirement for expedited mitigation for certain hazards. The requirements are adaptable to future scientific advancements and provide sufficient flexibility to be practicable for all sizes and types of farms to implement across the wide variety of agricultural water systems, uses, and practices. These revisions to the produce safety regulation will more comprehensively address a known route of

microbial contamination that can lead to preventable foodborne illness that is a significant public health problem.

DATES: This rule is effective [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

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I. Executive Summary

A. Purpose and Coverage of the Final Rule

In this final rule, ~~FDA~~the Food and Drug Administration (FDA, the Agency, or we) is amending the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” rule (2015 produce safety final rule), which was established in accordance with the FDA Food Safety Modernization Act (FSMA) and sets forth science-based minimum standards for the safe growing, harvesting, packing, and holding of produce, meaning fruits and vegetables for human consumption. This rule revises certain provisions in the 2015 produce safety final rule applicable to agricultural water¹ for covered produce other than sprouts, using a direct application method during growing activities (commonly referred to as “pre-harvest agricultural water”²). It establishes a regulatory framework of systems-based assessments and risk-tiered outcomes through which farms subject to the 2015 produce safety final rule (covered

¹ “Agricultural water” is defined at 21 CFR 112.3 as 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). Related to this definition is our definition of “direct water application method,” which means agricultural water used 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. If a specific use of water does not fit within the definition of agricultural water, then the requirements in subpart E do not apply to that specific use of water. See 80 FR 74354 at 74429.

² The 2015 produce safety final rule refers to pre-harvest agricultural water used during sprout production as “sprout irrigation water.”

farms) are required to identify known and potential hazards and implement effective preventive measures within specific timeframes based on risk.

The written assessments focus on agricultural water systems, including sources, and agricultural water practices that are key determinants of contamination risks associated with agricultural water, together with crop characteristics and environmental conditions that can impact the survival of pathogens. The assessments include a requirement to test pre-harvest agricultural water in certain circumstances—that is, when doing so would not delay action **where** most critical to protect public health and would further inform the farm’s determination as to whether measures are reasonably necessary. Moreover, the assessments are designed for use in diverse circumstances and require covered farms to evaluate a broad range of factors that impact pre-harvest agricultural water quality, providing results that are tailored to address hazards unique to their respective operations. This approach will be feasible to implement across the wide variety of agricultural water systems, practices, and uses, and it is adaptable to future advancements in agricultural water quality science.

Farms must use the information evaluated to make a written determination on the outcomes of their assessments. The outcomes are based on risk, and include the actions farms must take within a specific timeframe to ensure that their pre-harvest agricultural water is safe and is of adequate sanitary quality for the intended use(s). Within this framework for risk-tiered outcomes is a new expedited mitigation requirement relating to the impacts of certain adjacent and nearby land uses on pre-harvest agricultural water.

These amendments to the 2015 produce safety final rule are supported by scientific literature published since FDA promulgated the 2015 produce safety final rule and findings from FDA’s outbreak investigations since FDA promulgated the 2015 produce safety final rule. These

amendments are also supported by information and insights shared by an array of stakeholders through a variety of means since FDA promulgated the 2015 produce safety final rule (including through meetings, educational farm visits, and listening sessions), as well as information shared through the notice-and-comment process for this rulemaking. Feedback shared by stakeholders included information about the complexity of the previous pre-harvest agricultural water testing requirements, the practical implementation challenges associated with the uniform nature of those requirements, and findings from scientific studies demonstrating the need for additional testing in highly variable water with previously unaccounted for costs (see section III.C.). We have carefully considered the new information as we considered revisions to the 2015 produce safety final rule necessary to achieve our intended public health goals.

After considering available information, FDA has concluded this final rule will achieve improved public health protections by setting forth requirements for comprehensive pre-harvest agricultural water assessments. Those assessments will better enable covered farms to implement effective measures that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce, and to provide reasonable assurances that produce is not adulterated due to those hazards. Moreover, these revisions provide sufficient flexibility to be practicable for all sizes and types of farms and to account for differences in risk across varying agricultural water systems, uses, and practices.

B. Summary of the Major Provisions of the Final Rule

FDA is amending the 2015 produce safety final rule by revising certain provisions relating to pre-harvest agricultural water for covered produce other than sprouts, while retaining

the existing standards applicable to agricultural water for sprouts and for harvest and post-harvest activities conducted by covered farms.

For pre-harvest agricultural water for non-sprout covered produce, we are:

- Replacing the microbial quality criteria and uniform testing requirements in the 2015 produce safety final rule with new provisions for conducting pre-harvest agricultural water assessments for hazard identification purposes (including consideration of agricultural water sources, distribution systems, and practices, as well as adjacent and nearby land uses, and other relevant factors), and using the results of the assessments in making risk management decisions;
- Including a requirement to test pre-harvest agricultural water, in certain circumstances, (that is, when doing so would not delay action most critical to protect public health and would further inform the farm’s determination as to whether measures are reasonably necessary) for generic *Escherichia coli* (*E. coli*) (or other appropriate indicator organism, index organism, or analyte) to help inform covered farms’ agricultural water assessments;
- Adding new options for mitigation measures, providing covered farms additional flexibility in responding to findings from their pre-harvest agricultural water assessments;
- Requiring expedited implementation of mitigation measures for known or reasonably foreseeable hazards related to certain adjacent and nearby land uses;
- Requiring management review of pre-harvest agricultural water assessments; and
- Adding new definitions of “agricultural water assessment” and “agricultural water system.”

We are making additional amendments, such as adding examples and making other edits that are designed to provide clarity, such as reorganizing subpart E to group provisions of a

similar nature. We are also making conforming changes elsewhere in the 2015 produce safety final rule.

C. Legal Authority

~~FDA is amending certain requirements in the 2015 produce safety final rule relating to pre-harvest agricultural water for covered produce, other than sprouts, while retaining the standards applicable to agricultural water for sprouts and for harvest and post-harvest activities conducted by covered farms established by the 2015 produce safety final rule.~~ We are issuing this final rule under FDA’s authorities in sections 402, 419, and 701(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342, 350h, and 371(a)) and sections 311, 361, and 368 of the Public Health Service Act (PHS Act) (42 U.S.C. 243, 264, and 271). We discuss our legal authority in greater detail in section IV.

D. Costs and Benefits

~~We estimate costs of this rule.~~ Our primary estimates of annualized costs are approximately \$17.5 million at a 3 percent discount rate and approximately \$17.7 million at a 7 percent discount rate over 10 years.

~~We estimate benefits of this rule.~~ Our primary estimates of annualized benefits are approximately \$10.3 million at a 3 percent discount rate and approximately \$10.1 million at a 7 percent discount rate over 10 years. We discuss qualitatively non-quantified benefits of the rule stemming from recalls averted and increased flexibility for covered farms to comprehensively evaluate their agricultural water systems.

II. Table of Abbreviations/Commonly Used Acronyms in This Document

Table 1.--Table of Abbreviations and Acronyms

Abbreviation/Acronym	What It Means
BSAAO	Biological Soil Amendment of Animal Origin
CAFO	Concentrated Animal Feeding Operation

CAN	California Agricultural Neighbors
CDC	Centers for Disease Control and Prevention
CEA	Controlled Environment Agriculture
CFR	Code of Federal Regulations
CFU	Colony Forming Units
CWA	Clean Water Act
<i>E. coli</i>	<i>Escherichia coli</i>
EIS	Environmental Impact Statement
EPA	U.S. Environmental Protection Agency
FD&C Act	Federal Food, Drug, and Cosmetic Act
FRIA	Final Regulatory Impact Analysis
FSMA	FDA Food Safety Modernization Act
GAP	Good Agricultural Practices
GM	Geometric Mean
HACCP	Hazard Analysis and Critical Control Point
H-GAP	USDA Harmonized Good Agricultural Practices
HHS	Health and Human Services
IFSAC	Interagency Food Safety Analytics Collaboration
LGMA	Leafy Greens Marketing Agreement
<i>L. monocytogenes</i>	<i>Listeria monocytogenes</i>
mL	Milliliters
MPN	Most Probable Number
MWQP	Microbial Water Quality Profile
NASDA	National Association of State Departments of Agriculture
NOP	USDA National Organic Program
NASS	USDA National Agricultural Statistics Service
NPDWR	U.S. EPA National Primary Drinking Water Regulations
PCR	Polymerase Chain Reaction
PHS Act	Public Health Service Act
PRIA	Preliminary Regulatory Impact Analysis
QAR	Qualitative Assessment of Risk
RWQC	Recreational Water Quality Criteria
STV	Statistical Threshold Value
USDA	U.S. Department of Agriculture
UV	Ultraviolet

III. Background

A. FDA Food Safety Modernization Act

FSMA (Pub. L. 111-353), signed into law by President Obama on January 4, 2011, is intended to allow FDA to better protect public health by helping to ensure the safety and security

of the food supply. FSMA transformed the nation's food safety system by shifting the focus from responding to foodborne illness to preventing it.

FSMA enables FDA to establish a prevention-oriented framework that focuses effort where food safety hazards are reasonably likely to occur and is flexible and practical in light of current scientific knowledge and food safety practices. The law also provides enforcement authorities for responding to food safety problems when they do occur. In addition, FSMA gives FDA important tools to help ensure the safety of imported foods and encourages partnerships with State, local, Tribal, and territorial authorities, as well as foreign regulatory counterparts.

FDA has issued nine foundational rules that create risk-based standards and provide oversight at various points in the supply chain for domestic and imported human and animal food. The produce safety regulation, established in the 2015 produce safety final rule (80 FR 74354, November 27, 2015), is one of the nine foundational rules.

B. 2015 Produce Safety Final Rule

In November 2015, FDA finalized the produce safety regulation, which establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption (codified in the Code of Federal Regulations (CFR) at part 112 (21 CFR part 112)). In accordance with section 419 of the FD&C Act (21 U.S.C. 350h), the 2015 produce safety final rule sets forth procedures, processes, and practices to minimize the risk of serious adverse health consequences or death, including those that are reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into produce and to provide reasonable assurances that produce is not adulterated on account of such hazards. The regulation focuses on biological hazards (defining a "known or reasonably foreseeable hazard" as a biological hazard that is known to be, or has the potential to

be, associated with the farm or the food) and major routes of microbial contamination—including agricultural water; biological soil amendments; domesticated and wild animals; worker health and hygiene; and equipment, buildings, and tools. Farms subject to the requirements of part 112 are “covered farms”; however, for purposes of readability, we use the term “farms” to mean “covered farms” within the meaning of part 112 in this document.

Subpart E of the 2015 produce safety final rule includes a general requirement that agricultural water must be safe and adequate for its intended uses (§ 112.41). It also included microbial water quality criteria (§ 112.44) and requirements for testing certain water sources (§ 112.46). The microbial quality criteria were based on the intended use of the agricultural water--i.e., for growing activities for covered produce other than sprouts (including irrigation water applied to covered produce, other than sprouts, using a direct water application method and water used in preparing crop sprays) (commonly referred to as “pre-harvest agricultural water”)³, and for certain other specified uses, including sprout irrigation water and water applications that directly contact covered produce during or after harvest (commonly referred to as “harvest and post-harvest agricultural water”).⁴ For pre-harvest agricultural water for non-sprout covered produce, the microbial water quality criteria consisted of a geometric mean (GM) of 126 or less colony forming units (CFU) generic *E. coli* per 100 milliliters (mL), and a statistical threshold value (STV) of 410 or less CFU generic *E. coli* per 100 mL. The 2015 produce safety final rule preamble explained that we established the pre-harvest agricultural water microbial criteria based on our analysis of the then-current scientific information; we also explained that that

³ The 2015 produce safety final rule refers to pre-harvest agricultural water used during sprout production as “sprout irrigation water.”

⁴ Because sprouts present a unique safety risk, the 2015 produce safety final rule establishes sprout-specific requirements on multiple topics, including agricultural water. Sprouts are not the subject of this rulemaking.

scientific information relied on an underlying dataset that had the necessary scientific rigor and described illness rates due to incidental ingestion generalized across different bodies of water (see 80 FR 74534 at 74416 and 74441-74442).

For untreated surface waters, farms were required to establish an initial microbial water quality profile (MWQP) of at least 20 samples collected over a 2 to 4-year period, followed by at least 5 annual samples thereafter; and for untreated ground water sources, this would consist of an initial profile of at least 4 samples collected during the growing season or over a period of 1 year, followed by at least 1 annual sample thereafter (80 FR 74354 at 74452) (Ref. 1).

In the 2015 produce safety final rule, we explained that the pre-harvest agricultural water microbial criteria and testing requirements were not a direct indicator of the safety of agricultural water for immediate use; rather, they were designed as a long-term water quality management tool for use in understanding the microbial quality of water over time and determining how to appropriately use water from that source. 80 FR 74354 at 74430. Moreover, we acknowledged gaps in the then-current science related to use of indicator organisms for monitoring water quality and predicting pathogen presence and/or fecal contamination. 80 FR 74354 at 74427-74428. We discussed that while testing water for pathogens has the obvious advantage of directly targeting microorganisms in water that are a risk to public health, doing so is not without significant challenges. 80 FR 74354 at 74427-74428. In response to comments received during that earlier rulemaking, we considered, and declined, the option to establish a qualitative standard alone in lieu of a quantitative microbial quality requirement for pre-harvest agricultural water. 80 FR 74354 at 74443. However, since 2015, new scientific findings as well as findings from FDA outbreak investigations have demonstrated the need for an updated systems-based approach.

Table 2 lists the key FSMA 2015 produce safety final rule documents published in the *Federal Register*. The complete set of *Federal Register* documents associated with the FSMA 2015 produce safety final rule, including supporting materials, are available in the docket folders at <https://www.regulations.gov/docket?D=FDA-2011-N-0921> and <https://www.regulations.gov/docket?D=FDA-2021-N-0471>.

Table 2.--List of Key Federal Register 2015 Produce Safety Final Rule Documents

Description	Publication
Notice of proposed rulemaking (2013 proposed produce safety rule)	78 FR 3504, January 16, 2013
Notice of correction for the 2013 proposed produce safety rule	78 FR 17155, March 20, 2013
Supplemental notice of proposed rulemaking (2014 supplemental proposed rule)	79 FR 58434, September 29, 2014
Final rule (2015 produce safety final rule or final rule)	80 FR 74354, November 27, 2015
Technical amendment to the 2015 produce safety final rule	81 FR 26466, May 3, 2016
FSMA: Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules; Final rule	81 FR 57784, August 24, 2016
Extension of Compliance Dates for Subpart E; Notice of proposed rulemaking (2017 proposed compliance date extension)	82 FR 42963, September 13, 2017
Extension of Compliance Dates for Subpart E; Final rule (2019 compliance date extension)	84 FR 9706, March 18, 2019
Standards Relating to Agricultural Water; Notice of proposed rulemaking (2021 agricultural water proposed rule)	86 FR 69120, December 6, 2021
Extension of Compliance Dates for Subpart E; Supplemental notice of proposed rulemaking (2022 supplemental proposed rule)	87 FR 42973, July 18, 2022

C. New Information Since Issuance of the 2015 Produce Safety Final Rule

In November 2015, FDA began to conduct outreach to educate stakeholders about the requirements of the 2015 produce safety final rule, including through public meetings, speaking engagements, and participation in conferences convened by stakeholders representing a broad range of interests. FDA subject matter experts also participated in educational farm visits with State partners to observe a range of growing conditions and practices in varying regions.

Through these efforts we heard consistent feedback that the pre-harvest agricultural water microbial criteria and testing requirements for non-sprout covered produce in the 2015 produce safety final rule were “one-size-fits-all” and did not sufficiently allow for the diversity of farms, including a variety of water uses and availabilities. For example, we received feedback that the long-term MWQPs required in the 2015 produce safety final rule can be difficult, and even impossible, to establish for farms that grow rotational crops or crops on leased land, both of which are common throughout industry. 86 FR 69120 at 69123-69124. FDA also received information and feedback from other stakeholders, including water quality specialists and researchers, indicating that the 2015 pre-harvest microbial water quality criteria and testing requirements did not adequately capture variability that can occur within a surface water source, and that sanitary surveys may better help inform water management decisions compared to testing.

In the face of these concerns, including new concerns not previously expressed, in March 2017, FDA announced that we were considering how we might simplify the microbial quality and testing requirements for agricultural water while still protecting public health and that we intended to work with stakeholders as these efforts progressed (Ref. 2). As part of these efforts, we participated in numerous additional meetings, educational farm visits, and listening sessions with an array of stakeholders--including produce industry members, food industry trade associations, researchers, extension educators, consumer groups, and State and Federal partners--to reflect various perspectives on managing risks associated with pre-harvest agricultural water for non-sprout covered produce. See 86 FR 69120 at 69123-69125.

For example, in October 2017, FDA participated in a collaborative forum, sponsored by The Pew Charitable Trusts and the Robert Wood Johnson Foundation, where participants

representing farms, academia, food industry trade associations, consumer groups, and State and other Federal partners discussed ideas for how to amend the agricultural water requirements within the then-current framework of the rule, as well as, and potentially in combination with, ideas for frameworks that could improve public health outcomes long-term and allow for the incorporation of new scientific knowledge and learnings as they become available (Ref. 3).

Forum participants identified several possible approaches, including: (1) retaining the 2015 pre-harvest microbial water quality criteria and testing requirements and issuing companion guidance; (2) replacing the 2015 quantitative requirements with a qualitative standard and issuing companion guidance; (3) adopting private industry standards as a short-term measure while additional research continues; and (4) performing a multiyear quantitative microbial risk assessment to help fill research gaps. Forum participants identified advantages and disadvantages of each approach and also identified other areas for further consideration by FDA, including qualitative standards, data sharing, and the need for additional guidance.

The pre-harvest agricultural water requirements were also the focus of a 2-day Agricultural Water Summit, convened by the Produce Safety Alliance at Cornell University, in February 2018 (Ref. 4). The summit was attended by academics, produce industry, growers/grower associations, State agencies, Federal agencies, and supporting industries. During the summit, participants had many questions and concerns about reliance on testing as a mechanism for determining pre-harvest agricultural water quality, including that the 2015 pre-harvest agricultural water microbial criteria and testing requirements were not supported by scientific evidence sufficient to demonstrate their relevance to public health outcomes. Among other things, participants questioned the role of water testing, what the information tells farms about risks, and how farms would use that information to make water use management decisions.

Some participants emphasized farms' interest in preventing produce contamination while expressing concern that the resources that would be required to conduct testing might be better used for other approaches with relevance to public health outcomes.

Many of the discussions at the summit addressed hazards in the growing environment, including examples of how risk assessment has been conducted in other fields of study, such as for drinking water and wastewater management. During the summit, participants identified "agricultural water assessments" as a promising approach for managing water quality, suggesting that assessments may provide a more effective risk management strategy to farms than a numerical testing standard can provide (Ref. 4).

Moreover, scientific information has become available since the 2015 produce safety final rule issued that indicates potential limitations in basing risk management decisions on the previous pre-harvest agricultural water testing requirements and that supports a shift in regulatory approach away from those requirements. For example, various studies since 2015 indicate a high degree of variability in generic *E. coli* levels in surface waters (Refs. 5-10), which can reduce the precision of estimation of the GM and STV of a water source (Refs. 1, 7). Other studies since 2015 have underscored the limitations of generic *E. coli* as an indicator for pathogen presence (Refs. 11-16).

Further, a scientific evaluation of the 2015 pre-harvest agricultural water testing requirements found that the rolling data set of five samples per year used to update GM and STV values for untreated surface water sources leads to highly uncertain results and delays in detecting shifts in water quality (Ref. 7). Specifically, Havelaar et al. found that the 20-sample MWQP for untreated surface water was not sufficient to reliably characterize the quality of the irrigation water with higher variability in generic *E. coli* levels than was determined for the 2015

produce safety final rule (Refs. 1, 7). In simulation modeling, the rolling 20-sample MWQP responded “very slowly” to shifts in water quality. Increases in generic *E. coli* levels were detected only after one to six sample sets, thus delaying signals of changes in water quality and (and any needed measures) by one to six years depending on the nature and magnitude of the shift.

For surface water that had standard deviations up to three times higher than accounted for in the 2015 produce safety final rule, Havelaar et al. determined that an 180-sample MWQP would be required to obtain the same precision of the GM as required by the rule (Ref. 7). Havelaar et al. observed that the (nine-fold) increase in sampling might address the problem, but it would increase testing costs. We acknowledge their findings on the need for substantial testing for highly variable pre-harvest agricultural water. Such testing would be beyond what is required for pre-harvest surface water testing under the 2015 produce safety final rule, with an attendant increase in costs. Additionally, other recent studies demonstrate a high degree of variability in generic *E. coli* levels in surface waters for pre-harvest application (Refs. 5-10), suggesting similar questions about necessary additional testing and costs that were not accounted for in the 2015 produce safety final rule.

Havelaar et al. also suggested that additional understanding of the processes that drive variability in the quality of irrigation water sources might inform preventive or rapid corrective actions that have a larger impact on produce safety than the 2015 pre-harvest agricultural water requirements (Ref. 7). Additionally, for several years, FDA has conducted investigations of produce outbreaks to learn what factors may have contributed to the outbreaks of foodborne illness or food contamination events (Ref. 17). Findings from investigations of several outbreaks linked to consumption of produce since 2015--including: (1) the spring 2018 *E. coli* O157:H7

outbreak linked to romaine lettuce from the Yuma growing region (Refs. 18 and 19); (2) the fall 2018 *E. coli* O157:H7 outbreak linked to romaine lettuce from California (Ref. 20); (3) the fall 2019 *E. coli* O157:H7 outbreaks linked to romaine lettuce (Ref. 21); (4) the fall 2020 *E. coli* O157:H7 outbreak linked to leafy greens (Ref. 22); and (5) the Summer 2020 *Salmonella* Newport outbreak linked to red onions (Ref. 23)--highlight the importance of pre-harvest agricultural water quality and the potential impacts of adjacent and nearby land uses on agricultural water, which can serve as a route of contamination of produce. These outbreak investigations reiterate decades of scientific research demonstrating that pre-harvest agricultural water is a potential contributing factor in the introduction and spread of contamination to produce. See 86 FR 69120 at 69125-69127. Findings such as these build upon our peer-reviewed “FDA Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce” (QAR) (Ref. 17), which provides a scientific evaluation of the potential adverse health effects resulting from human exposure to microbiological hazards in produce to inform FDA’s implementation of section 419 of the FD&C Act, with a focus on public health risk associated with the on-farm contamination of produce, including from agricultural water.

D. 2021 Agricultural Water Proposed Rule

In light of recent studies and other new information gathered since issuance of the 2015 produce safety final rule, including findings from FDA produce outbreak investigations as well as feedback on the previous pre-harvest agricultural water requirements, on December 6, 2021, FDA issued a proposed rule, “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water,” (86 FR 69120; hereafter referred to as the “2021 agricultural water proposed rule”) that proposed to revise certain requirements relating to pre-harvest agricultural water for covered produce other than sprouts,

while retaining the existing standards applicable to agricultural water for sprouts and for harvest and post-harvest activities. For pre-harvest agricultural water for non-sprout covered produce, we proposed to replace the microbial quality criteria and uniform testing requirements with provisions for: requiring systems-based pre-harvest agricultural water assessments to evaluate the key determinants of risk attributable to agricultural water use practices, including a requirement to test pre-harvest agricultural water when doing so would not delay action **where** most critical to protect public health and would further inform the farm's determination as to whether measures are reasonably necessary; adding new options for mitigation measures; and adding a new requirement for expedited implementation of mitigation measures for hazards related to certain adjacent and nearby land uses. We also proposed to require management review of records related to agricultural water assessments and to add new definitions of "agricultural water assessment" and "agricultural water system" to the 2015 produce safety final rule.

We solicited comments on these proposed amendments. We also proposed additional amendments, such as reorganizing subpart E to group requirements of a similar nature and ensure that interested parties could readily view the proposed pre-harvest agricultural water revisions.

Additionally, in the preamble to the 2021 agricultural water proposed rule (86 FR 69120 at 69147) we explained that at that time, farms were required to comply with the subpart E pre-harvest, harvest, and post-harvest agricultural water requirements for covered produce (other than sprouts) beginning on January 26, 2024, for very small farms; January 26, 2023, for small farms; and January 26, 2022, for all other farms (see also 84 FR 9706). We also explained that we intended to exercise enforcement discretion for the subpart E pre-harvest, harvest, and post-

harvest agricultural water requirements for covered produce (other than sprouts) while working to address compliance dates in a targeted manner through the rulemaking process, with the goal of completing the rulemaking as quickly as possible.

The public comment period for the 2021 agricultural water proposed rule closed on April 5, 2022.

In the 2021 agricultural water proposed rule, we indicated that we were developing an online tool related to the pre-harvest agricultural water assessments described in the proposed rule. In March 2022, FDA released v1.0 of an online “Agricultural Water Assessment Builder” to help farms understand the proposed requirements for an agricultural water assessment (Ref. 24). Since then, we have released paper-based versions of the Builder in both English and Spanish to make the content more accessible to a broader array of users (Ref. 25). We have also updated the online version of the Builder to v1.1 to make it more user-friendly in response to stakeholder feedback. We expect to update the Builder to reflect the requirements we are finalizing here.

E. 2022 Supplemental Proposed Rule

On July 19, 2022, we published a supplemental notice to the 2021 agricultural water proposed rule (87 FR 42973) (2022 supplemental proposed rule) in which we proposed dates for compliance with the pre-harvest agricultural water requirements for covered produce other than sprouts in the 2021 agricultural water proposed rule. In light of the revisions we proposed to certain pre-harvest agricultural water requirements for non-sprout covered produce, we proposed to establish dates for compliance with the pre-harvest agricultural water requirements for covered produce other than sprouts as follows: 2 years and 9 months after the effective date of a final rule

for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses.

We also specified the duration of the period of enforcement discretion for the harvest and post-harvest agricultural water requirements for covered produce other than sprouts until January 26, 2025, for very small businesses; January 26, 2024, for small businesses; and January 26, 2023, for all other businesses. As discussed in the 2022 supplemental proposed rule, we specified the duration of our intended period of enforcement discretion to provide farms, regulators, educators, and other stakeholders additional time to facilitate compliance with those requirements.

We explained in the 2022 supplemental proposed rule that the proposed compliance dates for pre-harvest agricultural water requirements and our intent to exercise of enforcement discretion were intended to facilitate successful implementation and optimize public health protections. We reopened the comment period only with respect to the extension of compliance dates for pre-harvest agricultural water for non-sprout covered produce. The comment period for the supplemental proposed rule closed on September 19, 2022.

In this document, we use the broad term “agricultural water proposed rule” to refer to the complete proposed rule, including both the 2021 agricultural water proposed rule and the 2022 supplemental proposed rule.

F. Public Comments

After issuing the agricultural water proposed rule, we conducted numerous outreach activities. We held two virtual public meetings on February 14, 2022, and February 25, 2022, to solicit public comments on the proposed rule, inform the public about the rulemaking process (including how to submit comments, data, and other information to the rulemaking dockets), and

respond to questions about the proposed rule. The public meetings were attended by domestic and foreign industry representatives, academia, State and Federal regulators, retailers, third-party certification bodies, laboratories, consumer groups and others, and included discussion panels consisting of representatives from industry, the States, consumer groups, and retailers. We also held a consultation with Federally recognized Indian tribes on February 4, 2022, to provide an overview of the proposed rule, answer questions, and receive feedback.

Additionally, FDA participated in a webinar hosted by the National Association of State Departments of Agriculture (NASDA) on December 15, 2021, as well as five regional meetings (Southern Region (March 14, 2022); Western Region (March 11, 2022); Northwestern Region (March 2, 2022); North Central Region (March 2, 2022); and Northeast Region (March 11, 2022)) that were sponsored by State regulatory partners and attended by farms, irrigation districts, educators, environmental groups, and others. We also participated in numerous other meetings and speaking engagements to discuss the proposed rule, respond to questions, and receive feedback.

We received approximately 180 comment submissions on the agricultural water proposed rule by the close of both comment periods, each containing one or more comments on one or more issues. We received submissions from diverse members of the public, including produce farms; coalitions; trade organizations; academia; consumers; consumer groups; State and foreign government agencies; and other organizations. Some submissions included statements from multiple individuals.

In sections V and VI of this document we describe these comments, respond to them, and explain the changes we made to the agricultural water proposed rule, in addition to discussing our consideration of alternative approaches, such as requiring all farms to test their water as part

of their pre-harvest agricultural water assessments. We also discuss comments that ask us to clarify the proposed requirements or that disagree with, or suggest one or more changes to, the proposed requirements. Our responses to the comments include our reasons for determining whether to modify any of the proposed requirements. The remainder of this document establishes a final rule (“the final rule,” “this final rule,” “the rule,” or “this rule”) based on the agricultural water proposed rule.

G. General Overview of Changes in the Final Rule

In response to comments received and on our own initiative, we have made several changes to the proposed requirements for pre-harvest agricultural water assessments for non-sprout covered produce and for mitigation measures to reduce the potential for contamination of covered produce and food contact surfaces with known or reasonably foreseeable hazards associated with such agricultural water. We have provided clarification related to the timing of agricultural water assessments and exemptions from the requirement to prepare an agricultural water assessment. We have also revised the mitigation measures related to a time interval between last direct water application and harvest and a time interval between harvest and end of storage and/or use of other post-harvest activities to further emphasize the flexibility afforded to farms in ways to comply with those requirements and provide flexibility as science and post-harvest handling practices evolve. Consistent with the changes discussed above, we have revised the requirements for certain records that farms are required to establish and maintain. This final rule also includes a requirement to maintain scientific data or information in support of an alternative mitigation measure to align with the agricultural water records requirements in the 2015 produce safety final rule.

IV. Legal Authority

We are issuing this final rule under FDA's authorities in sections 402, 419, and 701(a) of the FD&C Act (21 U.S.C. 342, 350h, and 371(a)) and sections 311, 361, and 368 of the PHS Act (42 U.S.C. 243, 264, and 271).

Section 419(a) of the FD&C Act, in relevant part, directs FDA to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables that are raw agricultural commodities for which we have determined such standards minimize the risk of serious adverse health consequences or death. Section 419(a)(3) of the FD&C Act further requires that these minimum standards provide sufficient flexibility and are appropriate to the scale and diversity of the production and harvesting of raw agricultural commodities. Section 402(a)(3) of the FD&C Act provides that a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Section 402(a)(4) of the FD&C Act provides that a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. Additionally, section 701(a) of the FD&C Act grants the authority to issue regulations for the efficient enforcement of the FD&C Act. This rule includes requirements that are necessary to prevent food from being adulterated, and a regulation that requires measures to prevent food from being held under insanitary conditions whereby either of the proscribed results may occur allows for the efficient enforcement of the FD&C Act. The amendments we are finalizing to the 2015 produce safety final rule thus allow FDA to efficiently enforce sections 402 and 419 of the FD&C Act.

In addition to the FD&C Act, FDA's legal authority for the final rule derives from sections 311, 361, and 368 of the PHS Act, which provides authority for FDA to issue regulations to prevent the spread of communicable diseases from one State to another.

Specifically, the PHS Act authorizes the Secretary of HHS to make and enforce such regulations as “are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States ... or from one State ... into any other State” (section 361(a) of the PHS Act). (See sec. 1, Reorg. Plan No. 3 of 1966 at 42 U.S.C. 202 for transfer of authority from the Surgeon General to the Secretary; see Staff Manual Guide 1410.10 at <https://www.fda.gov/about-fda/reports-manuals-forms/staff-manual-guides> for delegation from the Secretary to FDA.) The provisions in this final rule are necessary to prevent food from being contaminated with human pathogens such as *Salmonella*, *Listeria monocytogenes* (*L. monocytogenes*), and *E. coli* O157, and therefore to prevent the introduction, transmission, or spread of communicable disease from foreign countries into the United States, or from one state in the United States to another. These amendments to the 2015 produce safety final rule will help prevent the spread of communicable diseases associated with contaminated produce.

V. Comments on the Proposed Rule and FDA Response

A. Introduction

We received approximately 180 comment submissions on the proposed rule by the close of both comment periods, each containing one or more comments on one or more issues. We received submissions from diverse members of the public, including produce farms; coalitions; trade organizations; academia; consumers; consumer groups; State and foreign government agencies; and other organizations. Some submissions included statements from multiple individuals.

In the remainder of this document, we describe the comments that are within the scope of this rulemaking, respond to them, and explain the revisions we made to the proposed rule. We have grouped similar comments together under the same number, and, in some cases, we have

separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance nor the order in which comments were received.

We received no comments regarding § 112.40 (“What requirements of this subpart apply to my covered farm?”) and are finalizing that provision as proposed. We received no comments regarding conforming changes in §§ 112.12, 112.151, or 112.161(b), or amendments to §§ 112.42, 112.44, and 112.46 through 112.49 related to providing additional clarity and reorganizing subpart E in its entirety to group provisions of a similar nature. We are finalizing these amendments without changes.

We received some comments on provisions we did not propose to revise and that are outside of the scope of this rulemaking. For example, we received comments on the definition of “agricultural water” (§ 112.3); the requirements for general agricultural water quality (§ 112.41); the requirements for inspections and maintenance of agricultural water systems (§ 112.42); the requirements for harvest and post-harvest agricultural water (§ 112.44); and the requirements for agricultural water treatment (§ 112.46). We do not address out of scope comments in this document.

We also received some comments that address FDA's plans for implementation activities that are outside the scope of this rulemaking. As such, we do not address those comments in this document. We nonetheless recognize the importance of having educational materials and technical assistance and are taking efforts to ensure that guidance, training, educational resources, and the FSMA Technical Assistance Network are available to help farms as they prepare to comply with the requirements in this rule.

Note that summaries of and responses to comments on the estimated costs and benefits of the proposed rule and other topics covered by the Preliminary Regulatory Impact Analysis (PRIA) may be found in the Final Regulatory Impact Analysis (FRIA) (Ref. 26).

B. General Comments on the Proposed Rule

Many comments made general remarks supporting or opposing the proposed rule without focusing on a particular proposed provision. Among comments that were supportive of the proposed rule, some provided general feedback suggesting that additional information would help clarify the rule. Several comments focused on other topics, such as alternative options to the regulatory approach for pre-harvest agricultural water and the shift from mandated agricultural water testing in the 2015 produce safety final rule to the proposed approach for pre-harvest agricultural water assessments. In the following paragraphs, we discuss and respond to such general comments.

1. General Comments

(Comment 1) Many comments support the proposed rule, suggesting that the proposed pre-harvest agricultural water assessments are more risk-based, flexible, and holistic than the pre-harvest agricultural water testing requirements in the 2015 produce safety final rule, which commenters characterized variously as complex, prescriptive, and “one-size-fits-all.” Many comments suggest that the proposed approach better accommodates the diversity in industry, noting the variety of conditions that can exist on farms when it comes to different regions, crops, water sources, and water uses. Many of these comments suggest that the proposed requirements will help prevent foodborne illness outbreaks and lead to improved public health outcomes. Among comments supportive of the proposed approach, some suggest that additional

information on agricultural water assessments would be beneficial to further clarify the proposed requirements.

In contrast, a few comments suggest that the proposed requirements for pre-harvest agricultural water assessments are too complicated. Some of these comments suggest that quantitative metrics (such as criteria derived from testing) would be easier for farms to understand and easier for regulators to enforce than agricultural water assessments, which are more qualitative in nature. Some of these comments suggest that the requirements for agricultural water assessments will not be more effective at preventing foodborne illness than mandated pre-harvest agricultural water testing.

(Response 1) We agree with comments received that support the proposed rule, including the systems-based assessments that are grounded in our QAR (Ref. 17), incorporate recent scientific data and other information available to FDA, and are designed to ensure that farms have robust and meaningful information about the quality of their pre-harvest water for use in risk management decision making. We developed this approach to pre-harvest agricultural water by considering the public health objectives we aim to achieve through pre-harvest agricultural water measures for covered produce other than sprouts while recognizing that each farm--whether foreign or domestic--has a unique combination of agricultural water source(s), growing practices, current and previous uses of the farmland, and adjacent and nearby land uses, among other factors, that may influence the safety of its agricultural water.

The rule establishes assessment factors with sufficient specificity to provide farms robust and meaningful information on the quality of pre-harvest agricultural water, while also offering adequate flexibility to account for the diversity of operations that we are required to consider in developing the regulations under 419(a)(3)(A) of the FD&C Act.

The requirements for comprehensive, systems-based pre-harvest agricultural water assessments and appropriate corrective and mitigation measures as needed will help farms identify potential sources of contamination and effectively manage their water. Specifically, farms must use the results of assessments to determine when, within the framework for risk-based outcomes, they are required to take measures to ensure that their pre-harvest agricultural water is safe and is of adequate sanitary quality for the intended use(s). The combination of assessments and risk-tiered outcomes require farms to identify and address sources of potential hazards through implementation of effective prevention-oriented mitigation measures within specified timeframes. Under the final rule, farms will assess hazards at the beginning of the growing season and implement mitigation measures for certain hazards earlier than under the 2015 produce safety final rule, ~~which~~. Further, under the 2015 produce safety final rule, farms were required to test pre-harvest agricultural water to be tested as close in time as practicable to, but prior to harvest ~~with, and use~~ those results ~~used~~ to determine whether to implement mitigation measures without the benefit of the written systems-based evaluation of potential sources of contamination we are requiring in this final rule.

We recognize that agricultural water assessments, by their nature, will require farms to consider a broader set of factors as part of the systems-based approach we are finalizing here, compared to the microbial quality criteria and testing requirements for pre-harvest agricultural water in the 2015 produce safety final rule. In addition to providing the specific factors farms must consider in their pre-harvest agricultural water assessments in § 112.43(a), we provide additional information on the requirements for agricultural water assessments throughout the remainder of section V. We reiterate our commitment to providing farms education, outreach, and technical assistance to facilitate compliance with the rule. We intend to pursue various

mechanisms, such as publishing guidance, holding webinars, and developing other educational resources, including work with other stakeholders (such as State agencies, educators, and extension agents), to do so. See also the response to comment 29.

Further, the knowledge and experiences gained since 2015 will be helpful in supporting successful implementation of the rule, including compliance with the requirements for pre-harvest agricultural water assessments. For example, we developed the 2015 produce safety final rule after considering, in part, that at the time of rulemaking, some farms had significant expertise in the area of food safety, and other farms had minimal knowledge in the area. We also considered that the produce farming community did not have the history of regulatory interaction with FDA and the same experience with food safety regulations as did the food manufacturing industry. 78 FR 3504 at 3530.

However, we recognize that since that time, knowledge and awareness of food safety, as well as the produce farming community's experience with food safety regulations, has evolved. For example, many farms, whether for the purposes of required training in accordance with § 112.22(c) (which we did not propose to change) or for other purposes, have since received food safety training, including on topics related to potential hazards in the growing environment.

Additionally, FDA has provided investigation reports for various produce-related outbreaks that have occurred since 2015 (e.g., Refs. 18-23), many of which discuss factors potentially contributing to contamination and provide recommendations for farms to consider in light of those findings. Moreover, other provisions in the 2015 produce safety final rule for which compliance dates have passed, such as those in subpart I, "Domesticated and Wild Animals" (§§ 112.81-112.83), may provide farms with useful information when evaluating the

degree of protection of a pre-harvest agricultural water system as part of an agricultural water assessment (see response to comment 55).

For these reasons we have concluded that sufficient support exists—including through identification of specific factors that farms must consider in § 112.43(a), information provided throughout this final rule, and knowledge and experiences gained since 2015 (including lessons learned from various produce-related outbreaks)—for farms to effectively implement the requirements for agricultural water assessments and risk-tiered outcomes that we are finalizing with this rule.

With respect to comments suggesting that the requirements for pre-harvest agricultural water assessments will be difficult to enforce, we disagree. The annual assessments employ a prevention-oriented quality-systems approach to food safety regulation that FDA has long used and successfully enforced across the highly diverse food industry that FDA regulates. For example, FDA issued the juice hazard analysis and critical control point (HACCP) regulation (that is, the Hazard Analysis and Critical Control Point Systems regulation in 21 CFR part 120) and the seafood HACCP regulation (that is, the Fish and Fishery Products regulation in 21 CFR part 123) more than 20 years ago, which establish mandatory frameworks through which industry assesses hazards that are reasonably likely to occur and designs tailored controls to prevent or eliminate them or reduce them to an acceptable level. More recently, in 2015, FDA issued the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (21 CFR part 117), under which food facilities conduct a qualitative assessment to identify and evaluate known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility to determine whether there

are any hazards requiring a preventive control. These regulations all require the development of a food safety plan.

As discussed in comment 18, we have incorporated many of these principles—such as an assessment of risk and the development of a food safety plan based on that assessment—into the requirements for pre-harvest agricultural water assessments in § 112.43. For example, in § 112.43(a), we require farms to evaluate and document specific factors as part of an assessment, all of which are key determinants of contamination risks associated with pre-harvest agricultural water. Based on that evaluation, in § 112.43(c), we require farms to make written determinations on whether measures under § 112.43(d) are reasonably necessary. We further require farms to take necessary and timely action in accordance with those determinations. Thus, the requirements we are finalizing here share common principles with other FDA food safety regulations that have been enforced.

Thus, based on the specific criteria we have included in § 112.43 and our experience enforcing other ~~similar~~ regulations that rely on similar food safety principles and the approaches to operation-specific criteria in § 112.43 assessments, we have concluded we can enforce the requirements we are finalizing here. For example, the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation includes requirements for hazard identification (see 21 CFR 117.130), and FDA has enforced that regulation. Additional information on inspection, compliance, and enforcement-related information can be found on the “FDA Data Dashboard” at <https://www.fda.gov/about-fda/transparency/fda-data-dashboard>.

