



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, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend the agricultural water provisions of the produce safety regulation that covered farms have found complex and challenging to implement. This proposal would replace the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) with provisions for systems-based agricultural water assessments that are designed to be more feasible to implement across the wide variety of agricultural water systems, uses, and practices, while also being adaptable to future advancements in agricultural water quality science and achieving improved public health protections. Additionally, we are proposing to require expedited mitigation for hazards related to certain activities associated with adjacent and nearby lands, in light of findings from several recent produce outbreak investigations. These proposed revisions to the produce safety regulation, if finalized, would more comprehensively address a known route of microbial contamination that can lead to preventable foodborne illness that is a significant public health problem.

DATES: Submit either electronic or written comments on the proposed rule by [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by

[INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] (see the “Paperwork Reduction Act of 1995” section of this document).

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time on [INSERT DATE 120 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions.”)

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand Delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2021-N-0471 for “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at Dockets Management Staff between 9 a.m. and 4 p.m. Eastern Time, Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more

information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, 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.

Submit comments on information collection issues under the Paperwork Reduction Act of 1995 to the Office of Management and Budget (OMB) at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The title of this proposed collection is "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water."

FOR FURTHER INFORMATION CONTACT:

*Regarding the proposed rule:* Samir Assar, Director, Division of Produce Safety, Office of Food Safety, Center for Food Safety and Applied Nutrition (HFS-317) 5001 Campus Dr., College Park, MD 20740, 240-402-1636, email: [samir.assar@hhs.fda.gov](mailto:samir.assar@hhs.fda.gov).

*Regarding the information collection:* Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

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I. Executive Summary

*A. Purpose and Coverage of the Proposed Rule*

FDA is proposing to amend the “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption” rule (80 FR 74354, November 27, 2015) (2015 produce safety final rule), which implemented section 105 of the FDA Food Safety Modernization Act (FSMA) (Pub. L. 111-353) and established science-based minimum standards for the safe production and harvesting of fruits and vegetables for human consumption (codified at part 112 (21 CFR part 112)). This proposed rule would revise certain provisions in the produce safety regulation applicable to agricultural water for produce subject to the requirements of part 112 (covered produce) other than sprouts, using a direct application method during growing activities (commonly referred to as “pre-harvest agricultural water”).<sup>1</sup> The proposed revisions are intended to address stakeholder concerns about complexity and practical implementation challenges (described more fully in section III.C.) by replacing certain pre-harvest agricultural water testing requirements with provisions for comprehensive pre-harvest agricultural water assessments that would help farms identify potential sources of contamination

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<sup>1</sup> The produce safety regulation refers to pre-harvest agricultural water used during sprout production as “sprout irrigation water.”

and effectively manage their water. The proposed agricultural water assessments would offer flexibility for farms subject to the requirements of 21 CFR part 112 (covered farms) to evaluate a broad range of factors that impact pre-harvest agricultural water quality, using a systems-based approach that would be feasible to implement across the wide variety of agricultural water systems, practices, and uses and would be adaptable to future advancements in agricultural water quality science. The proposed expedited mitigation requirements are designed to help address recent outbreak investigation findings relating to the impacts of certain adjacent and nearby land uses on pre-harvest agricultural water for (covered produce) other than sprouts.

In light of the identified implementation challenges with the current pre-harvest agricultural water testing requirements, the proposed rule, if finalized, would enhance public health protections by setting forth procedures for comprehensive pre-harvest agricultural water assessments 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.

#### *B. Summary of Major Provisions of the Proposed Rule*

FDA is proposing to amend the produce safety regulation 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 proposing to:

- Replace the microbial quality criteria and testing requirements §§ 112.44(b) and 112.46(b) with new provisions for conducting pre-harvest agricultural water assessments (proposed § 112.43) 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 risk management decision making;

- Include a testing option for certain covered farms that elect to test their pre-harvest agricultural water for generic *Escherichia coli* (*E. coli*) (or other appropriate indicator organism, index organism, or analyte) to help inform their agricultural water assessments;
- Add new options for mitigation measures in § 112.45(b), providing covered farms additional flexibility in responding to findings from their pre-harvest agricultural water assessments;
- Expedite implementation of mitigation measures under § 112.45(b) for known or reasonably foreseeable hazards related to certain adjacent and nearby land uses;
- Require management review under § 112.161 of pre-harvest agricultural water assessments; and
- Add new definitions of “agricultural water assessment” and “agricultural water system” to § 112.3 (subpart A) and make conforming changes in § 112.12 (subpart B), § 112.151 (subpart N), and § 112.161 (subpart O).

We solicit comments on these proposed amendments, which are described more fully in section VI.C. through H. We are proposing additional amendments, such as adding examples and reorganizing some provisions, which are described in section VI.I.

### *C. Legal Authority*

FDA is proposing to amend certain requirements in the produce safety regulation 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. These changes are consistent with our authority 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 proposed rule, if finalized. Our primary estimates of annualized costs are approximately \$11.3 million at a 3 percent discount rate and approximately \$11.2 million at a 7 percent discount rate over 10 years.

We estimate benefits of this proposed rule, if finalized. Our primary estimates of annualized benefits are approximately \$9.9 million at a 3 percent discount rate and approximately \$9.6 million at a 7 percent discount rate over 10 years. If finalized, the qualitative benefits of the rule would stem from increased flexibility for covered farms to comprehensively evaluate their pre-harvest agricultural water systems for non-sprout covered produce. These changes are being proposed, in part, to address practical implementation challenges of the current pre-harvest agricultural water testing requirements.

#### II. Table of Abbreviations and Acronyms Commonly Used in This Document

Table 1.--Table of Abbreviations and Acronyms

Abbreviation or Acronym	What it Means
AMS	Agricultural Marketing Service
BSAAO	Biological Soil Amendment of Animal Origin
CAFO	Concentrated Animal Feeding Operation
CDC	Centers for Disease Control and Prevention
CFU	Colony-Forming Units
Codex	Codex Alimentarius Commission
EA	Environmental Assessment
<i>E. coli</i>	<i>Escherichia coli</i>
EPA	Environmental Protection Agency
E.O.	Executive Order
FD&C Act	Federal Food, Drug, and Cosmetic Act
FSMA	FDA Food Safety Modernization Act
GAP	Good Agricultural Practices
GM	Geometric Mean
IFSAC	Interagency Food Safety Analytics Collaboration
LGMA	Leafy Greens Marketing Agreement
mL	Milliliters
MWQP	Microbial Water Quality Profile
PRIA	Preliminary Economic Analysis of Impacts
NPRM	Notice of Proposed Rulemaking
QAR	Qualitative Assessment of Risk

RV	Recreational Vehicle
RWQC	Recreational Water Quality Criteria
SDWA	Safe Drinking Water Act
STEC	Shiga toxin-producing <i>E. coli</i>
STV	Statistical Threshold Value
USDA	U.S. Department of Agriculture
UV	Ultraviolet
WGS	Whole genome sequencing
WHO	World Health Organization

### III. Background

#### *A. FDA Food Safety Modernization Act*

The 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 seven 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 is one of the seven foundational rules.

#### *B. Produce Safety Regulation*

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. In accordance with section 419 of the FD&C Act, the produce safety regulation 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.

The regulation established requirements for “covered produce,” defined in § 112.3 as produce that is subject to the requirements of this part in accordance with §§ 112.1 and 112.2. It includes a produce RAC that is grown domestically and a produce RAC that will be imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico (§ 112.1). Covered produce refers to the harvestable or harvested portion of the crop. (§ 112.3). Farms subject to the requirements are described in § 112.4.

Subpart E of the produce safety regulation includes a general requirement that agricultural water must be safe and adequate for its intended uses (§ 112.41). It also includes microbial water quality criteria (§ 112.44) and requirements for testing certain water sources (§ 112.46). The microbial quality criteria are 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), and for certain other specified uses, including sprout irrigation water and water applications that directly contact covered produce during or after harvest.<sup>2</sup>

Covered farms must establish a microbial water quality profile (§ 112.46(b)) for certain pre-harvest agricultural water for non-sprout covered produce, by calculating two numerical

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<sup>2</sup> Because sprouts present a unique safety risk, the produce safety regulation establishes sprout-specific requirements on multiple topics, including agricultural water. Sprouts are not subject to the Subpart E compliance date extension that applies to other covered produce.

values of generic *E. coli* in their water samples: a geometric mean (GM) (a measure of central tendency of a water quality distribution) and a statistical threshold value (STV) (a measure of variability of a water quality distribution, derived as a model-based calculation approximating the 90th percentile using the lognormal distribution). The GM and STV values are initially derived based on an initial survey data set that consists of a minimum total of 20 samples for untreated surface water sources (taken over at least 2 years and no more than 4 years) and 4 samples for untreated ground water sources (taken during the growing season or over a period of 1 year).

Following the initial survey, covered farms revise the GM and STV values based on annual survey data, which consists of at least 5 new samples per year for untreated surface water sources and at least one new sample per year for untreated ground water sources. The new samples are then combined with the most recent data from within the previous 4 years, to make up a rolling dataset of 20 samples for untreated surface water and 4 samples for untreated ground water. The GM and STV values are recalculated using this updated data set to update the microbial water quality profile for certain pre-harvest agricultural water for covered produce, other than sprouts (§ 112.46(b)). When testing untreated surface water or untreated ground water sources used during growing activities using a direct water application method, the initial and annual survey samples must be representative of covered farms' use of the water and must be collected as close in time as practicable to, but prior to, harvest.

In the produce safety final rule, FDA committed to implementing the final rule through a broad, collaborative effort to foster awareness and compliance with guidance, education, and technical assistance, coupled with accountability for compliance (80 FR 74354 at 74519). This proposal continues that commitment.

Table 2 lists the key FSMA produce safety regulation documents published in the *Federal Register*. The complete set of *Federal Register* documents associated with the FSMA

produce safety regulation, including supporting materials, are available in the docket folder at <https://www.regulations.gov/docket?D=FDA-2011-N-0921>.

Table 2.--List of Key Federal Register Produce Safety Regulation 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 (supplemental notice)	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	82 FR 42963, September 13, 2017
Extension of Compliance Dates for Subpart E; Final rule (subpart E compliance date extension or compliance date extension)	84 FR 9706, March 18, 2019

### *C. Stakeholder Concerns Regarding Certain Pre-Harvest Agricultural Water Requirements*

In November 2015, FDA began to conduct outreach to educate stakeholders about the new requirements of the produce safety rule and share the Agency’s implementation plans, in keeping with our commitment to a broad, collaborative effort to foster awareness about, and compliance with, the rule.

Upon release of the produce safety final rule in November 2015, FDA conducted a webinar with nearly 400 participants, in which FDA subject matter experts discussed the significant provisions of the rule and answered questions. Beginning in December 2015, subject matter experts discussed the produce safety regulation at a series of public meetings held in the United States and abroad. This included four regional meetings in Oregon (December 1, 2015); Vermont (December 15, 2015); Florida (January 27, 2016); and North Carolina (February 4, 2016), that were attended by growers and other interested stakeholders and sponsored by State regulatory partners. Also in December 2015, FDA officials and subject matter experts discussed the requirements of the produce safety rule and other foundational FSMA rules at a public meeting convened by the European Commission. Later that month, FDA subject matter experts

briefed U.S.-based embassy personnel on the contents of the FSMA rules, including the produce safety rule.

In 2016 and 2017, FDA continued outreach and education efforts to inform stakeholders, including industry, consumers, academia, and regulatory partners, about the produce safety rule requirements and FDA's implementation plans through 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 the range of growing conditions and practices across the United States (e.g., Alaska, Arizona, California, Colorado, Georgia, Maine, Maryland, Nevada, New Mexico, Oregon, Texas, Vermont, Washington, and Wisconsin). Through these farm visits, together with speaking engagements, conferences, coalition meetings, and questions about the rule submitted to the FSMA Technical Assistance Network, FDA gained an understanding that numerous industry stakeholders found certain provisions of subpart E to be difficult to understand, translate, and implement in their operations— in particular, the pre-harvest microbial quality criteria and testing requirements that required farms to establish a Microbial Water Quality Profile (MWQP) for each water source used for non-sprout covered produce. For example, FDA repeatedly heard from covered farms and produce industry associations that the pre-harvest agricultural water microbial quality criteria (§ 112.44(b)) and testing requirements (§ 112.46(b)) are too complicated to understand, and that questions remain about how to implement them in a practical manner. We also heard consistent feedback from covered farms and produce industry associations that these requirements do not sufficiently allow for a variety of water uses and availabilities.

Specifically, this feedback centered on the following issues:

- A number of these stakeholders stated that they have large numbers of water sources--in some cases, dozens of surface water sources, or upwards of one hundred ground water sources--for which they would have to establish individual MWQPs under the final rule.

- These stakeholders indicated that they find the alternatives in the final rule for the use of a different microbial water quality criterion (or criteria) and/or testing frequency for untreated surface water sources to be unworkable.
- While data sharing is one way that implementation challenges associated with sampling could be reduced, some stakeholders noted that it may be difficult to implement due to the requirements that water samples be representative of the particular use of the water and collected as close in time as practicable, but prior to, harvest.
- Some stakeholders noted implementation challenges with establishing long-term MWQPs for farms that grow rotational crops or on leased land, as they may not be using (or have access to) the same water source over multiple years.

Based on stakeholder feedback received as of March 2017, FDA publicly 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. 1).

As FDA subject matter experts continued stakeholder engagement activities, they gained additional feedback that was consistent with earlier messages that the pre-harvest requirements in subpart E were complex and challenging to implement, as they were:

- Inflexible, by imposing a “one-size-fits-all” approach that is difficult to implement across the wide variety of sources, uses, and practices covered by the rule;
- Too complicated to understand and implement, such as the calculation of the GM and STV; and
- Difficult to implement because covered farms with multiple pre-harvest agricultural water sources are required to establish individual microbial quality profiles for each agricultural water source.

After receiving consistent feedback from numerous stakeholders expressing concern about complexity and challenges with implementation of certain agricultural water requirements,

in the *Federal Register* of September 13, 2017 (82 FR 42963), FDA proposed to extend the compliance dates for subpart E for covered produce other than sprouts. FDA took that action based on feedback we received from numerous stakeholders raising issues regarding the practicality of some of these provisions (in particular the testing requirements for pre-harvest agricultural water). The additional time allotted by extending the Subpart E compliance dates for covered produce other than sprouts was intended to allow consideration of approaches to address these issues, as well as to identify opportunities to enhance the flexibility of these requirements beyond those reflected in the final rule.

As part of the continuing stakeholder engagement on agricultural water, in October 2017, FDA participated in a collaborative forum, sponsored by The Pew Charitable Trusts and the Robert Wood Johnson Foundation, where participants discussed ideas for how to amend the agricultural water requirements within the rule's current framework to address near-term challenges, 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. At the invitation of the sponsor, farms, academia, food industry trade associations, consumer groups, and other State and Federal partners also attended.

Forum participants identified several possible alternatives for pre-harvest agricultural water, including: (1) retaining the microbial water quality criteria and testing requirements for agricultural water used during growing activities and issuing companion guidance to recommend alternative approaches that would satisfy the regulation; (2) replacing the existing quantitative requirements with a qualitative standard and issuing companion guidance to recommend alternative approaches that would satisfy the regulation; (3) adopting private industry standards in guidance as a short term measure while research continues on analyte(s) and appropriate numerical thresholds; and (4) performing a multiyear quantitative microbial risk assessment to identify index and/or indicator organisms that can be used to characterize risk associated with



agricultural water across a variety of conditions. Forum participants identified advantages and disadvantages of each proposed approach and also identified other areas for further consideration by FDA, including qualitative standards, data sharing, and the need for additional guidance (Ref. 2).

Implementation challenges with the agricultural water requirements in subpart E were also the focus of a 2-day Agricultural Water Summit, convened by the Produce Safety Alliance in February 2018, to discuss implementation challenges and explore possible approaches that would be practical to implement while protecting public health (Ref. 3). FDA subject matter experts joined more than 350 other participants at the summit, including farmers and other produce industry members, researchers, extension educators, and State and Federal regulators. Additionally, approximately 200 people from eight different countries viewed the summit proceedings via webcast and had the opportunity to provide comments. The meeting was open to registration by the general public.

The summit included presentations and discussions on addressing food safety hazards in the growing environment. Participants discussed the complexities associated with farm environments. For example, participants noted that difficulties can arise due to variability in the following factors: (1) agricultural water source quality, including how it arrives and moves throughout the farm; (2) the methods of water application to the crop; (3) commodity characteristics that influence vulnerability to contamination; and (4) regional climatic effects. Participants identified “agricultural water assessments” as a promising approach for science-based management decisions that could take those factors into account. Participants also recognized that farmers would need additional educational tools to conduct this type of assessment (Ref. 3).

FDA produce safety experts continued farm visits into 2018 to gather additional feedback and perspectives from stakeholders, in addition to the information and insights from the Agricultural Water Summit and the Collaborative Forum. Joined on these visits by

representatives from the produce industry, academia, and government agencies, FDA visited nearly 100 farms in 2018, during which we observed a wide variety of water sources, distribution systems, and practices among farms of all sizes. As part of the farm visits, FDA often participated in listening sessions with farmers to learn about their water use practices, how they currently manage water quality, and their perspectives on how best to achieve public health protections related to agricultural water in a way that would be practicable and workable across a variety of operations (Ref. 4).

Throughout the produce safety rule outreach and education efforts, FDA also continued to engage with a broad range of stakeholders, including consumer protection groups, through coalition meetings, while also collaborating with State regulatory partners to prepare for produce safety rule implementation. FDA heard frequent and consistent concerns from covered farms and produce industry trade associations about the complexity and implementation challenges of certain subpart E requirements, which was reinforced in their comment submissions. In the face of widespread and steady concerns, including new concerns that were not expressed in response to the produce safety proposed rule, FDA concluded that it was in the public's interest to institute a delay to allow for further collaboration with an array of stakeholders and pursuit of solutions to achieve the shared goal of improved produce safety in a way that is more workable for covered farms.

Accordingly, in the *Federal Register* of March 18, 2019 (84 FR 9706), FDA extended the compliance dates for subpart E for non-sprout covered produce, as follows: January 26, 2024, for very small farms; January 26, 2023, for small farms; and January 26, 2022, for all other farms covered by the produce safety regulation. FDA noted that ignoring the widespread concerns raised about complexity and serious questions about how the requirements can be implemented in practical ways on farms would be likely to reduce the estimated public health benefits of the agricultural water provision of the 2015 final rule (84 FR 9706 at 9710). We recognized that farms that cannot understand the requirements and determine how to implement the requirements

are not likely to be realizing full food safety measures, which led us to conclude that further collaboration with stakeholders was necessary to understand the source of the complexity and develop a more workable solution for pre-harvest agricultural water that would increase produce safety.

In the compliance date extension final rule (84 FR 9706 at 9710), we also reiterated our commitment to ensuring that the produce safety rule addresses the risks associated with agricultural water and emphasized that produce remains subject to the other applicable provisions of the produce safety regulation and the FD&C Act notwithstanding the extension. We recommended that farms should continue to use good agricultural practices to help maintain and protect the quality of their water sources.

Stakeholders (including covered farms, consumer protection groups, and state governments) submitted various comments addressing the underlying subpart E requirements applicable to non-sprout covered produce in response to the compliance date extension proposed rule. FDA responded to comments on in the compliance date extension final rule (84 FR 9706). While substantive issues were outside the narrow scope of the compliance date extension rulemaking, we considered those comments in developing this proposed rule. Stakeholders also submitted comments on the underlying subpart E requirements to Docket No. FDA-2017-N-5094, “Review of Existing Center for Food Safety and Applied Nutrition Regulatory and Information Collection Requirements” (82 FR 42503 (September 8, 2017)). Although this docket was established as part of the implementation of two Executive Orders (E.O.) that have since been revoked (see E.O. 13992 (“Revocation of Certain Executive Orders Concerning Federal Regulation”)), we consider the comments submitted to this docket on the underlying requirements of subpart E (Refs. 5-10) as relevant to the purposes of this rulemaking.

Some comments indicate that stakeholder concerns on the agricultural water requirements were already addressed during rulemaking for the produce safety rule and argue that further action to consider stakeholder concerns is therefore unnecessary. These comments note that

stakeholders were given the opportunity to provide comment on pre-harvest agricultural water testing requirements when the notice of proposed rulemaking (NPRM) issued in 2013, and again when the supplemental NPRM issued in 2014. However, the feedback we received after the 2015 produce safety final rule was published about the complexity and the implementation challenges posed by the pre-harvest testing requirements was new and in addition to the comments on the proposed rule (84 FR 9706 at 9710). Some comments encouraged FDA to withdraw the proposed compliance date extension and focus on implementation, noting the public health benefits of the produce safety regulation and concluding that an extension would harm consumers more than it would help. As previously indicated, FDA decided to pursue a rigorous stakeholder engagement plan to consider the practical implementation of the agricultural water requirements and how to best achieve the important public health objectives of the rule.

Other comments indicate that certain agricultural water requirements in the 2015 produce safety final rule are too complex, overly prescriptive, and not practical to implement, urging FDA to reconsider the “one-size-fits-all” approach of the produce safety regulations that they state is not risk-based or adaptable based on future research. Some comments suggest that the pre-harvest agricultural water testing requirements in subpart E should be reduced to one annual test per source to be consistent with industry practice and some State requirements. Some comments cite concerns related to allowable testing methods, use of historical data and data sharing, the applicability of recreational water quality criteria to pre-harvest agricultural water, and considerations about crop rotations and short growing seasons. Some comments point out that certain areas where produce is grown lack nearby laboratories capable of testing water samples. Other comments assert that the produce safety regulation requires covered farms to hire a consultant or third party to test their water. Still other comments cite concerns about how the standards relate to foreign farms, in particular for covered farms located in foreign countries with a systems recognition arrangement with FDA.

Various comments indicate that a more flexible approach that incorporates region-, commodity-, and practice-specific information would be useful in addressing the diversity of agricultural water sources. These comments recommend taking into account practices and lessons learned under third-party auditing standards. Other comments assert that FDA should recognize the risk-based approaches that different commodity groups and different industry sectors are already using. Some comments suggest that FDA perform a multiyear quantitative microbial risk assessment for agricultural water to better understand the associated risks, while other comments propose building additional flexibility into the testing requirements to allow for future scientific advancements, such as the use of metagenomics. Still others cite a need for ongoing education, training, outreach, and guidance on a variety of agricultural water-related issues and recommend that FDA involve a variety of stakeholders, including the States, in any outreach and guidance efforts. We considered these comments in developing this proposed rule.

#### *D. Recent Outbreaks*

For more than a decade, FDA has conducted investigations of produce outbreaks to learn what factors may have contributed to the outbreaks of foodborne illness or food contamination events. These investigations (also known as environmental assessments, or EAs) are performed in collaboration with regulatory partners following initial outbreak response activities and focus on identifying possible causes, contributing factors, and measures to prevent reoccurrence of a similar event. We assess potential sources of microbial hazards not only in growing fields identified through traceback investigation of contaminated product but also potential sources in the larger growing area within the geographic area of interest. This commonly includes assessment of water sources and distribution systems used by growers during growing, harvesting, or post-harvesting activities. These investigations allow us to consider how a pathogen may be transported from a source in the surrounding area to the field and ultimately the product. FDA's investigations underscore decades of scientific research that pre-harvest agricultural water is a potential contributing factor in the introduction and spread of

contamination to produce. See, e.g., the QAR (Ref. 11), 2013 proposed rule 78 FR 3504 at 3559-3563, 2015 final rule 80 FR at 74354 at 74441-74446, and the discussion in section III.E. The proposed rule reflects new information and findings on the potential routes of microbial contamination of pre-harvest agricultural water from investigations of several recent outbreaks linked to consumption of produce.

#### 1. Spring 2018 *E. coli* O157:H7 Outbreak Linked to Romaine Lettuce From the Yuma Growing Region

In collaboration with the Centers for Disease Control and Prevention (CDC) and State partners, FDA led an EA of the Yuma growing region associated with the spring 2018 *E. coli* O157:H7 outbreak linked to consumption of romaine lettuce. Investigators found the outbreak strain in water samples from three locations along a 3.5-mile stretch of an open irrigation canal adjacent to a Concentrated Animal Feeding Operation (CAFO) (Ref. 12). One of these samples was collected immediately downstream from where shallow ground water is pumped into the irrigation canal (Ref. 13). The EA investigators also found an area where ground water may have been seeping directly into unlined sections of the canal within the 3.5-mile stretch where the outbreak strain was detected. Although no obvious route of contamination was determined, the investigators identified onsite wells at the CAFO as a potential route of ground water contamination from the CAFO (Ref. 13).

The EA team also found *Salmonella* spp. and other Shiga toxin-producing *E. coli* (STEC) strains in water samples collected during the investigation of the Yuma growing region, including *Salmonella* Agona, *S. Typhimurium*, and *E. coli* O178:H19, O6:H34, O181:H49, O153:H25, and O157:H7 (which did not match the outbreak strain) (Ref. 13).

The findings of the Yuma EA led FDA to issue a letter to State partners and the leafy greens industry that highlighted, in part, the importance of assessing and mitigating risks related to land uses near or adjacent to growing fields that may contaminate agricultural water or leafy

greens crops directly (such as nearby cattle operations, dairy farms, manure, and composting facilities) (Ref. 14).

## 2. Fall 2018 *E. coli* O157:H7 Outbreak Linked to Romaine Lettuce From California

Following a romaine lettuce outbreak in Fall 2018, FDA led an EA, in collaboration with CDC and the States, that found the outbreak strain in the sediment of an on-farm water reservoir in Santa Barbara County, CA (Ref. 15). We concluded that the water from the on-farm water reservoir where the outbreak strain was found most likely led to contamination of some romaine lettuce consumed during this outbreak. Investigators noted extensive wild animal activity in the area; adjacent land use, including the use of soil amendments; and animal grazing on nearby land by cattle and horses. They were unable to determine, though, how the outbreak strain of *E. coli* O157:H7 was introduced into this on-farm water reservoir.

## 3. Fall 2019 *E. coli* O157:H7 Outbreaks Linked to Romaine Lettuce

From late 2019 to early 2020, FDA and state and federal partners conducted multiple on-farm investigations of contamination of romaine lettuce with several strains of *E. coli* O157:H7 that resulted in three outbreaks of foodborne illness beginning in September and ending in December 2019 (Ref. 16). These outbreaks, which were all traced back to farms located in the Salinas, CA, growing region, collectively resulted in 188 people falling ill. As a result of sampling during the investigations, one of the outbreak strains of *E. coli* O157:H7 was detected in a fecal-soil composite sample taken from a cattle grate on public land less than 2 miles upslope from a farm with multiple fields tied to the outbreaks by traceback investigations. Other STEC strains, while not linked to the 2019 outbreaks, were found in closer proximity to where romaine lettuce crops were grown, including two samples from a border area of a farm immediately next to cattle grazing land in the hills above leafy greens fields and two samples from on-farm water drainage basins. Of note, the number of cattle we observed on nearby lands

during the 2019 investigations was far lower than the volume of what is considered a large concentrated animal feeding operation.

#### 4. Fall 2020 *E. coli* O157:H7 Outbreak Linked to Leafy Greens

From August to December 2020, FDA and multiple state and federal partners investigated a multi-state *E. coli* O157:H7 outbreak associated with the consumption of leafy greens (Ref. 17). The outbreak, which caused 40 reported illnesses in the U.S., was linked via genetic sequencing and geography to the 2019 outbreak (Ref. 16) and the 2018 leafy greens outbreak (in which the outbreak strain was detected in the sediment of an on-farm water reservoir) (Ref. 15). The investigation identified the outbreak strain in a cattle feces composite sample taken alongside a road approximately 1.3 miles upslope from a produce farm with multiple fields tied to the outbreaks by the traceback investigations. Three water samples tested positive for other STEC strains not linked to the outbreak (Ref. 17).

#### 5. Summer 2020 *Salmonella* Newport Outbreak Linked to Red Onions

From June to October 2020, federal and state agencies investigated a *Salmonella* Newport foodborne illness outbreak associated with consumption of red onions from the Southern San Joaquin Valley and Imperial Valley in California (Ref. 18). The outbreak, which caused 1,127 reported domestic illnesses and 515 reported Canadian cases, was the largest *Salmonella* outbreak in over a decade. The FDA, alongside state and federal partners, investigated the outbreak to identify potential contributing factors that may have led to red onion contamination with *Salmonella* Newport. While the outbreak strain (specific whole genome sequence (WGS)) was not identified in any of the nearly 2,000 subsamples tested, a total of 11 subsamples (10 water and 1 sediment) collected near one of the growing fields identified in the traceback were positive for *Salmonella* Newport, representing a total of three different genotypical strains (unique WGS patterns). Although a conclusive root cause could not be identified, several potential contributing factors to the 2020 red onion outbreak were identified,



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

While our investigation did not occur during any harvesting activities, visual observations of the implicated red onion growing fields suggested several plausible opportunities for contamination including irrigation water, sheep grazing on adjacent land, as well as signs of animal intrusion, such as scat and large flocks of birds which may spread contamination. Similarly, the investigation did not occur while packing activities were ongoing. However, visual observations and records review of packing house practices confirmed numerous opportunities for spread of foodborne pathogens such as *Salmonella*, including signs of animal and pest intrusion as well as food contact surfaces which had not been inspected, maintained, cleaned, or sanitized as frequently as necessary to protect against the contamination of produce.

While these outbreaks serve as recent examples of the role that water quality may play in produce safety, the potential for water to serve as a source or route of contamination in produce outbreaks has been a longstanding concern. For example, investigators identified several risk factors potentially related to a 2006 outbreak of *E. coli* O157:H7 associated with pre-packaged spinach, including the proximity of irrigation wells to surface water exposed to cattle and wildlife feces (Ref. 19). The outbreak strain was detected in river water, cattle feces, wild pig feces, and soil samples collected from one of the investigated farms. The outbreak strain also was detected in two surface water samples analyzed as part of a separate study (Ref. 20). (See also section VI.E.)