To the extent that comments voicing concerns with the proposed rule are suggesting that the requirements for pre-harvest agricultural water assessments are more than what is necessary

for public health purposes, we disagree. While we believe that requiring operational assessments and food safety plans that address the entirety of a farm's operations (including potential sources and routes of contamination addressed in other subparts of the 2015 produce safety final rule) would be more than a minimum standard and more than what is reasonably necessary for us to require to achieve the statutory purposes (80 FR 74354 at 74380), given the scientific support for pre-harvest agricultural water assessments; the limited scope of the assessments (i.e., the requirements only apply for pre-harvest agricultural water for non-sprout covered produce); and the knowledge and experiences gained since 2015, we continue to conclude that requiring farms to prepare a pre-harvest agricultural water assessment for non-sprout covered produce is a science-based minimum standard as described in section 419 of the FD&C Act. There is significant public health benefit in requiring farms to prepare a written assessment that considers various factors that affect the safety of their pre-harvest agricultural water and its appropriate use during pre-harvest activities for non-sprout covered produce. Such written assessments also require farms to identify the actions they will take to manage risks associated with their pre-harvest water. Further, in some instances, the written assessments will provide farms with a historical record that will allow them to more readily detect changes and react in a timely manner to protect public health.

With respect to comments suggesting that the requirements for agricultural water assessments will not be more effective at protecting public health than the 2015 pre-harvest agricultural water testing requirements, we disagree. As discussed further in response to comment 3, there are various limitations associated with testing, including that: the presence of indicators does not always signal the presence of pathogens; and the absence of detection of indicators does not guarantee that pathogens are absent (Refs. 27-30) (80 FR 74354 at 74428).

Moreover, since sampling frequency and location relative to the source of contamination are reported to affect the performance of generic *E. coli* as an indicator of fecal contamination (Refs. 31 and 32), non-detection of generic *E. coli* cannot be considered absolute confirmation that fecal contamination has not occurred; ~~and testing can~~ (80 FR 74354 at 74428). In light of these challenges, testing may inadvertently provide farms with a false sense of security as to the quality of their water, potentially resulting in farms not taking action where necessary to protect public health. Moreover, as discussed in response to comment 11, rather than relying on results of a multi-year rolling profile that might not always reflect a need for mitigation or elicit a timely reaction from farms to address potential hazards (Ref. 7), the approach we are finalizing here establishes requirements for measures that are directly responsive to the conditions identified as part of an assessment and requires that farms implement those measures within specific timeframes based on risk.

~~As also~~ noted in comment 11, our FRIA (Ref. 26) ~~estimates likely greater benefits under the requirements we are finalizing here compared to the testing approach in the 2015 produce safety final rule. Further, as our FRIA indicates (Ref. 26), that~~ the increase in costs associated with this rule compared to the 2015 pre-harvest agricultural water testing requirements is largely a result of more mitigation occurring in response to findings from pre-harvest agricultural water assessments than as a result of the previous testing requirements. ~~Because public health~~ As also discussed in the FRIA, we estimate likely greater benefits ~~arise from steps that farms take to mitigate or correct hazards, we consider the additional mitigation that will occur under this rule to be yet another benefit of~~ the requirements we are finalizing here, with more mitigation occurring in response to assessment findings than in response to the testing approach in the 2015 produce safety final rule.

(Comment 2) Some comments support the proposed requirements for pre-harvest agricultural water assessments, and further suggest that agricultural water assessments should be required for all agricultural water, including treated water, water from public water sources, water used for harvest and post-harvest activities, and for sprout irrigation water.

(Response 2) In light of these comments, we considered removing the proposed exemptions from the requirement to prepare an agricultural water assessment, including for water meeting certain requirements applicable to harvest and post-harvest agricultural water (proposed § 112.43(b)(1)); water from public water systems or supplies meeting certain requirements (proposed § 112.43(b)(2)); and agricultural water treated in accordance with § 112.46 (proposed § 112.43(b)(3)). However, we ultimately determined that eliminating the exceptions was not necessary, for the reasons described below.

Section 419 of the FD&C Act directs FDA to establish science-based minimum standards, including procedures, processes, and practices that are reasonably necessary to prevent introduction of hazards and provide reasonable assurances produce is not adulterated under section 402 of the FD&C Act. Subpart E of the 2015 produce safety final rule establishes requirements that are broadly applicable to all agricultural water--namely, the requirement in § 112.41 that all agricultural water must be safe and of adequate sanitary quality for its intended use, and the requirements in § 112.42 related to inspections and maintenance of agricultural water systems to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces and prevent the systems from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity. We consider applying these requirements to all agricultural water (including that used during pre-harvest, harvest, and post-harvest activities, ~~regardless of even~~ if

an exemption from other provisions in subpart E applies) as commensurate with the risk associated with the use of agricultural water for the growing, harvesting, packing and holding of covered produce.

With respect to comments about water from public water supplies, in the U.S., Public Water Systems are required under U.S. Environmental Protection Agency (EPA) National Primary Drinking Water Regulations (NPDWR) in 40 CFR part 141 to provide safe, clean water suitable for drinking and thus are at the lowest likelihood for pathogen contamination (Ref. 17). Similarly, public water supplies that meet the microbial requirement in § 112.44(a) are included in the exemption under proposed § 112.43(b)(2) (final § 112.45(b)(1)(ii)) to accommodate other public water supplies that are not governed by the requirements of the EPA drinking water program, but provide water of a quality that meets the microbial requirement of § 112.44(a). See also 78 FR 3504 at 3571. Given the nature of Public Water Systems and public water supplies meeting these requirements and the low likelihood of pathogen contamination of such systems, we consider it appropriate to exempt farms using such water sources as pre-harvest agricultural water for non-sprout covered produce from the requirement to prepare an agricultural water assessment under § 112.43 provided all requirements are met (including that the farm have results or certificates of compliance demonstrating that relevant requirements are met). (See § 112.45(b)(1)(ii) and by reference, § 112.44(c).) In light of the nature of these water ~~sources~~sources, we have concluded that to require farms to prepare an agricultural water assessment for such water sources would be more than a science-based minimum standard as described in section 419 of the FD&C Act. We also note that the exemption for public water systems or public water supplies meeting the requirements in § 112.45(b)(1)(ii) is consistent with the exemption from the pre-harvest agricultural water testing requirements in the 2015 produce

safety final rule as well as the exemption at § 112.44(c)(1) and (2) from the requirement to test agricultural water used for sprout irrigation and for harvest and post-harvest activities for covered produce.

In consideration of the risks associated with agricultural water uses outlined in § 112.44(a) (including harvest and post-harvest agricultural water), we have also established requirements in subpart E specific to those uses. This includes a stringent microbial quality criterion of no detectable generic *E. coli* per 100 mL of agricultural water and a prohibition on the use of untreated surface water (§ 112.44(a)). We established requirements applicable to the water uses specified in § 112.44(a) in the recognition that such water uses have high potential to serve as a vehicle of fecal contamination because if fecal contamination is present (along with the corresponding potential for pathogen presence), it is reasonably likely it could be transferred directly to covered produce through direct or indirect (via food-contact surfaces) contact with the agricultural water. See 80 FR 74354 at 74440. Moreover, we have established requirements in subpart E that are specific to agricultural water treatment. Specifically, § 112.46 establishes requirements related to treatment efficacy, delivery, and monitoring to ensure that treated agricultural water is safe and of adequate sanitary quality for its intended use and/or meets the relevant microbial quality criterion in § 112.44(a), as applicable. We also note that with respect to treated agricultural water, an exemption for water treated in accordance with § 112.46 is consistent with the exemption from the pre-harvest agricultural water testing requirements in the 2015 produce safety final rule as well as the exemption at § 112.44(c)(3) from the requirement to test agricultural water used for sprout irrigation and for harvest and post-harvest activities for covered produce.

We consider the requirements in subpart E that apply for agricultural water treatment, agricultural water used for sprout irrigation and harvest and post-harvest activities on covered produce, and public water systems and public water supplies meeting the requirements in § 112.44(c) to be reasonable and appropriate based on the risk associated with such water sources and practices. We do not consider it necessary or appropriate to require farms to prepare an agricultural water assessment for such water sources and practices, as doing so would be more than a science-based minimum standard as described in section 419 of the FD&C Act. Thus, we decline the request in the comments to broaden the provisions for agricultural water assessments in § 112.43 to apply to all agricultural water.

(Comment 3) While supportive of the general proposed approach for pre-harvest agricultural water assessments, some comments suggest that all farms should be required to test their pre-harvest agricultural water as one part of their agricultural water assessments. Several of these comments suggest that mandatory testing with assessments for all farms would help with objectivity and provide more certainty for farms and regulators. Some comments suggest that if testing is not required for all farms as part of an agricultural water assessment, farms may avoid testing water, lest the results show a need for treatment or other mitigation. Some comments suggest that farms should only be exempt from testing as part of an agricultural water assessment if they can demonstrate that testing is not necessary for public health purposes.

Conversely, some comments express support for what they consider to be a flexible approach to testing in the proposed rule, noting that they found the testing requirements in the 2015 produce safety final rule to be inflexible, expensive, cumbersome, and not risk-based. Some of these comments suggest that testing should not be required for all situations, and that mandatory testing for all farms would create unnecessary economic hardship for farms.

(Response 3) In light of these comments, we considered adding a requirement for all farms to test their pre-harvest agricultural water as one part of their agricultural water assessments. We considered the additional burden that would be imposed on farms by such a requirement and the impacts on public health that might result. For the reasons discussed below, we have concluded that a requirement for all farms to test their pre-harvest agricultural water as part of an assessment would be more than a minimum standard and more than what is reasonably necessary to prevent introduction of hazards and provide reasonable assurances produce is not adulterated under section 402 of the FD&C Act. Thus, we are retaining the requirements for agricultural water assessments and risk-tiered outcomes as proposed, including a requirement in § 112.43(c)(4) to test pre-harvest agricultural water as part of an assessment in certain circumstances.

First, a requirement for all farms to test pre-harvest agricultural water as one part of an assessment is not necessary given the nature of the potential sources of hazards for which immediate action is most critical to protect public health. For example, if a farm's agricultural water system was impacted by the presence of dead sheep in a canal or discharge of untreated sewage into a river, the outcome in § 112.43(c)(1), which requires immediate discontinuation of the relevant use(s) of the water and corrective measures prior to resuming that use, would apply, and agricultural water test results would be unlikely to provide information suggesting that those steps would not be appropriate or necessary to protect public health.

Moreover, requiring all farms to test in such circumstances could undermine public health protections by inadvertently providing farms with a false sense of security as to the quality of their water, potentially resulting in farms not taking action where necessary to protect public health. For example, throughout rulemaking for the 2015 produce safety final rule, we discussed

the role of water testing when it comes to understanding and managing water quality, including various challenges with using test results as a direct indicator of the safety agricultural water (78 FR 3504 at 3561-3563; 80 FR 74354 at 74427-74428). Of particular note, we discussed that the presence of indicators does not always signal the presence of pathogens, and the absence of detection of indicators does not guarantee that pathogens are absent (Refs. 27-30). We also discussed that since sampling frequency and location relative to the source of contamination are reported to affect the performance of generic *E. coli* as an indicator of fecal contamination (Refs. 31 and 32), non-detection cannot be considered absolute confirmation that fecal contamination has not occurred. 80 FR 74354 at 74428. We emphasized that we viewed the 2015 requirement outlining the GM and STV criteria as a water management tool for use in understanding the microbial quality of water over time and determining how to appropriately use water from that source, rather than as a direct indicator of the safety or adequacy of the sanitary quality of water for its immediate purposes. 80 FR 74354 at 74430. Further, we acknowledged that while testing water for pathogens allows for direct targeting of microorganisms in water that are a risk to public health, it can also present significant challenges, including those associated with large sample sizes, high costs, and the wide array of potential target pathogens (i.e., the presence or absence of one pathogen may not predict for the presence or absence of other pathogens). See response to comment 91 and 80 FR 74354 at 74427-74428.

Indeed, these challenges with using water test results as a direct indicator of water safety, particularly when it comes to surface water sources, have long been recognized, even before FDA initiating rulemaking to establish the 2015 produce safety final rule (see 78 FR 3504 at 3561-64 and 3567-71 and references cited therein, for example). However, despite the historical record of these challenges, comments received for the current rulemaking indicate that some

farms continue to believe that, even under the assessment framework, agricultural water test results should alone dictate the level of risk associated with a water system and whether action related to the farm's pre-harvest agricultural water is warranted (see comment 96). As such, we are concerned that--particularly in circumstances where quick action is most critical to protect public health (i.e., those situations that would lead to the outcomes in § 112.43(c)(1) or (2))--a requirement for all farms to test their water as part of an assessment would result in some farms using test results inappropriately to justify not taking action, to the detriment of public health. Further, a requirement for all farms to test pre-harvest agricultural water as part of an assessment could undermine public health protections by 1) delaying discontinuance and necessary corrective action for water that is not safe or of adequate sanitary quality for the intended use(s) (per § 112.43(c)(1)), and 2) delaying prompt implementation of mitigation measures to address conditions related to animal activity, BSAAOs, or the presence of untreated or improperly treated human waste on adjacent or nearby lands (per § 112.43(c)(2)).

Of particular note, when testing agricultural water, it can take time to develop a plan, collect samples, test the samples, and analyze the results in the context of the other information evaluated as part of an assessment--particularly when a farm is collecting samples over time to better understand the effects of certain conditions on water quality. As a result, if a farm initially identified a potential source of hazards as part of its assessment and were then to test the farm's agricultural water to better understand that condition, it could delay steps the farm takes to protect public health. This would be particularly problematic when it comes to conditions for which the outcomes in § 112.43(c)(1) and (2) are appropriate. While we considered whether to require farms to immediately discontinue the relevant use of the water until they have agricultural water test results demonstrating safety of the water, we determined that this, too,

would not be in the best interest of public health due to the challenges discussed above with using testing results as a direct indicator of the safety of the water and that doing so may result in farms inappropriately using test results to justify not implementing necessary measures.

Moreover, we emphasize that for some farms, a requirement to test their pre-harvest agricultural as one part of an assessment would impose significant burden without necessarily leading to additional public health benefits. For example, in preparing an agricultural water assessment, a farm that uses water from a pond as pre-harvest agricultural water might find that the pond is at a higher elevation than the surrounding land, and that conditions, such as large numbers of animals, are not present that would be reasonably likely to introduce known or reasonably foreseeable hazards. Depending on the circumstances, the farm might determine, along with the other factors evaluated under § 112.43(a), that the outcome in § 112.43(c)(3) is appropriate and that measures under § 112.45 are not reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces. Because test results would be unlikely to change the farm's determination in this (and similar) situations, and because the farm would not be implementing measures as a result of its assessment findings, requiring the farm to test would impose significant burden on the farm without providing added public health benefit.

In light of the concerns discussed above that a requirement for all farms to test their pre-harvest agricultural water as part of an assessment would provide farms with a false sense of security as to the quality of their pre-harvest agricultural water; delay or preclude action *where* most critical to protect public health; and impose significant burden on farms without commensurate public health benefits, we have concluded that a requirement for all farms to test their pre-harvest agricultural water as part of an assessment would be more than a minimum

standard and more than what is reasonably necessary to prevent introduction of hazards and provide reasonable assurances produce is not adulterated under section 402 of the FD&C Act.

(Comment 4) Some comments suggest that farms should be subject to different requirements depending on the risk associated with their crop, water source, or water use practices (such as the method and timing of water application). For example, several comments suggest that farms that grow certain low-risk crops or that use low-risk irrigation methods should be exempt from preparing an agricultural water assessment and/or from testing their agricultural water. Some comments suggest that farms growing low-risk crops and using low-risk water sources should be allowed to choose whether to conduct agricultural water testing, agricultural water systems inspections under § 112.42(a), or a combination of the two, while those growing higher-risk covered produce or using higher-risk water should be required to conduct both.

(Response 4) This rule, and the produce safety rule of which it is a part, acknowledges and ~~appropriately~~ differentiates requirements as appropriate based on the varying risks presented by different crops, water sources, and water use practices. For example, the requirements for agricultural water in subpart E do not apply to water that is not intended to, or not likely to, contact covered produce or food-contact surfaces because we ~~concluded~~ previously concluded that applying the requirements in subpart E to such water is more than what is reasonably necessary for us to require to achieve statutory purposes set forth in section 419 of the FD&C Act (that is, it is not reasonably necessary to apply the requirements to such water to prevent the introduction of known or reasonably foreseeable hazards into produce and to provide reasonable assurances that produce is not adulterated-). 80 FR 74254 at 74429.

However, we decline to establish differing requirements for pre-harvest agricultural water based on crop, water source, and/or agricultural water use practices alone.⁵ The QAR (Ref. 17) concluded that using crop physical characteristics alone seems to be a poor indicator of which commodities are at a greater or lesser likelihood of contamination that may lead to a foodborne illness outbreak. Rather, the specific conditions and practices associated with a produce commodity also influence the potential routes of contamination and the likelihood that a given route could lead to contamination and illness. Additionally, with respect to water sources, the QAR (Ref. 17) concluded that the microbial quality of source water is one of the key determinants in assessing the relative likelihood of contamination attributable to agricultural water. While noting that surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources, the QAR also concluded that though less likely to be contaminated than surface water, ground water continues to pose a public health risk, despite the regulation of many U.S. public wells under the Ground Water Regulation. Moreover, ground water sources (such as some wells) may contain deficiencies which, if left uncorrected, can result in hazards being introduced to the water source (Ref. 17).

While we continue to include agricultural water systems, water use practices, and crop characteristics as factors that farms must consider as part of their pre-harvest agricultural water assessments under § 112.43, we emphasize that this information must be considered in concert with the other factors of the systems-based assessment identified in § 112.43(a)(1) through (5). While we have incorporated testing agricultural water as part of a pre-harvest agricultural water

⁵ We note that because sprouts present a unique safety risk, the final 2015 produce safety final rule established sprout-specific requirements on multiple topics, including agricultural water. The agricultural water requirements for sprouts are different from the agricultural water requirements for other produce commodities (for example, sprout irrigation water is subject to the microbial criterion and testing requirements in § 112.44(a) and (b)).

assessment under § 112.43(c)(4), farms must not rely on test results alone in making decisions around the safe use of their agricultural water. Rather, results from pre-harvest agricultural water testing serve as an additional source of information for farms to consider alongside the other factors evaluated in § 112.43(a)(1) through (5) in making a determination as to whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with biological hazards associated with agricultural water. See also response to comment 83.

(Comment 5) Several comments request that FDA modify various requirements (such as the requirements for mitigation measures in § 112.45(b), and the definition of “agricultural water assessment” in § 112.3) so that farms may consider strategies or other practices already being implemented to control hazards with respect to agricultural water.

(Response 5) We agree that strategies or practices a farm is already implementing to control potential hazards may affect whether a condition is reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces. Further, farms must consider such strategies or practices in complying with various agricultural water requirements. For example, farms must consider the degree of protection of their agricultural water system under § 112.43(a)(1); this includes a situation in which a farm has a berm established that prevents runoff (which may contain hazards) from being introduced to an agricultural water system. As another example, farms must consider their agricultural water practices under § 112.43(a)(2); this includes a situation in which a farm only applies agricultural water from a certain water source to non-sprout covered produce early in the growing season. Farms must consider the relevant strategy or practice, along with the other information evaluated under § 112.43(a)(1) through (5), in determining 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. As farms must consider such strategies or practices they are currently implementing in complying with the requirements for pre-harvest agricultural water assessments, we do not consider it necessary to revise the requirements related to agricultural water to further emphasize the point.

(Comment 6) Several comments seek clarity on what is expected of farms in terms of assessing water that is outside the scope of “agricultural water.” A few comments express concern that in some of the outbreaks cited in the 2021 agricultural water proposed rule, the water used to grow the produce would not have been subject to the requirements in the proposed rule.

(Response 6) We define agricultural water in § 112.3, in part, as “water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food-contact surfaces.” If a specific use of water does not fit within the definition of agricultural water, then the requirements in subpart E, including those for pre-harvest agricultural water assessments for non-sprout covered produce, do not apply to that specific use of water. See 80 FR 74354 at 74429.

With respect to comments related to the outbreaks referenced in the 2021 agricultural water proposed rule (86 FR 69120 at 69125-69127) (Refs. 18-23), we acknowledge that a definitive source or route of contamination of the implicated produce could not always be determined. Nevertheless, findings from these outbreaks underscore the potential impacts of adjacent and nearby land uses on agricultural water, which we designed the requirements for pre-

harvest agricultural water assessments, in part, to address. See 86 FR 69120 at 69125-69127 and responses to comment 16 and comment 56.

(Comment 7) A few comments state that produce contamination can be attributed to more than agricultural water (e.g., airborne transmission or long-term persistence in soil) and request that FDA include these other methods of pathogen transmission in the proposed rule.

(Response 7) We agree that produce can become contaminated through various routes, including those other than water (Ref. 17). As such, the 2015 produce safety final rule focuses on major routes of microbial contamination--including agricultural water; biological soil amendments; domesticated and wild animals; worker health and hygiene; and equipment, buildings, and tools. This rulemaking, however, focuses specifically on certain requirements in Subpart E of that regulation relating to agricultural water.

(Comment 8) A few comments argue that the scope of the proposed rule is too narrow and FDA should include chemicals and biological toxins in the requirements for agricultural water assessments, since, the comments suggest, these agents pose a potential toxic disease risk to humans. Some comments seek clarity regarding what testing, if any, is expected for non-microbial contaminants, such as heavy metals and chemicals.

(Response 8) We disagree with suggestions to expand the scope of hazards covered by the rule. Section 419(c)(1)(A) of the FD&C Act requires that the 2015 produce safety final rule set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

This language provides FDA with discretion to determine what procedures, processes, and practices are “reasonably necessary” for the purposes identified in the statute with respect to the identified types of hazards.

As discussed in the 2015 produce safety final rule, FDA carefully considered different types of hazards and determined that the available data and information clearly establish that human pathogens constitute a biological hazard with the potential to cause serious adverse health consequences or death and result in the vast majority of foodborne illness known to be associated with produce consumption. On that basis we concluded that it was appropriate to establish the 2015 produce safety final rule to cover biological hazards and science-based standards necessary to minimize the risk of serious adverse health consequences or death associated with biological hazards (80 FR 74354 at 74377). Foodborne illness attribution data reported by the Interagency Food Safety Analytics Collaboration (IFSAC) (Refs. 33-35), a tri-agency group created by the Centers for Disease Control and Prevention (CDC), FDA, and U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service, reinforce the significance of biological hazards in produce. See also comment 13.

As further explained in the 2015 final rule, although the potential exists for physical or chemical (including radiological) hazards to contaminate produce, our analysis led us to conclude that non-biological hazards associated with produce rarely pose a risk of serious adverse health consequences or death for individuals that would consume the product. Chemical and physical hazards in produce: (1) occur only rarely at levels that can pose a risk of serious adverse health consequences or death (e.g., radiological contamination as a result of a nuclear power plant accident); (2) occur with greater frequency, but rarely at levels that can pose a risk of serious adverse health consequences or death (e.g., pesticide or mycotoxin residues); or (3) occur infrequently and usually do not pose a risk of serious adverse health consequences or death (e.g., physical hazards). Moreover, there are other programs in place for monitoring and/or controlling physical and chemical hazards that may contaminate produce. These programs include FDA's routine monitoring of chemical and pesticide residues, other FDA efforts (such as Closer to Zero to address environmental contaminants in food⁶), EPA's registration of pesticides, and various State and industry initiatives. In light of the severity and frequency of occurrence of these hazards in produce, and the existing regulatory structures that apply to these hazards, we concluded that it was not reasonably necessary to establish controls for physical or chemical hazards in the 2015 produce safety final rule. See 80 FR 74354 at 74376-74379.

We note that comments on the 2021 agricultural water proposed rule did not include data or other information demonstrating a need to expand the scope of the pre-harvest agricultural water requirements for covered produce other than sprouts to include chemical and

⁶ See "Closer to Zero: Reducing Childhood Exposure to Contaminants from Foods" at <https://www.fda.gov/food/environmental-contaminants-food/closer-zero-reducing-childhood-exposure-contaminants-foods>

physical hazards, nor is FDA aware of any such data or information. Therefore, we conclude that expanding the scope of the pre-harvest agricultural water requirements for covered produce other than sprouts is not reasonably necessary.

(Comment 9) Some comments seek clarity on which requirements of Subpart E the proposed rule supersedes or replaces.

(Response 9) As finalized with this rule, we are reorganizing subpart E in its entirety to group similar requirements. We note in particular that with this final rule, we are replacing §§ 112.44(b) and 112.46(b) in the 2015 produce safety final rule (microbial criteria and testing requirements, respectively, for pre-harvest agricultural water for covered produce other than sprouts) with requirements for written pre-harvest agricultural water assessments. While the requirement numbers may have changed for agricultural water used for sprouts; agricultural water used during harvesting, packing, and holding activities; and for treatment of agricultural water, this final rule does not substantively alter those standards as established in part 112, subpart E.

Table 3 summarizes the major changes made to the agricultural water provisions in subpart E between the 2015 produce safety final rule and this final rule, including the location of the relevant requirements. The second column does not reflect technical edits made to provisions that were designed to provide added clarity (for example, edits to add descriptive headings). While not reflected in the table below, conforming changes are also being made to §§ 112.12, 112.151, and 112.161(b) in light of our revisions to the microbial water quality criteria in § 112.44(b), the microbial die-off (calculated log reduction) rate in § 112.45(b), and the testing requirements in § 112.46(b) as set forth in the 2015 produce safety final rule. As discussed in

sections V.A., we received no comments on these conforming changes and are finalizing them without changes.

Table 3.--Summary of Changes Made to Subpart E Requirements Since the 2015 Produce Safety Final Rule

Subpart E Provisions in the 2015 Produce Safety Final Rule	Changes Made with this Final Rule	Location of Relevant Provision as Established with this Final Rule
§ 112.41: All agricultural water must be safe and of adequate sanitary quality for its intended use	None	§ 112.41
§ 112.42: Regularly inspect and maintain all agricultural water systems and implement measures to reduce potential for contact between covered produce and pooled water	None	§ 112.42
§ 112.43: If treating agricultural water, ensure that the treatment is effective and that treatment is delivered and monitored appropriately	None	§ 112.46
§ 112.44(a): Ensure that water used for certain purposes (for example, for sprouts and for harvest and post-harvest uses) contains no detectable generic <i>E. coli</i> per 100 mL and not use untreated surface water for such purposes	None	§ 112.44(a)
§ 112.44(b): Ensure that water used during pre-harvest activities for covered produce (other than sprouts) meets a GM of 126 generic <i>E. coli</i> per 100 mL and a STV of 410 generic <i>E. coli</i> per 100 mL	Replaced with provisions for pre-harvest agricultural water assessments and risk management determinations, with a requirement to test in certain circumstances	§ 112.43
§ 112.45(a): Immediately discontinue use (and take corrective measures prior to resuming use) if water is not safe or is not of adequate sanitary quality or if the microbial criterion of no detectable generic <i>E. coli</i> per 100 mL is not met for certain uses of water	None	§ 112.45(a)

<p>§ 112.45(b): Implement risk-reduction measures as soon as practicable but no later than the following year if the GM and STV microbial criteria in § 112.44(b) are not met for pre-harvest water uses for non-sprout covered produce</p>	<p>Removed pre-harvest microbial criteria and revised to account for pre-harvest agricultural water assessments; expanded measures to include the flexibility to change the water application method to reduce the likelihood of contamination of covered produce or to use an alternative mitigation measure; added expedited timing for mitigation related to certain uses of adjacent and nearby lands</p>	<p>§ 112.45(b)</p>
<p>§ 112.46(a): There is no requirement to test if farms can demonstrate that water: comes from a Public Water System that meets Safe Drinking Water Act regulations; comes from a public water supply that meets the microbial criterion in § 112.44(a); or is treated in accordance with § 112.43</p>	<p>Added similar exemptions from the requirements for a written pre-harvest agricultural water assessment</p>	<p>§ 112.44(c) for exemptions from testing water for uses specified in § 112.44(a); § 112.43(b) for exemptions from requirements for pre-harvest agricultural water assessments</p>
<p>§ 112.46(b): For untreated surface water sources used for pre-harvest applications for non-sprout covered produce, establish an initial MWQP with ≥ 20 samples collected over 2-4 years and update with ≥ 5 samples per year thereafter; for untreated ground water sources, establish an initial MWQP with ≥ 4 samples collected over 1 year and update with ≥ 1 sample per year thereafter</p>	<p>Replaced with provisions for pre-harvest agricultural water assessments, with a requirement to test in certain circumstances</p>	<p>§ 112.43</p>
<p>§ 112.46(c): For untreated ground water used for certain uses in § 112.44(a), initially test ≥ 4 samples over the course of 1 year and ≥ 1 sample per year thereafter</p>	<p>None</p>	<p>§ 112.44(b)</p>
<p>§ 112.47: Ensure that testing is done by the farm or other entity or third-party acting on its behalf, and that water samples be aseptically collected and tested using a method set forth in § 112.151</p>	<p>None</p>	<p>§ 112.47</p>
<p>§ 112.48: For water used during harvest, packing, and holding activities, ensure that: water is managed as necessary (such as by establishing and following water change schedules); water is visually monitored for buildup of organic material; and an appropriate temperature differential between the commodity and the water is maintained and monitored</p>	<p>None</p>	<p>§ 112.44(d)</p>
<p>§ 112.49: For pre-harvest water for non-sprout covered produce, farms may establish alternative microbial criteria, sampling frequencies for untreated surface water sources, or die-off rates between last direct water application and harvest so long as certain requirements are met</p>	<p>Replaced with provision allowing for alternative mitigation measures to those listed in § 112.45(b)(1)(i) through (v)</p>	<p>§ 112.45(b)(1)(vi)</p>

§ 112.50: Maintain certain records related to the farm's agricultural water, including test results	Added recordkeeping requirements related to pre-harvest agricultural water assessments; conforming changes to remove records related to microbial criteria and testing for pre-harvest agricultural water	§ 112.50
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2. Scientific and Public Health Support

(Comment 10) Some comments express concern that FDA lacks scientific support for the proposed rule. Of these, some comments raise general concerns about the state of the science on pre-harvest agricultural water quality as a basis for rulemaking. Other comments focus on the science relating to specific requirements, such as the assessment of crop characteristics, environmental conditions, and potential impacts of cattle operations on adjacent and nearby land, as well as the application of a pre-harvest time interval as a mitigation measure. These include comments focused on how farms will implement the rule with an emphasis on the need for scientific research reflecting real-world conditions for farms in various circumstances.

(Response 10) We disagree with the suggestion that the requirements for pre-harvest agricultural water assessments and risk-tiered outcomes lack scientific support. We address comments on the scientific support for specific provisions in relevant sections of this document. See, for example, comment 16 for discussion of comments the scientific evidence on potential risks posed by cattle operations and other animal activities on adjacent and nearby lands. We address comments on the scientific support for crop characteristics and environmental conditions as assessment factors in comment 63 and comment 68, respectively. Comment 114 discusses comments on the scientific basis for the 4-day pre-harvest time interval as a mitigation measure.

FDA outlined the history of contamination associated with produce, predominantly during growing, harvesting, packing, and holding, during the rulemaking to establish the 2015

produce safety final rule in part 112. See, for example, 78 FR 3504 at 3507 and 80 FR 74354 at 74731. As part of that rulemaking, we also developed a peer-reviewed QAR, which provides a scientific evaluation of the potential adverse health effects resulting from human exposure to microbiological hazards in produce, including from contaminated water used in growing, harvesting, packing, and holding activities (Ref. 17). With respect to water used during growing, harvesting, and post-harvesting activities, the QAR concludes in part that agricultural water can be a source of contamination of produce and that the microbial quality of source waters, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices. The QAR also concludes that while different commodities may have different risk profiles at different stages of production, all commodities have the potential to become contaminated through one or more of the routes identified, especially if practices are poor and/or conditions are insanitary. See also 86 FR 69120 at 69128.

Scientific information has also become available since FDA issued the 2015 produce safety final rule indicating potential limitations in basing risk management decisions on the previous pre-harvest agricultural water testing requirements. For example, various studies indicate a high degree of variability in generic *E. coli* levels in surface waters (Refs. 5-10), which can reduce the precision of estimation of the GM and STV of a water source (Refs. 1, 7). Additionally, a scientific evaluation of the 2015 pre-harvest agricultural water testing requirements found that the rolling data set of five samples per year used to update GM and STV values for untreated surface water sources results in highly uncertain results and delays in detecting shifts in water quality (Ref. 7). Specifically, Havelaar et al. found that the 20-sample MWQP for untreated surface water was not sufficient to reliably characterize the quality of the

irrigation water with higher variability in generic *E. coli* levels than assumed in the 2015 produce safety final rule. In simulation modeling, the rolling 20-sample MWQP responded “very slowly” to shifts in water quality. Increases in generic *E. coli* levels were detected only after one to six sample sets, thus delaying signals of changes in water quality and (and any needed measures) by one to six years depending on the nature and magnitude of the shift. Havelaar et al. suggested that additional understanding of the processes that drive variability in the quality of irrigation water sources might inform preventive or rapid corrective actions that have a larger impact on produce safety than the 2015 pre-harvest agricultural water requirements.

Moreover, we have extensively discussed other information that has become available since 2015, such as findings from several produce-related outbreak investigations, that support this rulemaking. In particular, in the 2021 agricultural water proposed rule, we discussed: (1) the spring 2018 *E. coli* O157:H7 outbreak linked to romaine lettuce from the Yuma growing region (Refs. 18 and 19); (2) the fall 2018 *E. coli* O157:H7 outbreak linked to romaine lettuce from California (Ref. 20); (3) the fall 2019 *E. coli* O157:H7 outbreaks linked to romaine lettuce (Ref. 21); (4) the fall 2020 *E. coli* O157:H7 outbreak linked to leafy greens (Ref. 22); and (5) the summer 2020 *Salmonella* Newport outbreak linked to red onions (Ref. 23); that highlight the importance of pre-harvest agricultural water quality and the potential impacts of adjacent and nearby land uses on agricultural water. These outbreak investigations underscore decades of scientific research demonstrating that pre-harvest agricultural water is a potential contributing factor in the introduction and spread of contamination to produce. 86 FR 69120 at 69125-69127. We also discussed foodborne illness attribution data reported by IFSAC (Ref. 33), a triagency group created by the CDC, FDA, and the USDA Food Safety and Inspection Service, that

reinforce the significance of biological hazards in produce. 86 FR 69120 at 69127. See also comment 13.

Comments did not indicate what data or information they considered to be lacking or provide information that alters FDA's conclusions made in light of the information referenced above. As such, we have concluded ~~there is adequate~~that the scientific information available ~~to~~supports this rulemaking and are finalizing the requirements for pre-harvest agricultural water assessments for non-sprout covered produce. However, we recognize that additional information on the requirements for agricultural water in subpart E will help support farms as they work to come into compliance. We provide information on the agricultural water requirements throughout this final rule, and, to the extent that certain requirements are not substantively changing with this rulemaking (such as the requirements in § 112.42 for agricultural water system inspection and maintenance), in the preamble to the 2015 produce safety final rule. Additionally, we recognize the need to provide farms with education, outreach and technical assistance to facilitate compliance with the rule, and we intend to pursue various mechanisms, such as publishing guidance, holding webinars, and developing other educational resources, including work with other stakeholders (such as State agencies, educators, and extension agents), to do so.

(Comment 11) Some comments express concern that FDA changed the pre-harvest microbial quality and testing requirements in the 2015 produce safety final rule in response to industry concerns, rather than in an effort to improve public health.

(Response 11) We are issuing this final rule having determined that it will enhance public health protections by setting forth requirements for comprehensive, systems-based agricultural water assessments evaluating a broad range of factors that may impact the quality of pre-harvest

agricultural water to assist farms in identifying and managing risks using appropriate corrective and mitigation measures, including expedited mitigation in certain circumstances. As discussed in the proposed rule, this comment response, and elsewhere in this rule, these revisions to the 2015 produce safety final rule reflect findings of our QAR (Ref. 17), new information we have gathered since publication of the 2015 produce safety final rule (including findings from several produce-related outbreaks), as well as information and feedback from an array of stakeholders, including the produce industry, educators, researchers, and regulators. As discussed in response to comment 1, we continue to conclude that the requirements for systems-based agricultural water assessments and risk-management determinations are consistent with our mandate to establish science-based minimum standards for the safe production and harvesting of produce to minimize the risk of serious adverse health consequences or death. As such, we disagree with comments suggesting that we are making these revisions to the 2015 produce safety final rule in response to industry concerns alone, and not in an effort to improve public health.

As part of rulemaking for the 2015 produce safety final rule, we developed a peer-reviewed QAR (Ref. 17), which provides a scientific evaluation of the potential adverse health effects resulting from human exposure to microbiological hazards in produce, including from contaminated water used in growing, harvesting, packing, and holding activities (Ref. 17). In part, the QAR discusses that public drinking water is generally considered the least likely to serve as a source of contamination, followed by ground water, surface water protected from runoff, and surface water unprotected from runoff. The QAR also notes that where contamination in a water source is known to exist, the likelihood of contamination is a function of contact with the commodity (example, whether contact is indirect or direct); commodity effects (characteristics) (for example, whether the surface is conducive to adhesion); and

application timing (for example, early or late in crop growth). These factors—the water source, method and timing of water application, and commodity characteristics—are all reflected in the requirements for comprehensive agricultural water assessments under § 112.43(a) due to the impact they can have on risk associated with pre-harvest agricultural water use.

Further, findings from investigations of several outbreaks linked to consumption of produce that have occurred since 2015 (Refs. 18-23) highlight the importance of pre-harvest agricultural water quality and the potential impacts of adjacent and nearby land uses on agricultural water. These outbreak investigations underscore decades of scientific research demonstrating that pre-harvest agricultural water is a potential contributing factor in the introduction and spread of contamination to produce. 86 FR 69120 at 69125-69127. Findings from our investigations into these outbreaks also informed the requirements that we are finalizing here—in particular, the requirement in § 112.43(c)(2) for expedited mitigation for conditions related to animal activity, BSAAOs, and untreated or partially treated human waste associated with adjacent and nearby lands.

With respect to feedback from stakeholders in the regulated community, as described further in response to comment 14, we designed the requirements for pre-harvest agricultural water assessments, in part, by taking into account the realities of many agricultural operations that resulted in the 2015 pre-harvest agricultural water testing requirements being challenging, and in some cases, impossible, for farms to implement. For example, while the long-term MWQPs required in the 2015 produce safety final rule can be difficult, and even impossible, to establish for farms that grow rotational crops or on leased land, we have incorporated flexibility in the requirements for the once-annual assessments we are finalizing with this rule to allow farms to account for these realities, which will assist farms in better evaluating and making

decisions regarding the use of pre-harvest agricultural water as appropriate to their unique operations and circumstances.

However, we emphasize that this rule is reflective of information and insights from stakeholders beyond just the regulated industry. For example, the pre-harvest agricultural water requirements were the focus of a 2-day Agricultural Water Summit, convened by the Produce Safety Alliance, in February 2018 (Ref. 4). The summit was attended by academics, produce industry, growers/grower associations, State agencies, Federal agencies, and supporting industries. During the summit, participants had many questions and concerns about water testing, what the information tells them about risks, and how to use that information to make water use management decisions. Participants also had questions about the generic *E. coli*-based standards in the 2015 produce safety final rule and suggested that the testing frequency required to establish a MWQP for surface or ground water sources lacked the necessary science to support its relevance to public health outcomes. Many of the discussions at the summit addressed hazards in the growing environment, including examples of how risk assessment has been conducted in other fields of study, such as for drinking water and wastewater management. During the summit, participants identified “agricultural water assessments” as a promising approach for managing water quality, suggesting that assessments may provide a more effective risk management strategy to farms than a numerical testing standard can provide.

Additionally, information has become available since issuing the 2015 produce safety final rule indicating potential limitations in basing risk management decisions on the previous pre-harvest agricultural water testing requirements. For example, various studies indicate a high degree of variability in generic *E. coli* levels in surface waters (Refs. 5-10), which can reduce the precision of estimation of the GM and STV of a water source (Refs. 1, 7). Other studies have

further contributed to our knowledge about the limitations of generic *E. coli* as an indicator for pathogen presence (Refs. 11-16). Further, a scientific evaluation of the 2015 pre-harvest agricultural water testing requirements found that the rolling data set of five samples per year used to update GM and STV values for untreated surface water sources results in highly uncertain results and delays in detecting shifts in water quality (Ref. 7). Havelaar et al. suggested that while increasing the number of samples might address these issues, doing so would increase costs and would not be an effective or efficient way to control the microbial quality of agricultural water sources. Rather, they suggested, additional understanding of the processes that drive variability in the quality of irrigation water sources might inform preventive or rapid corrective actions that have a larger impact on produce safety than the 2015 pre-harvest agricultural water requirements (Ref. 7).

While we established the 2015 pre-harvest agricultural water testing requirements as a long-term strategy to ensure that farms understand the quality of their water, pay attention to changes that may affect water quality, and make appropriate decisions about use of that water (80 FR 74354 at 74458), we recognize that if farms focus too heavily on results of microbial testing and whether quantitative metrics are met, they may be left with a false sense of security as to the quality of their water, and as a result, not investigate for conditions that may warrant further action to protect public health. Indeed, rather than relying on results of a multi-year rolling profile that might not always reflect a need for mitigation or elicit a timely reaction from farms to address potential hazards (Ref. 7), the approach we are finalizing here establishes requirements for measures that are directly responsive to the conditions identified as part of an assessment and requires that farms implement those measures within specific timeframes based on risk. Further, as our FRIA indicates (Ref. 26), the increase in costs associated with this rule

compared to the 2015 pre-harvest agricultural water testing requirements is largely a result of more mitigation occurring in response to findings from pre-harvest agricultural water assessments than as a result of the previous testing requirements. ~~Because public health~~As also discussed in the FRIA, we estimate likely greater benefits ~~arise from steps that farms take to mitigate or correct hazards, we consider the additional mitigation that will occur~~ under this rule ~~to be yet another benefit of~~ the requirements we are finalizing here, with more mitigation occurring in response to assessment findings than in response to the testing approach in the 2015 produce safety final rule.