During investigation of a 2006 outbreak of *E. coli* O157:H7 associated with iceberg lettuce, the outbreak strain was detected in water samples collected close to a suspect growing field and from a nearby dairy (Ref. 20). Investigators found that the dairy wastewater blending and distribution system used by the farm had inadequate backflow protection and presented a possible route for conveyance of contaminated water to fields adjacent to the suspect lettuce growing fields, as described more fully in section VI.E. Investigators also found the outbreak

strain of *Salmonella* Saintpaul in agricultural water during investigation of a 2008 produce outbreak (Ref. 22).

Persistent pathogens in agricultural water may serve as a recurring source of contamination. For example, two multistate outbreaks linked to tomatoes in 2002 and 2005 were caused by the same strain of *Salmonella* Newport, which was also detected in ponds used to irrigate tomato growing fields. (Ref. 23). On at least one of the farms investigated, pond water was used to dilute pesticides sprayed on tomato plants. Investigators isolated the outbreak strain in irrigation ponds through sampling conducted 2 years apart, suggesting persistent contamination (Ref. 23).

FDA outbreak investigations 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. This NPRM is designed to address those concerns by proposing to require covered farms to conduct comprehensive pre-harvest agricultural water assessments and implement 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 provide reasonable assurances that the produce is not adulterated on account of those hazards.

#### *E. Recent Information on Relative Food Safety Risks of Produce*

FDA outlined the history of contamination associated with produce, predominantly during growing, harvesting, packing, and holding, during the rulemaking to establish the produce safety regulations in part 112. See. e.g., 78 FR 3504 at 3507, 80 FR 74354 at 74731. Recent estimates by the Interagency Food Safety Analytics Collaboration (IFSAC) indicate that many foodborne illnesses are attributed to contaminated produce. A tri-agency group created by the CDC, FDA, and the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service, IFSAC developed a method to estimate the sources of foodborne illness using outbreak

data for four priority pathogens: *Salmonella*, *E. coli* O157, *Listeria monocytogenes*, and *Campylobacter* (Ref. 24).

In its 2019 Report (Ref. 25), IFSAC estimated that produce commodities cause 65 percent of foodborne *E. coli* O157 illnesses and over 40 percent of foodborne *Salmonella* illnesses. IFSAC attributed approximately 56 percent of *E. coli* O157 illnesses to vegetable row crops (such as leafy greens) and approximately 9 percent to fruits and other types of produce. IFSAC concluded that *Salmonella* illnesses came from a broad variety of foods, including more than 13 percent from fruits and more than 12 percent from seeded vegetables (such as tomatoes and cucumbers) (Ref. 25).

IFSAC derived estimates for 2018, its most recent reporting year, based on outbreaks that occurred from 1998 through 2018, relying most heavily on the most recent 5 years of outbreak data (Ref. 25). The analysis included 1,459 foodborne disease outbreaks, for which each confirmed or suspected implicated food fell into a single food category. Foods were categorized using a scheme IFSAC created to classify foods into 17 categories that closely align with the U.S. food regulatory agencies' classification needs (Ref. 26).

More recently, FDA tentatively identified certain FDA-regulated foods (including certain produce commodities) for inclusion on a Food Traceability List (Ref. 27) for which additional traceability recordkeeping requirements will be required, in accordance with FSMA section 204(d)(2)(A).<sup>3</sup>

To determine which foods should be included on the Food Traceability List (Ref. 27), FDA developed a risk-ranking model for food tracing (“the Model”), based on the following factors that Congress identified in the statute:

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<sup>3</sup> In the *Federal Register* of September 23, 2020 (85 FR 59984), FDA published a proposed rule to establish additional traceability recordkeeping requirements for entities that manufacture, process, pack, or hold foods the Agency has designated as high risk in accordance with FSMA section 204(d)(2)(A).

- Known safety risks of a particular food, including the history and severity of foodborne illness outbreaks attributed to such food, taking into consideration foodborne illness data collected by the CDC;
- Likelihood that a particular food has a high potential risk for microbiological or chemical contamination or would support the growth of pathogenic microorganisms due to the nature of the food or the processes used to produce the food;
- Point in the manufacturing process of the food where contamination is most likely to occur;
- Likelihood of contamination and steps taken during the manufacturing process to reduce the possibility of contamination;
- Likelihood that consuming a particular food will result in a foodborne illness due to contamination of the food; and
- Likely or known severity, including health and economic impacts, of a foodborne illness attributed to a particular food.

The Model was designed to be flexible and to consider a wide range of contaminants in FDA-regulated human foods (Ref. 28). To identify commodities for the Food Traceability List, the commodities and associated commodity-hazard pairs produced by the Model were ranked. Commodities with associated commodity-hazard pairs with criteria scores in the moderate to strong range were considered for inclusion on the list.

Based on data in the Model, we tentatively identified foods for inclusion on the Food Traceability List (Ref. 27), which was announced in conjunction with issuance of the Food Traceability proposed rule (85 FR 59984, September 23, 2020). When the FDA issues a final rule, we will also publish the Food Traceability List.

The proposed Food Traceability List (Ref. 27) includes the following types of produce:

- Cucumbers (fresh), includes all varieties of cucumbers;
- Herbs (fresh), includes all types of herbs, such as parsley, cilantro, basil;

- Leafy greens (fresh), includes all types of leafy greens, such as lettuce, (e.g., iceberg, leaf and romaine lettuces), kale, chicory, watercress, chard, arugula, spinach, pak choi, sorrel, and endive;
- Melons (fresh), includes all types of melons, such as cantaloupe, honeydew, and watermelon;
- Peppers (fresh), includes all varieties of peppers;
- Sprouts (fresh), includes all varieties of sprouts;
- Tomatoes (fresh), includes all varieties of tomatoes; and
- Tropical tree fruits (fresh), includes all types of tropical tree fruit, such as mango, papaya, mamey, guava, lychee, jackfruit, and starfruit.

On-farm contamination of produce is well documented in the literature. The peer-reviewed “FDA Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce” (QAR) (Ref. 11) provides a scientific evaluation of the potential adverse health effects resulting from human exposure to microbiological hazards in produce, with a focus on public health risk associated with the on-farm contamination of produce. 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 Environmental Protection Agency (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, groundwater 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. 11) 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.

Based on the foregoing, we continue to conclude that there is an ample history of microbiological contamination of produce on farms to justify requirements for pre-harvest agricultural water in part 112 to help prevent contamination and illness.

#### IV. Legal Authority

We are issuing this proposed rule under FDA's authorities in sections 402, 419, and 701(a) of the FD&C Act. and sections 311, 361, and 368 of the PHS Act.

Section 419(a) of the FD&C Act (21 U.S.C. 350h(a)), 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) (21 U.S.C. 350h(a)(3)) 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 (21 U.S.C. 342(a)(3)) 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 (21 U.S.C. 371(a)) grants the authority to issue regulations for the efficient enforcement of the FD&C Act. This proposed 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 proposing to the produce safety regulation thus would 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 proposed 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 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 21 CFR 5.10(a)(4) for delegation from the Secretary to FDA.) The provisions in the proposed rule are necessary to prevent food from being contaminated with human pathogens such as *Salmonella*, *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. We expect that the proposed amendments to the produce safety regulation, if finalized, will help prevent the spread of communicable diseases associated with contaminated produce.

#### V. Need for Regulatory Action and Proposed Regulatory Approach

We are proposing to amend subpart E of the produce safety regulation based on stakeholder feedback, new information we have gathered since issuance of the 2015 final rule, and findings from FDA investigations of produce-related outbreaks.

As described in section III.C., numerous stakeholders have provided feedback to FDA about the complexity and challenges of implementing the pre-harvest microbial quality criteria and testing requirements in subpart E for pre-harvest agricultural water for covered produce other than sprouts. Stakeholders shared their input and concerns during FDA's outreach and education efforts on the 2015 produce safety final rule, at the 2018 Agricultural Water Summit, and at meetings convened by others. Stakeholders also expressed concerns about these pre-harvest agricultural water testing requirements in comments submitted to other dockets, including for the compliance date extension rulemaking (84 FR 9706). (See section III.C. of this document.) The feedback has been consistent in its message about the implementation challenges of the pre-harvest agricultural water testing requirements and has come from individual growers and industry organizations that encompass various growing regions, farm sizes, and commodities.

FDA investigations of recent produce-related outbreaks have highlighted the role of pre-harvest agricultural water as a potential contributing factor in the introduction and spread of contamination to produce. Section III.D. discusses new information and findings from several recent investigations of the potential routes of contamination of pre-harvest agricultural water associated with activities conducted on lands adjacent and nearby to farms identified during traceback investigations and the agricultural water systems used by those farms.



This proposed rule would amend the agricultural water provisions of the produce safety regulation to replace the microbial criteria and testing requirements for pre-harvest agricultural water for covered produce (other than sprouts) that covered farms have found to be complex and challenging to implement, with provisions for comprehensive assessments of pre-harvest agricultural water systems, practices, and on-farm conditions. The proposed agricultural water assessments would provide additional flexibility to covered farms, using a systems-based approach that would be feasible to implement across the wide variety of pre-harvest agricultural water systems, uses, and farm operations and would be adaptable as scientific understanding of agricultural water quality expands in the future. We also are proposing to require expedited mitigation for hazards related to certain activities associated with adjacent and nearby lands in light of findings from several recent produce outbreak investigations. These proposed revisions to the produce safety regulation, if finalized, would set forth requirements for comprehensive pre-harvest agricultural water assessments 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 the produce is not adulterated on account of these hazards.

We developed this approach to pre-harvest agricultural water by considering public health objectives while recognizing that each covered 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. Cognizant of the practical implementation challenges we identified, we sought to identify an approach that: (1) is workable for covered farms of all sizes, both foreign and domestic; (2) provides sufficient specificity, while offering adequate flexibility, so that covered farms can understand what requirements apply and how to implement them to prevent produce contamination; (3) meets the public health objectives of the Agency and the relevant requirements set forth in the FD&C Act; and (4) enables FDA to verify compliance.

After evaluating relevant information gathered since publication of the final rule, and based on FDA's expertise and experience, we considered four options.

*A. Option A: Additional Guidance on Subpart E*

We considered the option of issuing additional guidance with more reference material, examples, and explanations for covered farms, while maintaining the existing pre-harvest agricultural water testing requirements in the produce safety regulation.

In particular, we contemplated issuing additional guidance to describe circumstances in which covered farms might satisfy the pre-harvest sampling and testing requirements through shared data with other covered farms. Discussions at a collaborative forum (Ref. 2) and the Agricultural Water Summit (Ref. 3), stakeholder comments and information gathered from farm visits and other stakeholder outreach (described in section III.C.) revealed several limitations with this option. There are currently few (if any) agricultural water data-sharing arrangements between covered farms, and such arrangements likely would be time-intensive and impractical to establish. For example, the diversity of agricultural water sources, distribution systems, and possible impacts from lands adjacent to and nearby each covered farm would make it difficult for many covered farms to rely on shared data to satisfy the requirement for samples adequately representative of their agricultural water at the time of application.

Moreover, some stakeholders indicated that guidance alone could not overcome difficulties with using alternative microbial quality criteria (or criterion) or alternative sampling frequency provisions of the produce safety regulation. Other stakeholders pointed out that, under § 112.171, the produce safety regulation only allows States, Federally recognized tribes, or countries from which food is imported into the United States to request a variance from FDA to use an alternative approach to the requirements set forth in the produce safety regulation.

In light of the foregoing, we concluded that issuing additional guidance as described above would not adequately address the practical implementation issues associated with the pre-harvest agricultural testing requirements in the produce safety regulation.

### *B. Option B: Risk Assessment/Research Followed by Rulemaking*

Based on comments and dialogue at collaborative fora and other stakeholder engagement activities, as described in section III.C., we considered whether to conduct another risk assessment, followed by a rulemaking to revise the pre-harvest agricultural water testing requirements. For example, we could perform a multiyear quantitative microbial risk assessment to identify index and/or indicator organisms to characterize risk associated with agricultural water across a variety of conditions, followed by rulemaking on pre-harvest agricultural water testing.

Alternatively, we could issue guidance on pre-harvest agricultural water based on industry standards while research is conducted to develop sufficient scientific information on other analyte(s) and appropriate numerical thresholds, followed by rulemaking to revise the pre-harvest agricultural water testing requirements. (This is different than Option A, which would involve additional guidance on the 2015 produce safety final rule testing requirements.)

Having reviewed the conclusions of the QAR (Ref. 11) and the 2019 IFSAC report (Ref. 25), and considered FDA's experience with investigations of produce-related outbreaks, we concluded that it is not necessary for FDA to conduct an additional risk assessment (or issue guidance based on industry standards) before conducting rulemaking to establish new pre-harvest agricultural water standards to 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 provide reasonable assurances that the produce is not adulterated on account of those hazards.

### *C. Option C: Retaining the Pre-Harvest Agricultural Water Requirements for Covered Produce*

#### *Other than Sprouts*

Another option would be to allow the existing testing requirements for pre-harvest agricultural water for non-sprout covered produce to go into effect after expiration of the compliance date extension (84 FR 9706).

When contemplating this option, we considered repeated stakeholder feedback that the testing requirements for pre-harvest agricultural water for non-sprout covered produce are difficult to understand and challenging to implement in a workable manner given the diversity of uses and sources of such water. We also considered additional information, gathered during recent outbreak investigations, on the variety of factors that impact on pre-harvest agricultural water for non-sprout covered produce.

Although we continue to believe that the existing rule with mandated testing frequency and water standards would, if implemented, result in overall improved agricultural water quality and improved public health, we understand that if confusion and infeasibility undermine successful implementation of the pre-harvest agricultural water requirements for non-sprout covered produce, then the desired public health improvements are not likely to result. Thus, we have sought an alternative means to achieve improved public health protections in this area.

In light of the foregoing, we concluded that retention of the subpart E pre-harvest requirements, as applicable to non-sprout covered produce, would not adequately address these issues in a timely manner.

*D. Option D: Rulemaking to Revise Certain Provisions of the Produce Safety Regulation*

As another option, we considered whether to engage in rulemaking to revise the pre-harvest agricultural water testing requirements for non-sprout covered produce.

In evaluating this option, we considered proceedings of the Agricultural Water Summit (Ref. 3), which included discussions and presentations on addressing hazards in the growing environment. In addition to discussing the feasibility of implementing the pre-harvest water quality profile and testing requirements of the produce safety regulation, Summit participants discussed the utility of pre-harvest agricultural water assessments given the diverse farm environments.

Summit participants identified several complex factors associated with agricultural water, including the variability in water source quality (such as how it arrives and moves throughout the

farm); the method of water application to the crop; commodity characteristics that influence vulnerability to contamination; and regional climatic effects. After several presentations and lengthy discussions of issues, Summit participants identified agricultural water assessments as a promising approach for science-based management decisions that could take the complexities of each farm into account. Similar themes emerged during discussions at the Collaborative Food Safety Forum (Ref. 2) and in stakeholder feedback on the final rule, as described in section III.C.