In light of the foregoing, we disagree with comments suggesting that we are replacing the previous pre-harvest agricultural water testing requirements with requirements for agricultural water assessments and risk-management determinations in response to industry concerns alone, and not in an effort to improve public health. We continue to consider it appropriate to pursue an alternative approach to the 2015 pre-harvest agricultural water testing requirements that protects public health and is adaptable for use in diverse circumstances. As such, with this rule, we are replacing the pre-harvest agricultural water testing requirements in the 2015 produce safety rule for covered produce other than sprouts with requirements for systems-based agricultural water assessments that are designed to achieve improved public health protections, while also being more feasible to implement across the wide variety of agricultural water systems, uses, and practices, and adaptable to future advancements in agricultural water quality science.

3. Options for Regulatory Approach

(Comment 12) A few comments suggest that issuing guidance would be a more appropriate approach to addressing pre-harvest agricultural water than rulemaking.

(Response 12) As discussed in the 2021 agricultural water proposed rule, FDA considered various options to address stakeholder concerns about complexity and practical implementation challenges with the pre-harvest agricultural water testing requirements in the 2015 produce safety final rule, one of which entailed developing additional guidance to support the requirements that were outlined in the 2015 produce safety final rule. We concluded that issuing additional guidance alone would not adequately address the practical implementation issues associated with the pre-harvest agricultural testing requirements in the 2015 produce safety final rule. For example, we contemplated issuing additional guidance to describe circumstances in which farms might satisfy the pre-harvest sampling and testing requirements through shared data with other farms. However, there are several limitations with this option, including challenges related to establishing data-sharing arrangements and difficulties in establishing such programs given the diversity of agricultural water systems and the 2015 requirements related to sample collection timing. Moreover, guidance alone could not overcome difficulties related to rotational crops or growing non-sprout covered produce on leased land, in which a farm may not be using (or have access to) the same water source over multiple years. See also response to comment 14. Further, while subpart P of the 2015 produce safety final rule allows requests for variances from one or more requirements of part 112, under § 112.171, only States, Federally recognized tribes, or countries from which food is imported into the United States are able to make such a request. See 86 FR 69120 at 69129.

Comments received on the 2021 agricultural water proposed rule do not provide new information on overcoming these practical implementation challenges through the issuance of guidance alone. As such, we have concluded that guidance alone would not adequately address

the practical implementation issues associated with the pre-harvest agricultural testing requirements in the 2015 produce safety final rule.

(Comment 13) Some comments state that FDA did not directly address why the option to conduct a risk assessment and research followed by rulemaking was not chosen, suggesting that the Agency moved forward with the proposed rule despite lacking sufficient information.

(Response 13) As discussed in the 2021 agricultural water proposed rule, FDA considered whether to conduct another risk assessment, followed by a rulemaking to revise the pre-harvest agricultural water testing requirements. We also considered whether to issue guidance on pre-harvest agricultural water based on industry standards while additional research is conducted, followed by rulemaking to revise the pre-harvest agricultural water testing requirements. For the reasons discussed below, we continue to conclude that it is not necessary for additional risk assessment or research to take place before conducting or finalizing this rulemaking.

As part of the rulemaking to establish the 2015 produce safety final rule in part 112, we developed a peer-reviewed QAR, which provides a scientific evaluation of the potential adverse health effects resulting from human exposure to microbiological hazards in produce, including from contaminated water used in growing, harvesting, packing, and holding activities (Ref. 17). In considering the option to conduct a risk assessment or additional research followed by a rulemaking to revise the pre-harvest agricultural water testing requirements, FDA reviewed the conclusions of the QAR. With respect to water used during growing, harvesting, and post-harvesting activities, the QAR concludes as follows:

- Agricultural water can be a source of contamination of produce.

- Public drinking water systems (domestically regulated by the EPA) have the lowest relative likelihood of contamination due to existing standards and routine analytical testing.
- Though less likely to be contaminated than surface water, ground water continues to pose a public health risk, despite the regulation of many U.S. public wells under the Ground Water Regulation.
- There is a significant likelihood that U.S. surface waters will contain human pathogens, and surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources.
- Susceptibility to runoff significantly increases the variability of surface water quality.
- Water that is applied directly to the harvestable portion of the plant is more likely to contaminate produce than water applied by indirect methods that are not intended to, or not likely to, contact produce.
- Proximity of the harvestable portion of produce to water is a factor in the likelihood of contamination during indirect application.
- Timing of water application in produce production before consumption is an important factor in determining likelihood of contamination.
- Commodity type (growth characteristics, e.g., near to ground) and surface properties (e.g., porosity) affect the probability and degree of contamination.
- Microbial quality of source waters, method of application, and timing of application are key determinants in assessing relative likelihood of contamination attributable to agricultural water use practices.

The QAR (Ref. 17) discusses that potential contributing factors cited in produce-associated outbreaks where water was identified as the likely source of contamination include runoff from nearby animal pastures and feed lots, raw sewage, and surface waters contaminated with feces (Ref. 36).

We have also considered scientific information that has become available since issuing the 2015 produce safety final rule indicating potential limitations in basing risk management decisions on the previous pre-harvest agricultural water testing requirements. For example, various studies indicate a high degree of variability in generic *E. coli* levels in surface waters (Refs. 5-10), which can reduce the precision of estimation of the GM and STV of a water source (Refs. 1, 7). Other studies have contributed to our knowledge about the limitations of generic *E. coli* as an indicator for pathogen presence (Refs. 11-16). Further, a scientific evaluation of the 2015 pre-harvest agricultural water testing requirements found that the rolling data set of five samples per year used to update GM and STV values for untreated surface water sources results in highly uncertain results and delays in detecting shifts in water quality (Ref. 7). Havelaar et al. suggested that additional understanding of the processes that drive variability in the quality of irrigation water sources might inform preventive or rapid corrective actions that have a larger impact on produce safety than the 2015 pre-harvest agricultural water requirements.

In addition to the findings from the QAR and scientific information on the previous pre-harvest agricultural water testing requirements that has become available since 2015, we considered conclusions from the 2019 IFSAC report (Ref. 33), and more recently, the 2020 and 2021 IFSAC report (Refs. 34 and 35, respectively), which reinforce the significance of biological hazards in produce. We also considered FDA's experience with investigations of produce-related outbreaks that occurred since we issued the 2015 produce safety final rule (Refs. 18-23), which

underscore the importance of pre-harvest agricultural water quality and highlight the potential impacts of adjacent and nearby land uses on agricultural water, which can serve as a route of contamination of produce. 86 FR 69120 at 69125-69127. These sources of information helped to inform the requirements we are finalizing here--in particular, the requirement for expedited mitigation for known or reasonably foreseeable hazards related to certain activities associated with adjacent or nearby lands in light of findings from several produce outbreak investigations--and further support the conclusions of our QAR (Ref. 17). See also response to comment 10.

Commenters did not indicate what data or information they felt was lacking regarding the option to conduct an additional risk assessment, nor did they provide information demonstrating that our conclusions in the proposed rule regarding that option were inappropriate. Therefore, we continue to conclude that it is not necessary for FDA to conduct an additional risk assessment or research before conducting rulemaking to establish new pre-harvest agricultural water standards. Further, given that the requirements for assessments are well-grounded in science, we do not consider it necessary to establish interim guidance based on industry standards in lieu of the requirements we are finalizing here.

While we do not consider it necessary to conduct additional risk assessment or research in order to establish standards for pre-harvest agricultural water, we note that the requirements for agricultural water assessments are designed, in part, to be adaptable to scientific advancements. To the extent that risk assessment and/or additional research related to pre-harvest agricultural water may continue to develop in the future, farms may use such information as an additional resource to further inform their agricultural water assessments under the approach we are finalizing here.

(Comment 14) A few comments express a preference for pre-harvest agricultural water testing requirements in the 2015 produce safety final rule compared to the proposed pre-harvest agricultural water assessments because, the comments suggest, many farms have already worked towards compliance with the 2015 testing requirements.

(Response 14) We understand that not all farms may have faced challenges with the pre-harvest microbial quality and testing requirements in the 2015 produce safety final rule. However, in light of frequent, consistent feedback from industry stakeholders regarding challenges associated with the pre-harvest microbial quality and testing requirements, as well as information and insights from other relevant stakeholders (such as academic researchers), findings of our QAR (Ref. 17), and new information gathered since publication of the 2015 produce safety final rule, we concluded that the most appropriate regulatory approach is to undertake rulemaking. See 86 FR 69120 at 69129-69130. As discussed further in response to comment 10, we continue to consider it appropriate to pursue and finalize an alternative approach that is adaptable for use in diverse circumstances. Thus, we are finalizing requirements for pre-harvest agricultural water assessments that are designed to achieve improved public health protections, while also being more feasible to implement across the wide variety of agricultural water systems, uses, and practices, and adaptable to future advancements in agricultural water quality science. We designed the requirements for pre-harvest agricultural water assessments to be flexible to account for the diversity of water systems, commodities, and operations that exist across industry, which included, as discussed below, taking into account the realities of many agricultural operations that resulted in the 2015 pre-harvest agricultural water testing requirements being challenging, and in some cases, impossible, for farms to implement.

For example, feedback on the 2015 pre-harvest agricultural water testing requirements indicated that long-term MWQPs can be difficult, and even impossible, to establish for farms that grow rotational crops or on leased land, both of which are widespread throughout the produce industry (Refs. 3 and 4). It has further been suggested that the financial investment needed to develop a long-term profile for a water source that is only used every few years may not result in commensurate food safety benefits (Ref. 4). Conversely, the requirements for once-annual assessments that we are finalizing here incorporate flexibility to allow farms to account for these realities. Such flexibility will assist farms in better evaluating and making decisions regarding the use of pre-harvest agricultural water as appropriate to their unique operations and circumstances, allowing risk-management decisions to be made even in the absence of historical knowledge of a water system. See also comment 35.

Farms with multiple water sources, for example, would face significant logistical challenges in complying with the 2015 testing requirements, since separate MWQPs would be required for each source (Ref. 4). These challenges would be particularly difficult to navigate for farms that grow multiple types of covered produce using different water application timings, given the 2015 requirements for samples to be representative of use and collected as close in time as practicable to, but prior to, harvest. As discussed further in response to comment 34, while we acknowledge that farms using multiple agricultural water systems during pre-harvest activities for covered produce (other than sprouts) will need to conduct an assessment for each system, several of the factors evaluated in the assessment might be similar across agricultural water systems, thus limiting the amount of information a farm needs to collect and consider. Further, the pre-harvest agricultural water assessments enable farms to focus on the key

determinants of contamination risks, without doing so in a way that will add significant burden to stakeholders.

Additionally, while data-sharing is one way that implementation challenges associated with 2015 pre-harvest agricultural water testing requirements may have been reduced, such data-sharing programs among multiple parties could be difficult (or impossible) to establish due to the aforementioned 2015 requirements for samples to be representative of use and collected close to harvest (Refs. 3 and 4). Conversely, the requirements for pre-harvest agricultural water assessments were built to be flexible enough for farms to consider and adjust for their unique circumstances without having to rely on others' actions in order to make use of the inherent flexibility. Moreover, because farms that test their water in accordance with § 112.43(c)(4)(ii) will be testing to better understand a narrow set of circumstances using an approach that incorporates greater flexibility related to sample collection requirements, concerns about testing burden associated with the 2015 pre-harvest agricultural water testing requirements are largely addressed with this rule.

Thus, although we recognize that some farms may not have faced practical implementation challenges with the 2015 pre-harvest agricultural water testing requirements, we continue to conclude that the requirements for pre-harvest agricultural water assessments achieve public health protections, while also being more feasible to implement across the diversity of farms and their agricultural water systems, uses, and practices. To the extent that some farms may be testing their pre-harvest agricultural water using the 2015 (or other) approach, we emphasize that nothing in this rule precludes them from continuing to do so, as long as they also comply with the requirements we are finalizing here, as applicable.

4. Responsibility

(Comment 15) ~~While~~Some comments, while generally supportive of the proposed pre-harvest agricultural water assessments, ~~some comments suggest~~voice concern that farms ~~should~~not will be required to account for and manage hazards that are outside the farm's control (for example, hazards that may be introduced by other water users or adjacent and nearby land uses). Some comments indicate that the Clean Water Act (CWA) requires State and/or Federal governments to hold polluters accountable, suggesting that it is therefore unjust to place that responsibility on farms. One comment suggests that irrigation districts should not allow livestock to graze in open drains, as doing so will introduce risk for downstream users who do not have control over that activity.

(Response 15) We recognize that farms may have little or no control over factors such as weather events, other water users, and adjacent and nearby lands. However, considering factors such as these, which may affect the quality of water source(s) even though they are not necessarily under a farm's control, is an important part of evaluating whether a farm's water source(s) meets the requirement in § 112.41 that agricultural water must be safe and of adequate sanitary quality for its intended use. Considering these factors under § 112.43(a), will help farms determine the appropriate and safe use of the agricultural water from their water source(s).

Further, we recognize that the CWA (33 U.S.C. 1251 et seq.) establishes the basic structure for regulating discharges of pollutants into the waters of the United States and regulating quality standards for surface waters (Ref. 37). Under the CWA, the EPA has implemented pollution control programs and developed national water quality criteria recommendations for pollutants in surface waters. We recognize that hazards may be introduced into an agricultural water system under conditions that may or may not be covered by the CWA and that in many instances, this may occur before an agricultural water system comes under a

farm's control. We emphasize that farms are not required to mitigate such hazards at the location where they originate, nor are farms expected to take action against other entities that may be introducing contaminants into a water system. Rather, farms are required to assess potential impacts from activities on nearby and adjacent lands and/or other water users on the quality of their agricultural water and, as appropriate, implement measures that are under the farm's control to reduce the risk associated with that water source or system to protect public health. For example, depending on the circumstances, this might entail the use of earthen berms on land that is under the farm's control to divert runoff from a nearby land use from entering the farm's surface water source. See also response to comment 105.

Additionally, we recognize the need to provide farms with outreach and education to facilitate compliance with the rule, including in those situations where hazards may originate outside of a farm's control. We are also aware of efforts underway to bring together members of agricultural communities on a large scale to further conversations and encourage discussions between land users in agricultural areas. For example, the California Agricultural Neighbors (CAN) Initiative is designed to provide an opportunity to foster collaboration and discuss enhanced neighborly food safety practices when various agricultural operations such as leafy green fields, cattle ranches, vineyards and compost sites are adjacent to one another (Ref. 38). Various action items have been identified as part of CAN, one of which entails steps that can be taken to foster neighbor-to-neighbor interactions and conversations (Ref. 39). See also response to comment 33. As efforts such as these progress, farms may consider participating as an additional means to help address crosscutting food safety issues.

(Comment 16) Some comments suggest that cattle producers will be negatively impacted by the requirement that farms assess the use of nearby and adjacent land. These comments

suggest that the proposed rule implies that adjacent or nearby cattle operations increase food safety risks for produce farms without sufficient scientific justification. Comments also request clarification that cattle operations are not required to change practices in order to assist produce farms in complying with the rule.

(Response 16) As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69135-69136), it is well established in the literature that animal activities on adjacent and nearby lands—including grazing, livestock operations, and wildlife intrusion—may introduce contamination to surface and ground water through runoff and through direct access by animals to waterways (Refs. 40-43). Moreover, we discussed in the proposed rule various produce related outbreaks (Refs. 18-22) in which investigators noted presence of concentrated animal feeding operations (CAFOs) or cattle grazing operations as potential sources of contamination to agricultural water systems and covered produce. See 86 FR 69120 at 69125-69127. In light of this information and findings from several produce related outbreaks, we consider it important for farms to evaluate animal impacts and activities in identifying conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces as part of their agricultural water assessments.

We acknowledge the longstanding colocation of animals and plant food production systems in agriculture and note that this rule does not prohibit the presence of animals on or near a farm, nor does it establish requirements or responsibilities for entities other than farms covered by the rule. Rather, the rule requires a farm to conduct an agricultural water assessment for hazard identification purposes and take any measures that 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 its pre-harvest agricultural water. This may

involve, for example, the farm implementing measures that are within its control, such as changing the method of water application under § 112.45(b) to reduce the likelihood of contamination of the covered produce.

5. Other Food Safety Standards

(Comment 17) Several comments note that many farms are already subject to third-party water quality standards that some produce farms follow. Comments seek clarity on whether the proposed rule aligns with these standards and, if some third-party standards are more stringent than FDA's regulation, whether an audit to those standards could be used to meet the rule's requirements.

(Response 17) ~~While we have not conducted an evaluation of third-party standards for alignment with the agricultural water requirements in subpart E, we~~We acknowledge the important role third-party standards may play in ensuring food safety and questions about alignment of FDA's produce safety rule requirements and third-party standards. For example, in 2018, FDA and USDA announced the alignment of the USDA Harmonized Good Agricultural Practices Audit Program (USDA H-GAP) with the requirements in the 2015 produce safety final rule (Ref. 44), which preceded both the 2021 agricultural water proposed rule and this final rule. In the announcement, we explained that while the requirements of both programs are not identical, the relevant technical components in the 2015 produce safety final rule are covered in the USDA H-GAP Audit Program. We also explained that the alignment will help farms by enabling them to assess their food safety practices as they prepare to comply with the produce safety rule. However, we also noted that USDA audits are not a substitute for FDA or state regulatory inspections.

~~We emphasize that~~In October 2023, FDA announced the final results of a voluntary pilot program on alignment of private third-party food safety audit standards with applicable FDA regulations (Ref. 45). It included a third-party primary production standard for non-sprout produce that we found to be in alignment with applicable provisions of the produce safety regulation--except for the subpart E agricultural water requirements that were excluded from the review as they were under reconsideration through this rulemaking. Our conclusion from the pilot is that FDA currently does not have adequate resources to review and evaluate the alignment of third-party food safety standards beyond the pilot—notwithstanding the value that such standards may have in facilitating industry's implementation of FSMA and the potential of these audits to inform risk prioritization. FDA will continue to assess future opportunities but is unable to undertake any additional alignment reviews at this time, including review of third-party standards for pre-harvest agricultural water for non-sprout produce.

Finally, as a general matter, a determination of alignment alone does not indicate that a farm audited to that standard is necessarily in compliance with the 2015 produce safety final rule. While a determination of alignment may help farms as they prepare to comply with requirements in the 2015 produce safety final rule, as discussed above, audits conducted under third-party standards found to be in alignment are not a substitute for FDA or State regulatory inspections.

(Comment 18) Some comments seek clarity on whether the proposed approach for pre-harvest agricultural water assessments is intended to be similar to a HACCP approach.

(Response 18) As discussed in response to comment 1, the annual pre-harvest agricultural water assessments employ a prevention-oriented quality-systems approach to food safety regulation that FDA has long used for the highly diverse food industry that FDA regulates. For example, FDA's juice HACCP regulation (21 CFR part 120), seafood HACCP regulation (21

CFR part 123), and Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (21 CFR part 117), establish frameworks under which industry qualitatively assesses, and as necessary, controls, potential hazards as appropriate to their operations. While we believe that a HACCP approach--particularly at the level required in parts 120, 123, and 117--would not necessarily be appropriate at the farm level (80 FR 74354 at 74379), many of the principles of HACCP can still be applied, such as an assessment of risk and the development of a food safety plan based on that assessment, and we have incorporated elements such as these within the requirements for pre-harvest agricultural water assessments in § 112.43.

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6. Other comments

(Comment 19) A few comments note the phrasing in the proposed rule that assessments are designed to be “adaptable to future advancements in agricultural water quality science” and express concerns that this language implies that FDA will make significant implementation decisions in the future without public discussion and input. A few comments seek clarity on whether and how emerging science or additional information relevant to agricultural water assessments will be incorporated into trainings.

(Response 19) We acknowledge that water quality science is expected to evolve over time, and we have designed the rule to achieve improved public health protections, while also being feasible to implement across the wide variety of agricultural water systems, uses, and practices, and adaptable to future scientific advancements. For example, we discuss in response to comment 115 that as more studies are conducted that examine in-field die-off for various circumstances (for example, different regions, environmental conditions, commodities, pathogens, and crop growth characteristics) (Refs. [45-4846-49](#)), farms may use that information to inform a time interval between last direct water application and harvest under § 112.45(b)(1)(ii). We anticipate that as new information becomes available, it will be shared with farms and other interested stakeholders through various mechanisms, including guidance in accordance with our good guidance practices regulation, 21 CFR 10.115, which generally provides an opportunity for public comment before a guidance document is finalized.

Additionally, new information and scientific advancements will likely be incorporated into training programs and other education and outreach materials in order to increase awareness by farms. For example, we are aware that food safety trainings intended to be specific to certain commodities (or commodity groups) have been held, which could be a mechanism in the future

by which information relevant to specific commodities will be shared. We are also aware of research organizations and universities that prioritize sharing their findings with the produce industry and related stakeholders. We also expect that as new science relates to region-specific considerations, local extension agents will play an important role in disseminating that information to interested parties.

(Comment 20) A few comments express concerns that the rule will result in farms increasing their reliance on ground water sources, which could be in conflict with the goals of certain state laws designed to help protect ground water resources. For example, some comments suggest that the exemption from the requirements to prepare an agricultural water assessment in proposed § 112.43(b)(1) related to untreated ground water will incentivize farms to make greater use of already-stressed resources. Several comments suggest that changing from surface water to ground water as a way to reduce risk associated with agricultural water may be difficult for some farms due to existing conservation laws.

(Response 20) We are not requiring farms to change their water sources, either for the purposes of an exemption from the requirements to prepare a pre-harvest agricultural water assessment or as a mitigation measure. Rather, we have incorporated flexibility to provide farms viable options 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 without needing to alter the source of agricultural water. See also response to comment 124.

In the Environmental Impact Statement (EIS) that was prepared during rulemaking for the 2015 produce safety final rule (Ref. [4950](#)), we discussed that, based on our qualitative analysis, we did not consider impacts to water resources to be significant, with the potential

exception related to ground water withdrawal, where existing significant adverse long-term impacts (i.e., water drawdown, potential subsidence, and the related continued degradation of water quality) may continue to be exacerbated as a result of excessive ground water use.

We also noted that we did not anticipate that the approach taken for pre-harvest agricultural water in the 2015 produce safety final rule (i.e., microbial criteria consisting of a GM and STV, with various actions a farm may take if the GM and/or STV are exceeded) would result in farms on a regional or national scale switching to ground water sources. For example, stakeholder feedback indicated that allowing for microbial die-off between last irrigation and harvest and/or microbial reduction or removal resulting from post-harvest practices provides farms viable options to meet the microbial quality criteria without needing to, for example, treat water or switch to a ground water source (Ref. [4950](#)).

Under this rule, those mitigation measures remain available as options. Further, with this rule we are incorporating additional mitigation measures beyond those in the 2015 produce safety final rule to provide farms with even more flexibility in ways to manage risks associated with pre-harvest agricultural water. (Specifically, this rule adds mitigation measures for changing the method of water application or taking an alternative mitigation measure in accordance with § 112.45(b)(1)(iv) and (vi), respectively.). We have provided various options for mitigation measures encompassing a range of possible costs (see the FRIA (Ref. 26)) to provide farms with flexibility in managing risks associated with their agricultural water as appropriate to their agricultural water systems, water use practices, and unique circumstances. Given the various options farms have under this rule, including options that involve more targeted changes (such as making necessary repairs to agricultural water systems), we do not expect farms to preferentially

alter the source of their agricultural water as a mitigation measure or for the purposes of an exemption from the requirements to prepare a pre-harvest agricultural water assessment.

As discussed in the Agency's finding of no significant impact for the current rulemaking and the evidence supporting that finding (Refs. ~~50-5251-53~~), the potential number of farms that could switch to ground water, potentially exacerbating drawdown, would be reduced compared with the 2015 produce safety final rule with the revisions to the subpart E provisions we are finalizing here (Ref. ~~4950~~). No significant adverse environmental impacts have been identified with this rule. See also section VIII.

(Comment 21) FDA received several comments related to conservation practices and environmental protection programs, which generally appear to be out of scope. Specifically, commenters urge FDA to encourage the co-management of food safety, conservation, and environmental protection. A few comments request that guidance and training on the rule for covered farms and inspectors acknowledge that animals and covered farms can co-exist, noting that this is especially important when it comes to conservation practices and/or diversified farms. In addition, one comment discusses state programs providing incentives for farmers to implement climate and environmentally friendly agricultural practices, such as use of energy-efficient irrigation systems, healthy soil practices (such as compost application), and establishment of seasonal and/or permanent vegetation for pollinators and wildlife. The comment expresses concern that farms may not participate in such environmental stewardship programs if doing so might be in conflict with the proposed requirements for pre-harvest agricultural water assessments. Further, comments recommend that FDA work with stakeholders to develop solutions that will help farmers co-manage such environmental sustainability goals with food safety.

(Response 21) As indicated, FDA considers these comments to generally be outside the scope of this rulemaking. However, to the extent they are in scope, FDA acknowledges the longstanding co-location of animals and plant food production systems in agriculture. 80 FR 74354 at 74482. As discussed in the 2021 agricultural water proposed rule, this rule does not prohibit the presence of animals (such as grazing animals or working animals) on a farm, nor does it require the destruction of wildlife habitat or the clearing of farm borders. Rather, the rule requires farms 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. 86 FR 69120 at 69135.

Additionally, as discussed in the 2015 produce safety final rule, we continue to encourage the co-management of food safety, conservation, and environmental protection. We consider it important to take into account the environmental practice standards and policies of other agencies in the context of food safety. 80 FR 74354 at 74365. We believe that the provisions of part 112 are consistent with existing conservation and environmental practice standards and policies and are not in conflict with federal or State programs. In addition, § 112.84, which we did not propose to change, codifies a statement that the requirements of part 112 do not require or permit the use of practices in violation of the Endangered Species Act (16 U.S.C. 1531-1544), and that the regulation does not require the use of practices that may adversely affect wildlife, such as removal of habitat or wild animals from land adjacent to produce fields. 80 FR 74354 at 74365.

C. Definitions (§ 112.3)

We proposed to add two new definitions for “agricultural water assessment” and “agricultural water system” in § 112.3 to provide clarity for terminology used in the proposed

requirements for pre-harvest agricultural water assessments. We received several comments on those proposed definitions and respond to comments about these definitions in the following paragraphs. We are finalizing the definitions for “agricultural water assessment” and “agricultural water system” as proposed, without changes.

1. Agricultural Water Assessment

(Comment 22) Several comments express support for the definition of “agricultural water assessment,” noting that the assessment, as defined, provides broad, science-based flexibility so as to be applicable to a wide variety of growing scenarios. One comment suggests the definition be revised to include an assessment of the severity of illness and injury from the hazard and the probability that the hazard will occur. Another comment recommends that FDA clarify in its definition of “Agricultural Water Assessment” that the assessment must be in written form.

(Response 22) We considered these comments, and as discussed below, are finalizing the definition of “agricultural water assessment” as proposed, without changes. An “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 (§ 112.3).

With respect to comments suggesting the definition be revised to capture the severity of illness and injury from the hazard and the probability that the hazard will occur, we note that as

discussed in response to comment 27 and comment 76, the requirements for agricultural water assessments provide a mechanism through which farms evaluate the risk associated with their pre-harvest agricultural water and use that information to determine 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. See also comment 18, where we discuss comments related to HACCP. As such, we do not consider this a necessary change to make. In response to comments suggesting that the definition of “agricultural water assessment” be revised to clarify that the assessment must be in written form, we note that § 112.43(a) already specifies that farms “must prepare a written agricultural water assessment” and that § 112.50(b)(2) requires farms to maintain a record of that agricultural water assessment. Therefore, we also do not consider this a necessary change to make. As such, we are finalizing the definition of “agricultural water assessment” as proposed, without changes.

2. Agricultural Water System

(Comment 23) Several comments support the proposed definition of “agricultural water system,” suggesting that the proposed definition helps provide clarity. In reference to farms that draw agricultural water from systems that span long distances (such as canals), a few comments suggest that the definition of “agricultural water system” be revised to better account for the point at which the water comes under the farm’s control.

(Response 23) We reviewed comments for the proposed definition of “agricultural water system” and agree that it will provide stakeholders with additional clarity that will be helpful, for example, to farms in determining the scope of where and what to inspect and maintain under

§ 112.42 and for those farms required to conduct a pre-harvest agricultural water assessment pursuant to § 112.43.

With respect to the comment requesting we revise the definition of “agricultural water system” to provide limitations regarding the point at which the water comes under a farm’s control, we note that certain factors over which a farm may have little or no control (such as water users upstream of a farm), will likely influence the identification or characterization of potential hazards associated with the farm’s agricultural water system(s). See also comment 15. As such factors are important to consider in meeting relevant requirements that apply for agricultural water systems (such as those in § 112.42 for inspections and maintenance of agricultural water systems and § 112.43 for pre-harvest agricultural water assessments), we decline to revise the definition of “agricultural water system” as requested by the comment. We also note that § 112.42 requires farms, in part, to inspect and maintain agricultural water systems *to the extent they are under the farm’s control* (emphasis added) to identify any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces and prevent the systems from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity. As such, we are finalizing the definition for “agricultural water system” as proposed, without changes, to mean 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 (§ 112.3).

We also anticipate that the configuration of agricultural water systems will vary from operation to operation, depending on individual water sources, the type of distribution system

(including whether a building or structure is a component), and the type of equipment used to apply agricultural water. Related to our definition of “agricultural water system” is our definition of “water distribution system,” which means a system to carry water from its primary source to its point of use, including pipes, sprinklers, irrigation canals, pumps, valves, storage tanks, reservoirs, meters, and fittings (§ 112.3).

D. General Comments Regarding Pre-Harvest Agricultural Water Assessments (§ 112.43)

In the 2021 agricultural water proposed rule, we proposed to require farms to prepare systems-based agricultural water assessments for pre-harvest agricultural water for non-sprout covered produce (proposed § 112.43). We proposed that the assessments would be conducted annually (and more frequently as needed), documented in writing, and used for hazard identification and risk management decision-making purposes. We respond to comments of a general nature regarding the requirement for farms to prepare an agricultural water assessment in the following paragraphs. As discussed below, in response to comments received, we are revising § 112.43(a) to clarify that agricultural water assessments must be prepared at the beginning of the growing season, as appropriate, but at least once annually. Comments on exemptions from the requirement to prepare an agricultural water assessment, the factors that farms must evaluate as part of an agricultural water assessment, and outcomes of an agricultural water assessment are discussed in sections V.E., V.F., and V.G., respectively.

(Comment 24) Several comments request greater specificity on when farms should conduct their annual agricultural water assessment (for example, prior to planting, prior to harvest, between planting and harvest, or prior to water use). Some comments request clarity on how frequently FDA expects farms to determine the likelihood of any given hazard (for example, at least annually). Other comments suggest that farms should be required to prepare an

agricultural water assessment at least annually, with an additional assessment within a week prior to harvest.

(Response 24) We anticipate that preparing an annual agricultural water assessment towards the beginning of the growing season may be of benefit for farms, as doing so may allow for early identification of conditions for which measures under § 112.45 may be reasonably necessary. (See, for example, § 112.43(c)(2), which outlines circumstances in which mitigation measures must be implemented promptly, and not later than the same growing season as the assessment.) However, we recognize that flexibility is needed to account for certain situations, such as for crops that have year-round growing seasons, and for farms that may have multiple crops with year-round or staggered growing seasons throughout the year. As such, to provide additional clarity, we are revising § 112.43(a) to require farms to prepare an agricultural water assessment “at the beginning of the growing season, as appropriate, but at least once annually.” We note that this change aligns with the requirement in § 112.42(a) for timing of agricultural water system inspections, which we did not propose to revise. See 80 FR 74354 at 74433.

Recognizing that farms may be more likely to prepare their agricultural water assessments towards the beginning of their growing season in light of this clarification, we also considered whether it would be warranted to require farms to conduct a reassessment close to harvest to reflect different practices and operations than might exist earlier in the growing season (such as during planting). However, we do not consider it necessary for farms to prepare an additional assessment close to harvest, as farms are already required to account for harvest conditions within their initial agricultural water assessments. (For example, the requirement in § 112.43(a)(2) for farms to evaluate the time interval between the last direct application of agricultural water and harvest of the covered produce indicates that farms must consider

conditions that are close to harvest as part of their assessments.) However, we emphasize that a farm must conduct a reassessment whenever a significant change occurs in the farm's agricultural water system, water use 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. A reassessment conducted under § 112.43(e) due to a significant change must evaluate any factors and conditions affected by the change.

(Comment 25) Some comments seek clarity on the relationship between inspections, maintenance, and pre-harvest agricultural water assessments in proposed §§ 112.42(a), 112.42(b), and 112.43, respectively. A few comments ask whether conducting an agricultural water system inspection would eliminate the need for an agricultural water assessment and vice versa. One comment requests clarification as to whether the intent is for inspections to inform assessments, which in turn, inform maintenance activities such as monitoring—and if so, requests that FDA clarify as such by reordering the sequence of those requirements to reflect that intent. Another comment suggests that FDA limit the scope of the inspection and maintenance requirements to water system components that are under the ownership, management, or contractual oversight of the operator to help clarify the differences in expectations between inspections and maintenance under § 112.42 and agricultural water assessments under § 112.43, the latter of which are intended to be more comprehensive in nature.

(Response 25) We agree that there are differences between the requirements in § 112.42 for inspection and maintenance of agricultural water systems used for all covered activities and the requirements we are finalizing in § 112.43 for pre-harvest agricultural water assessments for covered produce other than sprouts.

As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69133-69134), the requirements for pre-harvest agricultural water assessments in § 112.43 supplement the requirements for inspection and maintenance of agricultural water systems in § 112.42, the latter of which requires a farm to regularly inspect and routinely maintain the components of its agricultural water systems, to the extent that such components or systems are under its control. While § 112.42 entails inspecting and maintaining components of an agricultural water system to the extent that they are under the farm's control, and applies for all uses of agricultural water (not just water used for pre-harvest activities), § 112.43(a) requires farms to conduct a more comprehensive assessment of possible sources and routes by which known or reasonably foreseeable hazards are reasonably likely to be introduced into its pre-harvest agricultural water for non-sprout covered produce. Additionally, farms are required to establish records of the findings of their inspections under § 112.42 (§ 112.50(b)(1)), whereas they are required to establish more comprehensive records of their written agricultural water assessments, including the descriptions of factors evaluated and written determinations, in accordance with § 112.43 (§ 112.50(b)(2)). Moreover, unlike the inspection and maintenance requirements in § 112.42, findings from a farm's agricultural water assessment are directly tied to implementation of corrective or mitigation measures, as described in § 112.43(c).

While results of inspections and maintenance under § 112.42 can be used to inform an agricultural water assessment under § 112.43(a) (or the need for a reassessment under § 112.43(e)), meeting the requirements in § 112.42 does not eliminate the need for a farm to prepare an agricultural water assessment in accordance with § 112.43. For discussion related to records of agricultural water system inspections and assessments, see response to comment 133.

With respect to comments requesting that we reorder the provisions to clarify that inspections inform assessments, which in turn inform maintenance, we decline to make this change. Not only do the requirements for inspections and maintenance under § 112.42 have different applicability than the requirements for agricultural water assessments under § 112.43 as discussed above, but farms are required to base their agricultural water assessments, in part, on the results of any inspections and maintenance conducted under § 112.42. We expect that reordering the provisions may result in confusion as to their applicability and relationship, and as such, are finalizing the order of §§ 112.42 and 112.43 without change.

(Comment 26) A few comments ask FDA to clarify in the final rule that the assessment is intended to identify known or reasonably foreseeable *microbial* hazards, specifically.

(Response 26) As discussed in the 2015 produce safety final rule, the regulation focuses on biological hazards related to produce growing, harvesting, packing, and holding. We conducted a QAR (Ref. 17) and considered the findings of that assessment in finalizing the 2015 produce safety final rule. While we acknowledged the potential for nonbiological (physical or chemical (including radiological)) hazards in produce, we explained that we do not address such hazards in the produce safety rule. See 80 FR 74354 at 74355 and 74377 and response to comment 8. Further, the 2015 produce safety final rule defines “known or reasonably foreseeable hazard” to mean a biological hazard that is known to be, or has the potential to be, associated with the farm or the food (§ 112.3). We did not propose to change this definition from the 2015 final produce safety final rule. As the scope of the regulation and definition of “known or reasonably foreseeable hazards” are specific to biological hazards, we do not consider it necessary to revise the requirements for pre-harvest agricultural water assessments as suggested by the comments.

(Comment 27) One comment seeks clarity on how to assess known or reasonably foreseeable hazards that are inherent in the environment, such as *Listeria*, for purposes of an agricultural water assessment under § 112.43.

(Response 27) The information considered as part of an agricultural water assessment in § 112.43(a) will assist farms in determining whether measures under § 112.45 are reasonably necessary in light of concerns for the potential presence of environmental pathogens. For example, if a farm suspects that adjacent or nearby land that had historically been used for a grazing operation may contain pathogens, the farm might consider the topography of the land and likelihood of whether those hazards may be introduced to the water system. In combination with the other factors considered as part of its agricultural water assessment (for example, the farm's water use practices, crop characteristics, and environmental conditions (such as air temperature and UV)) -the farm must then consider whether measures are reasonably necessary to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces.

We also note that the requirements for systems-based agricultural water assessments are designed, in part, to be adaptable to future advancements in agricultural water quality science. We anticipate that this is an area where science will continue to evolve and provide stakeholders with an enhanced understanding of the ecology of human pathogens in the environment that may cause foodborne illness outbreaks. For example, FDA sometimes conducts multiyear environmental studies that are designed to elucidate environmental conditions that can impact food safety (Ref. [5354](#)). Factors that are studied may include, but are not limited to, pre-harvest water sources and uses, soil and soil amendments, topography of the growing region, areas where animals are present (such as wildlife and livestock), wind speed and direction, airborne

particulates, water runoff, and environmental factors (such as temperature, rainfall, fog, and dew). Within recent years, FDA, with support from State and local partners, has initiated two longitudinal multiyear studies that examine how pathogens survive, move through the environment of two different regions, and possibly contaminate produce (Refs. [5455](#) and [5556](#)). As these and similar efforts progress, farms will be able to use similar information learned about regions as an additional resource to further inform their agricultural water assessments.

(Comment 28) Many comments suggest that the proposed requirements for pre-harvest agricultural water assessments do not sufficiently acknowledge that the presence of a hazard does not necessarily represent a risk to water or produce that needs to be managed. Some of these comments express concerns that, as written, the proposed rule would require farms to implement mitigation measures if a hazard is present, even if the overall risk associated with the water (for example, in light of the other information evaluated as part of an assessment) is low.

(Response 28) We consider that the identification of potential sources of known or reasonably foreseeable hazards and consideration of the likelihood of those hazards being introduced to an agricultural water is an appropriate approach, within a risk-based framework, to implement the requirements of section 419 of the FD&C Act to set forth procedures, processes, and practices that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce and to provide reasonable assurances that the produce is not adulterated on account of such hazards. The systems-based framework in § 112.43 of evaluating conditions that are reasonably likely to introduce known or reasonably foreseeable hazards will help a farm determine, alongside the results of inspections and maintenance under § 112.42, whether corrective or mitigation 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.

In particular, we note that agricultural water assessments must identify conditions that are *reasonably likely* (emphasis added) to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces based on an evaluation of all factors identified in § 112.43(a)(1) through (5). These factors include: the agricultural water system (including the source, water distribution system, and degree of protection from possible sources of contamination); agricultural water use practices; crop characteristics; environmental conditions; and other relevant factors, including test results, where appropriate. (See also comment 29, where we respond to comments regarding the terms “reasonably likely” and “reasonably necessary.”)

Thus, if a farm identifies a potential source of contamination under § 112.43(a)(1), it is not a foregone conclusion that measures under § 112.45 are reasonably necessary. Rather, in consideration of all of the information evaluated under § 112.43(a)(1) through (5), the farm might ultimately determine, for example, that measures under § 112.45 are not 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 its agricultural water used in growing covered produce (other than sprouts).

Similarly, while two different farms might identify similar potential sources of contamination under § 112.43(a)(1), depending on the other information they evaluate in § 112.43(a)(1) through (5), their determinations under § 112.43(c) might differ. For example, one farm with a surface water source that is regularly subject to runoff from lands where animal grazing occurs may determine that mitigation measures are reasonably necessary under § 112.45,

since the farm applies agricultural water from that source to covered produce close to harvest, and environmental conditions and crop characteristics are not conducive to microbial die-off. However, another farm with different crop characteristics, environmental conditions and water use practices may determine that mitigation measures are not reasonably necessary, even if it uses pre-harvest agricultural water from a surface water source with similar runoff conditions.

As discussed further in comment 29, we have provided various examples throughout the proposed rule and this final rule that farms should consider in determining whether (and what kind of) measures are reasonably necessary. We remain committed to providing education, outreach, and training, and intend to pursue various mechanisms for disseminating information about the requirements of this rule to farms.

(Comment 29) Many comments request clarity related to the terms “reasonably likely” and “reasonably necessary” as they relate to the requirements for agricultural water assessments. These comments suggest that the terms are subjective and that without a more objective benchmark it will be difficult to consistently determine what is “reasonably likely” for a farm.

(Response 29) Given the diversity that exists across the operations of foreign and domestic farms and their agricultural water systems, uses, and practices, phrases such as “reasonably likely to introduce known or reasonably foreseeable hazards” and “determine whether measures are reasonably necessary” provide flexibility for farms to make decisions around the use of agricultural water as appropriate to their unique circumstances and operations, taking into account the requirement in § 112.41 that all agricultural water must be safe and of adequate sanitary quality for its intended use. We note that similar language appears in section

419(c)(1)(A) of the FD&C Act⁷, in the agricultural water requirements for harvest-, post-harvest, and sprout uses (which we did not propose to change) (e.g., § 112.44(d)), and in FDA's HACCP regulations (21 CFR part 120 and 21 CFR part 123) and FDA's Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food regulation (21 CFR part 117). This language is designed to be flexible given the diversity of commodities and operations to which these requirements apply, and in keeping with the principle that the farm bears the responsibility and accountability for establishing and implementing food safety systems tailored to its circumstances. We also note that such language is flexible to account for future scientific advancements, consistent with the requirements for pre-harvest agricultural water assessments we are finalizing with this rule.

What is considered a known or reasonably foreseeable hazard for one farm, in light of the conditions and potential impacts to its agricultural water system, may not be known or reasonably foreseeable hazard in the light of the conditions and potential impacts to the agricultural water system of another farm. For example, while a farm in one region might identify wild pigs as a potential source of known or reasonably foreseeable hazards to agricultural fields and surface waterways (Refs. [5657](#) and [5758](#)), wild pigs might not be considered a likely source of known or reasonably foreseeable hazards in regions where pigs are not prevalent. As another example, if runoff is likely to serve as a source of hazards, but the farm's agricultural water system is sufficiently protected (e.g., water from a well is conveyed through a piped distribution system, and both the well and distribution system are properly

⁷ Section 419(c)(1)(A) of the FD&C Act requires that the 2015 produce safety final rule set forth those procedures, processes, and practices that the Secretary determines to minimize the risk of serious adverse health consequences or death, including procedures, processes, and practices that the Secretary determines to be reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

constructed and maintained), then the farm might determine that runoff is not a condition that is reasonably likely to introduce known or reasonably foreseeable hazards to covered produce (other than sprouts) or food contact surfaces.

Further, farms must use information on the various factors evaluated as part of an agricultural water assessment under § 112.43(a)(1) through (5)--including information related to their agricultural water systems; agricultural water use practices; crop characteristics; environmental conditions; and other relevant factors, such as the results of pre-harvest agricultural water testing, where appropriate--to determine whether, given their unique conditions, 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 agricultural water used in growing covered produce (other than sprouts). Given the diversity that exists across industry in these factors, situations in which measures under § 112.45 are reasonably necessary for one farm will not necessarily be the same for another. Rather, the unique factors that are relevant to a farm and its agricultural water systems will together assist the farm in decision-making related to its pre-harvest agricultural water as appropriate for its relevant conditions, practices, and circumstances. See also response to comment 28.

We have provided various examples throughout the proposed rule and this final rule that farms should consider in identifying potential sources of hazards, evaluating the likelihood of hazards being introduced to covered produce (other than sprouts) or food contact surfaces, and determining whether (and what kind of) 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. See 86 FR

69120 at 69133 and sections V.F., V.G., and V.J. Such examples, and consideration for the principles presented in the context of each farm’s unique conditions, will assist farms in conducting their pre-harvest agricultural water assessments under § 112.43. However, we also recognize that guidance, educational materials, as well as trainings, will help farms understand the requirements of this final rule. We remain committed to providing education, outreach and training and intend to pursue various mechanisms for disseminating information to farms.

(Comment 30) A few comments suggest that under the proposed rule, any surface water source that a farm is preparing an agricultural water assessment for will be considered “hazardous,” and therefore require that the farm conduct mitigation measures.

(Response 30) The risk associated with agricultural water will vary from source to source. For example, ground water obtained from deep underground aquifers, with properly designed, located, and constructed wells, generally yields higher quality water with little variability due to the natural filtering capacity of soils, the depth pathogens would have to travel to compromise the source, and because it is not expected to be subject to environmental factors such as runoff (Refs. 17 and 5859). By contrast, surface waters, which are exposed to the environment, pose a higher potential for becoming contaminated with human pathogens due to runoff and greater variability in quality because of the potential for external influences (Ref. 17). However, we recognize that even within a single type of water source (e.g., surface water), the associated risk may vary depending, in part, on the nature and likelihood of hazards being introduced. For example, consider if a farm has two different holding ponds, —one that is at a higher elevation than surrounding lands, and the other that is at a lower elevation: ~~while~~ — both are considered surface water sources. However, the holding pond at the higher elevation may be

more well-protected from the introduction of hazards via runoff than the other holding ponds, and may therefore present less risk when used as pre-harvest agricultural water.

Additionally, we recognize that the risk associated with agricultural water also depends on how and when agricultural water is applied to covered produce, characteristics of the covered produce, and environmental conditions. As such, we require farms to evaluate these various factors under § 112.43(a) as part of their agricultural water assessments to assist them in determining 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. See also response to comment 28. Given the variability that exists across industry in water systems, operations, and conditions, not every surface water source will require that corrective or mitigation measures be implemented under § 112.45.

(Comment 31) Several comments seek clarity on how to weigh “low risk” and “high risk” elements within an assessment. For instance, comments seek clarity on how farmers should weigh a “low risk” crop irrigated with water from a “high risk” source. One comment seeks clarity on whether farms can continue using “low” or “medium-risk” practices until “specific science determines there is a real, attributable risk.”

(Response 31) Throughout the 2021 agricultural water proposed rule, this final rule, and supporting materials (such as the QAR (Ref. 17)), we have provided principles related to general risk associated with conditions and practices related to pre-harvest agricultural water sources and uses. For example, table 7 of the QAR (Ref. 17) demonstrates that public drinking water is generally considered the least likely to serve as a source of contamination, followed by ground water, surface water protected from runoff, and surface water unprotected from runoff. Further,

that table notes that where contamination in a water source is known to exist, the likelihood of contamination is a function of ~~contact~~:

- Contact with the commodity (example, whether contact is indirect or direct); ~~commodity~~
- Commodity effects (~~characteristics~~) (for example, whether the surface is conducive to adhesion); and application
- Application timing (for example, early or late in crop growth).

Given the diversity that exists across the operations of foreign and domestic farms and their agricultural water systems, uses, and practices, what might be considered “low” or “high” risk for one farm will not necessarily be the same for another.

As such, in establishing the requirements for pre-harvest agricultural water assessments, we have provided flexibility for farms to make decisions around the use of agricultural water as appropriate to their unique circumstances and operations. See also response to comment 29.

To the extent that comments are voicing concern over the scientific basis for the requirements for pre-harvest agricultural water assessments in § 112.43, comment 10 addresses those comments.

(Comment 32) One comment asserts that quantitative microbial risk assessment and risk modeling tools may help establish when certain “safe harbors,” such as the use of four days or more between last direct water application and harvest as a mitigation measure, may be appropriate for farms to use. Specifically, this comment suggests that the proposed approach for mitigation measures provides options for farms to choose from without caveats or limitations.

(Response 32) Given the diversity of operations, agricultural water sources, and agricultural water uses of domestic and foreign farms, the requirements for comprehensive, systems-based pre-harvest agricultural water assessments, which require farms to evaluate a

broad range of factors that may impact the quality of the water they use during pre-harvest activities, will assist farms in identifying, and managing, risks associated with pre-harvest agricultural water as appropriate for their relevant agricultural water systems, conditions, and practices. While we do not believe that quantitative risk benchmarks are necessary in order to establish science-based minimum standards within the framework of the comprehensive, systems-based agricultural water assessment we are finalizing here, we have included a requirement to test pre-harvest agricultural water as part of an assessment when doing so would not delay action ~~where~~ most critical to protect public health and would further inform the farm's determination as to whether measures are reasonably necessary. See § 112.43~~H~~(43(c))(4).

We also recognize that additional clarification, such as related to the circumstances under which certain mitigations may be appropriate, is appropriate. As such, we provide various examples throughout the proposed rule and this final rule that farms should consider in preparing their agricultural water assessments and taking actions based on their assessments. See 86 FR 69120 at 69133 and sections V.F., V.G., and V.J. For example, in comment 115, we explain that the use of microbial die-off between last direct water application and harvest as a mitigation measure under § 112.45(b) can be impacted by a broad range of conditions specific to a farm, such as the timing of water its water applications and relevant environmental conditions, crop characteristics, and pathogen characteristics.

Further, the QAR (Ref. 17) explains that where contamination of a water source is known to exist, the likelihood of contamination is a function of various factors, including contact with the commodity, commodity effects (characteristics), and application timing. Moreover, we discuss in our memos supporting the pre-harvest microbial die-off requirements in the 2015 produce safety final rule (Refs. [5960](#) and [6061](#)) that the reduction of pathogen populations on

produce surfaces to the point of non-detection is not guaranteed. As such, we disagree that use of a time interval between last direct water application and harvest alone can serve as a “safe harbor.”

We also note that the requirements for agricultural water assessments are designed, in part, to be adaptable to scientific advancements. To the extent that risk modeling and predictive analytics related to pre-harvest agricultural water may continue to develop in the future, farms will be able to use such information as an additional resource to further inform their agricultural water assessments under the approach we are finalizing here.

(Comment 33) A few comments suggest that evaluating various factors (such as the agricultural water source’s degree of protection under proposed § 112.43(a)(1)) will present a significant challenge to many farms and argues that broader collaborations across the agricultural sector will need to occur to achieve compliance with this requirement. The comment suggests that FDA foster relationships with irrigation water districts and engage in conversations with animal operations and livestock associations, or other federal partners such as the EPA and USDA’s Natural Resources Conservation Service to achieve compliance.

(Response 33) We are aware of efforts underway to bring together members of agricultural communities on a large scale, such as through the CAN (Ref. 38), which provides a roundtable opportunity to foster collaboration and discuss enhanced neighborly food safety practices when various agriculture operations such as leafy green fields, cattle ranches, vineyards, and compost sites are adjacent to one another. Various action items have been identified as part of the CAN initiative, including fostering neighbor-to-neighbor interactions and conversations, and building a research roadmap to understand key landscape processes to guide decision-making both now and into the future (Ref. 39).

Additionally, FDA sometimes conducts multiyear environmental studies in collaboration with State and local public health officials, academia, and members of the produce industry, that are designed to shed light on environmental conditions that can impact food safety (Ref. 32).

Within recent years, FDA, with support from State and local partners such as extension specialists, academic researchers, irrigation districts, industry groups, and farms, has initiated two longitudinal multiyear studies that examine how pathogens survive, move through the environment of two different regions, and possibly contaminate produce (Refs. [5455](#) and [5556](#)). Information learned through such efforts may help inform agricultural water assessments.

Further, as discussed in section V.K., FDA has collaborated with EPA to develop a testing protocol for evaluating the efficacy of antimicrobial chemical treatments against certain foodborne pathogens in agricultural water sources. We recognize the value of collaborating with Federal partners in related disciplines, and will consider additional collaborative efforts related to the requirements we are finalizing here.

(Comment 34) Some comments voice concern that it will be difficult to prepare agricultural water assessments for farms that use multiple sources of water for pre-harvest activities.

(Response 34) We acknowledge that farms using multiple agricultural water systems during pre-harvest activities for covered produce (other than sprouts) will need to conduct an assessment for each system unless an exemption under § 112.43(b) applies. However, several of the factors evaluated in the assessment (for example, agricultural water use practices, commodity characteristics, and environmental conditions) might be similar across agricultural water systems, thus limiting the amount of information a farm needs to collect and consider. We emphasize that under Subpart O, “Records” of the 2015 produce safety final rule, it is not necessary for farms to

keep all of the required information in only one set of records, nor do farms need to duplicate existing records, provided that, taken together, the records satisfy all of the applicable requirements. See § 112.163. Therefore, farms have flexibility in maintaining records for agricultural water assessments as long as all relevant requirements are met.

(Comment 35) Some comments voice concern that farms who lease land for short-term use (for example, one growing season) may face challenges in implementing the requirements for agricultural water assessments as they lack historical knowledge on adjacent lands and water systems available to them. One comment suggests that having multiple years of experience using surface water to cool strawberries in the field without any history of problems makes it difficult to identify risks.

(Response 35) We recognize that not all farms (including, for example, new farms and those growing covered produce on land under short-term lease), will have a historic understanding of their agricultural water systems, including uses of adjacent and nearby lands. While we understand that historical knowledge may be useful in preparing an agricultural water assessment, the absence of it does not preclude a farm from evaluating the factors in § 112.43(a)(1) through (5).

Moreover, we do not consider a lack of reported issues in the past as necessarily being indicative of the risks associated with a farm's agricultural water systems and pre-harvest water use. For example, between June and October 2020, Federal and State agencies investigated a *Salmonella* Newport foodborne illness outbreak associated with consumption of red onions (Ref. 23). We noted that the food vehicle in this outbreak, whole red onions, is a raw agricultural commodity that had not previously been documented as associated with a foodborne illness outbreak. Although a conclusive root cause could not be identified, several potential contributing

factors were identified, including a leading hypothesis that contaminated irrigation water used in a growing field may have led to contamination of the onions.

The QAR (Ref. 17) concluded that, although some types of produce have been repeatedly associated with outbreaks, all types of produce commodities have the potential to become contaminated through one or more of the potential routes of contamination, including water. Use of poor agricultural practices can lead to contamination and illness, even where the potential for contamination is relatively low. As such, it is important for all farms to consider the various factors under § 112.43(a) as part of their agricultural water assessments, even in the absence of any reported history of safety problems associated with their covered produce.

E. Exemptions from Agricultural Water Assessments (§ 112.43(b))

In § 112.43(b), we proposed various exemptions from the requirement to prepare a pre-harvest agricultural water assessment. We tentatively concluded that an agricultural water assessment would not be necessary when a farm can demonstrate that its pre-harvest agricultural water for non-sprout covered produce:

- Meets the requirements in § 112.44(a), including the microbial quality criterion, and, if untreated ground water, also meets the testing requirements in §§ 112.44(b), 112.47, and 112.151 (proposed § 112.43(b)(1));
- ~~meets~~Meets the requirements in § 112.44(c) for water from a Public Water System or public water supply (proposed § 112.43(b)(2)); or
- ~~is~~Is treated in accordance with § 112.46 (proposed § 112.43(b)(3)).

We received numerous comments on the exemptions in proposed § 112.43(b) and respond to those comments below. As discussed below, we are finalizing the exemptions from the requirement to prepare a pre-harvest agricultural water assessment and clarifying that an

exemption only applies if it is reasonably likely that the relevant quality of water will not change prior to the water being used as agricultural water.

(Comment 36) Some comments voice concern with the proposed exemptions in § 112.43(b), noting that while farms may be exempt from preparing an agricultural water assessment for water from a municipal source or treated water, depending on how the water is used, the water quality may change. These comments suggest that exempting water in these situations could be a gap in assessing the safety of the water.

(Response 36) We recognize that where the quality of water meeting the requirements in proposed § 112.43(b) may change before a farm uses it as pre-harvest agricultural water, it would be inappropriate for the farm to be eligible for an exemption from the requirement to prepare an agricultural water assessment for that water. As such, we are revising proposed § 112.43(b) to clarify that a farm is only exempt from preparing a written agricultural water assessment if the farm can demonstrate that the water meets the requirements in § 112.43(b)(1)(i), (ii), or (iii) and it is reasonably likely that the relevant quality of water 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) (§ 112.43(b)(2)).

For example, if a farm receives water that meets the requirements in § 112.44(c) for water from a Public Water System that furnishes water meeting the microbial requirements in 40 CFR part 141 and conveys that water through a closed distribution system that allows for water quality to be maintained, the farm may be eligible for an exemption under § 112.43(b), provided all requirements are met (including the requirement that the farm have results or certificates of compliance demonstrating that relevant requirements are met). However, if a farm conveys that water through an open canal system prior to using it as pre-harvest agricultural water for non-

sprout covered produce and it is reasonably likely that the quality of water will change prior to use of the water, the farm is not eligible for an exemption from the requirement to prepare an agricultural water assessment. The farm must consider the nature of the water source as part of their evaluation of the agricultural water system under § 112.43(a)(1).

(Comment 37) Several comments support the exemption in proposed § 112.43(b)(1) for water that meets the requirements of proposed § 112.44(a), noting that, in some cases, it may make sense for some farms to rely on test results rather than conducting annual (or more frequent, as appropriate) assessments. Some comments seek clarity about whether FDA intends for water tests to be performed each growing season for the sole purpose of demonstrating one's exemption from performing an agricultural water assessment. Comments also seek clarity as to when FDA would expect the testing to be completed (for example, before the season starts). Further, some comments question whether historical water testing data could be used for the purposes of an exemption from preparing an agricultural water assessment. Comments also request clarification on whether this exemption could be used for a farm that only uses pre-harvest water, but tests to the same standard as post-harvest water and meets all other relevant requirements.

(Response 37) We reviewed comments related to the exemption in proposed § 112.43(b)(1) and conclude that an agricultural water assessment is not necessary when a farm can demonstrate that its pre-harvest agricultural water for non-sprout covered produce meets the requirements in § 112.44(a) (including the stringent microbial quality criterion of no detectable generic *E. coli*) and the testing requirements in §§ 112.44(b), 112.47, and 112.151 that are applicable to agricultural water for sprout irrigation and harvest and post-harvest uses. While the provisions referred to in § 112.43(b)(1)(i) apply to water that is used for purposes outlined in

§ 112.44(a) (such as water used for harvest and post-harvest purposes), we note that a farm that only uses agricultural water for pre-harvest activities may still be eligible for this exemption, provided all applicable requirements are met.

For the exemption from the requirement to prepare an agricultural water assessment in § 112.43(b)(1)(i), if the water is untreated ground water, § 112.44(b) requires that a farm 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). If the four initial sample results meet the microbial quality criterion under § 112.44(a), the farm may test once annually thereafter. As such, in order to be eligible for the exemption in § 112.43(b)(1)(i), the farm must test the source of untreated ground water each growing season or year.

Recognizing the diversity that exists in industry as to when and how agricultural water is used, the requirement that samples be “representative of the intended use(s) of the water” provides farms with flexibility for sample collections under § 112.44(b). While one farm may, for example, collect a sample that is representative of use at the beginning of the growing season, another farm may, for example, collect a sample that is representative of use later in the year, or at some other time such as when production occurs year-round.

Regarding the use of historical data, we note that if a farm already possesses sufficient data (consisting of the minimum required number of samples) collected in the manner required under § 112.44(b), the farm is permitted to use that data in support of the exemption in § 112.43(b)(1)(i).

(Comment 38) Several comments address the exemption in proposed § 112.43(b)(2) for water that meets the requirements in § 112.44(c) for water from a Public Water System or public

water supply that furnishes water that meets the microbial water quality criterion on § 112.44(a). Some comments suggest that other water sources, such as water from public wastewater treatment systems, should be similarly exempt from preparing an agricultural water assessment, even if they do not meet the microbial criterion in § 112.44(a). A few comments specifically ask that the exemption be revised to apply to water from publicly owned systems (including from drinking water systems and wastewater treatment systems) that has been treated to meet a GM of 126 or less and an STV of 410 or less CFU generic *E. coli* per 100 mL, as opposed to expecting such water to meet the microbial criterion of no detectable generic *E. coli* per 100 mL. Some comments suggest that use of the GM and STV criteria for such purposes would shift the burden of proof to the water supplier, as compared to under the 2015 produce safety final rule requirements in which farms would be responsible for demonstrating that water meets such criteria.

(Response 38) In the U.S., Public Water Systems are required under NPDWR in 40 CFR part 141 to provide safe, clean water suitable for drinking and thus are at the lowest likelihood for pathogen contamination (Ref. 17). Similarly, public water supplies that meet the microbial requirement in § 112.44(a) are included in the exemption under proposed § 112.43(b)(2) to accommodate other public water supplies that are not governed by the requirements of the EPA drinking water program, but provide water of a quality that meets the microbial requirement of § 112.44(a). See 78 FR 3504 at 3571. Where a farm can demonstrate that its pre-harvest agricultural water for non-sprout covered produce meets microbial EPA drinking water standards or other comparable public water supply standards, we have concluded that it is not necessary to require farms to prepare a pre-harvest agricultural water assessment under § 112.43(a) provided

all requirements are met (including that the farm have results or certificates of compliance demonstrating that relevant requirements are met). See also response to comment 2.

We do not consider it appropriate to broaden the exemption in proposed § 112.43(b)(1) to include water from other public water supplies, such as wastewater treatment systems, since, as the comments note, water from these systems is often not treated to meet or be comparable to EPA's drinking water standards and may not similarly be at the lowest likelihood for pathogen contamination.

We also decline to provide an exemption from the requirements to prepare an agricultural water assessment for water supplied by a public water system that meets a GM of 126 and STV of 410 CFU generic *E. coli* per 100 mL of water, as we do not consider water meeting those criteria to provide the same level of confidence in the quality of water compared to water from a Public Water System or public water supply that meets or is comparable to microbial EPA drinking water standards. As such, we are finalizing the exemption in final § 112.43(b)(1)(ii) to refer to agricultural water that meets the requirements in § 112.44(c) for water from a public water system or public water supply.

(Comment 39) One comment notes that the exemption for water from a municipal source does not provide guidance on what farms should do in the case of potential water main breaks or other failures of the system. The comment suggests that FDA account for such circumstances and establish requirements for what farms should do when there are microbiological risks associated with a municipal source.

(Response 39) We recognize that water main breaks or other issues may occur on occasion that have the potential to affect the quality of water coming from public water systems. We emphasize that it is the farm's responsibility to ensure that the water the farm uses meets all

applicable requirements in subpart E, including that all agricultural water be safe and of adequate sanitary quality for its intended use (§ 112.41), even if the farm is eligible for an exemption from the requirement to prepare a pre-harvest agricultural water assessment under § 112.43(b).

Nonetheless, as discussed in comments 3 and 37, where a farm can demonstrate that its pre-harvest agricultural water for non-sprout covered produce meets microbial EPA drinking water standards or other comparable public water supply standards, we have concluded that it is not necessary to require farms to prepare a pre-harvest agricultural water assessment under § 112.43(a) provided all requirements are met (including that the farm have results or certificates of compliance demonstrating that relevant requirements are met). See § 112.43(b)(1)(ii) and, by reference, § 112.44(c). In the case of issues such as water main breaks or other failures occurring in a public water system or public water supply meeting the requirements in § 112.44(c), the system authority will oftentimes communicate the issue, along with recommendations for whether and how to use the impacted water, in an advisory to their affected constituents. Farms may find it helpful to consider such information in ensuring that the requirement in § 112.41 that all agricultural water be safe and of adequate sanitary quality for its intended use is met.

(Comment 40) Several comments voice concern over how the exemptions in proposed § 112.43(b) relate to controlled environment agriculture (CEA) farms (for example, indoor farms), including hydroponic or aquaponic operations. For example, one comment suggests that recirculated water used in such operations would be considered untreated surface water, and therefore, the exemption in proposed § 112.43(b)(1) would not apply. Some comments note that while hydroponic and aquaponic operations may source their water from a public water supply, water in these operations can be recirculated and/or held for extended periods of time prior to its

~~application of~~ use for produce. A few comments note that if farms recirculate that water without treatment or other controls, they could end up irrigating produce using contaminated water.

Other comments suggest that chemical treatment for the purposes of an exemption in proposed § 112.43(b)(3) may not be applicable in hydroponic and aquaponic operations due to concerns over a lack of treatment efficacy and that chemical treatment is not currently an option for aquaponic operations. For example, one comment notes that chlorine and chloramine are toxic to fish at certain concentrations and not labeled for use in aquaculture.

(Response 40) As discussed in comment 36, we are revising proposed § 112.43(b) to clarify that a farm is only exempt from preparing a written agricultural water assessment if the farm can demonstrate that the water meets the requirements in § 112.43(b)(1)(i), (ii), or (iii) and it is reasonably likely that the relevant quality of water 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) (§ 112.43(b)(2)). As such, it is important that each farm, including those involved in CEA, consider its unique operations in determining whether it is eligible for an exemption from the requirement to prepare an agricultural water assessment under § 112.43(b), including how the farm conveys and/or holds the water; how the farm manages the water prior to its point of intended use; and how the farm uses pre-harvest agricultural water for non-sprout covered produce.

For example, we are aware that in some CEA operations, such as those that employ deep water culture methods, pre-harvest agricultural water can be used for extended periods of time to grow multiple batches of covered produce in continuous production. For example, some operations introduce a new production raft to a growing pond when another raft is removed for harvest. Unless there are measures that will allow for the quality of water in § 112.43(b)(1)(i),

(ii), or (iii) to be maintained as new batches of covered produce are added to the system, a farm that implements such water use practices is unlikely to satisfy the requirements for an exemption in § 112.43(b). Examples of measures that may allow for the quality for water to be maintained prior to use as agricultural water for sequential batches of covered produce include, but are not limited to, ensuring that distribution system components and equipment surfaces do not serve as a source of contamination to the water and/or using other measures, such as adequate treatment, to maintain the quality of water.

Regardless of whether an exemption from the requirement to prepare an agricultural water assessment under § 112.43(b) applies, farms remain responsible for meeting all other applicable requirements of subpart E, including those related to inspection and maintenance of agricultural water systems (§ 112.42) and the requirement that all agricultural water be safe and of adequate sanitary quality for its intended use (§ 112.41).

(Comment 41) A few comments assert that in the 2021 outbreak of *Salmonella* Typhimurium associated with product from a hydroponic leafy green facility, the water would have been exempt from the requirement to prepare an agricultural water assessment under the proposed rule, as the water was from a municipal water source and was treated.

(Response 41) In response to comment 40, we discuss information that CEA farms should consider in determining whether they are eligible for an exemption under § 112.43(b). We also explain that regardless of whether a farm is eligible for an exemption under § 112.43(b), the farm remains responsible for ensuring the safe and adequate sanitary quality of the water used to grow covered produce (§ 112.41).

Regarding the outbreak of *Salmonella* Typhimurium associated with packaged leafy greens produced in a CEA indoor hydroponic operation specifically, we note that our

investigation did not result in the identification of the specific source or route of contamination of the leafy greens (Ref. 6462). However, we explained in our investigation report (Ref. 6462) that recovery of *Salmonella* Liverpool, a strain not associated with the outbreak, from a water sample of an indoor production pond highlights the importance of minimizing sources of microbial contamination as well as operating and maintaining production ponds in a manner that does not result in the spread of pathogens to produce. For example, while the growing ponds in the operation were filled with water sourced from a public water supply that was further treated on-site using a sand filtration and ultraviolet (UV) system, as our investigation report notes, once water was in the growing ponds, it was not routinely disinfected or otherwise treated. Moreover, while the operation indicated to investigators that ponds get treated in response to sample results revealing the presence of generic *E. coli*, the operation did not have a procedure or systematic approach to ensure adequate water treatment. We also noted that a water sample collected from a stormwater retention basin located outside of the CEA operations' property but approximately 25 feet from the CEA structure tested positive for the outbreak strain.

Although investigators did not observe specific routes of contamination to or from areas surrounding the CEA operation, we note that the report findings provide further evidence supporting the requirements that farms, including those involved in CEA, assess and mitigate risks associated with adjacent and nearby land uses that may impact operations in both rural and more urbanized settings. While we recognize that CEA may provide an additional degree of control compared to more traditional outdoor farming operations, we emphasize that it is still important for farms that participate in CEA to consider a range of potential sources of hazards in ensuring that subpart E requirements are met, including those above.

(Comment 42) A few comments request clarification on the documentation farms need to support an exemption from the requirement to prepare an agricultural water assessment. For example, one comment asks if all farms need to prepare an agricultural water assessment, but that for farms eligible for an exemption, doing so would only entail maintaining information relevant to the exemption.

(Response 42) If a farm satisfies the criteria for an exemption under § 112.43(b), the farm is not required to prepare a written agricultural water assessment. However, the farm is required to maintain records applicable to the exemption, such as:

- In support of the exemption in § 112.43(b)(1)(i), documentation of test results (§ 112.50(b)(5)) and analytical methods (if applicable) (§ 112.50(b)(12));
- ~~in~~In support of the exemption in § 112.43(b)(1)(ii), annual documentation of the results or certificates of compliance from a public water system or public water supply demonstrating that the water meets the relevant requirements in § 112.44(c) (§ 112.50(b)(6)); and
- ~~in~~In support of the exemption in § 112.43(b)(1)(iii), documentation of scientific data or information the farm relies on to support the adequacy of a treatment method (§ 112.50(b)(10)) and documentation of the results of water treatment monitoring (§ 112.50(b)(11)).

(Comment 43) Some comments seek clarity on whether the exemptions in proposed § 112.43(b) are permanent or temporary.

(Response 43) Farms are eligible for an exemption from the requirement to prepare a written agricultural water assessment under § 112.43(b) for as long as the relevant requirements

are met. This includes maintaining records applicable to the exemption, as discussed in response to comment 42.

F. Elements of an Agricultural Water Assessment (§ 112.43(a))

e We proposed to require farms that use pre-harvest agricultural water for non-sprout covered produce to prepare a written agricultural water assessment that would identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces, based on an evaluation of the farm's agricultural water system; agricultural water practices; crop characteristics; environmental conditions; and other relevant factors, including, if applicable, results of any testing conducted (proposed § 112.43(a)). We respond to the comments on proposed § 112.43(a) in the following paragraphs. We note that comments on testing conducted under § 112.43(d) are discussed in section V.H. As discussed in our response to comments, we are finalizing § 112.43(a) as proposed, with minor edits for clarification¹. Agricultural Water Systems

(Comment 44) Several comments contend that the proposed rule does not adequately address various types of agricultural water, since only ground water and surface water are identified in proposed § 112.43(a)(1), which would require farms to evaluate each agricultural water system (i.e., source and distribution system) used for growing activities for covered produce. These comments request that FDA clearly define various agricultural water types (including surface water, ground water, municipal water, and recycled water) and provide examples of when classification may change. For example, one comment requests clarity on what requirements in the proposed rule would apply for shallow ground water influenced by surface water.

(Response 44) We recognize that farms may use a variety of water sources and distribution systems for their pre-harvest agricultural water. As such, we are revising the requirement to clarify that considering whether a water source is ground water or surface water is just one example of the information farms might consider in evaluating the location and nature of the water source (see § 112.43(a)(1)(i)).

We do not consider it necessary or practical for us to define types of water sources other than “ground water” and “surface water” in § 112.3, as the conditions associated with such other sources are expected to vary widely and contain elements addressed within the definitions for ground water and surface water, which may result in confusion. For example, the term “recycled water” in common usage can refer to many different things--such as use of water from a canal system that is subject to return flows, or use of treated, recycled wastewater--such that it would be difficult to define “recycled water” in a way that is meaningful for hazard identification purposes across categories of recycled water. Rather, we intend farms to describe the specific conditions and characteristics associated with a water source that may affect the likelihood of known or reasonably foreseeable hazards being introduced when evaluating the location and nature of the source under § 112.43(a)(1)(i), including for recycled water. We provide examples of such considerations, including situations in which classification of a water source may change, in response to comment 30.

With respect to comments requesting clarity on whether different requirements apply based on water source, we note that the requirements for agricultural water quality in §§ 112.41 and 112.43 apply regardless of the source or type of water used as agricultural water. Farms must determine the appropriate use of their water sources by assessment as required under § 112.43, taking into account the standard in § 112.41 that all agricultural water must be safe and of

adequate sanitary quality for its intended use. As such, we are not establishing different requirements for pre-harvest agricultural water based on the nature of a farm's water source.

(Comment 45) A few comments seek clarity on how to classify municipal water stored in jugs, enclosed cisterns, food-grade tanker trucks, or barrels, and rainwater that is collected prior to use.

(Response 45) In evaluating each agricultural water system a farm uses for pre-harvest agricultural water in § 112.43(a)(1), farms are required to evaluate the location and nature of the water source; the type of water distribution system; and the degree of protection from possible sources of contamination. Considering such information will assist farms in evaluating the likelihood of known or reasonably foreseeable hazards being introduced to their pre-harvest agricultural water, the latter of which may then serve as a source of contamination to covered produce or food contact surfaces. For example, if farms hold pre-harvest agricultural water in storage vessels such as jugs, cisterns, or barrels, the following factors are relevant to consider as part of their agricultural water assessment under § 112.43(a)(1):

- Where they sourced the water from (and what they know about its quality at that point);
- ~~whether~~Whether the storage vessels are structured to protect that quality of water (such as whether they are kept closed to prevent entry of contaminants, such as from birds or other pests); and
- ~~whether~~Whether the storage vessels undergo any regular maintenance, cleaning and/or sanitizing to prevent them from serving as a source of contamination for the water.

Such storage vessels are part of the farm's agricultural water system as defined in § 112.3, and as such, under § 112.42 the farm must inspect and maintain the vessels, to the extent that they are under the farm's control, to identify any conditions that are reasonably likely to

introduce known or reasonably foreseeable hazards and prevent the systems from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity. In accordance with § 112.43(a), farms must also consider the results of any inspections and maintenance conducted under § 112.42 in preparing an agricultural water assessment.

(Comment 46) One comment requests that FDA provide information on the scope of water sources that would be considered adjacent and how those would be incorporated into agricultural water assessments.

(Response 46) We recognize that in some instances, known or reasonably foreseeable hazards may be introduced into an agricultural water system (defined at § 112.3) from a body of water that is not otherwise a part of that system. For example, a canal that a farm uses for pre-harvest agricultural water may be subject to known or reasonably foreseeable hazards from a nearby pond if, when it rains, runoff from the pond is introduced into the canal. If there are other bodies of water that may introduce known or reasonably foreseeable hazards to an agricultural water system (as in the above example), farms must consider that information in evaluating the degree of protection of the agricultural water system from possible sources of contamination under § 112.43(a)(1)(iii). For example, a farm might consider the nature of the other body of water, the proximity of the other body of water to the farm's agricultural water system, and local topography, as these factors might affect the likelihood of known or reasonably foreseeable hazards being introduced to the agricultural water system from the other body of water.

(Comment 47) Some comments seek clarity as to how the requirements to consider the location and nature of the water source in proposed § 112.43(a) applies in CEA farms, such as some hydroponic and aquaponic operations. Additionally, one comment suggests that indoor

farms should consider whether the surrounding building and/or other infrastructure may impact the quality of pre-harvest agricultural water.

(Response 47) Section § 112.43(a)(1) requires farms to evaluate each agricultural water system that they use for growing activities for covered produce, including, in part, the location and nature of the water source (for example, whether it is ground water or surface water) and the degree of protection from possible sources of contamination. Although CEA operations may provide an additional degree of control over some types of hazards compared to other operations, we emphasize that it is still important to consider a range of potential sources of hazards that might affect agricultural water used in CEA. For example, in our investigation report for the 2021 outbreak of *Salmonella* Typhimurium associated with packaged leafy greens produced in a CEA indoor hydroponic facility, we discussed various findings related to water use and highlighted the importance of assessing and mitigating risks associated with adjacent and nearby land uses that may impact CEA operations, in both rural and more urbanized settings (Ref. [6162](#)). See response to comment 41.

We also agree that it is important for farms in general (not just those participating in CEA) to consider buildings and/or other infrastructure that might affect the quality of their pre-harvest agricultural water. We note in particular that the definition of “agricultural water system” includes, in part, “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” (§ 112.3). As such, to the extent that any building, structure, or equipment is a component of a farm’s agricultural water system, the farm must inspect and maintain those components to the extent that they are under the farm’s control in accordance with § 112.42 and consider those

components in conducting an agricultural water assessment pursuant to § 112.43. For example, in evaluating the degree of protection of an agricultural water system from possible sources of contamination under § 112.43(a)(1)(iii), farms should consider whether buildings or structures that are part of its agricultural water system protect other components of the agricultural water system from possible sources of contamination (such as where a well house or storage shed might protect wells and/or water application equipment from debris, trash, domesticated animals, or other possible sources of contamination).

2. Degree of Protection of Each Agricultural Water System

a. General.

(Comment 48) A few comments request examples of types of hazards beyond animals, biological soil amendments of animal origin (BSAAOs), and human waste that should be considered as part of an agricultural water assessment. One comment suggests that farms might also consider maintenance activities in an irrigation district and whether a farm is near an airport subject to nearby chemical intrusion as part of an agricultural water assessment.

(Response 48) Section 112.43(a)(1)(iii) requires that as part of an agricultural water assessment, farms evaluate the degree of protection of the agricultural water system from possible sources of contamination. While other water users, animal impacts, and adjacent and nearby land uses related to animal activity, BSAAOs, or presence of untreated or improperly treated human waste are provided as examples of possible sources of contamination, we note that the list of examples in § 112.43(a)(1)(iii) is not exhaustive. For example, if applicable to the circumstances, the farm must consider the following potential sources of contamination as part of its agricultural water assessment: upstream maintenance activity (such as dredging) within a canal system that may affect the microbial quality of the water; urban development activities

from which runoff may introduce hazards to the agricultural water system; and human activities (such as recreational vehicle parks) that may introduce hazards to the agricultural water system. We note, however, that the 2015 produce safety final rule applies to biological hazards and not, for example, chemical hazards. See response to comment 8.

(Comment 49) Some comments suggest that farms with agricultural water systems that span long distances from source to point of delivery (such as some irrigation canals) will face challenges when preparing agricultural water assessments, as certain portions of the water system, such as those that relate to adjacent and nearby lands and/or other water users, may not be under the farm's control. A few comments suggest that additional clarity on how far upstream farms are required to consider impacts on their water systems would help, and request more information on what distance upstream farms are responsible for considering.

(Response 49) We recognize that some farms have pre-harvest agricultural water systems with water sources and/or distribution systems, such as irrigation canals or rivers, that span long distances or are impacted by land uses covering a wide area. We further recognize that factors that can affect water sources, including those related to adjacent and nearby lands and/or other water users, may be outside of a farm's control.

More broadly, due to the variability that exists in agricultural water systems and across different growing regions, including in the characteristics of water sources and the nature of potential sources of hazards, farms' consideration of other agricultural water users and/or adjacent or nearby lands will vary widely, include factors that may be outside of a farm's control, and will likely depend on each farm's unique agricultural water systems and growing operations. For example, the QAR (Ref. 17) found that the composition and chemistry of flowing waters can be expected to be largely influenced by their course through land used for purposes that may lead

to their contamination and, potentially, to the contamination of produce exposed to those waters. As such, we do not consider it appropriate to prescribe a distance for which farms must consider factors that have the potential to impact their water quality.

While we are not requiring farms to physically visit areas of an agricultural water system that are outside of their control, farms must include in their assessments information on sources of hazards (such as adjacent and nearby land uses and other water users) that have the potential to result in contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with agricultural water. We note that there are a variety of resources available to farms that may provide information as to the presence and nature of impacts that might affect the quality of their agricultural water. See response to comment 51.

(Comment 50) One comment requests that FDA revise the requirements for agricultural water assessments in proposed § 112.43(a) to clarify that farms are only required to consider the degree of protection and/or adjacent and nearby land uses for surface water sources, and that only possible sources of contamination within the surface water's drainage basin need to be considered.

(Response 50) We do not consider it appropriate to limit consideration for the degree of protection of an agricultural water system and/or adjacent and nearby land uses to surface water sources only, as doing so would not sufficiently capture the variety of water sources and potential sources of hazards that exist in industry. While surface water sources are generally more vulnerable to contamination, the potential for contaminants to be introduced to agricultural water is not limited to surface water (Ref. 17). For example, if a well is not sufficiently protected (for example, due to unprotected cross-connections or from having an impaired well cap, seals, and/or casing), it may increase the likelihood of hazards being introduced to the water. Similarly,

if the well is situated at a lower elevation than adjacent and nearby lands and is subject to runoff from those lands, it may be subject to the introduction of hazards. As occurrences such as these are important for farms to consider in complying with the requirements for pre-harvest agricultural water assessments, we decline to make the change suggested by the comment.

(Comment 51) Some comments state that farms will face difficulties in getting information on factors that are outside of their control (for example, other users of water and adjacent and nearby lands), such as when those areas are not available for farms to access due to ownership or geographic barriers. A few comments indicate comfort speaking with neighbors about their land use(s), whereas other comments state that some farms may face challenges in obtaining information on adjacent and nearby lands due to land users either being unwilling to share information or providing incomplete or inaccurate information. Some of these comments request that farms should be able to assume that, in the absence of obvious evidence to the contrary, neighbors are following the law. One comment expresses a concern that situations could arise in which a neighbor informs a farm that they are appropriately controlling hazards but are not doing so, and seeks clarity as to whether the farm would be held responsible in this situation. While some comments acknowledge that there may be other sources of information on adjacent and nearby lands, a few suggest that some of these resources (such as visual observation and mapping tools) are inadequate because they cannot reveal all specific hazards.

(Response 51) Farms are responsible for ensuring that all applicable requirements of subpart E are met, including the requirement in § 112.41 that all agricultural water be safe and of adequate sanitary quality for its intended use. While farms are not required to physically visit areas of an agricultural water system that are outside of their control, in preparing an agricultural water assessment under § 112.43, farms must include in their assessments information on

sources of hazards (such as adjacent and nearby land uses and other water users) that have the potential to result in contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with agricultural water.

Although farms may consider working with adjacent and nearby land users in evaluating adjacent and nearby land uses under § 112.43(a), there are a variety of resources available that may provide insight as to the presence and nature of impacts that can affect the quality of agricultural water. For example, information can be acquired through visual observation, from local extension agents and/or industry associations, or from online resources such as mapping tools, which may provide helpful information on topography and proximity to potential sources of hazards. Depending on the water source being used, there may also be organizations or water management authorities, such as irrigation district managers, that can serve as a source of information. We are also aware of efforts underway to bring together members of agricultural communities on a large scale, such as through the CAN Initiative (Ref. 38), to further conversations and encourage discussions between land users in agricultural areas. Various action items have been identified as part of CAN, one of which entails steps that can be taken to foster neighbor-to-neighbor interactions and conversations (Ref. 39). See also response to comment 33. As efforts such as these progress, they too may serve as an additional source of information for meeting the requirements in § 112.43. In some instances, farms may benefit from looking to a variety of resources to assist in their understanding of other water users and adjacent and nearby land uses to further inform their determinations under § 112.43(c) as to 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.