In light of the findings of our QAR (Ref. 11), stakeholder feedback, and new findings and information we have gathered since publication of the 2015 produce safety regulation (as described in section III.), we have concluded that the most appropriate regulatory approach is to undertake rulemaking. We acknowledge that the identified implementation challenges of the pre-harvest agricultural water testing requirements for non-sprout covered produce could prevent full realization of our intended public health objectives.

The proposed rule provides for comprehensive assessments of pre-harvest agricultural water for non-sprout covered produce that would be feasible to implement across a wide variety of pre-harvest agricultural water systems, uses, and farm operations and are adaptable as our scientific understanding of agricultural water quality expands over time. The proposed rule also would provide for expedited mitigation for certain hazards related to animal activity and other activities on adjacent and nearby lands in light of findings of FDA investigations.

The proposal sets forth procedures, processes, and practices to 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 those hazards. If finalized, the proposed rule would more comprehensively address the potential for pre-harvest agricultural water to serve as a route of contamination of non-sprout covered produce, by using a systems-based, preventive approach that is sufficiently flexible to accommodate a wide range of

agricultural water sources, uses, and practices and would be adaptable to future advancements in agricultural water quality science.

## VI. Description of the Proposed Rule

We are proposing to amend the produce safety regulation to address concerns about the practical challenges of implementing the pre-harvest agricultural water microbial water quality criteria and testing requirements by providing additional flexibility while continuing to protect the public health.

If finalized, the proposed rule would replace those pre-harvest agricultural water microbial criteria and testing requirements for non-sprout covered produce with requirements for pre-harvest agricultural water assessments that covered farms would use to determine appropriate measures for ensuring that their pre-harvest agricultural water is safe and of adequate sanitary quality under § 112.41. We also are proposing to enhance risk-based mitigation measures for pre-harvest agricultural water, including expedited mitigation measures to address known or reasonably foreseeable hazards in agricultural water systems due to animal activity, biological soil amendments of animal origin (BSAAOs), or human waste related to adjacent or nearby land uses. This proposed rule would add relevant definitions in subpart A and a requirement in subpart O for supervisory review of records of pre-harvest agricultural water assessments, as well as conforming changes in subparts B and N for the proposed revisions to pre-harvest agricultural water requirements.

To ensure that interested parties can readily view the proposed pre-harvest agricultural water revisions, we are proposing to reorganize and replace subpart E in its entirety. Of note, this proposed rule would not substantively alter the standards established in part 112, subpart E, for agricultural water used for sprouts, for which the compliance dates have passed, or for agricultural water used during harvesting, packing, and holding activities, or for treatment of agricultural water.

Sections VI.C. through VI.H. describe our proposed revisions to the pre-harvest agricultural water requirements in subpart E of the produce safety regulation and conforming changes to align four additional provisions (in subparts A, B, N, and O) relating to the subpart E pre-harvest agricultural water testing requirements that we are proposing to revise. We seek comment on our proposal to replace the pre-harvest agricultural water quality criteria and testing requirements with requirements for agricultural water assessments and enhanced mitigation measures for pre-harvest agricultural water for non-sprout covered produce, including expedited mitigation in certain circumstances.

The proposed rule also contains other edits that are designed to provide clarity, such as reorganizing subpart E to group provisions of a similar nature, as follows:

- General provisions for agricultural water for all uses (proposed §§ 112.40 through 112.42);
- Agricultural water assessments for pre-harvest agricultural water for covered produce other than sprouts (proposed § 112.43);
- Microbial water quality criterion and testing requirements for agricultural water for irrigation of sprouts and for harvest and post-harvest uses (proposed § 112.44);
- Corrective and mitigation measures for agricultural water for all uses (proposed § 112.45);
- Requirements relating to treatment methods for agricultural water for all uses (proposed § 112.46);
- Who conducts testing for agricultural water (proposed § 112.47);
- Reserved (proposed § 112.48 through 112.49); and
- Records relating to agricultural water for all uses (proposed § 112.50).

Each of the proposed technical edits is described in the relevant subsections below.

#### *A. Scope of the Rulemaking*

This proposed rule is narrow in scope. We are not proposing to amend the requirements of the produce safety regulation relating to Personnel Qualifications and Training (subpart C); Health and Hygiene (subpart D); Biological Soil Amendments of Animal Origin and Human Waste (subpart F); Domesticated and Wild Animals (subpart I); Growing, Harvesting, Packing and Holding Activities (subpart K); Equipment, Tools, Buildings, and Sanitation (subpart L); Sprouts (subpart M); Variances (subpart P); Compliance and Enforcement (subpart Q); and Withdrawal of Qualified Exemption (subpart R), which are in effect for covered farms of all sizes<sup>4</sup> (Ref. 29).

Further, this proposed rule would not amend the requirements of the produce safety regulation in General Provisions (subpart A), other than the definitions we propose to add to § 112.3; General Requirements (subpart B), other than the proposed conforming change to § 112.12; Analytical Methods (subpart N), other than the proposed conforming change to § 112.151; or Records (subpart O), other than the proposed revisions to § 112.161(b). Therefore, we are not soliciting comment on subparts A through B and N through O of the produce safety regulation (with limited exceptions for the proposed changes to §§ 112.3, 112.12, 112.151, and 112.161), as those subparts are outside the scope of this rulemaking. We also are not soliciting comment on subparts C, D, F, I, K through M, and P through R of the produce safety regulation, as those requirements are outside the scope of this rulemaking, as discussed above.

#### *B. Consistency with National Organic Program*

In accordance with section 419(a)(3)(E) of the FD&C Act, this proposed rule does not include any requirements that conflict with or duplicate the requirements of the National Organic Program established under the Organic Foods Production Act of 1990. Compliance with the provisions of this proposed rule would not preclude compliance with the requirements for

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<sup>4</sup> FDA announced its intent to exercise enforcement discretion for specific requirements related to written assurances in “Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry,” <https://www.fda.gov/media/110023/download> (last accessed May 13, 2020).



organic certification in 7 CFR part 205. Moreover, where this proposed rule and the National Organic Program would include similar or related requirements, our proposed requirements may be satisfied concurrently with those of the National Organic Program (i.e., to the extent the requirements are the same, compliance with this proposed rule could be achieved without duplication).

For example, proposed § 112.43(a)(1) would require a covered farm to evaluate the likelihood that adjacent and nearby land uses involving animal activity, the application of BSAAOs, or the presence of untreated or improperly treated human waste may contaminate pre-harvest agricultural water for covered produce (other than sprouts). This provision would not conflict with or duplicate National Organic Program requirements to manage plant and animal materials, soil fertility, and manure in a manner so that they do not contribute to contamination of water by pathogenic organisms (7 CFR §§ 205.203(c)-(d), 205.239(e)) and manage livestock operations to prevent runoff of wastes and contaminated waters to adjoining or nearby surface water and across property boundaries (7 CFR § 205.239(a)(5)).

Further, we note that the provisions for treatment of agricultural water in proposed § 112.46 are not in conflict with or duplicative of the National Organic Program guidance, “The Use of Chlorine Materials in Organic Production and Handling” (Ref. 30), which provides that residual chlorine levels in pre-harvest water agricultural water should not exceed the maximum residual disinfectant limit 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. Certified organic farms would be able to comply with the provisions of this proposed rule with respect to corrective or mitigation measures that would be reasonably necessary to implement under proposed § 112.45.

We seek comment on the tentative conclusion that this proposed rule does not conflict with or duplicate the requirements of the National Organic Program, while providing the same level of public health protection as required under FSMA.

### *C. Definitions (Proposed § 112.3)*

We propose to add two new definitions in § 112.3 to provide clarity for terminology used in the proposed requirements for pre-harvest agricultural water assessments.

#### 1. Agricultural Water Assessment

We propose to add a new definition of “agricultural water assessment.” As proposed, the term agricultural water assessment would be defined to mean an evaluation, conducted by a covered farm, of its agricultural water system used during growing activities for non-sprout covered produce, its agricultural water practices for such pre-harvest water, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) 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 corrective or mitigation measures for pre-harvest agricultural water are necessary to reduce the potential for contamination with such known or reasonably foreseeable hazards.

A definition of “agricultural water assessment” is needed to provide clarity, particularly in light of widespread use of similar terms that may have different meanings than the definition in this proposal. For example, the definition of agricultural water assessment we are proposing includes crop characteristics. By contrast, an “ag water system assessment,” as described by Western Growers (Ref. 31), or a “sanitary survey,” as described by some stakeholders (Ref. 3) do not consider this factor.

Crop characteristics also are a factor mentioned in the QAR (Ref. 11). Crop characteristics have long been identified as a factor influencing the potential for water to contaminate produce. In the 1998 FDA Good Agricultural Practices Guide, for example, we explained 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 (Ref. 32). In light of the role that crop

characteristics may play in contamination of produce, this would be an important component of an “agricultural water assessment” under this proposed rule.

## 2. Agricultural Water System

We are proposing to define the term “agricultural water system” to provide greater clarity and increase consistency in the interpretation of what comprises an agricultural water system that a covered farm must inspect under § 112.42(a), to the extent that the system is under the farm’s control. In this proposed rule, an “agricultural water system” means a source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities.

We developed the proposed definition of “agricultural water system” based on elements listed in § 112.42(a) of the produce safety regulation, which provides that an agricultural water system includes water sources, water distribution systems, facilities, and equipment. We also incorporated language from the definition of “water distribution system” in § 112.3 of the produce safety regulation, which describes a system for carrying water from its source to its point of use. Additionally, we added examples of buildings or structures that may be part of a water distribution system--for example, a well house, pump station, or shed--to clarify the meaning of “facilities” as a component of an agricultural water system. We expect that adding a definition that clearly describes the scope of “agricultural water system” will help covered farms ensure that inspections and maintenance activities under proposed § 112.42 would be of adequate scope and rigor.

We are seeking comment on the definitions of “agricultural water assessment” and “agricultural water system” in proposed § 112.3.

*D. Applicability (Proposed § 112.40)*

We are proposing to add new § 112.40 to summarize the requirements that would apply to a covered farm. The provision would include an explanatory table presenting the following:

If you are a covered farm using pre-harvest agricultural water in growing covered produce, other than sprouts:

- You must meet the requirements of §§ 112.41 (water quality standard), 112.42 (inspections and maintenance of agricultural water systems), 112.43 (agricultural water assessment), and 112.50 (records) and
- As applicable, you must meet the requirements of §§ 112.45 (measures), 112.47 (who may test), and 112.151 (methods). Any water treatment must be in accordance with § 112.46.

If you are a covered farm using agricultural water for sprout irrigation:

- You must meet the requirements of §§ 112.41 (water quality standard), 112.42 (inspections and maintenance of agricultural water systems), 112.44(a) (microbial quality criterion), unless excepted under 112.44(c), and 112.50 (records) and
- As applicable, you also must meet the requirements of §§ 112.44(b) (untreated ground water testing), 112.44(c) (exceptions from testing requirement), 112.45 (measures), 112.47 (who may test), and 112.151 (test methods). Any water treatment must be in accordance with § 112.46.

If you are a covered farm using agricultural water for harvesting, packing, or holding covered produce:

- You must meet the requirements of §§ 112.41 (water quality standard), 112.42 (inspections and maintenance of agricultural water systems), 112.44(a) (microbial quality criterion), unless excepted under 112.44(c), 112.44(e) (additional management and monitoring practices), and 112.50 (records) and

- As applicable, you also must meet the requirements of §§ 112.44(b) (testing untreated ground water), 112.44(c) (exceptions from testing requirement), 112.45 (measures), 112.47 (who may test), and 112.151 (test methods). Any water treatment must be in accordance with § 112.46.

*E. Pre-Harvest Agricultural Water Assessments (Proposed § 112.43)*

Proposed § 112.43 would require covered farms to conduct agricultural water assessments for the pre-harvest agricultural water for non-sprout covered produce. The proposed assessments would be conducted annually (and more frequently as needed), documented in writing, and used for hazard identification and risk management decision-making purposes in lieu of the pre-harvest microbial water quality criteria and testing requirements in §§ 112.44(b) and 112.46(b) of the produce safety regulation.

Covered farms would be exempt from the proposed agricultural water assessment requirement if they can demonstrate that their pre-harvest agricultural water for non-sprout covered produce:

- Meets the requirements for harvest and post-harvest agricultural water (proposed § 112.44(a) and, as applicable, §§ 112.44(b), 112.47, and 112.151);
- Meets the requirements for water from a Public Water System or public water supply (proposed § 112.44(c)); or
- Is treated in accordance with § 112.46.

Unless exempt (as described above), covered farms using pre-harvest agricultural water for non-sprout covered produce would evaluate their pre-harvest agricultural water system(s), agricultural water practices, crop characteristics, environmental conditions, and other relevant factors to identify any conditions that would be reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces. Certain covered farms also may opt to conduct testing to help inform their assessments.

Covered farms would use the results of their agricultural water assessments in determining whether corrective or mitigation measures for their pre-harvest agricultural water for non-sprout covered produce would be reasonably necessary to reduce the potential for contamination, or whether routine inspections and maintenance of their agricultural water systems would be adequate to ensure that their pre-harvest agricultural water is safe and of adequate sanitary quality for its intended use under §112.41.

To assist readers, Table 3 outlines the discussion of proposed § 112.43.

Table 3.—Discussion of Proposed § 112.43

1. Proposed § 112.43(a)--Elements of an Agricultural Water Assessment
2. Factors
3. Agricultural Water System
4. Location and nature of each water source
5. Type of water distribution system
6. Degree of protection of each agricultural water system
7. Degree of protection from contamination by other users
a. Animal impacts
b. Adjacent and nearby land uses
c. Animal activities as possible contributing factors in outbreaks
d. Endangered Species Act
e. BSAAOs
f. Untreated or improperly treated waste
8. Agricultural water practices
a. Time to harvest
b. Method of application
9. Crop characteristics
10. Environmental conditions
11. Other relevant factors
12. Written annual assessments
13. Proposed § 112.43(b)—Exemptions
14. Proposed § 112.43(c)—Outcomes
15. Proposed § 112.43(d)—Testing for Assessment Purposes
a. Generic <i>E. coli</i>
b. Frequency of testing
c. Microbial water quality criteria
d. Records relating to analytes, sampling frequencies, and pre-harvest water quality criteria
16. Proposed § 112.43(e)—Reassessment

1. Proposed § 112.43(a)--Elements of an Agricultural Water Assessment

Unless exempt under proposed § 112.43(b), covered farms using pre-harvest agricultural water for non-sprout covered produce would prepare a written assessment of their pre-harvest agricultural water, at least once each year, to identify any conditions that would be reasonably likely to introduce known or reasonably foreseeable hazards into or onto non-sprout covered produce or food contact surfaces.