We recognize that even with the variety of resources available to farms, farms may still face uncertainty with respect to other water users and adjacent and nearby lands that are outside of their control, such as if upstream users are not willing to share information. As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69137-69138), due to the nature of the risks associated with animal activity, BSAAOs, and untreated or partially treated human waste on adjacent and nearby lands, in the event of uncertainty, farms should consider accounting for the increased likelihood of hazard introduction to the water systems. Farms should use that information, particularly for surface water unprotected from runoff and in light of other factors evaluated under § 112.43(a), in determining whether measures under § 112.45 are reasonably necessary. See also response to comment 53.

(Comment 52) Some comments suggest that when evaluating the degree of protection of each agricultural water system, farms may recognize riparian buffers and filtrating vegetation for their role in protection water from sources of contamination.

(Response 52) We agree that buffers and filtrating vegetation, in addition to walls, earthen berms, ditches, or other barriers, may help minimize the influence of runoff on water sources and distribution systems. (See 86 FR 69120 at 69134 and 69136.) The comments did not request, nor are we requiring, farms to use any of these barriers in managing their identified risks. We further agree that there may be other mechanisms by which agricultural water systems are protected from possible sources of contamination via runoff, the impact of which farms may consider when conducting their agricultural water assessments.

b. Adjacent and nearby land uses.

(Comment 53) Several comments support the proposed rule's requirement for farms to assess adjacent and nearby land uses. Conversely, some comments assert that the proposed

requirement that covered entities must evaluate adjacent and nearby land uses represents an unreasonable burden on farms. A few of these comments claim that if farms are not able to prove that adjacent or nearby land use does not pose a risk, they would be forced to assume risks are present and undertake potentially overly conservative or unnecessary mitigations. One comment requests that FDA include in the final rule an alternative option for achieving the requirement to evaluate adjacent and nearby land use, suggesting that a provision for a written explanation for why the adjacent and nearby lands cannot be assessed, combined with water testing, would suffice. Another comment suggests that adjacent and nearby lands should only be evaluated for certain high-risk activities, although, the comment notes, what is considered “high risk” is also dependent on the water source and crop being grown.

(Response 53) As discussed in the 2021 agricultural water proposed rule (80 FR 74354 at 69126-69127), adjacent and nearby land uses have been identified as possible contributing factors in several produce outbreaks (Refs. 18-23, [57](#), [6258](#), [63](#) and [6364](#)). FDA’s investigations of such outbreaks underscore the importance of pre-harvest agricultural water quality and the potential impacts of adjacent and nearby land uses on agricultural water, which can serve as a route of contamination of produce. The requirements we are finalizing with this rule are designed to address these concerns by requiring farms to evaluate adjacent and nearby land uses in preparing an agricultural water assessment under § 112.43(a) and manage use of their pre-harvest agricultural water accordingly. As such, we decline to provide an alternative to the requirement that adjacent and nearby lands be evaluated under § 112.43(a) as part of an agricultural water assessment.

Moreover, we are providing for expedited implementation of mitigation measures under § 112.45(b) for known or reasonably foreseeable hazards related to certain adjacent and nearby

land uses. We recognize that activities associated with adjacent or nearby lands that introduce known or reasonably foreseeable hazards into a water source or distribution system are often not under a farm's control. While the farm may not have control over those potential hazards at their point of introduction into a water source or system, the potential hazards are important for the farm to consider in making decisions about the use of agricultural water on covered produce. Therefore, for animal activities, BSAAOs, or untreated or partially treated human waste associated with adjacent and nearby lands, it is important that the farm not only implement mitigation measures that are under its control to reduce the risk associated with that water source or system, but that it do so on an expedited basis to protect public health.

Many activities on adjacent or nearby lands may create or pose conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, which farms must consider under § 112.43(a) as part of an agricultural water assessment if applicable to their operations. Examples include other agricultural operations (such as land used for growing operations, animal grazing, dairy production, poultry production, barnyards, commercial animal feeding operations, and farms with working animals); composting sites; lands used for recreational activities (such as campgrounds); wastewater treatment facilities (or other potential sources of human waste like toilet facilities and sewage disposal systems); urban/suburban development activities; and lands with significant wildlife intrusion or habitat.

We recognize that farms may face uncertainty around evaluating information related to adjacent and nearby land uses such as these, such as if upstream users are not willing to share information. As discussed in the 2021 proposed rule (86 FR 69120 at 69137-69138), in the event of uncertainty, due to the nature of the risks associated with animal activity, BSAAOs, and

untreated or partially treated human waste on adjacent and nearby lands, 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 use of their water. However, we disagree that this will “force” farms to assume risks are present and implement mitigation measures that might otherwise not be necessary. Rather, farms should consider the increased likelihood of hazard introduction from such adjacent and nearby land uses, in addition to other information evaluated in § 112.43(a)(1) through (5), in determining whether measures under § 112.45 are reasonably necessary. As a result, farms may find, for example, that in light of the information evaluated under § 112.43(a)(1) through (5), mitigation may not be reasonably necessary to address potential hazards from an adjacent or nearby land use.

(Comment 54) Many comments request that FDA clarify the definition of and/or narrowly define “adjacent and nearby lands” in terms of distance, arguing that absent such a definition, it will be unclear what lands farms are responsible for considering. One comment notes that other food safety schemes define adjacent land as no CAFOs closer than 0.25 miles or 400 feet buffer from hobby farms. Another comment expresses concerns that in the Fall 2019 *E. coli* O157:H7 outbreak linked to romaine lettuce referenced in the proposed rule, the outbreak strain was found at a point nearly two miles upslope from the impacted farms, a distance the comment deems unreasonable for a farm to consider in its assessment.

(Response 54) In the 2021 agricultural water proposed rule (86 FR 69120 at 69135), we discussed “adjacent and nearby lands” with respect to agricultural water systems specifically, as adjacent and nearby lands may affect the safety of covered produce in ways not related to agricultural water, such as through movement of animals, equipment and tools, run-off into growing fields, and wind. We recognize that this may have led to uncertainty as to the lands that

farms are required to consider for assessment purposes, and are clarifying that for the purposes of subpart E, by “adjacent” land we are referring to land sharing a common border with the farm’s land. By “nearby” land we are referring to a broader category of land, including land that does not adjoin the farm’s land but has the potential to affect the farm’s agricultural water systems(s) based on the land’s location. For example, agricultural water may be affected by agricultural practices and runoff from those operations into surface water sources or open distribution systems that are used for agricultural water even if the operations’ lands are not adjacent to a farm’s land. See also 80 FR 74354 at 74433. Due to the diversity that exists in agricultural water systems and across different growing regions, what constitutes “adjacent” and “nearby” land will vary between farms and likely depend on each farm’s unique agricultural water systems. As such, we do not consider it appropriate to prescribe an upstream distance for which farms must consider uses of adjacent and nearby lands. See also response to comment 49.

c. Animal impacts and activities.

(Comment 55) Several comments seek clarity on how a farm should translate evidence of animal activity (e.g., scat from unidentified animals, tracks without scat, or damaged irrigation pipes from an unidentified animal) into risk, noting that different animals and animal activities represent different levels of risk to water safety. One comment expressed a concern that the requirement for farms to consider animal activity may lead to the outcome that a farm with any animal activity nearby will be expected to implement significant safety measures.

(Response 55) Examples of relevant factors for evaluating the degree of protection of agricultural water systems from potential sources of contamination associated with animals under § 112.43(a)(1)(iii) include, but are not limited to, the following:

- The presence and location of any animal activities, such as whether there are areas in which animals might be in close proximity and/or have direct access to pre-harvest agricultural water systems (such as for loafing or drinking). Included in this is consideration for any fencing, containment, or other measures that may affect animal access to agricultural water systems;
- ~~the~~The presence and location of potential attractants and habitats (such as heavy vegetation, wooded areas, water sources, or standing water) that may draw animals to agricultural water systems;
- ~~whether~~Whether runoff into agricultural water systems from lands currently or historically associated with animals is likely to occur, including whether there are earthen diversion berms, ditches, or other barriers that minimize runoff;
- ~~whether~~Whether animals have access to areas relevant to agricultural water systems at times when pre-harvest agricultural water is being applied to non-sprout covered produce; and
- ~~whether~~Whether any systems or structures are in place to handle, convey, or store animal waste (such as animal stalls, composting piles, pits, manure lagoons, or other waste containment structures or systems) that may serve as a possible source of contamination to agricultural water systems. Included in this, for example, is whether vehicles carrying animal waste follow traffic patterns that may result in the introduction of known or reasonably foreseeable hazards from the animal waste to agricultural water systems.

As discussed in the 2021 proposed rule, visual observations by a farm for purposes of §§ 112.81-112.83 in subpart I, “Domesticated and Wild Animals” of the 2015 produce safety final rule may provide useful information for evaluating the degree of protection of a pre-harvest

agricultural water system under § 112.43(a)(1)(iii) (86 FR 69120 at 69135). Additionally, a farm may 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 § 112.42, which we did not propose to change. 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.)

Given the diversity that exists across industry in water systems, operations, and conditions, we do not expect that every animal impact or activity will require that corrective or mitigation measures be implemented under § 112.45. While farms are required to evaluate the degree of protection of an agricultural water system from possible sources of contamination including animal impacts and adjacent and nearby land uses related to animal activity, they are required to consider that information, along with the other factors evaluated under § 112.43(a)(1) through (5), in determining whether measures under § 112.45 are reasonably necessary.

(Comment 56) One comment suggests that farms should take the type of animal activity into account when evaluating risks as part of an agricultural water assessment. For example, the comment asserts that management techniques such as prescribed grazing can result in less opportunity for contamination of water via runoff compared to CAFOs, since fecal matter is dispersed across a larger area of land where prescribed grazing occurs. The comment also states that dispersed feces in areas used for prescribed grazing are more likely to be inactivated by the sun's UV rays versus feces at a CAFO.

(Response 56) The risk posed by animal activities to a farm's agricultural water systems may depend on various factors and are not limited only to animal activities with high densities of animals, such as CAFOs. Animal activities have the potential to serve as a source of human

pathogens, and depending on the circumstances, may introduce hazards to agricultural water systems (Ref. 17). Animal activities can include those related to wildlife (e.g., birds or deer); animal intrusion, domesticated companion animals (e.g., dogs, cats); animals for protection (e.g., guard dogs); working animals (e.g., horses, mules); grazing animals; livestock (including CAFOs); poultry production; dairy production; and barnyards.

For example, as discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69125-69127), in the fall 2018 *E. coli* O157:H7 outbreak linked to romaine lettuce from California (Ref. 20), investigators noted that extensive wild animal activity in the area and animal grazing on nearby land by cattle and horses, among other things, may have served as potential sources of hazards. Similarly, in the fall 2019 *E. coli* O157:H7 outbreaks linked to romaine lettuce (Ref. 21), investigators observed cattle grazing land in the hills above leafy greens fields, with numbers of cattle far lower than the volume of what is considered a large CAFO. As discussed in the QAR (Ref. 17), exposure of produce to hazards from animals may occur, among other means, through runoff that enters the growing area and contaminated agricultural water. As such, we consider it important for farms to consider various animal impacts and activities, not just those related to CAFOs, for the potential to serve as sources of known or reasonably foreseeable hazards that may be introduced into an agricultural water system and contaminate covered produce.

D. BSAAOs.

(Comment 57) One comment requests more information on what FDA would consider to be “high risk” regarding agricultural water and the use of BSAAOs.

(Response 57) As discussed in response to comment 31, given the diversity across farms, “risk” related to BSAAOs will vary. For example, the QAR (Ref. 17) concluded that composting

is less likely than controlled chemical or physical treatments to fully eliminate human pathogens from animal waste; incompletely treated, or re-contaminated, BSAAOs may contain human pathogens; and biological soil amendments can transmit human pathogens to surface water or ground water when stockpiled or applied to fields. The use of BSAAOs both by the farm and by users of adjacent and nearby lands are factors to consider for purposes of an agricultural water assessment under § 112.43(a), and in making a risk management determination under § 112.43. We intend farms to consider information relevant to their specific circumstances in evaluating the various factors under § 112.43(a).

Examples of relevant factors for evaluating the degree of protection of agricultural water systems from potential sources of contamination associated with BSAAOs include, but are not limited to, the following:

- The location and proximity of areas where BSAAOs are held or applied to land in relation to agricultural water systems;
- ~~whether~~Whether runoff or tailwater returns into agricultural water systems from areas where BSAAOs are held or applied to land is likely to occur, including whether there are earthen diversion berms, ditches, or other barriers that minimize runoff;
- ~~whether~~Whether the BSAAOs are treated and to what extent;
- ~~whether~~Whether BSAAOs are applied to the land during times when pre-harvest agricultural water is being applied to non-sprout covered produce; and
- ~~whether~~Whether any systems or structures are in place to handle, convey, and store BSAAOs (such as composting piles, pits, manure lagoons, or other waste containment structures or systems) that may serve as a possible source of contamination to agricultural water systems. Included in this, for example, is whether vehicles carrying BSAAOs

follow traffic patterns that may result in the introduction of known or reasonably foreseeable hazards from the BSAAOs to agricultural water systems.

For farms subject to the 2015 produce safety final rule, we note that requirements in subpart F of part 112 (§§ 112.51-112.60) may apply, including § 112.52(a), which requires that farms handle, convey, and store any BSAAO in a manner and location such that it does not become a potential source of contamination to water sources and water distribution systems.

(Comment 58) One comment seeks clarity as to whether there are “specifications” for the use of BSAAOs and different types of irrigation methods under the proposed rule.

(Response 58) It is unclear to us what type of “specification” the commenter is referring to. However, we note that this rule does not establish requirements for allowable pre-harvest agricultural water application methods based on the source of known or reasonably foreseeable hazards to an agricultural water system. Farms remain responsible for ensuring that all applicable requirements are met, including the requirement in § 112.41 that all agricultural water be safe and of adequate sanitary quality for its intended use.

5. Untreated and improperly treated human waste.

(Comment 59) Some comments address the requirement in § 112.43(a)(1) to consider the degree of protection from possible sources of contamination, including untreated or partially treated human waste. One comment supports FDA’s recognition of the continued role of the CWA and pertains to the regulations laid out in 40 CFR Part 503 to protect public health and the environment from pathogens unrelated to land applied biosolids, suggesting and suggest that use the applications of treated municipal biosolids for land applications can be safely done.

Conversely, other comments suggest that application of biosolids from municipal or industrial sources requires further evaluation and/or research as it relates to impacts on agricultural water

and produce safety. One comment opposes the land application of municipal wastewater sludge and industrial waste (for example, slaughterhouse sludge), suggesting that there should be restrictions for the use of such materials on crops and that land applications of those materials may serve as a source of contamination to water sources.

(Response 59) Land As described in the QAR (Ref. 17), human waste may contain pathogens in relatively high concentrations. Runoff associated with human waste from adjacent and nearby lands may contaminate sources or distribution systems for pre-harvest agricultural water for non-sprout covered produce. As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69137), an evaluation of hazards associated with untreated or improperly treated human waste can include consideration of potential sources of contamination such as toilet facilities (portable and fixed), sewage systems, sewer overflows, septic tanks, and drain fields. 86 FR 69120 at 69137.

With respect to comments relating to land applications of treated sewage sludge (biosolids) and/or industrial waste (such as from slaughterhouses)), we note that such comments are outside the scope of this rulemaking. Rather, as part of a pre-harvest agricultural water assessment under § 112.43(a), farms are required to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces based on an evaluation of various factors, including the degree of protection of each agricultural water system from possible sources of contamination (§ 112.43(a)(1)(iii)). As part of this evaluation, farms consider the presence of potential sources of hazards (such as land applications of such materials); the likelihood of those hazards being introduced to their water systems (such as through runoff or seepage); and together with the other information evaluated in § 112.43(a)(1) through (5), make a determination as to whether

measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces from hazards associated with pre-harvest agricultural water.

~~As discussed in the 2021 agricultural water proposed rule, the use and disposal of treated sewage sludge (biosolids), including domestic septage, are regulated under 40 CFR Part 503. Subpart D of the Part 503 regulation protects public health and the environment through requirements designed to reduce the potential for contact with the disease-bearing microorganisms (pathogens) in sewage sludge and domestic septage applied to the land or placed on a surface disposal site (Ref. 64). In instances in which land applications of human waste do not meet the requirements in 40 CFR part 503 (or equivalent regulatory requirements), we encourage farms to consider the increased likelihood of hazard introduction to their agricultural water systems. Further, we~~We emphasize that other provisions of the 2015 produce safety final rule that we did not propose to change, including the prohibition on the use of human waste for growing covered produce (except sewage sludge biosolids used in accordance with the requirements of 40 CFR part 503, subpart D, or equivalent regulatory requirements) (§ 112.53), continue to apply.

It is important for farms to consider the increased likelihood of hazard introduction to their agricultural water systems for any land applications of ~~other~~ materials (such as treated sewage sludge (biosolids) and industrial wastes),² because those materials may serve as a source of known or reasonably foreseeable hazards that can be introduced into an agricultural water system (such as through runoff). Farms should consider the increased likelihood of hazard introduction to their agricultural water systems, particularly for surface water unprotected from runoff and in light of other factors evaluated under § 112.43(a), in determining whether measures are reasonably necessary under § 112.45.

f. Other water users.

(Comment 60) Several comments address FDA’s request for comment on water reuse for pre-harvest agricultural water. Some comments state that reused water can be used as safely as other types of water and may help farms faced with dwindling water supplies from other sources. A few of these comments specifically suggest that wastewater can be treated to be “fit for purpose,” in which it is treated to a level that is safe for a specific use on irrigated food crops. Some comments also note that the requirements related to quality and use of pre-harvest agricultural water in §§ 112.41, 112.42, and 112.43 are appropriate to apply for all types of water. However, a few comments suggest that reused water should be subject to testing before being used as pre-harvest water. Another comment requests that FDA clarify in the final rule and in subsequent guidance that untreated or improperly treated human waste is not present in treated recycled wastewater because water recycling includes proper treatment of human waste. The comment suggests that without additional guidance from FDA, a farm may interpret using a recycled water source as inherently risky even when it is not.

(Response 60) As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69134-69135), the requirements for agricultural water quality in §§ 112.41 and 112.43 apply regardless of the source or type of water used as agricultural water. Thus, a farm must determine the appropriate use of the recycled water in light of the conditions and practices on the farm by assessment as required under § 112.43, taking into account the standard in § 112.41 that all agricultural water must be safe and of adequate sanitary quality for its intended use. As comments suggest, farms also need to ensure that all other applicable requirements in subpart E are met, including those in § 112.42 for inspection and maintenance of agricultural water systems

to the extent they are under a farm's control, the results of which farms will consider in preparing an agricultural water assessment under § 112.43(a).

We are not aware of, and comments did not provide, data or information suggesting the need to require that all recycled or reused water be tested to adequately complete an agricultural water assessment. Therefore, consistent with our mandate to establish science-based minimum standards, including procedures, processes, and practices that are reasonably necessary to prevent introduction of hazards and provide reasonable assurances produce is not adulterated under section 402 of the FD&C Act, we are not establishing separate requirements related to testing or quantitative thresholds for water reuse. Users of such water, if appropriate, may test that water as one part of an assessment under § 112.43(d). While we provide examples of scientifically valid microbial criteria and sampling frequencies in our responses to comment 95 and comment 93, respectively, we expect that as the science evolves and more information is learned about unique considerations relevant to certain sources of water (such as water reuse), such information may be incorporated in future guidance.

We also recognize that some suppliers of recycled water (for example, a public utility), may furnish information on the water's microbial quality which can be considered while preparing agricultural water assessments and determining whether measures are reasonably necessary under § 112.45.

3. Agricultural Water Practices

(Comment 61) Some comments address the requirement in proposed § 112.43(a)(2) that farms assess the time interval between the last direct application of agricultural water and harvest of the covered produce. These comments suggest that agricultural water used early in the production cycle is less risky than water used closer to harvest and request that FDA recognize

this variation in risk when evaluating farms' assessments and records. Other comments note the variability in application-to-harvest intervals that exist across industry. For example, some comments note that for certain crops, agricultural water needs to be applied right up until harvest, whereas for other crops, there may be more flexibility as to the timing of the last water application. Others cite challenges associated with assessing the interval between the last direct application of agricultural water and harvest. These comments note that in some instances, the harvest date and/or the last water application is established by the shipper, and that such decisions may not be made until right before harvest.

(Response 61) As explained in the QAR (Ref. 17), the timing of water application is an important factor in determining the likelihood of contamination of produce, because many 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 (Ref. 65). 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 (Ref. 17). We recognize that the time interval between last direct application of agricultural water and harvest is likely to vary widely across industry, and as such, each farm must capture the practices unique to its operation within its agricultural water assessments and use that information, alongside the other factors evaluated under § 112.43(a), in determining whether measures 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 the farm's pre-harvest agricultural water.

Further, we recognize that there may be some instances in which there is uncertainty as to what the time interval between last application of agricultural water and harvest will be. In such instances, farms may use their previous experience and knowledge of agronomic practices to provide an estimate in their agricultural water assessment as to what the expected interval might be. For example, if a farm knows that the last water application generally occurs 1 to 2 weeks before harvest, even though the precise interval may vary and not be known until right before harvest, the farm may note that in its agricultural water assessment and use that information alongside other factors evaluated in § 112.43(a) in making decisions regarding use of its pre-harvest agricultural water.

4. Crop Characteristics

(Comment 62) Many comments address the proposed requirement in § 112.43(a)(3) that farms evaluate crop characteristics as part of their agricultural water assessments. Several comments seek clarification from FDA that characteristics of the crop include aspects beyond what is explicitly listed in the preamble of the proposed rule, such as whether the crop is grown in a manner that is exposed to pooled water or wet soil, whether it supports the growth of foodborne pathogens, and whether it has historically been linked to outbreaks where pre-harvest water use was a known or suspected route to contamination.

(Response 62) Section § 112.43(a)(3) requires farms to evaluate crop characteristics, including the susceptibility of the covered produce to surface adhesion or internalization of hazards, as part of their agricultural water assessments. Crop characteristics that a farm considers may extend beyond those provided as examples in § 112.43(a)(3), which we are finalizing as proposed, without changes. For example, a farm may have information suggesting that characteristics of its covered produce support the attachment, survival and/or growth of

pathogens that may be introduced via agricultural water. We also note that contact between covered produce and pooled water is addressed in § 112.42(b)(4), which we did not propose to substantively revise. Section 112.42(b)(4) requires that farms, as necessary and appropriate, implement measures reasonably necessary to reduce the potential for contamination of covered produce resulting from contact of covered produce with pooled water.

We emphasize that absence of a history of outbreaks associated with a particular commodity should not be relied upon as being indicative of that commodity having characteristics that inherently make it “safe”. For example, in our investigation of the summer 2020 outbreak of *Salmonella* Newport linked to red onions, we noted that the outbreak was remarkable because the food vehicle, whole red onions, is a raw agricultural commodity that had not been previously associated with a foodborne illness outbreak (Ref. 23). Although a conclusive root cause could not be identified, several potential contributing factors were identified, including a leading hypothesis that contaminated irrigation water used in a growing field may have led to contamination of the onions.

(Comment 63) Several comments oppose the proposed requirement in § 112.43(a)(3) that farms identify and assess crop characteristics in their agricultural water assessments and recommend that assessment of crop characteristics be included in guidance and/or training programs instead, rather than as enforceable requirements in the final rule. Some comments request that FDA provide research support and scientific information on characteristics that do, or do not, make a crop more susceptible to contamination. A few comments note that crop characteristics are not a factor in other produce safety programs, such as the Leafy Greens Marketing Agreement (LGMA) metrics, noting that under the assessment that LGMA requires,

leafy greens are treated equal, and water should be of adequate quality for its intended use no matter what covered produce crop is being grown.

(Response 63) All agricultural water must be safe and of adequate sanitary quality for its intended use (§ 112.41), and we consider that evaluating crop characteristics, alongside other factors identified in § 112.43(a), as part of a farm's agricultural water assessment will assist farms in determining whether this standard is met.

While the QAR concluded that using crop physical characteristics alone seems to be a poor indicator of which commodities are at a greater or lesser likelihood of contamination that may lead to a foodborne outbreak, it also explains that where contamination of a water source is known to exist, the likelihood of contamination is a function of various factors, including contact with the commodity, commodity effects (characteristics), and application timing (Ref. 17).

Moreover, in the 1998 Good Agricultural Practices (GAPs) Guide (Ref. [5859](#)), we explain that produce that has a large surface area (such as leafy vegetables) and produce with topographical features (such as rough surfaces) that foster attachment or entrapment may be at greater risk from pathogens, if they are present, especially if contact with agricultural water occurs close to harvest or during post-harvest handling. Studies have also shown that the contamination of produce by contact with irrigation water is dependent, in part, on the physical properties of the plant, such as surface texture (Ref. 66). Moreover, survival of pathogens on produce is known to be enhanced if the epidermal barrier has been broken by physical damage, such as punctures or bruising, or by degradation by plant pathogens or spoilage organisms (Refs. 67 and 68).

In light of the foregoing, we have concluded that there is sufficient evidence of the effect of crop characteristics on the safety of covered produce to which agricultural water is applied; therefore, and we are not removing crop characteristics as one of the factors farms are required to

evaluate under § 112.43(a). Peer-reviewed literature, cooperative extension, and academic or trade organization research may serve as additional sources of information on the effect of crop characteristics on pre-harvest agricultural water.

(Comment 64) Several comments assert that the crop characteristics listed in the preamble of FDA's proposed rule are not specific to water and therefore are outside the scope of the proposed rule. For instance, one comment asserts that crop characteristics contribute to risks related to cultivation, harvesting, packing, and holding practices as a whole and not to agricultural water in particular. The comment recommends that if FDA intends to retain crop characteristics as a factor in the final rule related to agricultural water, the Agency should explicitly state that consideration of crop characteristics is limited to how the characteristics relate to potential contamination from direct application of agricultural water.

(Response 64) We disagree that including consideration of crop characteristics as part of a farm's agricultural water assessment under § 112.43(a) is outside the scope of this rulemaking, as crop characteristics have long been identified as a factor influencing the potential for water to contaminate produce (see response to comment 63). However, we recognize that not all crop characteristics may be relevant to potential contamination of covered produce by agricultural water, and we emphasize that farms are only required to evaluate those characteristics that might influence the safety of covered produce in light of a farm's pre-harvest agricultural water.

(Comment 65) Several comments suggest that the inclusion of crop characteristics in agricultural water assessments will result in confusion, because, the comments claim, crop characteristics are only relevant to consider if an agricultural water source is already contaminated. For example, comments suggest that crop characteristics are only relevant to agricultural water use if the agricultural water is not of adequate sanitary quality and, therefore,

the farm would already need to undertake mitigation measures independent of crop characteristics.

(Response 65) We disagree that crop characteristics are only relevant to consider if a farm has already determined that water is not safe or not of adequate sanitary quality for its intended use. As discussed in the 2013 proposed rule, the principle of “safe and of adequate sanitary quality for its intended use” contains elements related both to the attributes of the source water used and the activity, practice, or use of the water. The way in which water is used for different commodities and agricultural practices can affect the risk of contamination of the produce. 78 FR 3504 at 3563. While the QAR concluded that crop physical characteristics alone seems to be a poor indicator of which commodities are at a greater or lesser likelihood of contamination that may lead to a foodborne outbreak (Ref. 17), consideration of various factors that play a role in the safety and quality of pre-harvest agricultural water on covered produce, of which crop characteristics is only one, will assist farms in making decisions around the use of their pre-harvest agricultural water. As such, farms are required to consider crop characteristics, in conjunction with each other factor in § 112.43(a)(1) through (5), in determining whether measures are reasonably necessary under § 112.45.

(Comment 66) A number of comments note that many farms grow a wide variety of crops and suggest that it would be burdensome and time-intensive for a farm to assess susceptibility for all crops, particularly for crops for which limited scientific data on susceptibility exists. Some question whether farms need to conduct separate assessments for each commodity they grow. One comment notes that some farms change what commodities they grow frequently, suggesting that requiring the farm to prepare an assessment with each change in commodity will be burdensome.

(Response 66) Farms have the flexibility to evaluate crop characteristics in § 112.43(a)(3) as appropriate given their pre-harvest agricultural water uses and growing operations. For example, while we recognize that some farms may be growing multiple types of crops using the same agricultural water system, in some instances, crops may have similar characteristics such that the farm may group them based on broad similarities. For example, a farm that grows multiple types of leafy greens may assess the characteristics of all types at once, noting, for example, the large, rough surface area that may increase the likelihood of contaminants being trapped and surviving for extended periods of time. Similarly, a farm that grows oranges, mandarins, and lemons may assess the characteristics of citrus fruit in general. To the extent that a single commodity may have a unique factor that sets them apart from the others, the farm may choose to note that unique characteristic within its agricultural water assessment, rather than establishing a separate evaluation for that one crop. For example, a farm might explain whether one type of leafy green is particularly susceptible to physical damage that has the potential to result in survival and/or growth of pathogens, if introduced.

Farms that change crops frequently are likely aware of what commodities (or types of commodities) it is reasonably likely they may grow. This knowledge, along with practices such as grouping crops based on similarities in characteristics as discussed above, will assist farms in efficiently evaluating crop characteristics as part of their assessments. Further, in the instance where a farm does begin growing a commodity whose characteristics were not already evaluated as part of its agricultural water assessment, we note that reassessments under § 112.43€ must evaluate any factors and conditions affected by the change. As such, a farm's reassessment in light of a new crop may be more limited in scope than if a farm were to prepare a completely new assessment under § 112.43(a).

(Comment 67) One comment suggests that for some covered produce grown in hydroponic systems (such as green onions and lettuce), human pathogens may be internalized via plant roots and translocated throughout the plant. The comment also suggests that surface characteristics of some crops grown in hydroponic systems, such a lettuce, are also applicable to consider as part of an agricultural water assessment, as hydroponic lettuce leaves have been shown to be suitable for attachment of *Listeria*.

(Response 67) We recognize that CEA operations have unique considerations compared to more traditional outdoor growing operations. We agree that in a CEA operation, crop characteristics may affect the safety of the covered produce if contaminants are introduced via agricultural water. As such, farms must consider crop characteristics as part of their agricultural water assessments under § 112.43(a). In response to comment 63, we provide general information on crop characteristics relevant to agricultural water assessments for non-sprout covered produce. We agree that if a farm has information reflective of its unique conditions regarding the effect of crop characteristics on the safety of covered produce to which agricultural water is applied--for example, in the case of hydroponic operations, studies demonstrating crop characteristics that are particularly relevant to practices used in such operations—then that too is relevant to the farm’s agricultural water assessment.

5. Environmental Conditions

(Comment 68) Many comments address the requirement in § 112.43(a)(4) that an evaluation of environmental conditions be included in a farm’s agricultural water assessment. A few comments suggest that weather conditions can be relatively easily evaluated as part of the agricultural water assessment and that basic information regarding controlling hazards from weather events is already included in grower training courses. In contrast, some comments

express concerns, suggesting that such a requirement is an unreasonable burden on farms that, the comments state, would have to obtain information on years of weather history, travel great distances to obtain information from U.S. Weather Service-approved stations, or access scientific journals for relevant data. Some comments suggest that scientific information on environmental impacts on produce safety is limited or nonexistent and it is unreasonable, therefore, to expect farms to evaluate it. Several comments seek clarity on how FDA will evaluate whether environmental factors have been sufficiently considered in the agricultural water assessment.

(Response 68) We considered the comments and are finalizing § 112.43(a)(4) as proposed, without changes. As described in the QAR (Ref. 17), survival of pathogens in the environment is influenced by complex physical, chemical, and biological interactions. 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, and humidity (Ref. 65). Changes in temperature and seasonality are expected to impact persistence of foodborne pathogens in the environment (Ref. 68). Seasonal changes in rainfall--particularly heavy rainfall and flooding events--can greatly affect surface water quality (Refs. 69 and 70) and may result in sediments, which can serve as reservoirs for pathogens, being dispersed within the water column (Ref. 71). Airborne transmission may also result in contamination of the environment--such as agricultural water and growing areas--particularly when dry, windy conditions are present (Ref. 72). Moreover, weather events, such as freezing or hail, can result in physical damage to the epidermal barrier or produce (e.g., punctures or bruising), that may allow for survival of pathogens on produce (Refs. 67 and 68). See the 2021 agricultural water proposed rule at 86 FR 69120 at 69138-69139.

In many instances, farms will be able to use their previous experience and knowledge of their growing region to assess the environmental conditions for their agricultural water assessment. For example, many farms already take weather and climatic conditions into account when making management decisions for the crops they grow, and when and how those plants are planted and harvested. We do not expect farms to obtain detailed reports of local conditions, conduct complex scientific analyses of weather events, or travel to weather stations in order to obtain such information. Rather, knowledge of general trends, such as the identification of wet seasons, average monthly temperatures, and seasonal trends in sun exposure, will likely provide farms with adequate information for their agricultural water assessment. If a farm is new to the growing region, the farm can obtain relevant information on environmental conditions from internet resources (such as average monthly temperatures and rainfall), cooperative extension, and other local resources.

(Comment 69) One comment notes that the weather in their area varies significantly by season (e.g., a rainy season and a dry season) and seeks clarity on whether FDA expects farms to take different measures depending on the season. Several comments suggest that weather is unpredictable, for example, due to effects of climate change, and request clarity on how this should be accounted for in an agricultural water assessment. One comment seeks clarity about whether 1 year of historical weather data is enough, and why historical data can be used to inform a current plan if weather can be variable year to year. Several comments assert that the proposed rule fails to adequately define environmental conditions (e.g., “regular weather”, “extreme weather events”, and “heavy rain”), making it difficult for farms to assess actual risk and for inspectors to consistently evaluate compliance. Several comments seek clarity on how a farm should assess rare weather events versus routine weather events, and seek guidance on what

constitutes an unusual weather event and successful strategies for managing risks associated with different weather patterns that can occur by region.

(Response 69) We recognize that weather is likely to vary both seasonally and year-to-year and expect that farms will take this variability into account for their agricultural water assessment and determinations under § 112.45. For example, if a farm identifies February through May as a rainy season, the farm may determine, alongside the other factors evaluated under § 112.43(a), that measures are reasonably necessary under § 112.45 during that time due to concern over rainfall introducing hazards to its agricultural water system via runoff and/or by stirring up sediments. However, the farm may determine that measures are not reasonably necessary during other times of the year, when rainfall is not as likely to impact its agricultural water system(s). Conversely, a farm may determine that its rainy season occurs early enough in the growing season that, considered alongside the other factors evaluated under § 112.43(a), measures may not be reasonably necessary. In the event a farm determines that corrective or mitigation measures are reasonably necessary in relation to an environmental condition, what measures are appropriate will largely depend on the nature of the other factors evaluated under § 112.43(a). For example, depending on a farm's water use practices and crop characteristics, the farm may find it appropriate to change the water application method under § 112.43(b)(1)(iv) in response to hazards that may be introduced as a result of an environmental condition. See response to comment 113 for discussion regarding mitigation measures following environmental events.

In most instances, farms will be able to use their previous experience and historical knowledge of their growing region to assess not only general "routine" trends in environmental conditions (e.g., yearly seasonal patterns in sun exposure), but also those conditions that might

happen on a less frequent basis, but that nonetheless have the potential to impact their agricultural water systems or covered produce (e.g., hurricanes, heavy winds, or rains that otherwise may occur on occasion). By recognizing these events within their agricultural water assessments, farms will be able to develop a plan to ensure the safety and quality of their pre-harvest agricultural water in the instance that such events do occur. However, we recognize that farms will not be able to anticipate every environmental condition that occurs. If an unanticipated environmental event occurs that is not already addressed within a farm's agricultural water assessment, the farm must consider whether it results in a significant change that necessitates a reassessment under § 112.43(e). For example, an earthquake that impairs a farm's piped distribution system, or series of atmospheric river events that repeatedly impact a farm's agricultural water system over a period of time, may necessitate a reassessment under § 112.43(e), depending on the circumstances. See also response to comment 100.

(Comment 70) Some comments suggest that by including the phrase “or covered produce” in proposed § 112.43(a)(4), FDA is requiring a farm to evaluate how environmental conditions affect each crop, independent of how the environmental conditions impact an agricultural water system. These comments contend that any requirement to evaluate how environmental conditions affects crops is outside the scope of Subpart E. Several comments suggest that environmental considerations are better addressed through guidance, training, or education.

(Response 70) We disagree that an evaluation of environmental conditions that may impact covered produce is outside the scope of this rulemaking, because some environmental conditions may have a direct effect on the susceptibility of the covered produce to surface adhesion or internalization of hazards from agricultural water. (See also the requirement in

§ 112.43(a)(3) to consider crop characteristics as part of an agricultural water assessment.) For example, if a weather event results in physical damage to a crop (such as if hail results in punctures or bruising), it may increase the susceptibility to survival of pathogens on the produce, if introduced by agricultural water (Ref. 68). As such, we continue to find it appropriate to require farms to consider environmental conditions that impact covered produce as part of their agricultural water assessments. However, we recognize that not all environmental conditions that affect covered produce may be relevant to potential contamination of covered produce by agricultural water, and we emphasize that farms are only required to evaluate those environmental conditions that may be relevant in light of a farm's pre-harvest agricultural water use.

(Comment 71) One comment asserts that weather and climate conditions vary by region, and it is unreasonable to expect farmers in one area of the country be required to account for potential weather events that do not apply to their region.

(Response 71) We do not expect farms to evaluate environmental conditions not relevant to their agricultural water systems and pre-harvest agricultural water use. As such, a farm in one region is not required to consider weather events that occur in another region, if the other region's weather is not relevant to the farm.

(Comment 72) One question seeks clarity on what FDA is looking for in terms of air temperatures and sun exposure. Specifically, the comment seeks clarity on whether a farm will need to provide separate assessments for each field depending on its sun exposure.

(Response 72) The requirements in § 112.43(a) to prepare an agricultural water assessment are specific to each agricultural water system that a farm uses for pre-harvest agricultural water. As such, farms are not necessarily required to prepare a separate agricultural

water assessment for each field they use to grow covered produce. (However, if, for example, a farm uses different agricultural water systems for different fields, the farm is required to prepare an agricultural water assessment for each of those systems in accordance with § 112.43(a).)

To the extent that different fields are exposed to varying degrees of sun exposure and temperature, the farm may note as much within its agricultural water assessment. Farms may find such information particularly helpful in considering the appropriateness of relying on in-field microbial die-off as a mitigation measure, if they determine mitigation measures under § 112.45(b) are reasonably necessary and increase the time interval between last direct water application and harvest as a result.

(Comment 73) Some comments seek clarity on how a farm should assess heavy rain that occurs several miles upstream.

(Response 73) Factors to consider in assessing heavy rains as part of an agricultural water assessment include, but are not limited to, the frequency of such events occurring; whether the rain event is reasonably likely to introduce known or reasonably foreseeable hazards into the agricultural water system (such as through runoff); and whether the farm can expect any other changes to occur by the time the water reaches the farm (such as adequate time to allow any stirred-up sediments to settle out of the water column). Considering this information, alongside the other factors evaluated under § 112.43(a), will assist farms in determining whether measures are reasonably necessary under § 112.45.

(Comment 74) One comment notes that farms may not irrigate after a heavy rain since the crops do not need additional water during that time, and requests clarity on how this should be considered under the proposed rule.

(Response 74) We recognize that the various factors identified in § 112.43(a) are likely to be interrelated, such as when farms cease irrigating their crops following a rain event. If a farm adjusts its water use practices based on other elements evaluated within its agricultural water assessment, the farm must include that as part of its evaluation and use all information considered under § 112.43(a) in determining whether measures are reasonably necessary under § 112.45.

(Comment 75) One comment suggests that environmental conditions may differ for CEA operations compared to outdoor farming, and provides various examples of environmental conditions they consider relevant to CEA, including condensation and subsequent dripping; use, maintenance, and cleaning of heating, ventilation, and cooling equipment; opening or closing of vents to the outdoor environment; and local pest populations. Moreover, the comment suggests that CEA operations such as hydroponic and aquaponic systems have other factors that should be considered as part of an agricultural water assessment, such as cleaning and sanitizing procedures for food contact surfaces; solids management (i.e. the accumulation of organic matter in the water); and UV irradiation and ozone treatments for water, which the comment suggests may have unknown efficacy in such systems.

(Response 75) We recognize that CEA operations face a unique set of conditions compared to more traditional outdoor growing operations and that environmental conditions such as weather events (e.g., rain and exposure to sun), may be less relevant to their agricultural water systems and covered produce than in open-field systems. We also recognize that CEA operations may have other factors that are more relevant to their operations than to those growing covered produce in an outdoor capacity that nonetheless have the potential to impact their agricultural

water systems and covered produce. Each farm must capture those conditions that are unique to its operation as part of its agricultural water assessment.

6. Other Relevant Factors

Comments regarding other relevant factors, with the exception of those related to testing as part of an assessment under § 112.43(d), are discussed below. Comments on testing conducted under § 112.43(d) are discussed in section V.H.

(Comment 76) Several comments support the language in proposed § 112.43(1)(5) that requires consideration of “other relevant factors” to provide farms with the option to incorporate unique circumstances or new scientific data in their agricultural water assessments.

(Response 76) We agree that it will be helpful for farms to capture any additional factors that are unique to their operations within their agricultural water assessments.