## 2. Factors

In light of the diversity of operations, practices, and conditions that may impact the pre-harvest agricultural water used by foreign and domestic covered farms for non-sprout covered produce, we propose to require a covered farm to assess the following factors (further described in paragraphs 3-11, below) for hazard identification purposes, under proposed § 112.43(a):

- Each agricultural water system (defined as proposed in § 112.3) used for pre-harvest agricultural water for non-sprout covered produce, including:
  - the location and nature of the water source (that is, whether the source meets the definition of ground water or surface water);
  - the type of water distribution system, such as whether the conveyance is open to the environment (for example, an open irrigation canal) or is closed to the environment (for example, a closed piping system);
  - the degree to which the agricultural water system(s) are protected from possible sources of contamination, including possible contamination by other users of the same agricultural water system and animal impacts (including by grazing animals, working animals, and animal intrusion on the covered farm); and
  - the degree to which the agricultural water system(s) are protected from possible sources of contamination, including by adjacent and nearby land uses—particularly any animal activity (for example grazing, or commercial animal feeding operations of any size), the application of BSAAOs, or the presence of untreated or improperly treated human waste;

- Agricultural water practices associated with each agricultural water system used for pre-harvest water for non-sprout covered produce, including:
  - the type of direct application method used (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 non-sprout covered produce;
- Crop characteristics, including the susceptibility of the covered produce to surface adhesion or internalization of hazards;
- Environmental conditions, such as:
  - the frequency of heavy rain or extreme weather events that may impact the agricultural water system(s) (such as by stirring sediments) or that may impact covered produce (such as damage to edible leaves) during growing activities;
  - air temperatures; and
  - sun (ultraviolet (UV)) exposure; and
- Other relevant factors, including, if applicable, the results of any testing conducted to inform the assessment.

### 3. Agricultural Water Systems

Proposed § 112.43 is intended to supplement the requirements of proposed § 112.42,<sup>5</sup> which would require a covered 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 proposed § 112.42 is focused on agricultural water system components under the covered farm's control, proposed § 112.43(a) would require covered 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 preharvest agricultural water

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<sup>5</sup> As described in section VI.I., we are proposing to minor revisions to § 112.42, which applies to agricultural water for pre-harvest, harvest, and post-harvest application to covered produce.



for non-sprout covered produce. While the covered farm may not have control over the factors assessed under proposed § 112.43(a), they are no less important for the farm to consider when determining the safe use of agricultural water on covered produce.

When conducting pre-harvest agricultural water assessments, covered farms would use the results of inspections and maintenance they performed under proposed § 112.42 for agricultural water systems under their control. For example, a covered farm using an on-farm pond as a pre-harvest agricultural water source would consider the results of any inspections and maintenance performed (including inspection findings documented in records under proposed § 112.50(b)(2)) as part of its pre-harvest agricultural water assessment (proposed § 112.43).

For hazard identification purposes, under proposed § 112.43, a covered farm would assess each pre-harvest agricultural water system it uses for non-sprout covered produce from water source to point of application. A covered farm could not satisfy the agricultural water assessment requirements in proposed § 112.43 solely based on inspection activities conducted under proposed § 112.42, for example, because the agricultural water assessment requires consideration of a broader range of factors, including agricultural water practices, crop characteristics, and other relevant factors.

For each agricultural water system used for pre-harvest agricultural water for non-sprout covered produce, a covered farm would consider:

#### 4. Location and Nature of Each Water Source.

Proposed § 112.43(a)(1) would require covered farms to evaluate the location and nature of each agricultural water source used during growing activities for non-sprout covered produce. The covered farm would need to identify whether the water source was ground water or surface water as a starting point for its agricultural water assessment.

The QAR (Ref. 11) 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. For example, groundwater 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. 11 and 32).

By contrast, surface waters, which are exposed to the environment, pose a higher potential for contamination due to runoff and greater variability in quality because of the potential for external inputs (Ref. 11). Runoff has the potential to carry pathogens and is known to mobilize pathogens from sediment reservoirs to the water column (Refs. 33-36). Runoff also carries pathogens to the surface water system from sources such as failing septic systems and deposited animal feces (Refs. 36 and 37).

#### 5. Type of Water Distribution System

Under proposed § 112.42(a)(1), a covered farm also would identify the type of water distribution systems used to convey pre-harvest agricultural water for non-sprout covered produce.

As the QAR (Ref. 11) notes, pathogens can potentially enter a water system anywhere along the path from source to distribution and use, potentially introducing hazards onto produce. Some water used for growing activities is conveyed through open systems of canals and laterals that can be subject to the introduction of hazards such as via runoff, animal intrusion, direct discharge, or seepage. For example, in the investigation of the Spring 2018 *E. coli* O157:H7 outbreak, investigators conducted a ground water assessment of the area near the 3.5-mile section of irrigation canal where the outbreak strain was detected in three samples. (Refs. 12 and 13). Investigators noted that one of those positive samples was collected immediately downstream from a shallow ground water discharge into the irrigation canal. Investigators also found an area where ground water may have been seeping directly into unlined sections of the canal within the 3.5-mile stretch where the outbreak strain was detected.

Other water is distributed through closed distribution systems, such as through piping that conveys water from the source to the field. If intact, properly constructed, and properly functioning, piped systems can help protect the water from the potential introduction of hazards during conveyance.

However, hazards may be introduced into closed piping systems, such as where interconnected with other systems without adequate backflow protection. For example, an environmental investigation of a 2006 *E. coli* O157:H7 linked to iceberg lettuce led investigators to a farm with an irrigation system that blended irrigation water from the local water district and dairy wastewater, and routed the blended water to fields (Ref. 21). Investigators reported that the irrigation and dairy effluent conveyance systems appeared to be combined into a complex piping network, which raised concerns about the potential of microbial cross-contamination between the growing fields of lettuce and nearby dairies. Six samples (water, soil, and environmental swabs) matching the outbreak strain by pulsed-field gel electrophoresis came from areas where the blended water was routed. Investigators concluded: “Because this system has been found to have inadequate backflow prevention devices, it presented a possible route of conveyance of contaminated water to fields adjacent to suspect lettuce growing fields associated with this outbreak.” (Ref. 38).

Covered farms with open and closed components in their agricultural water distribution systems would consider the individual properties and characteristics of each component when conducting a pre-harvest agricultural water assessment under proposed § 112.43(a)(1).

#### 6. Degree of Protection of Each Agricultural Water System

In evaluating each agricultural water system used for pre-harvest water for non-sprout covered produce under proposed § 112.43(a)(1), a covered farm would consider the likelihood that various external conditions (including those described in paragraphs 7, 11, and 12 below) could introduce known or reasonably foreseeable hazards to pre-harvest agricultural water, such as from:

- Other users of the agricultural water system;
- Animal impacts, including grazing animals, working animals, and animal intrusion on the covered farm; and
- Adjacent and nearby land uses involving animal activity, application of BSAAOs, or presence of untreated or improperly treated human waste.

Under proposed § 112.43(a)(1), a covered farm would evaluate whether there are measures in place to contain possible sources of contamination (such as discharges or runoff) away from the agricultural water system, including any measures implemented by the farm itself or by another entity (proposed § 112.43(a)(1)). For example, the QAR (Ref. 11) indicates that farms may be able to minimize the influence of discharge or runoff into on-farm surface water held in impoundments, catches, and ponds, such as through walls or earthen berms. Other farms may have little to no control over upstream runoff into a larger, shared body of water, such as a river. While flowing waters generally may be exposed to the same types of factors as on-farm ponds, reservoirs, and water containment structures, their composition and chemistry 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.

#### 7. Degree of Protection from Contamination by Other Users

In assessing the degree of protection of the agricultural water system(s) under proposed § 112.43(a)(1), a covered farm would consider the potential for known or reasonably foreseeable hazards to be introduced by other users of any pre-harvest agricultural water source or distribution system used for non-sprout covered produce. For example, a covered farm that draws water for crop protection sprays from a pond that is also used for recreational swimming would need to consider whether that use of the source for recreational swimming would be reasonably likely to introduce known or reasonably foreseeable hazards into the agricultural water system, such as through introduction of human waste.

Under proposed § 112.43(a)(1), covered farms that reuse (or recycle) water as a source for pre-harvest agricultural water would need to consider the potential for known or reasonably foreseeable hazards to be introduced by the prior use of the water. This would include consideration of impacts relating to the nature of the prior use. We note that the requirements for agricultural water quality in proposed §§ 112.41 and 112.43 apply regardless of the source or type of water used as agricultural water. If finalized, a covered farm would 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.

We anticipate that some covered farms would treat the recycled water themselves (or through a third party acting on their behalf) in accordance with the proposed treatment requirements. Proposed § 112.46 would require the treatment method to be effective and delivered in a manner to ensure that the treated water is consistently safe and of adequate sanitary quality for its intended use(s). If finalized as proposed, the treated water would be monitored using an adequate method and frequency to ensure that it is consistently safe and of adequate sanitary quality for its intended use(s).

We seek comment on the types of water reuse that covered farms might use for pre-harvest agricultural water. We also seek comment from interested parties on providing greater specificity on testing for water reuse, such as by setting quantitative thresholds in the final rule, or by providing testing recommendations in guidance, for recycled water applied during growing activities for covered produce (other than sprouts), consistent with our mandate to establish science-based minimum standards for agricultural water that are reasonably necessary to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards into covered produce, and to provide reasonable assurances that the produce is not adulterated under section 402 of the FD&C Act.

a. *Animal impacts.* Under proposed § 112.43(a)(1), a covered farm would consider the potential for hazards to be introduced into its pre-harvest agricultural water sources or distribution systems from animals, including grazing animals, working animals, and wild animal intrusion on the farm.

As discussed in the QAR (Ref. 11), both wild and domesticated animals may be a source of human pathogens, including animals that only sporadically show symptoms (Ref. 39) or that may be asymptomatic shedders (Refs. 40 and 41). Animal waste has been shown to harbor many bacterial pathogens--for example, the predominant source of *E. coli* O157:H7 in animal feces is cattle, and the predominant source of *Salmonella* in animal feces is poultry (Ref. 11). The QAR (Ref. 11) identifies other domesticated animals (including sheep, goats, and swine) and wild animals can carry human pathogens as well, such as pathogenic *E. coli* in deer, feral swine, pigeons, and seagulls, and *Salmonella* in rodents and wild birds.

FDA acknowledges the longstanding co-location of animals and plant food production systems in agriculture. This proposed rule would not prohibit the presence of animals (such as grazing animals or working animals) on a covered farm, nor would it require the destruction of wildlife habitat or the clearing of farm borders. Rather, the proposed rule would require a covered farm to evaluate and take measures to prevent the introduction of known or reasonably foreseeable hazards into or onto non-sprout covered produce or food contact surfaces by pre-harvest agricultural water.

Proposed § 112.43(a)(1) is intended to provide a covered farm with information about animal impacts on its pre-harvest agricultural water system(s) and to facilitate measures as needed under proposed § 112.45. Some covered farms will be aware of potential animal impacts from grazing animals, working animals, or animal intrusion through assessments done under subpart I (§§ 112.81-112.84) of the produce safety regulation--which, under certain circumstances, requires a covered farm to assess the relevant areas used for a covered activity for evidence of potential contamination of covered produce (such as observation of significant

quantities of animals, significant amounts of animal excreta, or significant crop destruction). (See 80 FR 74354 at 74478-74485.) When determining the probability that animals will contaminate its covered produce under subpart I of the produce safety regulation, a covered farm may consider the presence of animal attractants such as water sources or standing water on or near the farm (Ref. 42). Visual observations by a covered farm for purposes of §§ 112.81-112.83 could provide useful information for evaluating the degree of protection of a pre-harvest agricultural water system under proposed § 112.43(a)(1). For example, if a covered farm determines that there is a reasonable probability that wild animals will contaminate their crop, the covered farm must assess the relevant growing area for evidence of potential contamination in accordance with § 112.83(b)(1) of the produce safety regulation. The covered farm could consider findings from this assessment--for example, whether significant amounts of animal excreta are observed--when evaluating the likelihood of hazards being introduced into their pre-harvest agricultural water sources.

Additionally, a covered farm would be aware of potential animal impacts on agricultural water systems through inspections and maintenance performed on agricultural water sources and agricultural water systems it controls under proposed § 112.42. For example, pooled water in close proximity to the crop may serve as an attractant for pests and other animals which may in turn introduce hazards into pooled water that may contaminate produce. (See 80 FR 74354 at 74434.)

*b. Adjacent and nearby land uses.* Proposed § 112.43(a)(1) would require a covered farm to consider whether it is reasonably likely that known or reasonably foreseeable hazards would be introduced into agricultural water systems by activities conducted on lands adjacent to or nearby its sources or distribution systems for pre-harvest agricultural water for non-sprout covered produce.

By “adjacent” land, we are referring to land sharing a common border with the water source or distribution system. By “nearby” land, we are referring to a broader category of land, including land that does not adjoin the water source or distribution system but has the potential to

affect the covered farm's agricultural water source or distribution system based on the land's location (80 FR 74354 at 74433).

Under proposed § 112.43(a)(1), covered farms would be required to consider the likelihood of introduction of known or reasonably foreseeable hazards related to animal activity on adjacent and nearby lands, for example:

- Grazing on public or private lands;
- Commercial animal feeding operations of any size; and
- Other animal activity, such as dairy production, poultry production, barnyards, and significant wildlife intrusion or habitat.

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. 43-46). Strong associations have been reported with *E. coli* O157:H7 originating from upstream pastures with unrestricted access to waterways (Ref. 47). Indicators of fecal contamination in water systems have been reported to be related to various types of livestock operations--for swine (Ref. 48), poultry (Ref. 49), and cattle (Ref. 50). Animals from densely populated farms or farms with a high population of immature animals have an increased likelihood of harboring various pathogens (Ref. 51). Runoff has the potential to increase the number of pathogens in the water column if its origins include human, livestock or wildlife feces, because it has the potential to increase the amount of suspended sediments which are likely to harbor pathogens (Ref. 43).

*c. Animal activities as possible contributing factors in outbreaks.* FDA investigators have identified animal operations of various sizes as possible contributing factors in several produce outbreaks.<sup>6</sup> In particular, animal operations in proximity to, or upstream of, an

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<sup>6</sup> In many instances, these operations did not meet the EPA's definition of large CAFO. Under 40 CFR 122.23(b), a CAFO is a lot or facility (other than an aquatic animal production facility) where animals have been, are, or will be stabled or confined and fed or maintained for a total of 45 days or more in any 12-month period; and crops, vegetation, forage growth, or post-harvest residues are not sustained in the normal growing season over any portion of the lot or facility. A large CAFO stables or confines 1,000 or more cattle (other than mature dairy cows or veal calves); 700 dairy cows; or 500 horses, for example.



agricultural water source or distribution system may pose a significant risk in some circumstances. Topography is another important factor to consider in evaluating whether adjacent or nearby lands may serve as a source of contamination. For example, animal grazing was identified as a possible contributing factor in investigations of three 2019 *E. coli* O157:H7 outbreaks linked to romaine lettuce, in which one of the outbreak strains was detected in a fecal-soil composite sample taken from a cattle grate on public land less than 2 miles upslope from a farm with multiple fields tied to the outbreaks by traceback investigations (Ref. 16). Additional STEC strains were found in two samples collected from cattle grazing land in the hills above leafy greens fields identified by traceback evidence, though neither of the strains were linked to human illness. During collection of these samples, investigators observed cattle grazing on hills above the identified leafy greens fields, but far fewer than would be present on a large CAFO. Investigators estimated that each of these adjacent grazing lands had between 50 and 150 head of cattle.

Cattle and horse grazing on adjacent lands were identified as potential contributing factors in an investigation of a Fall 2018 *E. coli* O157:H7 outbreak linked to romaine lettuce, in which the outbreak strain was detected in a sediment sample from an on-farm water reservoir (Ref. 15). Although investigators were not able to determine how the contamination was introduced into the water reservoir, they identified several risk factors, including between 250 and 500 cattle grazing on land adjacent to romaine lettuce production on a farm identified by traceback investigation. This was a notable observation given that FDA's outbreak investigations have repeatedly demonstrated the heightened risk of contamination associated with grazing activities near produce growing areas and agricultural water sources, unless appropriate measures are taken to mitigate the risks.

In the investigation of the Spring 2018 *E. coli* O157:H7 outbreak, a large cattle CAFO was located adjacent to the 3.5-mile stretch of irrigation canal where the outbreak strain was found (Ref. 12). One of these samples was collected immediately downstream from where

shallow ground water is pumped into the irrigation canal. The EA investigators also found an area where ground water may have been seeping directly into unlined sections of the canal within the 3.5-mile stretch where the outbreak strain was detected. Investigators identified on-farm wells at the CAFO as a possible route of ground water contamination (Ref. 13).

Nearby cattle feeding operations also were identified as a possible source of contamination during an investigation of a 2013 *E. coli* O157:H7 outbreak, with 33 reported illnesses, linked to ready-to-eat salads (Ref. 52). Based on traceback information, investigators conducted on-farm sampling and investigation. Of the ten soil and water samples collected, five were positive for *E. coli* O157:H7 but not the outbreak strain.

Feral swine and cattle were identified as possible vectors for surface water contamination in an investigation of a 2006 *E. coli* O157:H7 outbreak traced to bagged spinach (Ref. 20) The outbreak strain was detected in feral swine feces, cattle feces, surface water, and river sediment samples collected from a ranch with cattle pastures located adjacent to a leased field where spinach implicated by traceback was grown. Samples were matched by pulsed-field gel electrophoresis and multilocus variable number tandem repeat analysis (Ref. 20). Although investigators made no definitive determination on the route of contamination, they concluded that fecal loading of surface waterways by livestock and wildlife with subsequent contamination of wells used for irrigation was one possible route of transmission to plants in the field (Ref. 20).

Under proposed § 112.43(a)(1), a covered farm would evaluate animal activity on adjacent and nearby lands, such as grazing or commercial animal operations of any size, to identify any condition(s) that may introduce a known or reasonably foreseeable hazard into a source or distribution system used for pre-harvest agricultural water for non-sprout covered produce. Animal activities that may introduce contamination into sources or distribution systems include, but are not limited to, livestock feeding operations of any size, dairy production, poultry production, barnyards, or significant wildlife intrusion or wildlife habitat. In evaluating adjacent and nearby land uses under proposed § 112.43(a)(1), a covered farm could, for example, consider

the effects of any fencing, containment, or other measures employed to prevent animal access to water sources or distribution systems, or earthen diversion berms, ditches, or other barriers to help minimize the influence of runoff on sources and distribution systems. Information on adjacent or nearby land uses could be acquired through visual observations, discussions with local extension agents or associations, online resources such as mapping tools, or other means that are appropriate to the circumstances.

The factors a covered farm might consider in evaluating the likelihood of hazards being introduced from adjacent or nearby lands may depend on the specific animal activity in question. For example, if a covered farm draws water from a stream with upstream grazing and pasturing of animals, the covered farm might consider the proximity of the grazing and pasture areas to the stream, whether the animals have direct access to the stream for loafing and drinking, and whether runoff from the grazed and pastured lands is likely to be introduced into the stream.

While a covered farm might consider similar factors to these if it draws water from a canal with an upstream dairy operation, there may be additional factors to consider when evaluating the likelihood of introduction of hazards, such as whether the operation has any best management practices in place (such as to prevent overflow of manure lagoons), the locations of waste storage or composting operations relative to the canal, and animal and traffic patterns throughout the dairy that have the potential to spread contaminants.

We recognize that farms may face uncertainty around evaluating factors like these where they are unable to obtain the relevant information, such as if adjacent or nearby land users are not willing to share information. Due to the nature of the risks associated with animal activity, in these instances, farms should consider accounting for the increased likelihood of hazard introduction to the water systems from adjacent or nearby lands when making decisions around the safe use of their water.

d. *Endangered Species Act*. Section 112.84 of the produce safety regulation clarifies that the regulation does not authorize or require covered farms to take actions

that would constitute the “taking” of threatened or endangered species in violation of the Endangered Species Act (16 U.S.C. 1531-1544), or require covered farms to take measures to exclude animals from outdoor growing areas, or destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages.

We note that nothing in proposed subpart E would require covered farms to take measures to exclude animals from covered farms or from adjacent or nearby lands, or to destroy animal habitat or otherwise clear farm borders.

*e. BSAAOs.* Proposed § 112.43(a)(1) also would require covered farms to evaluate the presence of BSAAOs on adjacent and nearby lands that may introduce known or reasonably foreseeable hazards into sources and distribution systems for pre-harvest agricultural water for non-sprout covered produce, such as through runoff.

Section 112.3 of the produce safety regulation defines BSAAO to mean “any biological soil amendment which consists, in whole or in part, of materials of animal origin, such as manure or non-fecal animal byproducts including animal mortalities, or table waste, alone or in combination. The term biological soil amendment of animal origin does not include any form of human waste.”

The QAR (Ref. 11) concluded that biological soil amendments can transmit human pathogens to surface water or ground water when stockpiled or applied to fields. 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. (See also 80 FR 74534 at 74461-74478.)

Soil amendments have been identified as possible sources of pathogens in produce outbreak investigations (Ref. 11). For example, investigators identified soil amendments on adjacent lands as a possible source of contamination in the 2018 romaine lettuce outbreak in which the outbreak strain of *E. coli* O157:H7 was introduced into the on-farm water reservoir (Ref. 15).

In evaluating whether the application of BSAAOs on adjacent and nearby lands may introduce contamination into sources or distribution systems for pre-harvest agricultural water for non-sprout covered produce, a covered farm would consider whether the BSAAO is treated or applied to the land in accordance with the produce safety regulation (such as where adjacent or nearby lands are covered farms subject to the produce safety regulation) or any other Federal, State, or international regulations, recommendations, or guidelines for soil amendments. Covered farms would consider whether any BSAAOs on adjacent and nearby lands are handled, conveyed, and stored in a manner and location so that they do not become a potential source of contamination to water sources and water distribution systems for pre-harvest agricultural water for non-sprout covered produce (proposed § 112.43(a)(1)).

Factors to consider when evaluating the likelihood of potential hazards being introduced into a water system include, for example: (1) the distance between the fields and the water source; (2) the measures, if any, an upstream farm uses to control runoff; (3) whether the BSAAOs are treated and to what extent; (4) how BSAAOs are handled, conveyed, and stored on the land; and (5) whether runoff is likely to occur. In the event of uncertainty about use of BSAAO on adjacent and nearby lands, such as where the upstream farm does not provide information, farms should consider accounting for the increased likelihood of hazard introduction to the water systems from such BSAAO uses when making decisions around the safe use of their pre-harvest agricultural water.

*f. Untreated or improperly treated human waste.* Proposed § 112.43(a)(1) also would require covered farms to consider adjacent and nearby land uses related to untreated or improperly treated human waste.

As described in the QAR (Ref. 11), 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--such as where untreated or improperly treated human waste is applied as a soil

amendment or where human waste systems are not properly constructed and maintained. Covered farms also should consider whether any portable toilet facilities on adjacent and nearby lands are appropriately located away from water sources and distribution systems in the event of malfunctioning, flooding, or high winds. Fixed human waste systems also may introduce contamination to water sources or water distribution systems. For example, investigators identified a recreational vehicle (RV) park as a potential source of contamination in a 2010 STEC O145 outbreak associated with romaine lettuce (Ref. 53). Investigators found that the RV park property had multiple septic leach systems with subterranean moisture in the area that drains into an irrigation canal.

When evaluating proposed § 112.43(a)(2)-(4), the covered farm would consider the likelihood that any hazards, if present in its agricultural water system, would be reasonably likely to introduce hazards into or onto non-sprout covered produce, due to the agricultural water practices employed by the farm, the characteristics of the crop(s) to which the pre-harvest agricultural water is applied, and the environmental conditions that may impact the introduction and/or persistence of hazards. An evaluation of the hazards associated with untreated or improperly treated human waste from adjacent or nearby lands could include consideration of potential sources of contamination, such as wastewater treatment plants, toilet facilities (portable and fixed), sewage systems, septic tanks, and drain fields. In considering whether hazards associated with human waste from adjacent or nearby lands might be introduced to water systems, covered farms might consider: (1) whether and how the human waste is treated; (2) whether the source of human waste is discharged directly into the water system; (3) the proximity of the potential source to the water system; (3) the topography between the potential source of human waste and the water system; and (4) whether there are any physical measures in place between the potential source of human waste and water system that would reduce the likelihood of hazards being introduced. In the event of uncertainty about adjacent and nearby land uses related to untreated or improperly treated human waste, such as if adjacent and nearby

land users are not willing to share information, farms should consider accounting for the increased likelihood of hazard introduction to the water systems from such land uses when making decisions around the safe use of their pre-harvest agricultural water.

We note that in the United States, 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. 54).

## 8. Agricultural Water Practices

*a. Time to harvest.* In evaluating any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces under proposed § 112.43(a)(2), a covered farm would consider the interval between the last time pre-harvest agricultural water was applied to the covered produce and the date of harvest. For example, a covered farm that uses furrow irrigation and crop protection sprays for its non-sprout covered produce would consider the timing of both types of applications.

As explained in the QAR (Ref. 11), the timing of water application is an important factor in determining the likelihood of contamination, because pathogens die off over time on the surface of produce. Generally, bacteria or pathogens in water that is applied early in the growing cycle are subject to die-off from several environmental forces, such as UV exposure, temperature, humidity, and the presence of competitive organisms (Ref. 55). 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. 11). For more discussion of microbial die off rates, see section VI.F.

*b. Method of application.* Proposed § 112.43(a)(2) also would require a covered farm to evaluate the method(s) by which pre-harvest agricultural water is applied to non-sprout covered produce during growing activities.

The most frequently used irrigation methods include overhead sprinkler (or spray), surface and subsurface drip, furrow, flood, and seep irrigation (Ref. 56). The QAR (Ref. 11) explains that different irrigation methods present different risks based on the extent to which the irrigation water is directly applied to the harvestable portion of the crop.<sup>7</sup> Overhead sprinkler irrigation increases the risk of contamination as compared with furrow and subsurface drip irrigation (Ref. 57). The location of the harvestable portion of a plant in relation to irrigation water plays a significant role in contamination in studies of lettuce, cantaloupe, and bell pepper (Ref. 58). The likelihood of produce contamination may be reduced if irrigation water is delivered by subsurface drip irrigation as compared to using the same water to irrigate by overhead spray (Refs. 33 and 59).

Pathogenic *E. coli* has been recovered from lettuce tissue after surface irrigation and spray irrigation with suspensions of *E. coli* O157:H7; the level of contamination was lower from drip than from sprinkler irrigation (Ref. 60). The lettuce leaves remained contaminated with *E. coli* O157:H7 even after washing, indicating that surface and spray irrigation of food crops with water of unknown microbiological quality may introduce risk.

## 9. Crop Characteristics

Under proposed § 112.43(a)(3), a covered farm would be required to evaluate whether the covered produce has any characteristics that make it vulnerable to contamination, such as whether it is susceptible to surface adhesion of bacteria or internalization of microbial hazards. This includes increased susceptibility to internalization of hazards due to physical damage from

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<sup>7</sup> Irrigation water as described in the QAR is broader than the definition of agricultural water in § 112.3 of the produce safety regulations that would apply under this proposed rule.



weather events (such as freezing of an epidermal peel and hail damage) or biological damage (such as phytopathogens).

The QAR (Ref. 11) concluded that:

- The physical characteristics of the crop is one of the likely factors contributing to the likelihood of contamination, exposure, and illness.
- In particular, the growth characteristics (e.g., near to the ground) and surface properties (e.g., porosity) affect the probability and degree of contamination.
- No physical characteristics were identified that would be protective against contamination.

As discussed in the QAR (Ref. 11), although some physical characteristics of produce commodities (e.g., netted rind of cantaloupe or large, rough surface area of some leafy greens) may increase the likelihood of contaminants being trapped and surviving long enough to cause illness, physical characteristics that could alter the potential for contamination (e.g., smooth surfaces) do not always appear to do so. For example, while honeydew melon has a smooth rind, seemingly making it less likely to harbor pathogens, it has been associated with outbreaks. Some crops are more susceptible to the persistence and growth of human pathogens, including co-infections with plant pathogens (Ref. 61). (See also, the Codex Alimentarius Commission, Code of Hygienic Practice for Fresh Fruits and Vegetables (CXC 53-2003) (the Codex Code) section 3.2.1.1.1 (Ref. 62). We anticipate that as more information is learned about how commodity characteristics can impact produce safety, covered farms would use this information to further inform their pre-harvest agricultural water assessments.

## 10. Environmental Conditions

Proposed § 112.43(a)(4) would require a covered farm to evaluate the potential impacts of weather conditions, including seasonal rainfall patterns, the frequency of extreme weather events (such as heavy winds or rain), and other relevant agro-ecological conditions (such as temperature, sunlight (UV exposure)). As described in the QAR (Ref. 11), survival of pathogens

in the environment is influenced by complex physical, chemical, and biological interactions. Some pathogens are widely distributed and naturally capable of long-term survival under a wide range of natural conditions (e.g., *Listeria monocytogenes*) while the distribution of others (e.g., *Salmonella*, *E. coli* H7:O157) may be more narrowly defined by temperature, sunlight (UV exposure), moisture level, pH, available nutrients and related factors, each of which may limit survival to some degree.

Changes in temperature and seasonality are expected to impact persistence of foodborne pathogens in the environment (Ref. 56). In general, the survival of pathogens in water sources decreases with increasing temperatures (Ref. 56). For example, in mid-latitude areas, it is thought that the overall survival of foodborne pathogens in soils, manure-amended soils and surface waters is likely to decrease with increasing temperatures (Ref. 63). However, exceptions may be observed in certain geographic areas and/or on certain farm environments due to factors that confound the effects of temperature, such as nutrient levels and humidity (Refs. 63 and 64).

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. 65). One study (Ref. 66) found that *E. coli* was present in air samples from the edge of a beef cattle feedlot, indicating that airborne transfer of microorganisms can occur. Another study (Ref. 67) found that *E. coli* was recovered from 20 percent of air samples from an almond orchard downwind from a poultry operation and from 0.48 percent of air samples from an almond orchard not located near an animal operation. Increased levels of global dust activity due to desertification as well as increased wind speeds associated with storm systems may promote the dispersal and persistence of some microbial hazards in the environment, especially those that demonstrate higher levels of resistance to environmental conditions, such as spore-formers (Ref. 63).