We also emphasize that there are provisions in other subparts of the 2015 produce safety final rule, which we did not propose to change, that specify requirements for protecting agricultural water sources and distribution systems from potential sources of contamination. For example, farms are required to handle, convey and store any biological soil amendment of animal origin in a manner and location such that it does not become a potential source of contamination to covered produce, food contact surfaces, areas used for a covered activity, water sources, water distribution systems, and other soil amendments (§ 112.52(a)). Additionally, subpart L of the 2015 produce safety final rule specifies requirements for ensuring that toilet facilities (§ 112.129(b)(1)); hand-washing facilities (§ 112.130(c)); sewage (§ 112.131(b) through (d)); trash, litter, and waste (§ 112.132(a)(2)); plumbing (§ 112.133(c) through (d)); and domesticated animal excreta and litter (§ 112.134(a)) do not serve as a source of contamination for covered

produce, food contact surfaces, areas used for a covered activity, agricultural water sources, and agricultural water distribution systems.

G. Outcomes (§ 112.43(c))

In § 112.43(c), we proposed for a farm to determine, based on the farm's evaluation under proposed § 112.43(a), whether corrective or mitigation 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 its agricultural water used in growing covered produce (other than sprouts). We proposed that if a farm's pre-harvest agricultural water does not meet certain criteria in § 112.43(c), the farm would be required to either implement mitigation measures or test the water, consider the test results as part of the assessment, and take appropriate action (proposed § 112.43(c)(4)). We also proposed to require farms to record their determination and take appropriate action (proposed § 112.43(c)).

We received several comments related to outcomes under proposed § 112.43(c) and discuss these comments in the following paragraphs. We discuss comments related to testing in section V.H. As discussed below, we are finalizing § 112.43(c) as proposed, with minimal changes.

(Comment 77) A few comments express concerns with § 112.43(c)(1) through (3), arguing that the "tiered approach" to hazard analysis may result in farms expending efforts and resources toward strategies for addressing hazards that do not represent the biggest risk, while expending less effort and resources to address risks that may be more critical. For example, one comment suggests there is a lack of framework for determining when a hazard warrants immediate action or not, noting in particular that animal activity, BSAAOs, or untreated or

improperly treated human waste may result in water not being safe or of adequate sanitary quality for its intended use. This comment also suggests the proposed rule could create challenges for farms when deciding which hazards to prioritize addressing when most hazards fall within the same tier.

(Response 77) As discussed in response to comment 28, we consider that the requirements for agricultural water assessments, in which farms evaluate various factors identified in § 112.43(a)(1) through (5), provide a mechanism through which farms evaluate the risk associated with their pre-harvest agricultural water and use that information to determine if measures are reasonably necessary under § 112.45. Further, we have established timeframes for

implementing corrective or mitigation measures commensurate with the risk associated with the relevant condition. For example:

- Under § 112.43(c)(1), if pre-harvest agricultural water is not safe or not of adequate sanitary quality for its intended use(s), farms are required to immediately discontinue such use(s) of water and take corrective measures under § 112.45(a) prior to resuming use. We consider such situations to reflect circumstances where it is most necessary to take immediate action in order to protect public health;
- Under § 112.43(c)(2), for conditions that are reasonably likely to introduce known or reasonably foreseeable hazards and are related to animal activity, application of a BSAAOs, or the presence of untreated or improperly treated human waste on adjacent or nearby lands, the farm must implement mitigation measures under § 112.45(b) promptly, and no later than the same growing season as the agricultural water assessment. Because farms often do not have control over those potential hazards at their point of introduction into a water source or system, it is important that the farm not only implement mitigation measures that are under its control to reduce the risk associated with that water source or system, but that it do so on an expedited basis to protect public health; and
- Under § 112.43(c)(4)(i), for conditions that are reasonably likely to introduce known or reasonably foreseeable hazards and are not related to the aforementioned uses of adjacent or nearby lands, the farm must implement mitigation measures under § 112.45(b) as soon as practicable and no later than 1 year after the date of the farm's agricultural water assessment or reassessment. We note that this timing is consistent with the timing for implementing measures in § 112.45(b) of the 2015 produce safety final rule.

We recognize that one potential source of hazards may be associated with various outcomes depending on conditions relevant to the farm. For example, animal activity associated with adjacent and nearby lands, along with the other information evaluated in § 112.43(a)(1) through (5), can result in: the farm immediately discontinuing that use of the water and implementing corrective measures prior to resuming use (§ 112.43(c)(1)); the farm implementing mitigation measures on an expedited basis (§ 112.43(c)(2)); or there not being any conditions for which measures under § 112.45 are reasonably necessary (§ 112.43(c)(3)). Evaluation of the factors identified in § 112.43(a), which we discuss in section V.F., will assist farms in determining which outcome in § 112.43(c) is appropriate for their circumstances.

With respect to the comment suggesting that some farms have multiple sources of hazards that result in the same outcome, we note that the requirements for pre-harvest agricultural water assessments are designed to provide a holistic evaluation of a farm's agricultural water system, water use practices, and other conditions relevant to the farm for hazard identification purposes. Consistent with the comprehensive nature of agricultural water assessments, the requirements for outcomes in § 112.43(c), too, are designed to be implemented on a systems-wide basis. To further clarify the systems-based nature of these requirements, we are revising the requirements related to outcomes of agricultural water assessments in § 112.43(c). (See § 112.43(c)(2), which we have revised to read "If you have identified *one or more* conditions" in lieu of "*a* condition," as proposed (emphasis added).) As such, measures that a farm implements under § 112.45 may be appropriate in light of the totality of information evaluated under § 112.43(a), such as where changing the water application method to reduce the potential for contamination of covered produce may be adequate to address various conditions that result in the same outcome under § 112.43(c).

(Comment 78) Some comments request that FDA provide additional clarity on what constitutes a situation where a farm might determine the water is not safe or not of adequate sanitary quality for its intended uses which would trigger a corrective measure versus situations in which mitigation measures would be an appropriate means of reducing risk.

(Response 78) Section 112.45 outlines two different types of measures--corrective measures and mitigations measures--that are required under § 112.43(c) if certain conditions exist. For pre-harvest agricultural water, “corrective measures” refer to those that farms must implement under § 112.45(a) if the water is not safe or is not of adequate sanitary quality for its intended use. Corrective measures are used in circumstances where it is necessary to take immediate action to protect public health, in that farms are required to immediately discontinue use of the water and implement corrective measures prior to resuming that use. Conversely, “mitigation measures” in § 112.45(b) provide more flexibility in the timing of decisions as compared to the immediate action required under § 112.45(a), in that the mitigation measures must be implemented as soon as practicable and no later than 1 year after the date of the farm’s agricultural water assessment or reassessment (as required by § 112.43), except that mitigation measures in response to known or reasonably foreseeable hazards related to animal activity, BSAAOs, 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.

Given the diversity that exists across industry, and that risk associated with pre-harvest agricultural water is a function of the various factors evaluated as part of an assessment under § 112.43(a), we do not expect that situations in which measures under § 112.45 are reasonably necessary for one farm will necessarily be the same for another. However, there are some

conditions that, absent information or circumstances indicating otherwise (such as if the farm is not using pre-harvest agricultural water during the time period of interest), are likely to result in the outcome in § 112.43(c)(1), in which the water is not safe or is not of adequate sanitary quality for its intended use(s) and the farm is required to immediately discontinue use of the water and take corrective measures under § 112.45(a) before resuming such use. For example:

- Incidents in which raw sewage is introduced to an agricultural water system (for example, leakage of sewage from a ruptured pipe or improper release of sewage from a sewage treatment facility into an agricultural water system);
- Situations where a significant amount of animal waste is introduced to an agricultural water system (such as might result from a manure lagoon overflowing into an agricultural water system); and
- The presence of dead and decaying animals in an agricultural water system (for example, a well in which an animal has died, or a canal in which sheep have entered and drowned).

We emphasize that these examples are not the only circumstances in which the outcome under § 112.43(c)(1) will apply, nor do circumstances need to be as clear-cut as these in order for § 112.43(c)(1) to be appropriate. For example, due to the nature of the above examples and the high likelihood for those conditions to introduce human pathogens to pre-harvest agricultural water, such conditions are likely to result in the outcome under § 112.43(c)(1) regardless of the agricultural water practices, crop characteristics, and environmental conditions evaluated under § 112.43(a) (e.g., even if affected water is only applied early in the growing season, a determination under § 112.43(c)(1) is likely appropriate). However, there may be other conditions (such as runoff from certain uses of adjacent and nearby lands), for which the factors evaluated under § 112.43(a) play a larger role as to whether a determination under § 112.43(c)(1)

~~or (2)~~ is appropriate. Considering the diversity that exists across industry, the requirement for farms to evaluate a broad range of factors as part of their pre-harvest agricultural water assessments will assist them in identifying and managing risks associated with pre-harvest agricultural water as appropriate for their agricultural water systems, conditions, and practices.

(Comment 79) One comment notes that § 112.43(c) references an “evaluation” required in § 112.43(a). However, the comment suggests, § 112.43(a) does not require an “evaluation”, it requires an “assessment,” and as such, requests FDA to revise the phrasing in §§ 112.43(a) and (c) to avoid potential confusion.

(Response 79) Proposed § 112.43(a), which we are finalizing here, requires that an agricultural water assessment identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces, *based on an evaluation of* the factors identified in § 112.43(a)(1) through (5) (emphasis added). As this is consistent with use of the term “evaluation” in § 112.43(c), we decline to make the change requested by the comment.

(Comment 80) One comment recommends changes to the text of the codified to improve clarity, noting that, as written, § 112.43(c)(1) through (4) use both positive and negative criteria, which could lead to confusion.

(Response 80) We have considered the comment. To improve clarity, we are revising § 112.43(c)(3), which in the proposed rule read, “If you have identified no conditions...,” to instead say “If you have not identified any conditions...”. We also note that we have provided a plain language summary of the outcomes in § 112.43(c) in table 4 to aid in understanding of the requirements. See comment 81.

(Comment 81) One comment suggests that the third scenario described in table 4 of the 2021 agricultural water proposed rule (describing what must occur if there is one or more known or reasonably foreseeable hazards not related to animal activity, BSAAOs, or untreated or improperly treated human waste for which mitigation is reasonably necessary) is missing from § 112.43(c), and is therefore not enforceable.

(Response 81) In the preamble language accompanying the table referenced by the comment (86 FR 69120 at 69140), we explained that if a farm determines that mitigation measures are reasonably necessary to reduce the potential for contamination of such produce or food contact surfaces with a known or reasonably foreseeable hazard that is not related to animal activity, a biological soil amendment of animal origin, or untreated or improperly treated human waste on adjacent or nearby lands, the farm would be required to either: implement mitigation measures under § 112.45(b) as soon as practicable and no later than the following year; or test the water pursuant to § 112.43(d), consider the results as part of their assessment in making a determination under § 112.43(c), and implement measures as needed under § 112.45. This outcome corresponds to § 112.43(c)(4), which we are finalizing as proposed, without changes. However, we recognize that the phrasing used in the table may have resulted in uncertainty, and as such, we are revising the table to clarify the role that adjacent and nearby lands play in the outcomes under § 112.43(c). See table 4.

Table 4.--Summary of Outcomes of a Pre-Harvest Agricultural Water Assessment for Covered Produce (Other than Sprouts) (§ 112.43(c))

If you determine...	Then you must...
that your agricultural water is not safe or is not of adequate sanitary quality for intended use(s)	immediately discontinue use(s) <i>AND</i> take corrective measures before resuming use of the water for pre-harvest activities
there is one or more known or reasonably foreseeable hazards related to animal activity, BSAAOs, or untreated or improperly treated	implement mitigation measures promptly, and no later than the same growing season

human waste on adjacent or nearby land for which mitigation is reasonably necessary	
there is one or more known or reasonably foreseeable hazards not related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby land, for which mitigation is reasonably necessary	implement mitigation measures as soon as practicable and no later than the following year <u>OR</u> test water as part of the assessment and implement measures, as needed, based on the outcome of the assessment
there are not any known or reasonably foreseeable hazards for which mitigation is reasonably necessary	regularly (at least once each year) inspect and adequately maintain the water system(s)

H. Testing as Part of an Assessment (§ 112.43(d))

For farms that test agricultural water as one part of an assessment, we proposed that such testing must use scientifically valid collection and testing methods and procedures (proposed § 112.43(d)). We proposed to require that samples of pre-harvest agricultural water be collected aseptically immediately prior to or during the growing season and be representative of the water used in growing non-sprout covered produce (proposed § 112.43(d)). We proposed to require that samples be tested for generic *E. coli* as an indicator of fecal contamination, or for another scientifically valid organism, index organism, or other analyte (proposed § 112.43(d)(2)). Additionally, we proposed to require that the frequency of testing and any microbial criteria applied be scientifically valid and appropriate to assist in determining, in conjunction with other data and information evaluated under paragraph § 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 (proposed § 112.43(d)(3)). We are finalizing the requirements as proposed, with minimal changes, and respond to the comments we received on testing as part of an assessment below.

1. General

(Comment 82) Some comments suggest that proposed § 112.43(d) should specify that when testing pre-harvest agricultural water as one part of an assessment, sample collection should occur at specific times, such as “as close to harvest as reasonably possible,” to reduce the opportunity for farms to “cherry-pick” collecting samples at times when water quality is expected to be good.

(Response 82) We do not consider it necessary to require farms that test pre-harvest agricultural water under § 112.43(c)(4) to collect samples at specific times (for example, as close to harvest as possible), as doing so may limit the usefulness of test results in further informing the farm’s agricultural water assessment. For example, if a farm identifies a condition that may allow for the introduction of hazards to its agricultural water early in the growing season (e.g., a well head that needs repairing) and tests pre-harvest agricultural water under § 112.43(c)(4), requiring that water samples be collected close to harvest would not provide the farm with information as to whether water quality was degraded and/or if repairs made to the well head were effective in as timely a manner as testing early in the growing season. As such, we decline to make this change.

(Comment 83) Several comments supportive of the general proposed approach for pre-harvest agricultural water assessments note that agricultural water testing only provides a “snapshot in time” of water quality. These comments suggest that because of this, water testing alone may be of limited effectiveness in ensuring produce safety.

(Response 83) While we have included a requirement in § 112.43(c)(4)(ii) for farms to test their pre-harvest agricultural water as part of an assessment in certain circumstances, it does not mean that farms can rely on test results alone in making decisions around the use of their water. Rather, results from pre-harvest agricultural water testing serve as an additional source of

information that farms may use to further inform their agricultural water assessments.

Specifically, farms that test their pre-harvest agricultural water as part of their assessment must consider the test results in concert with the other factors evaluated under § 112.43(a) and use information in making determinations under § 112.43(c) as to whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces due to hazards associated with pre-harvest agricultural water.

(Comment 84) Some comments express a concern that because farms are not required to test pre-harvest agricultural water under the proposed rule, inspectors and farms may come to different conclusions about situations in which testing should occur.

(Response 84) As discussed in response to comment 3, we are not requiring all farms to test their pre-harvest agricultural water. Rather, § 112.43(c)(4) requires that farms either test the water, consider the results as part of the assessment, and take appropriate action; or implement mitigations measures as soon as practicable and no later than 1 year after the date of the assessment. Whether or not to test pre-harvest agricultural water or to implement mitigation measures under § 112.43(c)(4) is up to the discretion of the farm.

(Comment 85) Some comments voice opposition to mandatory product testing as a follow-up activity when water test results reveal unacceptable results.

(Response 85) Farms are not required to conduct product testing as a follow-up to results of pre-harvest agricultural water testing under § 112.43(c)(4).

(Comment 86) Some comments seek clarity on testing requirements that would apply for rainwater that is collected and stored.

(Response 86) If a farm that collects rainwater to use for pre-harvest agricultural water tests the water as one part of its assessment, the requirements in § 112.43(d) apply.

(Comment 87) Some comments address testing of agricultural water used in CEA farms, such as hydroponic and aquaponic operations. Some comments suggest that water used in hydroponic or aquaponic systems should be performed on a risk- and science-driven basis (e.g., as applicable to each individual farm's unique food safety hazards) to support requirements in the proposed rule. Other comments state that if a hydroponic or aquaponic farm test its pre-harvest agricultural water as part of an assessment, a sampling frequency of 20 samples over a 2 to 4 year period would likely not be adequate for detection of hazards due to the nature of such systems and the use of recirculating water.

(Response 87) As discussed in response to comment 93, we are not establishing a specific testing frequency that farms are required to follow if testing their pre-harvest agricultural water as one part of an assessment. Rather, § 112.43(d)(3) provides flexibility for farms to use a sampling frequency that is scientifically valid and appropriate. This enables farms that test their pre-harvest agricultural water as part of an assessment under § 112.43(c)(4)(ii) to take into account conditions that are unique to their operations and practices when establishing appropriate sampling frequencies under § 112.43(d)(3). We discuss conditions that may be relevant to some CEA farms in response to comments 39, 40 and 46, which farms may consider in establishing an appropriate sampling frequency under § 112.43(d)(3).

(Comment 88) Several comments express concerns about the availability and/or cost of laboratories that can perform testing for agricultural water.

(Response 88) Farms that test their pre-harvest agricultural water as one part of an assessment under § 112.43(c)(4)(ii) are not required to use a third-party laboratory to analyze test samples. See § 112.47, which we did not propose to change, which specifies that farms may meet the requirements related to agricultural water testing in § 112.43(c)(4)(ii) using results performed

by the farm or by a person or entity acting on the farm's behalf, or data collected by a third-party (or parties), provided applicable requirements are met. Additionally, we have provided flexibility in analytes, sampling frequency, and microbial quality criteria farms may use (§ 112.43(d)). The approach taken for testing as part of an assessment, which provides for flexibility as science evolves, will allow farms to make decisions around pre-harvest agricultural water testing as applicable to their given operations and the nature of current science. See also response to comment 98, where we discuss test methods that may be used if testing agricultural water for generic *E. coli*.

(Comment 89) Many comments request real-world examples of what acceptable testing approaches may look like given the variety in commodity production practices, seasonal lengths, and growing environments. Some comments note that development of technical tools, such as statistical toolkits, would be of benefit to farms. These comments suggest that FDA work with industry organizations and other partners to develop such resources.

(Response 89) We provide information on analytes, sampling frequencies, and microbial criterion (or criteria) that may be used in accordance with the requirements in § 112.43(d) throughout the remainder of this section. While we have provided examples of analytes, sampling frequencies, and microbial water quality criteria that farms may choose to use (see, e.g., comments 90, 93 and 95, respectively), we recognize that there is interest in the development of testing frameworks that are specific to various circumstances, such as those based on hazards, commodity(ies) grown, and regional considerations. We encourage collaborations across various groups in the agricultural community (for example, produce farms, State and Federal Government agencies, academic researchers, and extension specialists) as they relate to pre-harvest agricultural water assessments, including frameworks for testing agricultural

water that are reflective of the variety of water systems and practices that exist across industry. We remain committed to working with stakeholders to advance critical work in the realm of agricultural water quality science.

2. Generic *E. coli* and Other Analytes

(Comment 90) Some comments seek clarification on the extent of flexibility offered to a farm in using an appropriate analyte (i.e., different than generic *E. coli*) in their testing protocol. A few comments ask if farms must determine that generic *E. coli* is an appropriate fecal indicator bacteria to test for, and how a farm may determine if a different fecal indicator bacteria is more appropriate. Some of these comments request clarity on whether farms using an alternate analyte still have to test for generic *E. coli*. A number of comments assert that farms should be able to select the most appropriate analyte for their circumstances. Some comments address water testing for hydroponic and aquaponic systems, noting that generic *E. coli* may not be the most relevant indicator of water quality in these systems.

(Response 90) Final § 112.43(d)(2) provides farms that test their pre-harvest agricultural water as one part of an assessment the flexibility to test for generic *E. coli* or for any other scientifically valid indicator organism, index organism, or other analyte. As such, if testing for any other scientifically valid indicator organism, index organism, or other analyte, a farm does not also have to test for generic *E. coli*.

While generic *E. coli* has an extensive history of use as an indicator of fecal contamination and is considered the best indicator for monitoring water quality (Ref. 73) (78 FR 3504 at 3562), the potential use of other indicator organisms, index organisms, or other analytes for monitoring water quality continues to be of interest for agricultural water, as well as related disciplines. For example, in its 2012 Recreational Water Quality Criteria (RWQC) EPA

provided various examples of possible alternate indicators, including *Bacteroidales*, *Clostridium perfringens*, human enteric viruses, and coliphages (Ref. 74). We anticipate that as science evolves and more information about other indicator or index organisms is learned, testing for organisms other than generic *E. coli* may be used to inform pre-harvest agricultural water assessments by farms.

We note that we are not requiring farms to notify or seek approval from FDA as to the analytes, sampling frequencies, and microbial criterion (or criteria) the farm uses when testing agricultural water as part of an assessment. However, if a farm uses a scientifically valid indicator organism, index organism, or analyte other than *E. coli*, the farm is required to maintain records of scientific data or information it relies on to support the use of that organism or analyte in accordance with § 112.50(b)(3). (Farms are not required to keep such documentation if testing their agricultural water for generic *E. coli*.) We discuss the term “scientifically valid” in the 2015 produce safety final rule to mean an approach that is based on scientific information, data, or results published in, for example, scientific journals, references, text books, or proprietary research (see 80 FR 74354 at 74371).

(Comment 91) Some comments seek clarity on whether farms will be expected to test for pathogenic microorganisms in their water, with some suggesting that doing so would not be of benefit to farms.

(Response 91) Farms are not required to test their pre-harvest agricultural water for human pathogens. As discussed in the 2015 produce safety final rule, we acknowledge that testing for pathogens allows for direct targeting of microorganisms in water that are a risk to public health; however, we continue to believe sampling water for pathogens presents challenges compared to sampling water for indicator organisms. For example, challenges associated with

pathogen testing include those related to larger sample sizes; inherently higher costs; and the wide array of potential target pathogens (i.e., the presence or absence of one pathogen may not predict for the presence or absence of other pathogens). See 80 FR 74354 at 74427-74428. As discussed in section I.A., we believe that this rule will enhance public health protections by setting forth procedures for comprehensive pre-harvest agricultural water assessments and corrective and mitigation measures that minimize the risk of serious adverse health consequences or death, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable biological hazards into or onto produce, and to provide reasonable assurances that produce is not adulterated on account of those hazards.

(Comment 92) Some comments note that the bacteria detected in their water is often different than the bacteria found on their crops, and that water quality seems to change as it goes through their water distribution system. These comments seek clarity on how the rule would address such a situation.

(Response 92) In this scenario, if the farm tests its water under § 112.43, the farm must consider both its water test results as well as information about its water distribution system (in addition to the other factors evaluated under § 112.43(a)) in determining whether measures are reasonably necessary under § 112.45. For example, in preparing an agricultural water assessment under § 112.43(a), a farm finds that large flocks of birds rest in its open water distribution system, and that test results for samples collected upstream and downstream of the birds indicate that the birds are causing water quality to degrade. In light of these findings, and depending on the other factors evaluated under § 112.43(a), the farm may determine that 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 the farm's pre-harvest agricultural water for non-sprout covered produce.

3. Frequency of Sampling

(Comment 93) Some comments interpret the rule as requiring a specific number of testing samples per year and oppose this requirement. Some comments seek clarity about whether the minimum frequency of testing for pre-harvest agricultural water changed from 20 samples within 2 to 4 years per the 2015 produce safety final rule, to four times during the growing season or over a period of 1 year per § 112.44(b)(1) of the proposed rule. Other comments request clarity as to whether testing may be conducted at a lower frequency than that established in the 2015 produce safety final rule. A few comments suggest that one test per season prior to use would likely be sufficient for deep wells. Some comments request that FDA support research and education to help farms understand what sampling frequency is adequate.

(Response 93) Section 112.43(d)(3) requires that for farms that test their pre-harvest agricultural water as one part of an assessment, the frequency of testing samples must be scientifically valid and appropriate to assist in determining, in conjunction with other factors evaluated under § 112.43(a), 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 their agricultural water used in growing covered produce (other than sprouts).

Farms have the flexibility to use any sampling frequency, as long as the requirements in § 112.43(d)(3) are met. ~~While the sampling frequencies for untreated surface water and untreated ground water used for pre-harvest agricultural water in the 2015 produce safety final rule are examples of approaches that farms may choose to use to comply with § 112.43(d)(3), they are~~

~~not required to do so. For example, other options~~ For example, this could include sampling frequencies a farm establishes based on its historical data and/or knowledge of water quality variability within its source. Sampling approaches that take into consideration other site- or region-specific data or information may also be appropriate. ~~As~~ We recognize that agricultural water quality science is likely to continue to evolve and may inform sampling frequencies appropriate for use when testing pre-harvest agricultural water as part of an assessment. As agricultural water quality science continues to develop, and as farms learn more about water quality relevant to their sources, systems, and operations--for example, through an evaluation of data shared between farms, within water systems, and/or within regions--such information ~~may~~ can, and should, be used to establish sampling frequencies that are appropriate to ~~their~~ farms' specific circumstances and conditions.

While the sampling frequencies for untreated surface water and untreated ground water used for pre-harvest agricultural water in the 2015 produce safety final rule are examples of approaches that farms may choose to use to comply with § 112.43(d)(3) if testing their water for generic *E. coli*, they are not required to do so. Further, if a farm tests its water for generic *E. coli* and has scientifically valid data or information to support use of a sampling frequency that is more reflective of its unique conditions than that used in the 2015 produce safety final rule, the farm must use that information in establishing an appropriate sampling frequency under § 112.43(d)(3). Moreover, because the sampling frequencies in the 2015 produce safety final rule were developed for farms that test their pre-harvest agricultural water for generic *E. coli*, a farm that tests for any other scientifically valid indicator organism, index organism, or other analyte in accordance with § 112.43(d)(2) may not use those sampling frequencies unless it has scientific data or information supporting use of those frequencies for the relevant organism or analyte.

We note that farms are required to maintain records of scientific data or information they rely on to support the use of a sampling frequency in accordance with § 112.50(b)(4). As discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69143), if a farm tests its water under § 112.43(d) for generic *E. coli* using the sampling frequencies and pre-harvest microbial water quality criteria outlined in the 2015 produce safety final rule, the farm can document its use of such sampling frequencies and microbial criteria in meeting the requirements of § 112.50(b)(4), as we have already determined these sampling frequencies and microbial criteria to be scientifically valid and appropriate for purposes of § 112.43(d). See also response to comment 95 regarding the use of the pre-harvest microbial water quality criteria from the 2015 produce safety final rule.

We would also like to clarify that the sampling frequency in § 112.44(b)(1) referenced by comments is specific to untreated ground water when used for any of the purposes specified in § 112.44(a) (e.g., water used during or after harvest activities in a manner that directly contacts covered produce). This requirement does not apply for farms that test their pre-harvest agricultural water for non-sprout covered produce as part of an assessment under § 112.43(c)(4).

(Comment 94) Some comments seek clarity around whether historical test results can be used to justify the safety of their agricultural water. Several comments encourage flexibility with regard to sampling frequency requirements by allowing inclusion of historic testing data in an assessment that may not have been conducted at the same level of frequency as discussed in the proposed rule.

(Response 94) We recognize the value in utilizing historical test results, particularly when it comes to analyzing trends in water quality over time, which may help to further inform a farm's agricultural water assessment. Historical data may be particularly useful in situations in

which potential hazards are introduced into a water system intermittently, such that a farm is able to compare data over time to further inform its conclusions of whether measures are reasonably necessary under § 112.45. For example, if a farm is concerned that the quality of its water may be affected by rain due to runoff into a water source and/or stirring up of sediments, the farm may use water quality data collected over time to determine if water quality is degraded following rain events compared to baseline (i.e., limited or no rain) conditions.

As discussed in response to comment 93, we are not establishing a specific testing frequency that farms are required to follow if testing their pre-harvest agricultural water as one part of an assessment. Rather, if a farm tests its pre-harvest agricultural water as part of an assessment under § 112.43(c)(4)(ii), § 112.43(d)(3) provides flexibility regarding the frequency of sample collection. As also discussed in response to comment 93, farms can use historical data and/or knowledge of water quality variability within relevant water sources to inform sampling frequencies under § 112.43(d)(3) that are scientifically valid.

4. Microbial Water Quality Criteria

(Comment 95) Many comments support the additional flexibility in proposed § 112.43(d) for farms to apply any microbial criterion or criteria that would be scientifically valid and appropriate. Some comments support for the use inclusion of a GM of 126 or less CFU generic *E. coli* per 100 mL and an STV of 410 or less CFU generic *E. coli* per 100 mL in the preamble as a standard for agricultural water. In contrast, several comments oppose reliance on inclusion of these criteria in the preamble, and suggest that because these standards were developed for recreational water, they are not suitable for agricultural water since agricultural water is not directly ingested by humans. Some of these comments request clarification on whether any studies have been conducted to determine thresholds of fecal indicator bacteria in agricultural

water to levels of risk to human health. Some comments request FDA remove reference to the GM and STV in the preamble because, the comments state, use of those criteria, even if not included in the codified requirements, will continue result in the criteria continuing to be used as a benchmark even if they as new metrics are replaced by a new metric supported by more current science developed. Other comments suggest that FDA retain proposed § 112.43(d) as written, but and further clarify in the preamble that adherence to the 2015 microbial standards is are not required in order to reduce confusion.

(Response 95) The microbial water quality criteria in the 2015 produce safety final rule for pre-harvest agricultural water, which were established using the science underlying EPA's 2012 RWQC (Ref. 74), consist of a GM of 126 or less CFU generic *E. coli* per 100 mL, and an STV of 410 or less CFU generic *E. coli* per 100 mL. We established these pre-harvest microbial water quality criteria using the science underlying EPA's 2012 RWQC (Ref. 74). We described the rationale for our use of the science underlying the RWQC and our thinking on its relevance to agricultural water in a reference memorandum that accompanied the 2014 supplemental proposed rule (Ref. 75). We are not aware of, and comments did not suggest, an alternative standard that is applicable across the diversity of operations, agricultural water sources, and agricultural water uses. However, we recognize that use of the GM and STV criteria for pre-harvest agricultural water for non-sprout covered produce is not without its challenges, particularly in light of information that has become available since 2015 indicating potential limitations in basing risk-management decisions on the 2015 pre-harvest agricultural water testing requirements.

Of particular note, a scientific evaluation of the 2015 pre-harvest agricultural water testing requirements found that the rolling data set of five samples per year used to update GM

and STV values for untreated surface water sources results in highly uncertain results and delays in detecting shifts in water quality (Ref. 7). Additionally, various studies indicate a high degree of variability in generic *E. coli* levels in surface waters (Refs. 5-10), which can reduce the precision of estimation of the GM and STV of a water source (Refs. 1, 7). In recognition of such limitations associated with the previous pre-harvest testing requirements, findings from our QAR (Ref. 17), other information we have gathered since 2015 (including findings from several produce-related outbreaks), as well as information and feedback from an array of stakeholders, we are replacing the pre-harvest water quality criteria and uniform testing requirements in the 2015 produce safety final rule with requirements for systems-based agricultural water assessments that include testing in certain circumstances. See comment 11. ~~Moreover, to allow for advancements in agricultural water quality science~~

~~Further, we acknowledge that science around agricultural water quality and related disciplines is likely to continue to evolve. For example, in EPA's second 5-year review of the 2012 RWQC (Refs. 76 and 77), EPA notes plans to develop new quantitative polymerase chain reaction (PCR)-based RWQC that better protect certain sensitive populations; expand its recommended RWQC to protect people from exposure to viruses; and explore new methods to determine whether a waterbody is contaminated with human feces.~~

~~Thus, to allow for scientific advancements,~~ we have incorporated flexibility into § 112.43(d)(3) so that farms that test their pre-harvest agricultural water as part of an assessment can use any microbial criteria (or criterion) provided certain requirements are met. A farm can rely on a microbial criterion or criteria available in the scientific literature or made available by a third party (such as a trade association, commodity board, academia, or cooperative extension services) provided that the microbial criterion or criteria is scientifically valid and appropriate

based on the circumstances. (We discuss the term “scientifically valid” in the 2015 produce safety final rule (see 80 FR 74354 at 74371).)

We recognize that agricultural water quality science is likely to continue to evolve and may inform standards appropriate for use when testing pre-harvest agricultural water as part of an assessment. While farms that test their pre-harvest agricultural water as one part of an assessment may choose to use the criteria established in the 2015 produce safety final rule to meet the requirements in § 112.43(d)(3), they are not required to do so. Further, if a farm has scientifically valid data or information to support use of a microbial criterion or criteria that is more reflective of its unique conditions, the farm must use that information in establishing an appropriate microbial criterion or criteria under § 112.43(d)(3).

As discussed in response to comment 83, we emphasize that farms must not rely on test results alone in making decisions around the use of their water; rather, results from pre-harvest agricultural water testing serve as an additional source of information that farms may use to further inform their agricultural water assessments.

We intend to issue guidance on the requirements in § 112.43(d)(3), as appropriate.

(Comment 96) Some comments suggest that farms should be required to take action based on an individual test result, as doing so would emphasize the short temporal nature of many microbial hazards. Some comments seek clarity as to whether water that meets the EPA recreational water standards should be considered low, medium, or high risk. A few comments ask whether farms could choose to comply with the new rule through the previous rule’s testing thresholds (including the GM and STV) rather than through preparing an agricultural water assessment. Some comments request FDA clarify that if a farm is conducting surface water testing and finds that the water has a MWQP with a GM of 126 or less CFU generic *E. coli*/100

mL water and an STV of 410 or less CFU generic *E. coli*/100 mL water, then no further mitigation measures should be required to use that water for pre-harvest activities. Conversely, some comments suggest that it is inappropriate to assume that water above or below this benchmark is always going to be higher or lower risk, and other factors (such as how the water is used, crop characteristics, etc.) should be considered, rather than strict adherence to quantitative water quality criteria.

(Response 96) We agree with comments suggesting that water below or above a certain microbial water quality criterion (or criteria) based on indicator organisms does not guarantee the absence of pathogens that can contaminate covered produce as a result of pre-harvest agricultural water. See 80 FR 74354 at 74428. We are not aware of, and comments did not provide, information suggesting that this conclusion is incorrect. As such, whether or not agricultural water meets a microbial criterion (or criteria) established in accordance with § 112.43(d) is not the sole determinant of whether corrective or mitigation measures are reasonably necessary under § 112.45. See also response to comment 83.

For example, if a farm tests its water as one part of an assessment per § 112.43(c)(4), in addition to determining whether the water meets the criterion (or criteria) established in accordance with § 112.43(c)(3), the farm can, for example, look at test results collected over time for potential insight into changes in water quality that might indicate hazards being introduced into the water system. Even if the water does not exceed the criterion (or criteria) the farm establishes, the farm may find, for example, that migratory birds are causing water quality to degrade when present in the area. As another example, the farm may find when looking at historical data that test results had at one time consistently shown lower levels of generic *E. coli*

than more recent data, potentially indicating that a change occurred that is affecting the farm's water system.

In such circumstances, even if the water does not exceed the criterion (or criteria) the farm establishes, the trends in water quality changes over time show a potential source(s) of contamination to a farm's agricultural water. A farm must consider this information, along with other factors, in conducting its agricultural water assessment (§ 112.43(c)(4)(ii)). As discussed in response to comment 95, while farms that test their pre-harvest agricultural water as part of an assessment may choose to use the GM and STV criteria established in the 2015 produce safety final rule to meet the requirements in § 112.43(d)(3), they are not required to do so.

(Comment 97) Some comments suggest that FDA mandate presence/absence indicator testing for pre-harvest agricultural water to make testing more simplified than the 2015 produce safety final rule while still providing insight into whether and which mitigation and corrective actions are required.

(Response 97) We disagree with comments suggesting that it would be appropriate to require presence/absence testing for indicator organisms for pre-harvest agricultural water. We consider that the flexibility in § 112.43(d)(3) is appropriate to maintain due to the diversity in agricultural water systems and practices that exists across industry. For example, a farm that uses pre-harvest agricultural water from a ground water source such as a well may determine that presence/absence testing is appropriate to use, as ground water sources generally provide high quality water and show little variability due to the natural filtering capacity of soils (Ref. 17). However, another farm that uses agricultural water from a surface water source may determine that quantification methods are appropriate to use, as surface water sources are subject to the

influence of various environmental factors that can impact and change the system continually (Ref. 17).

(Comment 98) Some comments ask FDA to identify a unit of measurement for analytes to be “organism” or “counts” per 100 mL instead of CFU, because in some methods of analysis, results are provided as a most probable number (MPN). The comment asserts that use of CFU limits allowable testing methods.

(Response 98) We do not consider this necessary to do, as we do not specify microbial water quality criteria in CFU when testing pre-harvest agricultural water as part of an assessment. See, for example, § 112.43(d)(3), which requires that “...any microbial 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).”

Further, while the method of analysis in § 112.151(a) (EPA Method 1603) provides results for generic *E. coli* testing in terms of CFU, if a farm tests pre-harvest agricultural water for generic *E. coli* under § 112.43(d)(2), the farm may use a scientifically valid method that is at least equivalent to EPA Method 1603 in accuracy, precision, and sensitivity (§ 112.151(b)(1)). We have provided a list of testing methodologies that meet the requirements in § 112.151(b)(1) (Ref. [7678](#)). Included in this list are methods that report results in CFU and methods that report results as MPN, which farms may use when testing their agricultural water for generic *E. coli*.

I. Reassessment (§ 112.43(e))

In § 112.43(e)(1), we proposed that a farm must conduct an agricultural water assessment, at a minimum, each year that the farm applies pre-harvest agricultural water to non-sprout covered produce. In § 112.43(e)(2), we proposed that a farm must conduct a reassessment whenever a significant change occurs in its agricultural water system(s), agricultural water practices, crop characteristics, environmental conditions, or other relevant factors that would impact hazard identification or a risk management determination, as described in proposed § 112.43(c). For the reassessment in proposed § 112.43(e)(2), we proposed that a farm must 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). We received several comments seeking clarification on the proposed reassessments and respond to the comments in the paragraphs below. We are finalizing the requirements for reassessments in § 112.43(c) as proposed, without change.

(Comment 99) Several comments seek clarity on what situations would be considered a “significant change” in an agricultural water system that would warrant a reassessment.

(Response 99) In the 2021 agricultural water proposed rule, we tentatively concluded that it would be reasonable and appropriate to require farms to conduct a written pre-harvest agricultural water assessment annually, and whenever a significant change would impact the hazard identification or risk management determination relating to pre-harvest agricultural water for non-sprout covered produce. We are not aware of, and comments did not provide, information suggesting that this conclusion is incorrect. However, we recognize that additional information on the requirements in § 112.43(e) will help support farms as they work to come into compliance.

Section 112.43(e) requires, in part, that a farm conduct a reassessment whenever a significant change occurs in its agricultural water system(s), agricultural water practices, crop characteristics, environmental conditions, or other relevant factors that impacts hazard identification or a risk management determination as described in § 112.43(c). For example, as discussed in the 2021 agricultural water proposed rule (86 FR 69120 at 69138), a change from an untreated ground water source to an untreated surface water source, or the installation and use of a new water distribution system, is a significant change that requires a reassessment under § 112.43(e), as the degree of protection and likelihood of hazards being introduced are likely to differ and may impact risk management determinations. As another example, some changes in the use of adjacent or nearby land--such as if adjacent or nearby land is used for a new dairy production operation--are significant changes, as the new use of that land may differ in its potential to introduce hazards into the agricultural water system.

Changes in agricultural water practices, including the method or timing of water application, also are significant changes that require a reassessment, as different practices present different risks to the crop. For example, overhead sprinkler irrigation may increase the risk of contamination as compared with furrow and subsurface drip irrigation (Ref. [7779](#)). Furthermore, bacteria or pathogens in water that is applied early in the growing cycle are subject to greater die-off from several environmental forces, such as UV exposure, temperature, humidity, and the presence of competitive organisms compared to bacteria or pathogens in water that is applied late in the growing cycle (Ref. 65). See 86 FR 69120 at 69138. Similarly, growing a different type of covered produce than previously grown is a significant change, as the unique characteristics associated with the crop might affect whether it is vulnerable to contamination from agricultural water. See 86 FR 69120 at 69138. As discussed further in response to comment 100, various

environmental conditions, such as unexpected flooding that may introduce new hazards into an agricultural water system, are also significant changes that require a farm to conduct a reassessment.

Other sources of information may also indicate that a significant change has occurred for which a reassessment is required, such as, for example, if information suggests that a pathogen may be present in a farm's pre-harvest agricultural water (which the farm may be aware of through voluntary testing, knowledge or experience, or other means), or if an outbreak investigation or other findings indicate a potential role for pre-harvest agricultural water in serving as a source or route of contamination to covered produce.

In instances where there is a significant change for which a farm is required to conduct a reassessment, the farm must evaluate the impacts of those changes on the factors in § 112.43(a)(1) through (5), any new hazards identified, and the outcome and determination under § 112.43(c).

(Comment 100) Several comments seek clarity as to whether a reassessment is necessary in response to extreme weather events if those events are normal, expected, and included in a farm's initial assessment. Some comments question whether a farm can amend an assessment following such an extreme weather event rather than conducting an entirely new one.

(Response 100) The requirement to consider environmental conditions as part of an agricultural water assessment in § 112.43(a)(4) includes not only general "routine" trends in environmental conditions (e.g., yearly seasonal patterns in rainfall), but also those conditions that, based on knowledge, history or experience, are reasonably likely to happen on a less frequent basis, but that nonetheless have the potential to impact agricultural water systems or covered produce (e.g., heavy rains that occur on occasion). This includes, if applicable, any

extreme weather events that have the potential to affect the farm's agricultural water systems or operations. Thus, if a farm evaluated relevant extreme weather events as part of its agricultural water assessment under § 112.43(a), the farm is not required to conduct a reassessment each time such an event occurs. See also response to comment 69.

However, we also recognize that not all weather events can be anticipated. Unanticipated weather events or weather changes that go beyond what was considered as part of a farm's assessment (such as unexpected flooding that may introduce new hazards into a surface or ground water source, or an earthquake, which may affect a farm's piped distribution system) are significant changes that warrant a reassessment under § 112.43(e)(2). The reassessment must evaluate any factors and conditions that are affected by such change, including the factors in § 112.43(a)(1) through (5), any new hazards identified, and the outcome and determination under § 112.43(c).