Precipitation and its effects (e.g., discharge and flow rate), along with temperature, are common factors reported to affect the microbial quality of watersheds with agricultural land

inputs. Seasonal changes in rainfall--particularly heavy rainfall and flooding events--can greatly affect surface water quality (Refs. 33 and 62) and may result in sediments, which can serve as reservoirs for pathogens, being dispersed within the water column (Ref. 68). One study (Ref. 48) found that that as rainfall increases, populations of various indicators (fecal coliforms, generic *E. coli*, *Enterococcus*) increased; moreover, swine-specific markers were detected more frequently in water samples in the 48 hours following a rainfall event greater than the mean.

Rainfall events are reported to result in enhanced loading of fecal pollutants from adjacent lands into water systems (Ref. 63) and increased transport of pathogens onto growing fields (Ref. 63). Alternately, rainfall may also have a dilution effect on pathogens or indicator organisms that are already present in growing areas (Ref. 63). Although more research is needed, the possibility of splash dispersal and internalization of pathogens may also become problematic during periods of rainfall (Refs. 62 and 69), especially when increased levels of pathogens are transported to growing areas.

#### 11. Other Relevant Factors

Under proposed § 112.43(a)(5), covered farms would consider any other factors relevant to identifying any conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce (other than sprouts) or food contact surfaces. Those relevant factors may include, for example, whether the covered farm elected to conduct testing under § 112.43(d) to help inform its agricultural water assessment, as discussed below.

#### 12. Written Annual Assessments

Under proposed § 112.43(a), covered farms using pre-harvest agricultural water for non-sprout covered produce would prepare a written assessment of their pre-harvest agricultural water, at least once each year, to identify any conditions that would be reasonably likely to introduce known or reasonably foreseeable hazards into or onto non-sprout covered produce or food contact surfaces, unless the farm is exempt under proposed § 112.43(b).

A written agricultural water assessment would help FDA to verify that covered farms conducted comprehensive assessments that included all of the elements required by proposed § 112.43(a) and made a written determination as required by proposed § 112.43(c). A written agricultural water assessment also would allow covered farms using pre-harvest water for non-sprout produce to more effectively manage their agricultural water (such as in evaluating the effectiveness of any mitigation measures), identify trends and changes impacting their agricultural water systems (such as a change in nearby land use that might introduce known or reasonably foreseeable hazards), and help identify potential sources of contamination of the water system and covered produce. Records of annual agricultural water assessments also would help covered farms in determining whether changed conditions would require covered farms to conduct a reassessment under proposed § 112.43(f)(2), prior to an annual reassessment.

The proposed requirement for an annual, written agricultural water assessment for pre-harvest agricultural water, with the elements described in paragraphs (a)(1)-(5), aligns with the Codex Code Section 3.2.1.1 (Ref. 63), which recommends the assessment of agricultural water for suitability for use, and the USDA Harmonized GAP Plus+ Standard, section F-4.1 (Ref. 70).

### 13. Proposed § 112.43(b)--Exemptions

Proposed § 112.43(b) would create various exemptions from the requirement to conduct an assessment of pre-harvest agricultural water for application to non-sprout covered produce.

Under proposed § 112.43(b)(1), a covered farm would be exempt from the requirement to conduct an assessment for pre-harvest agricultural water if the farm can demonstrate that the agricultural water meets the requirements of proposed § 112.44(a), which is applicable to agricultural water used for sprout irrigation or for harvest or post-harvest uses--i.e., untreated ground water that meets the microbial water quality criterion of no detectable generic *E. coli*, based on testing requirements in proposed §§ 112.44(b), 112.47, and 112.151. The exclusion in proposed § 112.43(b)(1) does not apply to untreated surface water, because proposed § 112.44(a)

prohibits the use of untreated surface water for sprout irrigation or harvest or post-harvest application on covered produce.

For example, if a covered farm uses the same untreated ground water source for pre-harvest and harvest application to non-sprout covered produce, the farm would be exempt from conducting an agricultural water assessment for the untreated ground water provided that the farm could demonstrate, through results of testing as required by proposed §§ 112.44(b), 112.47, and 112.151, that its agricultural water meets microbial water quality criterion in proposed § 112.44(a).

Ground water obtained from deep underground aquifers with properly designed, located, and constructed wells, is not subject to the impacts of runoff from adjacent and nearby lands and similar conditions evaluated as part of an agricultural water assessment. As explained in the 2015 produce safety final rule (80 FR 74354 at 74430), the microbial quality requirement of no detectable generic *E. coli* in § 112.44(a) in untreated ground water is intended to address the known or reasonably foreseeable hazards associated with fecal contamination of agricultural water. The stringency of the requirements in proposed § 112.44(a) is commensurate with the risks associated with using contaminated water for sprout irrigation and for harvest and post-harvest uses.

Proposed § 112.43(b)(2) would exempt a covered farm from the requirement to conduct an agricultural water assessment for pre-harvest agricultural water for non-sprout covered produce that a covered farm receives from a public water system that the covered farm can demonstrate:

- Meets the microbial requirements of EPA Safe Drinking Water Act (SDWA) regulations in 40 CFR part 141 (or the regulations of a State approved to administer the SDWA program) through public water system results or certificates of compliance or
- Meets the microbial quality criterion in § 112.44(a) through public water system results or certificates of compliance.

Proposed § 112.43(b)(3) would exempt a covered farm from the requirement to conduct an agricultural water assessment for pre-harvest agricultural water for non-sprout covered produce that is treated in accordance with proposed § 112.46 (such as through application of an EPA-registered antimicrobial pesticide product).

Although we are not proposing to require covered farms to treat their agricultural water to meet applicable requirements, we note that scientists from FDA's Center for Food Safety and Applied Nutrition have developed a test protocol for evaluating the efficacy of antimicrobial chemical treatments against public health organisms in agricultural water sources and submitted it to EPA. On April 29, 2020, EPA approved FDA's testing protocol, which potential chemical registrants can now use to develop data to support registration of their pesticide products for treatment of agricultural water used during growing activities (Ref. 71).

We tentatively conclude that an agricultural water assessment would not be necessary when a covered farm can demonstrate that its pre-harvest agricultural water for non-sprout covered produce meets the microbial quality criterion of no detectable generic *E. coli* and testing requirements that would be applicable to agricultural water for sprout irrigation and harvest and post-harvest uses; EPA drinking water standards or other public water supply standards; or the treatment requirements in proposed § 112.46. We seek comment on this tentative conclusion.

#### 14. Proposed § 112.43(c)--Outcomes

Under proposed § 112.43(c), a covered farm would use the information gathered through inspection and maintenance of its agricultural water system and evaluation of its agricultural water practices, the crop characteristics, environmental conditions, and other relevant factors for hazard identification purposes, as described in § 112.43(a). The covered farm also would make a written determination of any corrective or mitigation measures to implement based on:

- The farm's evaluation of factors described in proposed § 112.43(a)(1) through (5);

- Any conditions the farm identified that would be reasonably likely to introduce known or reasonably foreseeable hazards (specifically, biological hazards, as explained in section III.B.) into or onto covered produce or food contact surfaces; and
- The results of any inspections and maintenance conducted by the farm, pursuant to proposed § 112.42, of any agricultural water systems used during growing activities for non-sprout covered produce.

Proposed § 112.43(c) would require a covered farm to record the determination in the written agricultural water assessment and take appropriate action, as described in table 4:

Table 4.--Summary of Outcomes of a Pre-Harvest Agricultural Water Assessment for Covered Produce (Other than Sprouts) (Proposed § 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)	<ul style="list-style-type: none"> <li>• Immediately discontinue use(s) <i>And</i></li> <li>• Take corrective measures before resuming use of the water for pre-harvest activities</li> </ul>
there is one or more known or reasonably foreseeable hazards related to animal activity, BSAAOs, or untreated or improperly treated human waste for which mitigation is reasonably necessary	<ul style="list-style-type: none"> <li>• Implement mitigation measures promptly, and no later than the same growing season,</li> </ul>
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	<ul style="list-style-type: none"> <li>• Implement mitigation measures as soon as practicable and no later than the following year <i>Or</i></li> <li>• Test water as part of the assessment and implement measures, as needed, based on the outcome of the assessment</li> </ul>
that there are no known or reasonably foreseeable hazards for which mitigation is reasonably necessary	<ul style="list-style-type: none"> <li>• Regularly (at least once each year) inspect and adequately maintain the water system(s)</li> </ul>

With respect to pre-harvest agricultural water for non-sprout covered produce, under proposed § 112.43(c):

- If the covered farm determines the agricultural water is not safe or is not of adequate sanitary quality for its intended use(s), the farm would be required to immediately discontinue use of the water and take corrective measures under proposed § 112.45(a) before resuming such use(s);
- If the covered 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 related to animal activity, a biological soil

amendment of animal origin, or untreated or improperly treated human waste on an adjacent or nearby land, the farm would be required to implement the mitigation measures within the same growing season as the assessment.

- If the covered 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 proposed § 112.45(b) as soon as practicable and no later than the following year; or
  - test the water, pursuant to proposed § 112.43(d), consider the results as part of the assessment in making a determination under § 112.43(c), and implement measures as needed under proposed § 112.45;
- If the covered farm determined that no corrective or mitigation measures under proposed § 112.45 were reasonably necessary to reduce the potential for contamination of such produce or food contact surfaces, the farm would be required to regularly inspect and adequately maintain the agricultural water system(s) under proposed § 112.42, and conduct a written agricultural water assessment annually and whenever a significant change occurs (such as a change in the manner or timing of water application) that would increase the likelihood that a known or reasonably foreseeable hazard would be introduced into or onto covered produce or food contact surface.

We are maintaining the requirements for corrective measures in § 112.45(a), as explained and supported by the 2015 produce safety final rule (80 FR 74354 at 74429-74431, 74440-74441), including the requirement that if a covered farm determines or has reason to believe that the agricultural water is not safe or of adequate sanitary quality for its intended use, then the farm must immediately discontinue such use. For example, if in performing the



agricultural water assessment a covered farm finds that there is a dead and decaying sheep in the canal upstream and at a close distance from where it draws water, the farm would have reason to believe that the agricultural water is not safe or of adequate sanitary quality for its intended use because the water is reasonably likely to contain human pathogens transferred by the dead and decaying sheep. Therefore, the farm would have to immediately discontinue that use of the water and take corrective measures under proposed § 112.45(a) before resuming such use(s).

We also are maintaining the requirements to mitigate other risks as soon as practicable and no later than the following year, also supported by the produce safety final rule (80 FR 74354 at 74441-74446), except that a covered farm would be required to implement mitigation measures under proposed § 112.45(b) 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 promptly, and no later than the same growing season as the agricultural water assessment. For example, if in performing their agricultural water assessment, a covered farm identifies upstream lands used for animal grazing from which runoff is likely to introduce known or reasonably foreseeable hazards into the water source based on the topography of the land, the farm would be required to implement mitigation measures promptly, and no later than the same growing season as the agricultural water assessment. (We note that proposed § 112.43(c)(2) is not intended to include those situations in which animal or human waste impacts result in water no longer being safe or of adequate sanitary quality for its intended use under § 112.41. In those instances, a covered farm would be required under § 112.43(c)(1) to immediately discontinue that use of the water and take corrective measures under § 112.45(a) before resuming such use.)

Animal activity, BSAAOs, and untreated or improperly treated human waste have been identified as possible causal or contributing factors in several large produce outbreaks in recent years. The pathogens associated with animal and human waste are well established, as are the

risks associated with introduction of animal or human waste into agricultural water used in growing covered produce (Ref. 11).

Subparts B, F, I, and L of the produce safety regulation require covered farms to take appropriate measures to minimize the risk of serious adverse health consequences or death from the use of, or exposure to, covered produce, including those measures reasonably necessary to prevent the introduction of known or reasonably foreseeable hazards associated with animal activity, BSAAOs, and untreated and improperly treated human waste on the covered farm.

In considering how best to achieve public health protections under this proposed approach, we determined that animal activity, BSAAOs, or human waste impacts on water sources and systems related to adjacent or nearby lands should elicit an expedited timeline for implementation of mitigation measures. We recognize that activities associated with adjacent or nearby lands that introduce contaminants into a water source or distribution system are often not under a covered farm's control. While the covered farm may not have control over potential hazards at their point of introduction into a water source or system, the potential hazards are no less important for the farm to consider when determining the safe use of agricultural water on covered produce. Therefore, it is important that the covered 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.

#### 15. Proposed § 112.43(d)--Testing for Assessment Purposes

Proposed § 112.43(d) would establish the requirements applicable to testing that a covered farm chooses to conduct to provide additional information for its agricultural water assessment. The testing option for pre-harvest agricultural water for non-sprout covered produce under proposed § 112.43(d) is science-based and also provides for flexibility as science evolves. For example, a covered farm that opts to test pre-harvest agricultural water under this provision would be required to test its agricultural water for generic *E. coli* as an indicator of fecal

contamination, but also may test for another scientifically valid indicator organism, index organism, or other analyte.

Proposed § 112.43(d) also would require that samples of pre-harvest agricultural water tested as part of an agricultural water assessment be collected aseptically immediately prior to or during the growing season, representative of the water used in growing non-sprout covered produce, and tested using a scientifically valid method.

Additionally, proposed § 112.43(d) would 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.

*a. Generic E. coli.* *E. coli* remains a commonly used analyte used as an indicator of fecal contamination and currently is the preferred indicator for monitoring water quality (80 FR 74354 at 74428). However, 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. 72). Additionally, as part of the 2017 5-year review of the 2012 RWQC, EPA evaluated the science related to the recreational waters and public health to determine if revisions to the criteria (which specify densities for enterococci and generic *E. coli*) were appropriate (Ref. 73). While it did not ultimately revise the 2012 RWQC during the 2017 review cycle, EPA emphasized that further scientific research and analysis is likely to contribute to future reviews of the 2012 RWQC. EPA noted, in part, that with further scientific development, the use of viral indicators such as coliphages may help to further advance public health protections. FDA

anticipates that as science evolves and more information about other indicator or index organisms is learned, testing for other organisms may be used to inform pre-harvest agricultural water assessments by covered farms, if finalized as proposed.

*b. Frequency of sampling.* The 2015 produce safety final rule established sampling frequencies for covered farms to use in developing microbial water quality profiles for pre-harvest agricultural water for non-sprout covered produce. For untreated surface waters, this consists of an initial profile of at least 20 samples collected over a 2-4-year period, followed by at least 5 annual samples thereafter; for untreated ground water sources, this consists of an initial profile of at least 4 samples collected during the growing season or over a period of one year, followed by at least 1 annual sample thereafter (80 FR 74354 at 74452) (Ref. 74).

During outreach activities, some stakeholders, including covered farms and some State regulators, indicated that they found the pre-harvest microbial water quality criteria and testing requirements in the 2015 produce safety final rule to be overly complex. (See section III.B. through III.C.) Some farms anticipated that it would be infeasible to implement the pre-harvest agricultural water testing requirements in their operations--and asked for additional flexibility--in addition to the alternatives and variances already allowed by the produce safety regulation. Moreover, various stakeholders shared the opinion that, as new science continues to become available in the realm of water quality monitoring, farms should have the flexibility to take those findings into account when establishing or updating their sampling programs (Refs. 3 and 75).