(Comment 101) Some comments note that what may be considered a "significant change" for one farm would not be considered a significant change for another. For example, the comment notes that switching water sources is a common practice in some areas and may not be perceived by farms as significant.

(Response 101) We recognize that some farms may make changes to their pre-harvest agricultural water systems and practices as a routine matter, such as farms that routinely use one water source early in the growing season and switch to another water source after plants become established; or those that change water sources throughout the season as weather and water availability changes. Farms that make routine changes to their systems or operations may account for such activities in their annual assessment, rather than conducting a reassessment each time a change is made, provided they conduct and document an assessment that accurately

describes and evaluates each of their agricultural water systems, the water use practices associated with each of their agricultural water systems, and other factors required by § 112.43(a).

(Comment 102) Noting that farms may not become immediately aware of changes to certain factors that are outside of their control (such as uses of adjacent and nearby lands), a few comments suggest that proposed § 112.43(e) be revised to clarify that a farm is only responsible

for conducting a reassessment if the farm is *aware* of there being a significant change (emphasis added).

(Response 102) Farms are responsible for ensuring that all applicable requirements of subpart E are met, including the requirement in § 112.41 that all agricultural water be safe and of adequate sanitary quality for its intended use.

We recognize that farms may not always be made immediately aware of changes to factors that are outside of their control (such as adjacent and nearby land uses and other water users) that might affect their agricultural water systems. As discussed in response to comment 51, farms must include in their assessments information on sources of hazards that have the potential to result in contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with agricultural water. Information as to the presence and nature of impacts that might affect the quality of their agricultural water can be acquired through a variety of resources, including from visual observation; local extension agents, industry associations, or local water management authorities; and online resources such as mapping tools, which may provide helpful information on topography and proximity to potential sources of hazards.

Further, § 112.42(b) requires farms to regularly monitor each system, to the extent that it is under the farm's 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. If during such monitoring a farm identifies a condition that is considered a "significant change," the farm must conduct a reassessment under § 112.43(e). See also response to comment 25, in which we discuss the relationship between inspections, maintenance, and pre-harvest agricultural water assessments.

Given the various resources available to farms that can provide information regarding factors that might otherwise be outside a farm's control (see comment 51), we do not believe it is necessary to modify the language regarding significant changes that require a reassessment under § 112.43(e).

J. Corrective and Mitigation Measures (§ 112.45)

We proposed requirements for implementing corrective and mitigation measures for pre-harvest agricultural water that 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 agricultural water for covered produce (§ 112.45). We did not propose to change the requirement from § 112.45(a) of the 2015 produce safety final rule that if agricultural water is not safe or not of adequate sanitary quality for its intended use(s) as required under § 112.41, and/or if a farm's 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), the farm must immediately discontinue such use(s) and implement corrective measures prior to resuming such use. In § 112.45(b), we proposed various mitigation measures for pre-harvest agricultural water that farms would implement to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with the water.

We discuss comments received on proposed § 112.45 below. Note that in this section, we include comments specific to use of treatment as a corrective or mitigation measure; we discuss general comments related to agricultural water treatment and the pre-harvest agricultural water treatment efficacy testing protocol in section V.K.

1. General

(Comment 103) Several comments express general support for the range of options FDA has outlined as possible measures to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards. In contrast, many comments suggest the rule lacks sufficient criteria on when measures are necessary or which measures are effective in various scenarios. Some comments express a concern that the proposed rule places too much responsibility on farms to make decisions about mitigation measures without sufficient guidance or input from FDA. The comments request that FDA consider delineating specific requirements regarding necessary measures for the highest risk situations.

(Response 103) The provisions for pre-harvest agricultural water assessments are designed to be flexible to account for the diversity of operations, practices, and conditions that may impact the pre-harvest agricultural water used by foreign and domestic farms for non-sprout covered produce. Given the diversity that exists across industry, we recognize that measures implemented under § 112.45 will vary by farm.

By providing a range of possible measures, farms will be able to make decisions around their agricultural water as appropriate to their agricultural water systems, water use practices, operations, and local conditions. However, we recognize the need for clarity, and we have provided general principles throughout the preamble to assist farms in determining whether (and what kind of) measures may be appropriate for their given circumstances. For example, in our response to comment 105, we discuss that measures under § 112.45(b)(1)(i), which entails making necessary changes (for example, repairs), generally are more relevant when the farm has some control over the point at which potential source of known or reasonably foreseeable hazards. However, that may not always be introduced the case, such as if a farm builds a berm to

reduce runoff from a source of hazards into an agricultural water system. As another example, in response to comment 123, we explain that changing the water application method under § 112.45(b)(1)(iv) for root crops may not be an appropriate mitigation measure, as it may be difficult to effectively minimize contact between agricultural water and the harvestable portion of the crop. For additional examples and information, see section V.G. for comments related to outcomes, and the remainder of this section for comments related to corrective and mitigation measures.

Further, we recognize the need to provide farms with education, outreach and technical assistance to facilitate compliance with the rule, and we intend to pursue various mechanisms, such as publishing guidance, holding webinars, and developing other educational resources, including working with other stakeholders (such as State agencies, educators, and extension agents), to do so.

(Comment 104) Some comments express concerns that the corrective and mitigation measures included in the proposed rule are not feasible for many farms due to challenges associated with increased costs, water scarcity, environmental conditions, farm setup/infrastructure, labor shortages, and the need to use water for pest management practices. Some of these comments suggest that measures like water treatment, which comments note can be costly and complex to implement, calibrate, and operate, may be particularly challenging for small farms. Many comments request that FDA explicitly allow for other mitigation measures beyond those specifically listed in the codified.

(Response 104) Given the diversity that exists across industry, we recognize the importance of flexibility in § 112.45, which we have included by providing a range of possible

measures, including the option in § 112.45(b) to use an alternative mitigation measure that meets the requirements in § 112.12.

With respect to comments about small farms, we note that we are finalizing staggered compliance dates for the pre-harvest agricultural water requirements for non-sprout covered produce based on farm size as follows: 2 years and 9 months after the effective date of a final rule for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses. See also section VI for a discussion of comments about compliance dates. We expect that the flexibility in § 112.45, along with the extended compliance dates, will provide sufficient time and flexibility for small and very small farms to receive education and adjust their practices (if needed) to comply in a cost-effective manner with the requirements in subpart E.

Also with respect to comments about costs, we estimate costs of measures in our FRIA (Ref. 26).

(Comment 105) Some comments assert that the proposed rule lacks clarity on corrective or mitigation measures for farms to effectively control hazards from adjacent or nearby cattle operations and requests that FDA establish educational resources that define effective strategies, based on science and research. Some comments suggest that the farm's responsibility over the quality of water (including steps the farm takes to implement mitigation measures) should be based on the degree of control the farm has over the water, and that the farm should not be responsible for activities on adjacent or nearby lands or upstream water users that are not under the farm's control.

(Response 105) We recognize that farms may have little or no control over adjacent and nearby land uses and other water users, and do not require farms to access areas that are not

under their control to meet relevant requirements in subpart E. However, while farms may have little or no control of such uses of land and other water users, the requirement to consider these potential sources of hazards as part of an agricultural water assessment will help farms determine the appropriate and safe use of their water source(s). See also response to comment 15. While it is generally preferred that sources of known or reasonably foreseeable hazards be addressed at the point where potential hazards are introduced to an agricultural water system, we recognize that this may not always be feasible for farms (such as where hazards may originate from adjacent or nearby land uses or from other water users), nor are we suggesting that farms gain access to such lands or other water uses to do so.

Taking measures under § 112.45(a)(1) (which includes, but is not limited to, re-inspecting the affected agricultural water system and making necessary changes) and § 112.45(b)(1)(i) (which entails making necessary changes (for example, repairs)) generally are more relevant when the farm has some control over the potential source of known or reasonably foreseeable hazards. However, this may not always be the case. For example, even if a source of hazards is outside of a farm's control, depending on the circumstances, measures such as building a berm to reduce runoff, installing a windbreak, or making repairs to a well-head may be appropriate to reduce the potential for known or reasonably foreseeable hazards being introduced into its agricultural water system.

We have incorporated a range of options for measures in § 112.45 in the recognition that not every measure will be an appropriate or viable option for every farm. See also response to comment 103. We note in particular that the mitigation measures identified in § 112.45(b) include those that a farm can implement whether or not the farm has control over the potential source of known or reasonably foreseeable hazards at the point where hazards may be introduced

to an agricultural water system. For example, while a farm may have little or no control over adjacent and nearby land uses, if the farm determines that mitigation measures are reasonably necessary under § 112.45(b), depending on the circumstances, the farm might determine that changing the water application method is appropriate to reduce the likelihood of contamination of the covered produce.

(Comment 106) While supportive of the proposed rule, some comments request that water testing be required as a way to verify that corrective or mitigation measures were effective. These comments seek clarity on how, without test results, farms might demonstrate that their water is safe and of adequate sanitary quality. One comment notes that the proposed rule differs from LGMA metrics in its omission of a retesting requirement for agricultural water that fails to meet a specified standard for generic *E. coli* and requests that FDA include such a retesting requirement, suggesting that retesting is essential to determine whether mitigation measures were effective.

(Response 106) We disagree that testing is essential to determine if corrective or mitigation measures were effective, as there are other actions farms may take to verify the effectiveness of such measures. For example, if a farm makes necessary changes as a mitigation measure under § 112.45(b)(1)(i), such as repairing a leak within the farm's piped distribution system in order to protect it from possible sources of contamination, re-inspection of the agricultural water system to visually confirm that the repair was successful may be sufficient. As another example, if a farm changes the method of water application to reduce the likelihood of contamination of covered produce as a mitigation measure under § 112.45(b)(1)(iv), the farm might regularly monitor the system while the covered produce is being irrigated to confirm that the water application method is limiting contact with the produce as intended. In yet other

instances, such as when treating agricultural water as a mitigation measure (§ 112.45(b)(1)(v)); applying a time interval between last direct water application and harvest to allow for microbial die-off (§ 112.45(b)(1)(ii)); or applying a time interval between harvest and end of storage and/or using other activities during or after harvest to allow for microbial die-off and/or removal (§ 112.45(b)(1)(iii)), the farm is required to maintain scientifically valid data or information to support use of those measures (see § 112.50(b)(8) and (10)). While farms may choose to test their water to assist them in evaluating the efficacy of corrective or mitigation measures that they implement, we emphasize that as discussed in comment 83, farms must not rely on test results alone in making decisions around the safe use of their agricultural water.

If a farm determines that its mitigation measures are not effective to reduce the potential for contamination of the covered produce or food contact surfaces with known or reasonably foreseeable hazards, it must discontinue use of the agricultural water until it has implemented mitigation measures adequate to reduce the potential for such contamination, consistent with § 112.41 (§ 112.45(b)(2)).

(Comment 107) Some comments request that FDA provide specifics around when pre-harvest water must be treated as a corrective or mitigation measure. A few comments suggest FDA specify “high-risk” situations in which water must be treated, such as requiring that all surface water must be treated unless the farm has data demonstrating that pathogens are not present in the water. These comments note that farms participating in LGMA are not permitted to use untreated surface water in overhead irrigation systems in the 3 weeks leading up to harvest, and suggest that FDA could similarly specify uses for which untreated surface water is prohibited. Some comments suggest that treatment would be the only viable mitigation measure

for some operations. A few comments suggest the rule state that if other effective options for mitigation are not available, then farms would be required to treat their water.

(Response 107) Recognizing the wide degree of diversity that exists in industry—including in potential sources of known or reasonably foreseeable hazards, agricultural water systems, growing operations, water use practices, crop characteristics, and environmental conditions-- what might be considered “low” or “high” risk for one farm may not necessarily be the same for another. See comment 31. Moreover, given the diversity that exists in industry, we recognize that not every mitigation measure will be appropriate for every farm to use. As such, we do not consider it appropriate to specify situations in which farms are required to implement mitigation measures, or more specifically, treat their pre-harvest agricultural water.

With respect to commenters’ suggestion to specify that if other mitigation measures identified in § 112.45(b) are not available to a farm that the farm would be required to treat the water, we note that § 112.45(b)(2) requires that if a farm fails to implement appropriate mitigation measures, or if the farm determines that the measures were not effective, the farm must discontinue use of the pre-harvest agricultural water until adequate mitigation measures have been implemented. As such, it is likely that farms will implement any of the measures available to them and appropriate to their conditions, including treatment, to avoid being required to cease that use of pre-harvest agricultural water. As such, we consider the change requested in the comments to be unnecessary.

We also disagree with commenters’ suggestion to require treatment of agricultural water unless the farm has data indicating that pathogens are not present in the agricultural water system. In the 2015 produce safety final rule, we discuss various challenges associated with sampling water for pathogens. These include challenges related to larger sample sizes; inherently

higher costs, and the wide array of potential target pathogens (i.e., the presence or absence of one pathogen may not predict for the presence or absence of other pathogens). See 80 FR 74354 at 74427-74428. We are not aware of, and comments did not provide, information to suggest otherwise. See also comment 91. As such, we decline this suggestion.

(Comment 108) A few comments ask for clarity regarding whether pre-harvest water treatment must be done during the entire growing season, or only a certain amount of time before harvest.

(Response 108) If a farm treats its pre-harvest agricultural water based on its agricultural water assessment, the necessary timing for implementing agricultural water treatment will depend on the specific conditions at the farm. For example, if the farm treats its pre-harvest agricultural water in response to a condition in which there may be ongoing introduction of known or reasonably foreseeable hazards into the agricultural water system, it may be an appropriate response for the farm to treat that water each time it is used as pre-harvest agricultural water. For example, in situations where runoff introduces known or reasonably foreseeable hazards into the agricultural water system, and the farm is not able to prevent such events from occurring, it may be appropriate for the farm to treat the water each time it is used. Or, depending on the nature of the potential source of hazards as well as other information evaluated under § 112.43(a), treatment of agricultural water only during certain times of the growing season may be sufficient to reduce the potential for contamination of covered produce. For example, depending on the circumstances, the farm might determine that treatment is only necessary when agricultural water is applied close to harvest.

Conversely, if a farm determines that the introduction of known or reasonably foreseeable hazards is not on-going, it may be appropriate to treat the water as an isolated event.

For example, if the farm is able to prevent additional runoff from being introduced to the agricultural water system, it may be appropriate to treat contaminated water still residing in the water distribution system as a one-time event, rather than treating the water as a regular practice.

If a farm treats its pre-harvest agricultural water, it is required to comply with the requirements in § 112.46, which we did not propose to substantively revise, including that the treatment be effective to make the water safe and of adequate sanitary quality for its intended use, and be delivered and monitored in a manner and with a frequency adequate to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use.

2. Corrective Measures

(Comment 109) A few comments request clarity on what corrective measures would be appropriate for the example provided in the proposed rule in which a dead and decaying sheep results in water being not safe or not of adequate sanitary quality for its intended use.

(Response 109) In the 2021 agricultural water proposed rule, we provided the example that, if in performing the agricultural water assessment a farm finds that there is a dead and decaying sheep in the canal upstream and at a close distance to where it draws water, the farm would have reason to believe that the agricultural water is not safe or not 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. Therefore, the farm would have to immediately discontinue that use of the water and take corrective measures under § 112.45(a) before resuming such use(s). 86 FR 69120 at 69141.

In this scenario, one appropriate response is for the farm to re-inspect the entire affected agricultural water system to the extent it is under the farm's 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 the changes were effective (§ 112.45(a)(1)). Steps the farm takes to meet the requirements in § 112.45(a)(1) include, at a minimum:

- Re-inspecting the entire water system potentially affected by the dead sheep to the extent it is under the farm's control to identify any relevant conditions (such as additional dead sheep, including carcass materials that may have contaminated the farm's water distribution system if applicable);
- ~~removing~~Removing the dead sheep and any related hazards identified during the re-inspection and allowing time for contaminants to clear the canal and bypass the point at which the farm draws water from the canal;
- ~~cleaning~~Cleaning any necessary equipment that may have been contaminated (such as the water distribution system impacted by the sheep); and
- ~~visually~~Visually verifying that all carcass materials have been removed.

Once the farm has taken all of the appropriate steps in light of its specific circumstances, it may resume using the water for direct water application irrigation of its covered produce.

(Comment 110) With respect to the requirements in proposed § 112.45(a)(1), some comments seek clarity as to whether pre-harvest agricultural water for produce commodities other than sprouts needs to meet the water microbial quality criterion in § 112.44(a).

(Response 110) The requirements in § 112.44(a), including the microbial criterion of no detectable generic *E. coli* per 100 mL of agricultural water, do not apply to pre-harvest agricultural water for non-sprout covered produce (see § 112.40), and as such, the reference to § 112.44(a) within § 112.45(a)(1) also does not apply to pre-harvest agricultural water for non-sprout covered produce.

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3. Mitigation Measures

In § 112.45(b), we proposed various mitigation measures for pre-harvest agricultural water that farms would implement to reduce the potential for contamination of covered produce (other than sprouts) or food contact surfaces with known or reasonably foreseeable hazards associated with the water. We received various comments requesting clarification on the proposed mitigation measures and respond to such comments below.

Consistent with the requirements for pre-harvest agricultural water assessments that are designed to be adaptable to future advancements in agricultural water quality science, we are revising § 112.45(b)(1)(ii) regarding use of a time interval between last direct application or agricultural water and harvest to remove reference to a “minimum interval of 4 days.” We are also removing commercial washing as an example of a post-harvest activity in § 112.45(b)(1)(iii) to further emphasize that other post-harvest activities may be used as mitigation measures.

We did not receive comments on the proposed mitigation measure in § 112.45(b)(1)(i), in which farms would make necessary changes (such as repairs) to address any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, and are finalizing that provision as proposed, without change. As noted above, we discuss general comments related to agricultural water treatment and the pre-harvest agricultural water efficacy testing protocol in section V.K.

a. General.

(Comment 111) Several comments urge FDA to allow more time for farms to undertake mitigation measures, citing supply chain constraints. A few comments suggest that it may not be practical to implement mitigation measures (such as those requiring construction) mid-season. In contrast, several other comments express concern that the rule, as proposed, gives farms too

much time to implement mitigation measures. Some comments are particularly concerned that the rule appears to allow farms up to 1 year to undertake mitigation measures for hazards not related to animal activity, BSAAOs, or untreated or improperly treated human waste on adjacent or nearby lands and question whether that timing adequately protects public health. Similarly, some comments question whether making mitigations for hazards related to animal activity, BSAAOs, or human waste on adjacent or nearby lands within the growing season is sufficiently protective of public health, particularly since growing seasons can span many months and include the growth of multiple covered crops. The comments seek clarity on the meaning of “growing season” within the rule.

(Response 111) The mitigation measures listed in § 112.45(b) provide greater flexibility in the timing of decisions as compared to the immediate action required under § 112.45(a), in that the mitigation measures must be implemented as soon as practicable and no later than 1 year after the date of the farm’s 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 BSAAOs 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. While the requirement that mitigation measures be implemented as soon as practicable and no later than 1 year after the date of the farm’s agricultural water assessment or reassessment is consistent with the timing for implementing measures in § 112.45(b) of the 2015 produce safety final rule, as discussed in the 2021 agricultural water proposed rule, we have incorporated expedited mitigation measures for hazards related to certain activities associated with adjacent and nearby lands in light of several

produce-related outbreaks that occurred since we issued the 2015 produce safety final rule. See 86 FR 69120 at 69145.

We have incorporated this flexibility to allow sufficient time to make any necessary adjustments to farms' current practices. For example, we recognize that some mitigation measures identified in § 112.45(b)(1), such as making necessary changes (for example, repairs) or changing the method of water application, may take time to implement, as they might entail changes to current, or adoption of new, infrastructure and equipment on the farm. Conversely, other mitigation measures, such as increasing the time interval between last direct water application and harvest to allow for microbial die-off, may be relatively easily adopted by farms without need for significant advance preparation or changes to the farm's infrastructure or operations.

The allowable timeframes for implementing mitigation measures in §§ 112.43(c)(4)(i) and 112.43(c)(2) (i.e., “no later than one year after the date of the agricultural water assessment” and “no later than the same growing season as the assessment,” respectively) are included in the recognition that, as discussed above, farms may not be able to immediately implement mitigation measures in every circumstance. Moreover, these end points are important in that they provide a basis after which, if a farm does not implement mitigation measures, the farm is required to discontinue such use of the water until the farm has implemented adequate mitigation measures in accordance with § 112.45(b)(2). However, inclusion of these end points in § 112.43(c)(4)(i) and 112.43(c)(2) does not permit farms to wait until the end of the year after the date of the assessment or the end of the same growing season as the assessment (as applicable) to implement mitigation measures under § 112.45(b). Rather, farms must implement mitigation measures “as soon as practicable” or “promptly,” respectively, as applicable to their circumstances.

For example, if a farm determines that mitigation measures are reasonably necessary under § 112.45 in accordance with § 112.43(c)(4)(i), the farm must implement mitigation measures “as soon as practicable.” Various timeframes may be “practicable,” depending on circumstances relevant to the farm. For example, it may be practicable for the farm to make modifications for the crop in the field at the time the farm makes the determination; during the next harvest if the farm has multiple harvests of a crop; or during the next growing season if the farm has multiple growing seasons within a year. If none of these timeframes are practicable or applicable to the farm’s operation, it must make the modifications to its water use practices no later than 1 year after the date of the agricultural water assessment. For this reason, too, we disagree with comments suggesting it would be appropriate to provide additional time to implement mitigation measures, and we are finalizing the timing for implementing mitigation measures as proposed, without change.

(Comment 112) Some comments seek clarification about whether crop characteristics should influence mitigation measures and, if so, request that FDA provide examples.

(Response 112) We recognize that appropriate mitigation measures in § 112.45(b) are likely to depend, in part, on the characteristics of the commodity being grown. For example, the effectiveness of microbial die-off (such as might occur prior to harvest and/or during post-harvest storage) and changing the water application method in reducing the risk associated with covered produce as a result of agricultural water are all likely to depend, in part, on the characteristics of the commodity. We discuss these measures further in comments 115, 121 and 123.

(Comment 113) Some comments seek guidance on when and how to mitigate hazards after a weather event, such as heavy rain, has occurred.

(Response 113) If a farm determines that mitigation measures under § 112.45(b) 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, the nature of the mitigation measure and timing for implementation will depend on the specific circumstances relevant to the farm, including the nature of the other information evaluated under § 112.43(a).

For example, if rain events are expected to increase runoff from adjacent or nearby lands used to graze sheep, a farm might determine, after also considering the other factors required to be evaluated in § 112.43(a)(1) through (5), that mitigation measures are reasonably necessary under § 112.45(b). Depending on the circumstances, the farm might increase the time interval between last direct application of water and harvest based on scientifically valid data and information, which the farm is required to do promptly, and no later than the same growing season as the assessment in accordance with § 112.43(c)(2). Or, if appropriate to the covered produce being grown, the farm might change the water application method to reduce the likelihood of contamination of the covered produce.

As another example, if a farm experiences an earthquake and observes seepage on the soil surface above an underground pipe that carries spent wash water, it might indicate that the pipe ruptured. If the seepage is in proximity to a well used as pre-harvest agricultural water, depending on the information evaluated under § 112.43(a), the farm might determine that mitigation measures under § 112.45(b) are reasonably necessary. In this scenario, the farm might decide that making necessary changes (for example, repairs) to the piping system, as well as making any necessary repairs to protect the well from contamination, together is an effective mitigation measure, which the farm is required to do as soon as practicable, and no later than 1

year after the date of the farm's agricultural water assessment in accordance with § 112.43(c)(4)(i).

b. Time interval between last application and harvest.

(Comment 114) Several comments support the ability to increase the time interval between last water application and harvest to a minimum of 4 days as a mitigation measure under proposed § 112.45(b)(1)(ii). These comments suggest that this option is effective, adds flexibility, and does not require a farm to have extensive knowledge of mathematics or microbial science. In contrast, some comments voice concern over the use of a 4-day interval. Some of these comments suggest that by including a time interval of 4 days, it places a burden on regulators to develop evidence justifying why longer die-off may be necessary in some circumstances. Other comments oppose inclusion of a 4-day time interval because, comments state, it effectively creates a scientifically unsupported "safe harbor" for farms, with limited parameters on the conditions in which application of such a time interval may not be warranted. Several comments ask that FDA remove the 4-day time interval from codified and instead include it in subsequent guidance which can be more easily updated as science evolves.

(Response 114) Consistent with the requirements for pre-harvest agricultural water assessments that are designed to be adaptable to future advancements in agricultural water quality science, we are revising § 112.45(b)(1)(ii) to remove reference to a "minimum interval of 4 days." Instead, final § 112.45(b)(1)(ii) entails farms "increasing the time interval between last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off, provided [the farm has] scientifically valid supporting data and information." We expect this change will further reinforce that farms may consider and adopt scientifically valid approaches other than that established for the 2015 produce safety final rule, both now and as

agricultural water quality science continues to evolve. Further, recognizing that survival of pathogens and other microorganisms on produce commodities prior to harvest is dependent upon various factors (see response to comment 115), such a change will reinforce that farms may utilize scientifically valid time intervals as appropriate to their unique conditions.

While we are removing reference to a “minimum interval of 4 days” from § 112.45(b)(1)(ii), we continue to believe it is appropriate for farms to use a time interval between last direct water application and harvest based on that used in the 2015 produce safety final rule. As such, if a farm does not test its pre-harvest agricultural water but increases the time interval between last direct application of water and harvest as an appropriate mitigation measure, the farm may choose to increase its time interval to a minimum of 4 days, based on the data used to support the approach in the 2015 produce safety final rule. (See also response to comment 117, in which we discuss “maximum” vs. “minimum” intervals.) If a farm tests its pre-harvest agricultural water and increases the time interval between last direct application of water and harvest as a mitigation measure, in light of the approach established for the 2015 produce safety final rule, the farm may 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 establishes in accordance with § 112.43(d)(3).

We consider the scientific data and information used to support the approach to a pre-harvest time interval established for the 2015 produce safety final rule as an example of adequate supporting scientific data and information farms may use in accordance with § 112.45(b)(1)(ii) (Refs. [5960](#) and [6061](#)). See also 80 FR 74354 at 74444-74445. As such, a farm may use one of the approaches described immediately above for implementing a pre-harvest time interval as a

mitigation measure under § 112.45(b) without having to develop and maintain additional supporting scientific data and information. Prior to using one of these approaches, however, the farm should consider whether the studies evaluated in support of pre-harvest microbial die-off in the 2015 produce safety final rule are reflective of conditions relevant to the farm. If a farm has scientifically valid data or information to support use of an increased time interval that is more reflective of its unique conditions, the farm must use that information in establishing an appropriate time interval under § 112.45(b)(1)(ii). See also comment 115.

(Comment 115) Several comments note that it may be difficult for a farm to make decisions regarding sufficient time intervals for microbial die-off due to lack of scientific information or expertise, and seek further guidance from FDA. Some of these comments contend that the effectiveness of microbial die-off as a mitigation method depends on various factors that are not listed in the proposed rule (e.g., climate and environmental conditions, differences between pathogens, and crop characteristics that could impact bacterial survival). Some comments request that FDA clarify how pathogens capable of longer-term survival (e.g., *Listeria*) are to be considered in determining time intervals between last water application and harvest. Several comments ask FDA to provide scientific data for microbial die-off in response to UV rays and for specific pathogens and commodities. Some comments request that farms be required to ensure that any die-off period used is validated for the conditions of their operation and specific hazards being targeted.

(Response 115) We agree that microbial die-off between last direct water application and harvest can be impacted by a broad range of conditions, such as timing of water application, environmental conditions, crop characteristics, and pathogen characteristics. As discussed in response to comment 114, we are revising § 112.45(b)(1)(ii) to remove reference to a “minimum

interval of 4 days.” Instead, final § 112.45(b)(1)(ii) provides farms the opportunity to increase the time interval between last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off, provided the farm has scientifically valid supporting data and information. We expect that such a change will further reinforce that farms may utilize scientifically valid time intervals as appropriate to their unique conditions.

As discussed in response to comment 114, we consider the scientific data used to support the approach to a time interval between last direct water application and harvest in the 2015 produce safety final rule to be one example of scientifically valid data and information (Refs. [5960](#) and [6061](#)) (80 FR 74354 at 74444-74445). Further, we recognize that as science continues to evolve, time intervals that are more appropriate for a farm to use may become increasingly available.

For example, the studies we reviewed in determining an appropriate time interval for the 2015 produce safety final rule included those that looked at various types of leafy greens, carrots, and grass (the latter of which we considered a useful surrogate for at least some produce commodities with regard to leaf structure, and noted that particulates are just as likely to occur in grass irrigation water as in irrigation water used on produce crops) (Refs. [5960](#) and [6061](#)).

However, we recognize that microbial die-off on produce surfaces prior to harvest may differ for other commodities. Moreover, the studies evaluated included five field trials for *E. coli* O157:H7 (including surrogates), one field trial and one greenhouse study examining *Salmonella*, and three trials examining viral decay. While the studies evaluated reflect a few different growing conditions, we recognize that some farms may face different environmental conditions, which could affect the microbial die-off that occurs between last water application and harvest. Similarly, we recognize that not all pathogens or other microbial organisms will necessarily

follow the same die-off kinetics as those assessed in studies evaluated for the 2015 produce safety final rule.

As more studies are conducted that examine in-field die-off for various circumstances (for example, different regions, environmental conditions, commodities, pathogens, and crop growth characteristics) (Refs. [45-4846-49](#)), it is likely that the science will continue to evolve. As we learn more about microbial die-off on produce surfaces prior to harvest, those findings can, and should, be accounted for if a farm increases the time interval between last direct application of agricultural water and harvest as a mitigation measure under § 112.45(b).

Scientific data and information used in support must be relevant to the farm's conditions (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., rapid short-term die-off and a gradual long-term die-off) under § 112.45(b)(1)(ii). Evaluating various factors under § 112.43(a), such as the timing of water applications, environmental conditions, and crop characteristics, will help farms identify conditions relevant to establishing an increased time interval between last direct water application and harvest in accordance with § 112.45(b)(1)(ii). We intend to issue guidance on this topic, as appropriate.

(Comment 116) Several comments assert that a time interval for in-field microbial die-off only makes sense if preceded by microbial water testing, which would allow farms to calculate an acceptable die-off interval rate that may differ from 4 days. These comments note that the 2015 final rule indicated the importance of sampling water sources when a die-off period is used as a mitigation measure, whereas the 2021 proposed rule did not propose to require sampling to establish a baseline understanding of the microbial presence in the water.

(Response 116) While we recognize that pre-harvest agricultural water testing may provide information for farms to consider in implementing an increased time interval between last direct water application and harvest under § 112.45(b)(1)(ii), we disagree that farms should be required to test their pre-harvest agricultural water to do so. For example, if a farm increases the time interval between last direct water application and harvest as a mitigation measure, and in doing so, decides to only apply water from that agricultural water system early in the growing season (which could be, for example, weeks to months prior to harvest), calculations based on test results may not be needed in order to justify use of that time interval as a mitigation measure. Rather, the farm must implement that increased time interval as supported by scientifically valid data and information in accordance with § 112.45(b)(1)(ii). See also comment 115.

(Comment 117) A few comments note perceived inconsistencies as to whether the 4 days referenced in proposed § 112.45(b)(1)(ii) is intended to be a minimum interval between last direct application of agricultural water and harvest or a maximum interval. For example, these comments note that the 2015 final rule references research to determine that a maximum die-off period of four days is appropriate, but suggest that FDA now uses the same research in the 2021 proposed rule to say a minimum of 4 days for die-off is appropriate.

(Response 117) The mitigation measure involving an increased time interval between last direct application of agricultural water and harvest in the 2015 produce safety final rule consisted, in part, of using a microbial die-off rate of 0.5 log per day to achieve a (calculated) log reduction of the farm's GM and STV to meet the microbial water quality criteria in previous § 112.44(b), for no greater than 4 consecutive days (see § 112.45(b)(1)(i)(A) in the 2015 produce safety final rule). In light of our proposal to remove the quantitative pre-harvest microbial quality criteria in the 2015 produce safety final rule, we revised our approach to the mitigation measure

involving an increased time interval between last direct application of agricultural water and harvest to better reflect the proposed requirements for systems-based pre-harvest agricultural water assessments.

As discussed in the 2015 produce safety final rule, a 4-day interval corresponds to the general mid-point in time representing neither end of the range where microbial die-off can be expected to occur (Refs. [5960](#) and [6061](#)) (80 FR 74354 at 74445). In the proposed rule, we stipulated a minimum (as opposed to a maximum) time interval of 4 days in the recognition that not all farms will have the benefit of quantitative test data to support a time interval of fewer than 4 days, and that additional die-off is likely to occur beyond 4 days, even if not at the same rate.

However, as discussed in response to comment 114, we are removing reference to “4 days” from the codified provision at § 112.45(b)(1)(ii) to further reinforce that farms may use approaches based on scientific data and information other than that used to establish the 2015 produce safety final rule, both now and as agricultural water quality science continues to evolve. While farms may use an approach to a time interval between last direct water application and harvest based on that established for the 2015 produce safety final rule (see comment 114), the farm should first consider whether the studies evaluated in support of pre-harvest microbial die-off in the 2015 produce safety final rule are reflective of conditions relevant to the farm (Refs. [5960](#) and [6061](#)). See also 80 FR 74354 at 74444-74445 and response to comment 115.

(Comment 118) Many comments assert that a 4-day time interval between water application and harvest, or between harvest and the end of storage, is not feasible in some environments or for some crops. For example, some of these comments note that shippers sometimes request application of water to “freshen” crops before shipping, and that farms are unable to prevent this practice, which presents a challenge for using a 4-day time interval as a

mitigation. Other comments suggest that a pre-harvest time interval may not be feasible for crops (such as strawberries, cabbages, and peas) that require frequent water applications to support crop viability (for example, due to soils being sandy, to reduce heat stress on crops, or as part of the farm's pest management strategy). A few comments note that some farms, for example, hydroponic and aquaponic operations, irrigate their produce continuously and that therefore, there is no interval between water application and harvest that would be applicable to their practices.

(Response 118) As discussed in comment 114, we are revising § 112.45(b)(1)(ii) to remove reference to a minimum interval of 4 days, as we expect this will further reinforce that farms may consider and adopt scientifically valid approaches other than that established in the 2015 produce safety final rule, both now and as agricultural water quality science continues to evolve. However, we recognize that even with this change, an increased time interval between last direct water application and harvest may not be appropriate for every farm to use as a mitigation measure. We expect that providing a range of possible measures, of which a time interval between last direct water application and harvest is only one, will assist farms in making decisions about their agricultural water use that reflects their agricultural water systems, operations, and conditions.

We would also like to clarify that the 4-day time interval referenced in the 2021 agricultural water proposed rule was specific to the time interval between last direct water application and harvest (proposed § 112.45(b)(1)(ii)), and not the time interval between harvest and end of storage (proposed § 112.45(b)(1)(iii)), for which we are not establishing a specific, broadly applicable, microbial die-off rate or time interval. See also comment 121.

(Comment 119) Some comments seek clarity on whether a farm can use the sampling framework in the 2015 final rule to define a time interval between last application of agricultural water and harvest of fewer than 4 days. Several comments ask whether FDA recognizes the MWQP calculator by University of California, Davis as “other scientifically valid data” and, if so, request clarification on whether a 1-day interval would be acceptable if justified by the calculator.

(Response 119) In comments 93, 95 and 114, we explain that the sampling frequency, microbial quality criteria, and approach to a time interval between last direct water application and harvest established for the 2015 produce safety final rule are examples of approaches supported by scientifically valid data or information that fulfill applicable requirements under §§ 112.43(d)(3) and 112.45(b)(1)(ii). (We discuss the term “scientifically valid” in the 2015 produce safety final rule (see 80 FR 74354 at 74371).) As such, farms that test pre-harvest agricultural water as one part of an assessment and increase the time interval between last direct application of water and harvest as a mitigation measure can choose to use those methods and approaches. However, as discussed in response to comment 114, if a farm considers using an approach to a pre-harvest time interval based on that established for the 2015 produce safety final rule, the farm should first consider whether the studies evaluated in support of pre-harvest microbial die-off in the 2015 produce safety final rule are reflective of conditions relevant to the farm (Refs. [5960](#) and [6061](#)). See 80 FR 74354 at 74444-74445 and response to comment 115. To the extent that a farm uses a calculator or other tool to provide decision-making support, the farm remains responsible for ensuring that all applicable requirements are met, including that any microbial criteria (or criterion), sampling frequencies, pre- or post-harvest time intervals, or other activities (as applicable) be supported by scientifically valid data or information.

c. Time interval between harvest and end of storage and/or conducting other activities.

(Comment 120) A few comments request that increasing the time interval between harvest and the end of storage be removed as a mitigation measure in the final rule, since, the comments suggest, the factors associated with microbial die-off during storage are complex and may make it difficult to determine the adequacy of a post-harvest time interval. Other comments suggest that commercial washing specifically should be removed as an allowable mitigation, as including it reinforces an inaccurate perception that commercial washing always reduces pathogens on produce surfaces. A few comments note that commercial washing with an antimicrobial is designed to prevent the spread of pathogens from contaminated produce to other, uncontaminated produce, and not to remove microorganisms from contaminated produce. Some comments note that farms are not required to use an antimicrobial in their post-harvest wash water and suggest that including commercial washing as a mitigation measure may ultimately increase risk if water is not managed properly.

(Response 120) We recognize that microbial die-off and/or removal during post-harvest storage and as a result of other post-harvest activities is likely dependent on a variety of factors, such as commodity characteristics, storage time and conditions, and relevant production practices. Farms are not required to treat their post-harvest agricultural water, and post-harvest agricultural water, if not adequately managed, has the potential to serve as a source or route of contamination. However, if properly performed and scientifically valid given a farm's production practices, commercial washing has the potential to result in microbial die-off or removal from produce surfaces. For example, the World Health Organization has attributed a 1-log reduction in microbial load to washing (Ref. 65). See also 79 FR 58434 at 58446. As such, we are not removing § 112.45(b)(1)(iii) as an allowable mitigation measure.

However, we recognize there may be post-harvest activities other than commercial washing that have the potential to result in microbial die-off or removal on covered produce. See, for example, 80 FR 74354 at 74370, where we provide controlled atmosphere storage as another example of a post-harvest activity that may be appropriate for use as a mitigation measure with adequate supporting data and documentation. As such, we are removing commercial washing as an example of a post-harvest activity in § 112.45(b)(1)(iii) to further reinforce that farms may use other activities during or after harvest as a mitigation measure, provided the farm has adequate supporting data and documentation. This revision will further encourage farms to consider other post-harvest activities that may result in microbial die-off or removal from produce surfaces both now, and in the future as potential advancements in post-harvest handling practices occur (Refs. [7880](#) and [7981](#)). In light of our removal of the pre-harvest agricultural water microbial quality and testing requirements in the 2015 produce safety final rule, we are also revising § 112.45(b)(1)(iii) to remove reference to microbial die-off “rates” and microbial removal “rates,” specifically.

(Comment 121) A number of comments request that FDA provide further guidance, scientific information, and examples on how farms may use a time interval between harvest and end of storage or commercial washing as mitigation measures under proposed § 112.45(b)(1)(iii). For example, a few comments request additional guidance, noting that the factors associated with microbial die-off during post-harvest storage and handling are complex and may depend, for example, on crop characteristics. Some comments request clarity on what type of organisms should be studied in order to justify the use of post-harvest storage or handling as a mitigation measure, noting that if producers attempt to develop data in-house, they will not be able to use pathogens to conduct in-house studies.

(Response 121) As discussed in the 2014 supplemental proposed rule and the 2015 produce safety final rule, we do not have sufficient information to support the derivation of appropriate, broadly applicable microbial die-off or removal rates between harvest and end of storage or during post-harvest activities such as commercial washing. See 79 FR 58434 at 58446 and 80 FR 74354 at 74444. We have not been provided with and are not aware of information that changes our position. Rather, farms that increase the time interval between harvest and the end of storage and/or conduct other post-harvest activities as a mitigation measure in accordance with § 112.45(b)(1)(iii) must establish parameters for such practices as appropriate to their circumstances (for example, in consideration of commodity characteristics, storage time and conditions, and/or other relevant production practices), as supported by scientifically valid data and information.

For example, a farm that uses commercial washing as a mitigation measure under § 112.45(b)(1)(iii) must do so as appropriate to its circumstances. The appropriateness of using commercial washing as a mitigation measure may be affected by, for example, the characteristics of the covered produce being washed (such as where commodity characteristics may protect potential contaminants from removal); the method of commercial washing (such as through a single-pass system vs. one that uses recirculated water); and any monitoring or management practices the farm has in place to reduce the potential for the agricultural water to serve as a source or route of contamination to covered produce (for example, the practices specified in § 112.44(d)).

We are not requiring farms to conduct “in-house” studies in order to support use of a mitigation measure under § 112.45(b)(1)(iii), nor are we establishing parameters on what studies conducted to support such practices should entail. Rather, we require that any increased time

interval between harvest and the end of storage and/or other post-harvest activities used in accordance with § 112.45(b)(1)(iii) be supported by scientifically valid data or information. See 80 FR 74354 at 74371.

(Comment 122) Some comments seek clarity around the term “commercial washing” in proposed § 112.45(b)(1)(iii), such as whether it would include processes that use water for cooling purposes (for example, hydrocooling, dump tank, spray bar, and ice-injection processes), and whether it is an available mitigation measure for all covered produce, or just select commodities.

(Response 122) As discussed in response to comment 120, we are removing commercial washing as an example of a post-harvest activity in § 112.45(b)(1)(iii) to reinforce that farms may use other activities during or after harvest that result in microbial die-off or removal, provided the farm has adequate supporting data and documentation. While post-harvest activities conducted under § 112.45(b)(1)(iii) could involve the use of agricultural water, it is not required, such as where controlled atmosphere storage may result in microbial die-off or removal (as supported by scientifically valid data and information). (See 80 FR 74354 at 74371).

Additionally, we note that activities allowed as mitigation measures under § 112.45(b)(1)(iii) are not limited to any commodities in particular. However, as discussed in response to comment 121, farms must establish parameters for any post-harvest activities used in accordance with § 112.45(b)(1)(iii) as appropriate to their circumstances (e.g., in consideration of commodity characteristics, storage conditions, and/or other relevant production practices) and as supported by scientifically valid data and information.

d. Changing the method of water application.

(Comment 123) Some comments request that FDA identify use of drip and seepage irrigation as effective strategies for reducing risk because in such systems, the water distribution occurs below the soil surface (never touching any above-ground portion of the plant) and the soil naturally filters out any potential microbial hazards.

(Response 123) It is unclear to us whether comments are requesting that we identify drip and seepage irrigation as methods that do not result in contact between agricultural water and the crop, or that we identify use of drip and seepage irrigation as water application methods that could be broadly applied as mitigation measures under § 112.43(b)(1)(iv).

To the extent that comments are requesting we identify drip and seepage irrigation as broadly applicable mitigation measures in § 112.43(b)(1)(iv), we decline to do so, as the effectiveness of using those application methods as a mitigation measure is a function of multiple factors, including the water application method, characteristics of the crop (such as whether the harvestable portion grows near, on, or in the ground), and any relevant practices the farm may have in place. For example, changing the water application method for root crops may not be an appropriate mitigation measure, as it may be difficult to effectively minimize contact between agricultural water and the harvestable portion of the crop while allowing the crop access to water needed to survive and grow. However, for non-root crops, changing the water application method may be effective as a mitigation measure under § 112.45(b), if making the change minimizes the water that is in direct contact with the harvestable portion of the crop. For example, changing from overhead to microjet irrigation for some tree fruit (such as citrus) or from microjet to drip irrigation for some covered produce that grows near the ground (such as bell peppers) may reduce the likelihood of contamination of the covered produce in accordance

with § 112.45(b)(1)(iv). Additionally, there may be instances where multiple practices—such as the use of plastic mulch along with changes in water application methods—together serve as effective mitigation measures under § 112.45(b)(1)(iv).

e. Alternative mitigation measure.

(Comment 124) Several comments suggest that changing water sources (from surface water to ground water, for instance) might be considered a possible alternative mitigation measure.

(Response 124) We have incorporated flexibility in § 112.45 to provide farms viable options 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 without needing to alter the source of agricultural water, such as making necessary changes (for example, repairs) or changing the method of water application to reduce the potential for contamination of covered produce. However, if a farm changes the water source it uses for pre-harvest agricultural water, it is a significant change, and a reassessment under § 112.43(e) is required. The reassessment must evaluate the impacts of the change on the factors in § 112.43(a)(1) through (5), any new hazards identified, and the outcome and determination under § 112.43(c). See also section V.I.

We believe that providing a range of mitigation measures for farms to use in § 112.45(b), including the ability to use an alternative mitigation measure provided the requirements in § 112.12 are met, provides farms with an appropriate level of flexibility in selecting mitigation measures that are reasonably necessary to reduce the potential for covered produce or food

contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water.

K. Treatment of Agricultural Water

The proposed rule contained edits designed to provide clarity, such as reorganizing subpart E to group provisions of a similar nature, which included moving the provisions related to agricultural water treatment to § 112.46. Additionally, as discussed in the 2021 agricultural water proposed rule, although we are not requiring farms to treat their agricultural water, scientists from FDA's Center for Food Safety and Applied Nutrition, in collaboration with EPA, developed a testing protocol for evaluating the efficacy of antimicrobial chemical treatments against certain foodborne pathogens in agricultural water sources (Ref. [8082](#)). Since the efficacy protocol was approved by EPA on April 29, 2020, we have worked with EPA to provide various updates to enhance flexibility (where appropriate) and meet the current needs scientifically and practically (Ref. [8183](#)).

We received various comments on agricultural water treatment in general, as well as the pre-harvest agricultural water efficacy testing protocol, which we discuss below. For comments regarding treatment as a corrective or mitigation measure, see section V.J.

As discussed in section V.A., we did not propose to substantively revise the requirements for agricultural water treatment in § 112.46; therefore, comments on § 112.46 are outside the scope of this rule. However, we intend to issue guidance on these requirements in the future.

(Comment 125) Many comments note that there are currently no chemical treatment options approved by EPA for use in pre-harvest agricultural water against human pathogens, and express concerns that this may prohibit the use of water treatment as a corrective or mitigation measure until such products are approved. Some comments suggest that the lack of available

chemical treatments may result in some farms using pesticides in an unapproved manner in order to comply with the proposed rule.

(Response 125) Farms are not required to treat their agricultural water. Rather, farms have a range of options, and treatment of water is one such option. Additionally, if a farm treats agricultural water, § 112.46 allows for non-chemical suitable methods of treatment. See 80 FR 74354 at 74436-74437. Further, as discussed in the 2015 produce safety final rule, like all registered pesticide products, registrations for antimicrobial products are specific to the use that was considered as part of the registration process, and thus the products may be legally used for the specified registered use only. See 80 FR 74354 at 74436.

(Comment 126) Some comments voice concern that farms are not required to test the quality of their water prior to treating it. These comments suggest that the chemicals approved using the treatment efficacy protocol have limited usefulness in ensuring that treated pre-harvest water contains no detectable generic *E. coli* per 100 mL of water, as a farm would be unable to document that an EPA-labeled treatment that achieves 3-log removal is expected to result in pre-harvest water containing no detectable generic *E. coli* per 100 mL of water unless the farm knows that the starting concentration of generic *E. coli* is less than 1,000 CFU per 100 mL.

(Response 126) We understand commenters to be referring to language in the pre-harvest agricultural water treatment efficacy protocol specifying that results of testing should demonstrate a minimum of 3-log reduction of each of the test organisms as compared to the control count (Ref. [8082](#)). We understand that a 3-log reduction is the minimum level of reduction of pathogens the EPA will consider when registering an antimicrobial treatment that includes a public health claim. While the requirements for agricultural water treatment in § 112.46 refer in part to § 112.44(a) (which includes a microbial criterion of no detectable generic

E. coli per 100 mL of water), we note that the requirements in § 112.44(a) do not apply to pre-harvest agricultural water for non-sprout covered produce (see § 112.40).

We did not propose to substantively revise § 112.46, which includes requirements related to treatment efficacy.

(Comment 127) Some comments request that FDA remove chemical treatment of irrigation water as an allowable mitigation strategy in the proposed rule so as to avoid potential effects on the environment.

(Response 127) As discussed in response to comment 125, farms are not required to treat their agricultural water. Rather, farms have a range of options, and treatment of water (such as with physical treatment, chemical treatment, or other suitable method) is one such option. With respect to environmental concerns related to chemical treatment of agricultural water, we note that environmental and health-related risk assessments of pesticide products are conducted by EPA prior to their registration and use. See 80 FR 74354 at 74434-74435.

However, we recognize that improper use, management, or disposal associated with chemical treatment of agricultural water can create adverse environmental impacts. During rulemaking for the 2015 produce safety final rule, and in accordance with the National Environmental Policy Act and its implementing FDA regulations, we evaluated the potential effects of the 2015 produce safety final rule on the human environment in the United States in an EIS (Ref. [4950](#)). That document has a detailed discussion of the potential impacts such as those related to pesticide use, chemical treatment of agricultural water, and changes in ground water demand. See also 80 FR 74354 at 74434-74435. At the time of this rulemaking, as was also the case at the time of preparation of the Agency's finding of no significant impact and environmental assessment for the 2021 agricultural water proposed rule (Refs. [5051](#) and [5152](#)),

there are no pesticide products which have been registered by EPA for treatment of agricultural water during pre-harvest activities. No significant adverse environmental impacts have been identified with this final rule (Ref. [§ 253](#)). We are not aware of, and comments did not provide, data or information suggesting these findings are incorrect. Therefore, further analysis of potential impacts would be speculative.

(Comment 128) Several comments agree with FDA's tentative conclusion that the proposed rule does not conflict with or duplicate the requirements of organic certification under USDA's National Organic Program (NOP) standards (7 CFR part 205). However, a few comments express concern that chemical products approved by the EPA for use on pre-harvest water in the future (such as chlorine compounds) may not be allowed for use under the NOP.

(Response 128) As discussed in the 2015 produce safety final rule (80 FR 74354 at 74439-74440), compliance with the provisions of the 2015 produce safety final rule, including the provisions related to agricultural water in subpart E, does not preclude compliance with the requirements for organic certification in 7 CFR part 205. We continue to conclude that in accordance with section 419(a)(3)(E) of the FD&C Act, this rule does not include any requirements that conflict with or duplicate the requirements of the NOP established under the Organic Foods Production Act of 1990. See also 86 FR 69120 at 69132.

If a farm treats its agricultural water, non-chemical water treatment options (including pesticide devices such as filter units, UV light units, and ozonator units) may be also used in compliance with § 112.46, which we did not propose to substantively revise. Thus, this rule does not require organic farms to use a substance that is prohibited in organic production. We also note that the provisions for treatment of agricultural water in § 112.46 are not in conflict with or duplicative of [the NOP regulations which permit the use of chlorine materials in organic](#)

production and handling in accordance with certain limitations (see 7 CFR 205.601(a) and 205.605(b)). Additionally, NOP guidance, “The Use of Chlorine Materials in Organic Production and Handling” (Ref. ~~82~~), ~~which~~⁸⁴, provides ~~that residual chlorine levels in pre-harvest water agricultural water should not exceed the maximum residual disinfectant limit information about compliant use of chlorine~~ under the ~~Safe Drinking Water Act (40 CFR part 141), and post-harvest agricultural water is permitted to contain chlorine materials at levels approved by the FDA or the EPA for such purpose.~~organic regulations. See 86 FR 69120 at 69131.

(Comment 129) Some comments suggest that treatments that are effective against the bacterial pathogens identified in the efficacy protocol cannot necessarily be expected to have the same level of effectiveness against viral and protozoan pathogens, such as *Cyclospora cayatanensis*. Moreover, comments claim that in many situations, a farm may not know what specific microbial hazards may be present in an agricultural water and request that FDA clarify whether all known or reasonably foreseeable hazards must be considered when selecting a treatment.

(Response 129) We recognize that pathogens present in agricultural water systems may vary, and that not every treatment will be effective against every possible pathogen. While farms are required to consider the *conditions* that are reasonably likely to introduce known or reasonably foreseeable hazards as part of their pre-harvest agricultural water assessments (emphasis added), we do not necessarily expect farms to identify the specific microbial hazards associated with each condition in order to treat their water as a corrective or mitigation measure. Nonetheless, if a pathogen is known to be, or is likely to be, associated with a farm’s pre-harvest agricultural water (which the farm may be aware of through voluntary testing, knowledge or

experience, or other means) and the farm treats the water, the farm must consider the presence of that pathogen in selecting an appropriate method of treatment.

For example, the efficacy protocol for the development and registration of antimicrobial treatments for pre-harvest agricultural water, as updated in January 2023 (Ref. [8082](#)), specifies Shiga-toxin producing *E. coli* and *Salmonella enterica* as test organisms. As such, any chemistries approved using this protocol will specify those organisms on their labels. (While the protocol originally included *L. monocytogenes*, in a January 2023 update (Ref. [8183](#)), we explained that we were removing *L. monocytogenes* from the protocol at that time.) We emphasize that a variety of measures are available for farms to use in § 112.45, not just those related to chemical treatment of agricultural water. As we continue to learn more about the known or reasonably foreseeable hazards present in pre-harvest agricultural water sources and systems, we will consider working with EPA to account for other pathogens in efficacy protocols to support registration of chemical treatments.

(Comment 130) Some comments disagree with what they suggest is a requirement under the proposed rule for farms to treat their water with products labeled for specific pathogens. A few comments request that FDA provide flexibility related to the treatment efficacy protocol and requirements that chemical treatments be validated for efficacy against specific test organisms.

(Response 130) As discussed in the 2015 produce safety final rule, although some antimicrobial substances are regulated by FDA, most antimicrobial substances that might be used by farms in agricultural water are regulated by the EPA (Ref. [8285](#)) (80 FR 74354 at 74439). We anticipate that the treatment efficacy protocol (Ref. [8082](#)), which EPA approved, will facilitate the registration of chemical treatments and increase the options for corrective and mitigation measures available to farms. We anticipate that having several chemical treatment options

available encompassing a range of chemistries and applications will help ensure coverage over an industry with such variable practices and conditions.

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L. Records Relating to Agricultural Water (§ 112.50)

We proposed to add new requirements in § 112.50 for records relating to pre-harvest agricultural water assessments. We also made revisions to conform with the proposed changes to the subpart E provisions, including to revise the requirements of § 112.161(b) to require supervisory review of records of pre-harvest agricultural water assessments and determinations.

We received various comments on the recordkeeping requirements in § 112.50 and respond to those comments in the following paragraphs. As discussed below, we are revising § 112.50(b)(7) to further reinforce flexibility afforded to farms in establishing records related to certain actions taken under § 112.45. We are also revising § 112.50(b)(8) to reflect the changes we are making to § 112.45(b)(1)(ii) and (iii) (see section V.J.). Additionally, consistent with § 112.50(b)(8) in the 2015 produce safety final rule, we are adding the following record requirement: for farms using an alternative mitigation measure in accordance with § 112.45(b)(1)(vi), records of scientific data or information the farm relies on to support that measure (§ 112.50(b)(9)). We have renumbered the subsequent recordkeeping provisions accordingly. We received no comments on the conforming revisions to § 112.161(b) and are finalizing it without change.

(Comment 131) Some comments seek clarity on what standards of Subpart O, “Records,” apply for pre-harvest agricultural water assessments. A few comments request that FDA clarify which records, including those for agricultural water reassessments, are required to be in writing. A few comments request that FDA provide templates for records, with a few of those comments seeking clarity on whether a printed copy of the Agricultural Water Assessment Builder tool would satisfy the records requirements in § 112.50. Others request that FDA provide sufficient education and outreach to assist farms in complying with the recordkeeping requirements.

(Response 131) Subpart O of the 2015 produce safety final rule established the general requirements applicable to documentation and records that farms must establish and maintain under part 112, including records related to agricultural water. We discuss the requirements in subpart O in the 2015 produce safety final rule. See 80 FR 74354 at 74510-74514.

Section 112.43(a) requires that farms, in part, prepare a *written* agricultural water assessment (emphasis added). The requirement that agricultural water assessments be in writing also applies for any reassessments conducted under § 112.43(e).

As referenced by the comments, we have made an Agricultural Water Assessment Builder (Ref. 24) available to help stakeholders understand the requirements in the 2021 agricultural water proposed rule for pre-harvest agricultural water assessments. While we expect to update the Builder to reflect this final rule, use of the Builder does not mean that farms are in compliance with the relevant requirements.

(Comment 132) A few questions seek clarity on whether agricultural water assessments prepared by farms will be accessible to outside parties.

(Response 132) Records obtained by FDA in accordance with part 112, including agricultural water assessments, are subject to the disclosure requirements under 21 CFR part 20 (§ 112.167). Our disclosure of information is subject to the Freedom of Information Act (5 U.S.C. 552), the Trade Secrets Act (18 U.S.C. 1905), the FD&C Act, and our implementing regulations under 21 CFR part 20, which include protection for confidential commercial information and trade secrets. See 80 FR 74354 at 74514.

(Comment 133) Several comments request that FDA clarify which records can satisfy multiple requirements both for subpart E and for other sections of the rule that may be related (for example, subparts I and F). Many comments ask whether records used for water system

inspections can also be used to satisfy the agricultural water assessment recordkeeping requirements.

(Response 133) Under § 112.163(a), farms are not required to duplicate any existing records, including those for agricultural water assessments, if those records contain all of the required information and satisfy the relevant requirements. Similarly, if a farm has records containing some but not all of the required information, § 112.163(b) provides the flexibility to keep any additional information required either separately or combined with existing records.

With respect to comments asking about records for agricultural water system inspections and agricultural water assessments, we note that records of a farm's agricultural water system inspection in § 112.50(b)(1) may not be appropriate to fulfill, in full, the requirement to maintain records of written agricultural water assessments in § 112.50(b)(2), as the requirements in § 112.43 for agricultural water assessments require consideration of a broader range of factors than those considered for water system inspections under § 112.42(a). See also response to comment 25.

(Comment 134) Some comments request that FDA simplify the recordkeeping requirements for farms that choose to wait at least 4 days between the last direct water application and harvest by allowing farms to document practices in written standard operating procedures instead of requiring farms keep records documenting each individual time they use the 4-day interval on each crop.

(Response 134) We agree that flexibility with respect to records of certain mitigation measures is warranted and are revising proposed § 112.50(b)(7) to remove specific reference to § 112.45(b)(1)(ii) and (iii) (regarding a time interval between last water application and harvest, and a time interval between harvest and end of storage (and/or conducting other post-harvest

activities), respectively). For example, if a farm implements an increased time interval between last direct water application and harvest as a mitigation measure under § 112.45(b)(1)(ii) and adopts that increased time interval as a routine practice, capturing that practice in a single record suffices such that maintaining a record of each individual instance the time interval is applied is not necessary. This, too, applies to any increased time intervals between harvest and end of storage and/or other post-harvest activities that a farm implements as a mitigation measure under § 112.45(b)(1)(iii), if the farm adopts the relevant practice(s) as a routine activity.

(Comment 135) One comment notes that proposed § 112.45(b) requires the implementation of certain “mitigation measures” under specified conditions, yet the associated records requirement in § 112.50(b)(7) requires “documentation of actions you take in accordance with § 112.45.” The comment requests that § 112.50(b)(7) be modified to read, “Written documentation of mitigation measures you take in accordance with § 112.45.”

(Response 135) We decline to make this change, as § 112.45 includes required actions beyond the mitigation measures specified in § 112.45(b). See § 112.45(a), which requires, in certain circumstances, that a farm immediately discontinue use of agricultural water and, before resuming use of the water, implement corrective measures in § 112.45(a)(1) or (2).

VI. Effective and Compliance Dates

In the 2021 agricultural water proposed rule, we proposed to establish an effective date 60 days after the date of publication of the final rule. In the 2022 supplemental proposed rule, we proposed to establish dates for compliance with the pre-harvest agricultural water provisions for covered produce other than sprouts as follows: 2 years and 9 months after the effective date of a final rule for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses. We

also specified the duration of the period of enforcement discretion for the harvest and post-harvest agricultural water requirements for covered produce other than sprouts until January 26, 2025, for very small businesses; January 26, 2024, for small businesses, and January 26, 2023, for all other businesses.

We received several comments in response to the 2021 proposed rule as well as the 2022 supplemental proposed rule regarding the proposed effective date for a final rule as well as the proposed compliance dates for the requirements that apply for pre-harvest agricultural water for non-sprout covered produce. We respond to these comments here. While in the 2022 supplemental proposed rule we noted that we were reopening the comment period only with respect to the compliance dates for the proposed pre-harvest agricultural water provisions for covered produce other than sprouts, we received some comments related to the end of our intended period of enforcement discretion for the harvest and post-harvest agricultural water requirements for non-sprout covered produce.

After considering comments, we are finalizing the effective date as proposed, i.e., 60 days after publication of this rule. We are also finalizing compliance dates as proposed, such that compliance dates are those shown in table 5.

Table 5.--Compliance Dates for Requirements in Subpart E for Covered Activities Involving Covered Produce (Except Sprouts Subject to Subpart M)

Size Of Covered Farm	Provisions Related to Harvest and Post-Harvest Agricultural Water	Provisions Related to Pre-Harvest Agricultural Water
	Compliance Date	Proposed Compliance Date
Very Small Business	January 26, 2024	2 years and 9 months after the effective date of this rule
Small Business	January 26, 2023	1 year and 9 months after the effective date of this rule
All Other Businesses	January 26, 2022	9 months after the effective date of this rule

(Comment 136) Several comments support FDA’s proposed compliance dates for pre-harvest agricultural water requirements, suggesting that the proposed compliance dates allow sufficient time for farms to understand and comply with the requirements. In contrast, other comments express a concern that the proposed compliance dates for pre-harvest agricultural water requirements do not allow sufficient time for on-farm preparedness and development of educational and training materials to support successful implementation. A few comments suggest specific compliance dates from 1 to 3 years after the final rule publishes based on farm size would be appropriate, whereas others suggest that a single compliance date for all agricultural water provisions 2 years after publication of the final rule would be more appropriate.

(Response 136) In light of the extensive outreach we conducted following issuance of the proposed rule and anticipated education, outreach and training on this final rule, we decline commenters’ request to provide additional time for farms to come into compliance with the pre-harvest agricultural water requirements for non-sprout covered produce and are finalizing compliance dates for those provisions as proposed, without change. To the extent that comments are suggesting we establish a single set of compliance dates for all uses of agricultural water (pre-harvest, harvest, and post-harvest) and/or establish a single compliance date that applies for farms of all sizes, we discuss such feedback in response to comments 141 and 137, respectively.

Regarding outreach conducted following issuance of the 2021 proposed rule, as discussed in further detail in section III.F., we conducted numerous outreach activities following issuance of the agricultural water proposed rule. These included participation in various webinars; consultations, two virtual public meetings; regional meetings sponsored by State regulatory partners; and numerous other meetings and speaking engagements to discuss the proposed rule,

respond to questions, and receive feedback. Further, we are exploring other mechanisms, such as webinars, updated training programs, workshops, and educational resources, to provide industry with information to facilitate compliance the requirements we are finalizing here. We also anticipate updating our Agricultural Water Assessment Builder, including both the online and paper-based versions, to reflect the pre-harvest agricultural water requirements we are finalizing here.

Additionally, we note that although the compliance dates we are finalizing here apply for all requirements for pre-harvest agricultural water for non-sprout covered produce, many of these requirements have not changed since publication of the 2015 produce safety final rule. See § 112.40 and response to comment 9. For example, other than technical amendments to provide additional clarity (such as adding descriptive headings and consolidating certain requirements), the requirements in § 112.42 for agricultural water system inspections and maintenance remain the same as when the 2015 produce safety final rule published. As such, we expect that many farms may already be aware of, and have received education and training on, some of the requirements that apply for pre-harvest agricultural water that are not changing with this final rule. While we recognize the value of outreach and training regarding the requirements in § 112.43 for pre-harvest agricultural water assessments and outcomes, we disagree that farms will need more than the established compliance periods to adapt their programs to the specific requirements of this rule.

(Comment 137) Many comments support staggered compliance dates for the pre-harvest agricultural water provisions based on farm size. Some comments note that extended compliance dates are especially important in order to provide enough time for training, technical assistance, and updates to practices, infrastructure, and equipment to occur. Conversely, some comments do

not support staggered compliance dates based on farm size, contending that staggered compliance dates create unnecessary complexity for organizations that conduct training since they will first have to target only large farms, and then conduct training for small farms as the different compliance dates grow near.

(Response 137) We disagree that we should establish a uniform compliance period for the pre-harvest agricultural water requirements for non-sprout covered produce across all farm sizes. The purpose of staggered compliance dates is to give businesses of various sizes time to come into compliance with the rule technically, financially, and operationally. In light of practical considerations for small and very small businesses, we consider that additional time for small and very small farms to come into compliance is warranted. Moreover, we note that staggered compliance dates based on farm size is consistent with compliance dates for requirements in the 2015 produce safety final rule that we did not propose to change, and is consistent with the statutory provisions in section 419(a)(3)(A) and (c)(1)(B) of the FD&C Act, which direct us to provide sufficient flexibility to be practicable for all sizes and types of businesses, including small businesses.

(Comment 138) Some comments urge FDA to set pre-harvest compliance dates only after sufficient research is conducted regarding the impact of farming practices on pre-harvest agricultural water quality and safety, and mitigation measures that are appropriate to address various conditions. Several comments suggest that “proven” mitigation measures need to be made available before farms should be expected to implement the requirements for agricultural water assessments.

(Response 138) We disagree with these comments. While we have designed the rule to be adaptable to future scientific advancements, we note that there is long-standing scientific support

for the mitigation measures identified in § 112.45(b). See, for example, the GAPs Guide (Ref. [5859](#)) and the QAR (Ref. 17). We also discuss the scientific reasoning behind the proposed requirements for agricultural water assessments (including mitigation measures) throughout the 2021 agricultural water proposed rule and in section V of this final rule. To the extent that science related to pre-harvest agricultural water quality continues to evolve, farms will be able to use such information to further inform covered their pre-harvest agricultural water assessments. We anticipate that as new information becomes available, it will be shared with covered entities through various means. See response to comment 19.

(Comment 139) A few comments suggest that FDA and States will need time to make progress on partnerships related to the pre-harvest agricultural water provisions. These comments suggest that partnerships should be in place before compliance with the pre-harvest requirements is required.

(Response 139) FSMA recognizes a critical role for FDA’s State regulatory partners. To this end, FDA has established the FDA-State Produce Safety Implementation Cooperative Agreement Program⁸, through which most states have developed produce safety programs (Ref. [8486](#)).

(Comment 140) Several comments disagree with the proposed effective date of 60 days after publication of the final rule, arguing that 60 days is not enough time for farms to implement necessary changes in order to come into compliance with the proposed requirements.

(Response 140) “Effective date” and “compliance date” do not mean the same thing. The effective date is the date that requirements amend the current CFR; and for this rule, the

⁸ See “FDA-State Produce Safety Implementation Cooperative Agreement Program” at <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/grants-and-cooperative-agreements/fda-state-produce-safety-implementation-cooperative-agreement-program>.

compliance date is the date at which a farm is required to be in compliance with the pre-harvest agricultural water requirements for non-sprout covered produce.

We proposed that the effective date of this rule would be 60 days after the date of publication of the final rule in the *Federal Register*. However, we proposed to provide for a longer timeline for farms to come into compliance with the pre-harvest agricultural water provisions depending on the size of the farm--i.e., 2 years and 9 months after the effective date of a final rule for very small businesses; 1 year and 9 months after the effective date of a final rule for small businesses; and 9 months after the effective date of a final rule for all other businesses. See also table 5. As discussed throughout this section, we are finalizing the effective and compliance dates as proposed.

(Comment 141) We also received various comments on FDA's intention to exercise enforcement discretion for harvest and post-harvest agricultural water. One comment notes that most farms have already begun complying with the harvest and post-harvest agricultural water requirements, and voices support for FDA's intent to exercise enforcement discretion for those requirements as described in the 2022 supplemental proposed rule. In contrast, some comments request that FDA provide more time for training and other outreach. A few of these comments note that even though FDA did not propose changes to the requirements for harvest and post-harvest agricultural water, some of the provision numbers for those requirements may change with a final rule, which could result in confusion. A few comments assert that bifurcated compliance dates will be confusing, and create unnecessary complexity by, for instance, requiring educators to conduct separate trainings for the harvest/post-harvest and pre-harvest agricultural water requirements.

(Response 141) As discussed in the 2022 supplemental proposed rule, we reopened the comment period on the 2021 proposed rule solely to request public comment on the proposed compliance dates for the proposed pre-harvest agricultural water provisions for covered produce other than sprouts. As we did not propose to change the requirements that apply for harvest and post-harvest agricultural water, we did not propose a compliance date extension for those provisions for covered produce other than sprouts. However, we stated our intent to exercise enforcement discretion for the harvest and post-harvest agricultural water requirements for non-sprout covered produce until specific dates, which were staggered according to the size of the farm, to provide farms, regulators, educators, and other stakeholders additional time to facilitate compliance with those provisions.

With respect to comments suggesting there will be confusion due to the renumbering of various provisions that apply for harvest and post-harvest agricultural water, we note that § 112.40 specifies which provisions in subpart E are applicable to harvest and post-harvest agricultural water. Additionally, our response to comment 9 summarizes the major changes being made to the agricultural water provisions in subpart E between the 2015 produce safety final rule and this final rule, including the location of the relevant requirements. We expect this information, along with training, technical assistance, educational visits, and on-farm readiness reviews, will reduce potential confusion associated with reorganizing the provisions of subpart E.

VII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, Executive Order 14094, the Regulatory Flexibility Act (5 U.S.C. 601-612), the

Congressional Review Act/Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 801, Pub. L. 104-121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4).

Executive Orders 12866, 13563, and 14094 direct us to assess all benefits, costs, and transfers of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Rules are “significant” under Executive Order 12866 Section 3(f)(1) (as amended by Executive Order 14094) if they “have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities.” ~~Rules are “significant” under Executive Order 12866 Section 3(f)(4) (as amended by Executive Order 14094) if they “raise legal or policy issues for which centralized review would meaningfully further the President’s priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.”~~ OIRA has determined that this final rule is not a significant regulatory action ~~as defined by~~ under Executive Order 12866 Section 3(f)(4~~1~~).

Because this rule is not likely to result in an annual effect on the economy of \$100 million or more or meets other criteria specified in the Congressional Review Act/Small Business Regulatory Enforcement Fairness Act, OIRA has determined that this rule does not fall within the scope of 5 U.S.C. 804(2).

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because some small entities may

incur costs larger than 3 percent of annual revenues, we cannot certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes estimates of anticipated impacts, before issuing “any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year.” The current threshold after adjustment for inflation is \$~~177~~183 million, using the most current (~~2022~~2023) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

We estimate costs of the rule resulting from reading the rule, conducting pre-harvest agricultural water assessments, conducting mitigation measures when reasonably necessary based on the outcomes of the pre-harvest agricultural water assessments, and recordkeeping as a result of the pre-harvest agricultural water assessments. Our primary estimates of annualized costs are approximately \$17.5 million at a 3 percent discount rate and approximately \$17.7 million at a 7 percent discount rate over 10 years.

We estimate benefits of this rule resulting from the dollar burden of foodborne illnesses averted, and we estimate forgone benefits of this rule resulting from foodborne illnesses not averted due to the pre-harvest agricultural water microbial quality criteria and testing provisions in the 2015 produce safety final rule. Our primary estimates of annualized benefits are approximately \$10.3 million at a 3 percent discount rate and approximately \$10.1 million at a 7 percent discount rate over 10 years. In the FRIA, we discuss ~~qualitative~~non-quantified benefits of the rule stemming from avoiding overly broad recalls ~~averted and~~of products that would have

occurred absent the rule. We also discuss non-quantified benefits relating to increased flexibility for covered farms to comprehensively evaluate their agricultural water systems, in light of the requirements for pre-harvest agricultural water assessments being designed to accommodate a wide range of agricultural water sources, uses, and practices.

We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. The full analysis of economic impacts is available in the docket for this final rule (Ref. 26) and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

VIII. Analysis of Environmental Impact

The Agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. We have considered the changes made between the 2021 proposed rule and this final rule and have concluded that the Agency's finding of no significant impact for the proposed rule, and the evidence supporting that finding, contained in an environmental assessment, continue to apply (Refs. [50-5251-53](#) and [8587](#)). The Agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

IX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). A description of these provisions is given in the Description section with an estimate of the annual recordkeeping burden. Included in the estimate is the time for reviewing

instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Standards for the Growing, Harvesting, Packing, and Holding of Produce; Recordkeeping--OMB Control Number 0910-0816--Revision.

Description: This rule replaces recordkeeping requirements (found in part 112, subpart E) associated with sampling and testing of pre-harvest agricultural water for non-sprout covered produce with requirements to prepare and maintain documentation of written pre-harvest agricultural water assessments for non-sprout covered produce.

Description of Respondents: Farms subject to the regulation in part 112.

In the following paragraphs, we describe and respond to the comments pertaining to the proposed information collection.

(Comment 142) One comment seeks clarity on how this rule adds to the paperwork burden of the produce safety rule in terms of hours and numbers of records. This comment also requests clarification as to whether the calculated time burden in the 2021 agricultural water proposed rule includes reassessments and maintenance activities, and expresses a view that FDA may have underestimated the time burden of this rule if such activities were not included in the calculations.

(Response 142) Our estimates of the burden of the information collection in the 2021 agricultural water proposed rule and this final rule reflect only the requirements that we are finalizing here for pre-harvest agricultural water assessments for non-sprout covered produce. This includes the requirement in § 112.43(e) for farms to conduct a reassessment at least once annually, and whenever a significant change occurs in their agricultural water system 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. See the third column in table 6 below, in which we assume 1.1 agricultural water assessments per year in light of this requirement, consistent with our FRIA (Ref. 26). Comments did not provide information to suggest that revisions to this approach are necessary or appropriate. As such, we use the same approach to estimating the burden of information collection in this final rule as we did in the 2021 agricultural water proposed rule, with the only change being to update farm counts based on more recent data sources used in the FRIA compared to that used in the PRIA. For discussion related to the estimated time to conduct recordkeeping specifically, see comment 143.

(Comment 143) A few comments suggest that the estimates in the proposed rule for time to conduct recordkeeping for pre-harvest agricultural water assessments, which ranged from 4-9 hours depending on farm size, is too low in light of challenges that some farms may face. For example, a few comments suggest that some farms may face challenges in conducting agricultural water assessments, such as the following: having multiple water sources; having long growing seasons; having water sources that span long distances; lacking historical knowledge of water systems and adjacent lands; lacking technical background; having limited personnel and/or financial resources; and not speaking or reading English.

(Response 143) We recognize that the time it takes farms to conduct recordkeeping for pre-harvest agricultural water assessments is likely to range for a variety of reasons, including those referenced in the comments. To account for a range in the amount of time recordkeeping for agricultural water assessments may take, in the FRIA (Ref. 26), we provide low, most likely, and high estimates based on farm size (see tables 31-33 in that document). To estimate the burden of information collection associated with the requirements for pre-harvest agricultural

water assessments, we use the “most likely” values in the FRIA for each farm size. We are not aware of, and comments did not provide, data or information suggesting estimates that are more applicable across the diversity that exists in industry in agricultural water systems, operations, and conditions. As such, we use the same estimates for the time to conduct pre-harvest agricultural water assessments when estimating the burden of information collection in this final rule as we did in the 2021 agricultural water proposed rule, consistent with estimates in the PRIA (Ref. [8688](#)) and FRIA (Ref. 26).

Burden Table: Upon consideration of these comments and in light of updated farm count data in the FRIA compared to the PRIA, we estimate the burden of the information collection as follows:

Table 6.--Cumulative Average Annual Burden, Covered Farms of All Sizes

21 CFR part 112, subpart E: Requirements that Apply Regarding Records	No. of Respondents	No. of Records per Respondent	Total Annual Records	Average Burden per Farm (in hours)	Total Hours
Agricultural Water Assessment and Records Maintenance--Very small covered farms (§ 112.50(b)(2))	9911	1.1	10902	4	43608
Agricultural Water Assessment and Records Maintenance--Small covered farms (proposed § 112.50(b)(2))	2057	1.1	2263	8	18102
Agricultural Water Assessment and Records Maintenance--All other (Large) Covered Farms (proposed § 112.50(b)(2))	5392	1.1	5931	9	53381
Cumulative totals for covered farms of all sizes	17360		19096	7	115091
Cumulative average 7 burden hours per covered farm annually					

Farms using pre-harvest agricultural water for non-sprout covered produce are required to prepare and maintain records of their agricultural water assessments unless exempt under § 112.43(b). We estimate that a total of 17,360 farms (9,911 very small farms, 2,057 small farms,

and 5,392 other (large) farms) will be subject to information collection requirements under this rule, consistent with figures in our FRIA (Ref. 26) for this final rule and informed by a 2018 USDA survey of farms' irrigation practices (Ref. 8789). The change in these numbers compared to estimates provided in the 2021 agricultural water proposed rule are a result of updates to farm counts between the PRIA for the 2021 agricultural water proposed rule (Ref. 8688) and the FRIA for this final rule (Ref. 26). The PRIA relied on farm counts from the FRIA for the 2015 produce safety final rule (based on 2012 National Agricultural Statistics Service (NASS) Census of Agriculture data), whereas the FRIA relies on 2017 NASS Census of Agriculture data (the most recent available).

We assume affected farms will conduct approximately 1.1 assessments annually, in accordance with the requirement to conduct assessments annually and whenever a significant change occurs that increases the likelihood that a known or reasonably foreseeable hazard will be introduced into or onto covered produce or food contact surfaces (Ref. 26). We are assuming a range of burden: 4 hours of burden for very small farms, 8 hours of burden for small farms, and 9 hours for other (large) farms, based on estimates of the amount of time in hours to conduct recordkeeping for pre-harvest agricultural water assessments (Ref. 26). These numbers are consistent with that used in the 2021 agricultural water proposed rule as well as the PRIA (Ref. 8688) and the FRIA for this final rule (Ref. 26).

The information collection provisions in this final rule have been submitted to OMB for review as required by section 3507(d) of the Paperwork Reduction Act of 1995.

Before the effective date of this final rule, FDA will publish a notice in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is

not required to respond to, a collection of information unless it displays a currently valid OMB control number.

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X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we conclude that the rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement is not required.

XI. Consultation and Coordination with Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at <https://www.regulations.gov>. References without asterisks are not on public display at <https://www.regulations.gov> because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the

Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

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*15. Truitt, L. N., K. M. Vazquez, R. C. Pfuntner, et al., “Microbial Quality of Agricultural Water Used in Produce Preharvest Production on the Eastern Shore of Virginia.” *Journal of Food Protection* 80, no. 10 (2018): 1661-1672.

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List of Subjects in 21 CFR Part 112

Administrative practice and procedure, Agriculture, Animals, Food grades and standards, Foods, Fruits, Packaging and containers, Reporting and recordkeeping requirements, Safety, Vegetables, Waste treatment and disposal.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 112 is amended as follows:

PART 112--STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

1. The authority citation for part 112 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 350h, 371; 42 U.S.C. 243, 264, 271.

2. Amend § 112.3 by adding in alphabetical order the definitions for “Agricultural water assessment” and “Agricultural water system” to read as follows:

§ 112.3 What definitions apply to this part?

* * * * *

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.

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.

* * * * *

3. In § 112.12, revise paragraph (a) to read as follows:

§ 112.12 Are there any alternatives to the requirements established in this part?

(a) You may establish alternatives to certain specific requirements of subpart E of this part, as specified in § 112.45(b), provided that you satisfy the requirements of paragraphs (b) and (c) of this section.

* * * * *

4. Revise subpart E to read as follows:

Subpart E--Agricultural Water

Sec.

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

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

112.42 What requirements apply to inspecting and maintaining my agricultural water systems?

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

112.44 What requirements apply to agricultural water used as sprout irrigation water and in harvesting, packing, and holding covered produce?

112.45 What measures must I take for agricultural water to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards?

112.46 What requirements apply to treating agricultural water?

112.47 Who must perform the tests required under this subpart?

112.48 - 112.49 [Reserved]

112.50 Under this subpart, what requirements apply regarding records?

Subpart E--Agricultural Water

§ 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)	§ 112.45	(measures)
	§ 112.42	(inspections and maintenance)	§ 112.46	(treatment)
	§ 112.43	(agricultural water assessment)	§ 112.47	(who may test)
	§ 112.50	(records)	§ 112.151	(test methods)
(b) Sprout irrigation water	§ 112.41	(quality standard)	§ 112.44(b)	(testing untreated ground water)
	§ 112.42	(inspections and maintenance)	§ 112.45	(measures)
	§ 112.44(a)	(microbial quality criterion)	§ 112.46	(treatment)
	§ 112.50	(records)	§ 112.47	(who may test)
			§ 112.151	(test methods)
(c) Harvesting, packing, or holding covered produce	§ 112.41	(quality standard)	§ 112.44(b)	(testing untreated ground water)
	§ 112.42	(inspections and maintenance)	§ 112.45	(measures)

	§ 112.44(a)	(microbial quality criterion)	§ 112.46	(treatment)
	§ 112.44(d)	(additional management and monitoring)	§ 112.47	(who may test)
	§ 112.50	(records)	§ 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 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, 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:

(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 systems, to the extent they are under your control, as necessary and appropriate to prevent the systems from being a source of contamination to covered produce, food contact surfaces, or areas used for a covered activity. 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 casings, 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).

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

(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 produce (other than sprouts) or food contact surfaces, based on an 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 by stirring sediments) or covered produce (such as damage to edible leaves) during growing 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), or (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 paragraph (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 paragraph (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 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 the 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) Used during or after harvest activities in a manner that directly contacts covered produce (for example, water that is applied to covered produce for washing or cooling activities, 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);

(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) *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) 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) 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 for agricultural water to reduce the potential for contamination of covered produce or food contact surfaces with known or reasonably foreseeable hazards?

(a) *Discontinue 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(s) 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), you

must immediately discontinue such use(s). 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 § 112.46.

(b) *Implement mitigation measures.* (1) 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 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.

§ 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.

§ 112.47 Who must perform the tests required under this subpart?

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

(1) Results from agricultural water 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 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 methods as set forth in § 112.151, as applicable.

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

(2) 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 use of an index organism, indicator organism, or other analyte, other than testing for generic *E. coli* for purposes of § 112.43(c)(4)(ii);

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

(8) Scientific data or information you rely on to support 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) 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).

5. In § 112.151, revise the section heading and paragraph (b)(2) to read as follows:

§ 112.151 What methods must I use to test the quality of water to satisfy the requirements of subpart E of this part?

* * * * *

(b) * * *

(2) For any other indicator of fecal contamination, index organism, or other analyte you may test for pursuant to § 112.43(d), a scientifically valid method.

6. In § 112.161, revise paragraph (b) to read as follows:

§ 112.161 What general requirements apply to records required under this part?

* * * * *

(b) Records required under §§ 112.7(b); 112.30(b); 112.50(b)(2), (5), (7), and (11); 112.60(b)(2); 112.140(b)(1) and (2); and 112.150(b)(1), (4), and (6) must be reviewed, dated, and signed, within a reasonable time after the records are made, by a supervisor or responsible party.

Dated: _____.