We continue to believe that the information used to support the sampling frequencies in the 2015 produce safety final rule for pre-harvest agricultural water for non-sprout covered produce is well-grounded, broadly-applicable science. Therefore, for purposes of proposed § 112.43(d), covered farms that opt to test their untreated surface water for purposes of proposed § 112.43(d) may initially collect at least 20 samples over a 2-4-year period, with at least 5 samples collected annually thereafter; covered farms that opt to test their untreated ground water may initially collect at least 4 samples over a growing season or year, with at least 1 sample

collected annually thereafter. Depending on the conditions that may affect their pre-harvest agricultural water, covered farms may consider collecting additional samples as needed to better understand 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 their pre-harvest agricultural water for non-sprout covered produce.

We recognize that there are circumstances--for example, when access to a body of water varies from year to year--in which some covered farms may not be able to collect samples spanning multiple years. In situations such as these, covered farms may consider collecting at least 5 samples per year for untreated surface water sources, or at least 4 samples per year for untreated ground water sources used for pre-harvest application to non-sprout covered produce.

However, we are also providing flexibility in proposed § 112.43(d)(3) for covered farms to use any sampling frequency when testing under proposed § 112.43(d)(3), provided that it is adequate to assist in determining, in conjunction with other data and information evaluated under § 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 for non-sprout covered produce. For example, other options could include sampling frequencies a covered farm establishes based on its historical data and/or knowledge of water quality variability within its source. A covered farm also could, for example, include consideration for other site- or region-specific data or information indicating that a certain sampling frequency is appropriate. We expect that as covered 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--that such information may be used to establish sampling frequencies that are appropriate to their specific circumstances and conditions.

*c. Microbial water quality criteria.* The microbial water quality criteria established by the 2015 produce safety final rule for pre-harvest agricultural water consist of a GM of 126 colony forming units (CFU) generic *E. coli* per 100 milliliters (mL), and an STV of 410 CFU generic *E. coli* per 100 mL--using the science underlying EPA's RWQC (80 FR 74354 at 74441-74442).

The information used to support the pre-harvest agricultural water quality criteria in the 2015 produce safety final rule is the best science currently available that is broadly applicable to the range of conditions that exist across the diversity of operations, agricultural water sources, and agricultural water uses of domestic and foreign covered farms. Therefore, if a covered farm decides to test its pre-harvest agricultural water for generic *E. coli* under proposed § 112.43(d) to inform its agricultural water assessment, the farm may use 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 as microbial criteria.

However, we acknowledge stakeholder concerns and recognize that the science around agricultural water quality criteria continues to evolve (Ref. 3). We recognize that there may be other options for microbial water quality criteria (for example, alternative criteria relevant to an indicator organism other than generic *E. coli*).

Proposed § 112.43(d) would offer additional flexibility to apply any microbial criterion or criteria that would be scientifically valid and appropriate to assist in determining, in conjunction with other data and information evaluated under proposed § 112.43(a), whether measures under § 112.45 are reasonably necessary to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with known or reasonably foreseeable hazards associated with pre-harvest agricultural water. We are not proposing to require that covered farms notify or seek approval from FDA prior to applying a microbial criterion or criteria when electing to test their pre-harvest agricultural water. Rather, we would provide flexibility for a covered farm to determine which microbial criterion or criteria to apply, when supported by scientific data or information demonstrating scientific validity and appropriateness

under proposed § 112.43(d). For example, a covered farm could rely on microbial criterion or criteria available in the scientific literature or made available by a third party, such as a trade association, provided that the microbial criterion or criteria would be scientifically valid and appropriate based on the circumstances.

When possible, covered farms may continue to collect water quality data over time--whether historical data, new data, or both--that can assist in analyzing trends. For example, this approach may be useful in situations in which potential hazards are introduced into a water system intermittently, such that a covered farm is able to compare data to further refine its assessments of whether measures under § 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.

*d. Records relating to analytes, sampling frequencies, and pre-harvest water quality criteria.* If a covered 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 covered farm could document its use of such sampling frequencies and microbial criteria in meeting the requirements of proposed § 112.50(b)(4), as we have already determined these sampling frequencies and microbial criteria to be scientifically valid and appropriate for purposes of proposed § 112.45(b).

Under proposed § 112.50(b)(3)-(4), a covered farm that tests its pre-harvest agricultural water using a scientifically valid indicator organism other than generic *E. coli*, or an index organism or other analyte would be required to maintain records under proposed § 112.50 of the scientific data or information used to support its selection of other indicator organism, index organism, or other analyte, as well scientifically valid and appropriate sampling frequency and microbial criterion (or criteria) being applied. (See also section VI.G. regarding proposed records requirements.)

Such data and information could be developed by the covered farm, available in the scientific literature, or available to the farm through a third party. Such scientific support could be derived from the science underlying commodity-specific or other guidance or recommendations, including those developed by industry, academia, trade associations, or other stakeholders.

#### 16. Proposed § 112.43(e)--Reassessment

Under proposed § 112.43(e), a covered farm would conduct an agricultural water assessment, at a minimum, each year that the farm applies pre-harvest agricultural water to non-sprout covered produce. A covered farm also would 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 § 112.43(c). For example, a change from an untreated ground water source to an untreated surface water source would be a significant change that would require a reassessment under proposed § 112.43(e). The reassessment would evaluate the impacts of those changes on the factors in proposed § 112.43(a)(1) through (5), any new hazards identified, and the outcome and determination under proposed § 112.43(c).

Agricultural water assessments are the primary tool that covered farms would use under this proposed rule for hazard identification and risk management for their pre-harvest agricultural water used for non-sprout covered produce. Specifically, covered farms would use the outcomes of their pre-harvest agricultural water assessments (proposed § 112.43), together with the results of any inspections and maintenance performed (proposed § 112.42), in determining whether measures (proposed § 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 pre-harvest agricultural water.



The proposed requirements for an agricultural water assessment align with domestic produce safety standards, such as the USDA Harmonized GAP Plus+ Standard, section F-4.1 (Ref. 70), and international standards, such as the Codex Code Section 3.2.1.1 (Ref. 62), which recommends the periodic assessment of agricultural water for suitability for use.

For the foregoing reasons, we have tentatively concluded that it would be reasonable and appropriate to require covered farms to conduct a written pre-harvest agricultural water assessments annually, and whenever significant changes would impact the hazard identification or risk management determination relating to pre-harvest agricultural water for non-sprout covered produce.

#### *F. Mitigation Measures (Proposed § 112.45)*

Proposed § 112.45 would establish requirements for implementing corrective and mitigation measures for pre-harvest, harvest, and post-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. This provision is supplemented by proposed § 112.42, which would require covered farms to conduct routine maintenance of agricultural water systems to the extent of their control including, for example, taking steps to prevent pooled water from contaminating covered produce.

We are proposing to retain the requirement from § 112.45(a) of the produce safety regulation to immediately discontinue use of any agricultural water that is not safe or not of adequate sanitary quality for its intended use(s), until the covered farm implements effective corrective measures and the agricultural water meets the requirements of § 112.41. We also propose to retain the requirement, from § 112.45(a) of the produce safety regulation, to discontinue use of harvest or post-harvest water that does not meet the microbial water quality criterion in § 112.44(a) until effective corrective measures are implemented.

Under this proposed rule, a covered farm would make a determination under § 112.43(c), based on the outcome of its agricultural water assessment, as to whether mitigation measures would be 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 pre-harvest agricultural water. A covered farm would be required to implement mitigation measures under proposed § 112.45(b) as soon as practicable and no later than one year after the date of the agricultural water assessment or reassessment (as required by proposed § 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 its assessment. (See the discussions of adjacent and nearby land uses and outcomes in section VI.E.)

Under proposed § 112.45(b), mitigation measures include:

- Making 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;
- Increasing the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off (with a minimum interval of 4 days between application and harvest, except as supported by test results conducted under proposed § 112.43(d), or other scientifically valid data or information in accordance with proposed § 112.12);
- Increasing the time interval between harvest and the end of storage using an appropriate microbial die-off rate, and/or conducting other activities, such as commercial washing, to reduce pathogens using appropriate microbial removal rates, except as supported by scientifically valid data and information;

- Changing the method of water application to reduce the likelihood of produce contamination (such as by changing from overhead spray to subsurface drip irrigation of certain crops);
- Treating the water in accordance with proposed § 112.46; and
- An alternative mitigation measure, in accordance with proposed § 112.12.

We are revising our approach to mitigation measures involving microbial die-off and/or removal in proposed § 112.45(b)(1) to reflect our proposal to remove the pre-harvest microbial quality criteria and testing requirements from the produce safety rule. These changes also reflect feedback we have received throughout stakeholder engagement activities.

Proposed § 112.45(b)(1)(i) would provide for an established time interval between last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off, with a minimum interval of 4 days between application and harvest, except as supported by test results conducted under § 112.43(d), or other scientifically valid data or information in accordance with § 112.12.

Survival of pathogens and other microorganisms on produce commodities prior to harvest is dependent upon several environmental factors, including sunlight (UV) intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate (Ref. 55). Generally, pathogens and other microbes die-off or are inactivated relatively rapidly under hot, dry, and sunny conditions compared to inactivation rates observed under cloudy, cool and wet conditions. The impact of these variables results in a range of microbial die-off rates of 0.5 to 2.0 log per day, as explained in the 2015 produce safety final rule (80 FR 74534, 74443-74446).

In general, high initial rates of die-off during the period immediately following contamination suggests field conditions through the first few days are critical in reducing microbial populations on produce compared to weeks after the event. (80 FR 74354 at 74445.) In studies reporting decay constant(s) measured over time (e.g., 0 hours to 14 days or more),

pathogen die-off rates were found to be highest immediately following contamination (inoculation) and to slow over time; this phenomenon is known as "tailing" and suggests that pathogen die-off curves are biphasic (80 FR 74354 at 74445).

A die-off rate of 0.5 log per day provides a reasonable estimate of die-off under a broad range of variables including pathogen characteristics, environmental conditions, crop type, and watering frequency (80 FR 74354 at 74416). We derived this die-off rate based on a review of currently available scientific literature and recognize that microbial die-off rates are dependent on various environmental factors, including sunlight intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate.

We reviewed available literature for a time interval that is appropriate when applying a microbial die-off rate of 0.5 log per day. (See 80 FR 74354 at 74444-74445.) The studies we reviewed indicate that greater microbial die-off or decay rates occur during the early timeframe post-contamination, and although the die-off rate in these studies was established from survival data or decay rates for bacterial studies ranging from 2-7 days, the specific timeframe for the biphasic shift in die-off was not identified. Within this range identified in the literature, we determined that a time interval of 4 days is reasonable because it serves as a general mid-point in time representing neither end of the range where microbial die-off was observed in these studies.

Based on this information, in § 112.45(b)(1)(i)(A) of the produce safety final rule, we allowed covered farms to apply a time interval between last irrigation and harvest using a microbial die-off rate of 0.5 log per day, for no greater than 4 days, if their water quality exceeded the pre-harvest microbial water quality criteria (80 FR 74354 at 74443). We consider the scientific data used to support this approach as one example of adequate supporting scientific data and information on which a time interval between last direct application and harvest could be established under proposed § 112.45(b). Therefore, we have tentatively concluded that it would be appropriate to allow covered farms to use the following approaches for implementing a pre-harvest time interval as a mitigation measure under proposed § 112.45(b), without having to

develop and maintain additional supporting scientific data and information. We seek comment on this tentative conclusion.

#### 1. Time Interval without Testing Data

If a covered farm does not test its pre-harvest agricultural water as part of an agricultural water assessment under proposed § 112.43(d) but determines that the application of a time interval prior to harvest would be an appropriate mitigation measure, the farm could use a time interval between last direct application of agricultural water and harvest of at least 4 days. This would correspond to the broadly-applicable time frame identified in the 2015 produce safety final rule that corresponds to the amount of time associated with the first phase of die-off, when bacterial reduction rates are greatest on produce surfaces and before “tailing” of bacterial populations occurs. Lacking quantitative test data, the covered farm could not use less than 4 days as a time interval between last direct application and harvest under proposed § 112.45(b)(1)(ii), unless the farm had scientifically valid data or information to support use of a die-off rate of 0.5 log per day for less than 4 days in accordance with proposed § 112.12.

#### 2. Time Interval with Testing Data

If a covered farm tests its pre-harvest agricultural water as part of an agricultural water assessment under proposed § 112.43(d) and determines that the application of a time interval prior to harvest is an appropriate mitigation measure, the farm could choose to use a microbial die-off rate of 0.5 log per day, for potentially less than 4 days between last direct water application and harvest, to achieve a (calculated) log reduction to meet the criteria the farm would establish per proposed § 112.43(d)(3). (Alternately, the covered farm could choose to use a different time interval (and accompanying die-off rate) if the farm has scientifically valid data or information in accordance with proposed § 112.12.)

While we consider the information used to support the use of a die-off rate of 0.5 log per day with a maximum time interval of 4 days as being one example of adequate supporting scientific data and information on which a time interval between last direct application and

harvest could be established under proposed § 112.45(b), we recognize that covered farms may have additional information on in-field die-off that is applicable to their unique circumstances. For example, we acknowledged in both the 2014 supplemental produce safety notice and the 2015 produce safety final rule that practices and conditions on a covered farm and circumstances unique to a specific commodity could result in higher die-off rates between last irrigation and harvest, especially with little or no precipitation, coupled with high ultraviolet radiation, high temperature exposures, or low humidity.

Moreover, during outreach activities related to agricultural water (as described in section III.C), stakeholders described the diversity of pathogens, commodities, and climates that may be associated with different microbial die-off rates and/or time intervals. We also are aware that further research on the various conditions that exist is likely to impact the appropriate use of a pre-harvest application interval (Ref. 3). As more studies are conducted that examine in-field die-off in various circumstances (Refs. 76-78), we expect that this is an area where science will continue to evolve.

Therefore, to provide additional flexibility to allow for future science while continuing to protect public health, we are proposing to allow covered farms to use a time interval other than the minimum 4 days between last direct water application and harvest as a mitigation measure, if they have adequate supporting scientific data and information. We expect that any microbial die-off rate and accompanying maximum time interval that a covered farm establishes and uses would be supported by an equally robust and rigorous scientific analysis to that described above for the 0.5 log per day die-off rate with accompanying 4-day time interval. We expect that scientific data and information used to support a pre-harvest time interval would be relevant to conditions on the covered farm (such as the region, crop, and environment), and be similarly characterized in a manner that addresses the likely biphasic nature of microbial die-off (i.e., the two different decay constants of a rapid short-term die-off and a gradual long-term die-off). We also expect that the scientific approach would not increase the likelihood that the

covered produce will be adulterated compared to the microbial die-off rate standard in § 112.45(b)(1)(i)(A) of the produce safety regulation.

Consistent with § 112.45(b)(1)(ii) of the produce safety regulation, we are proposing to allow covered farms to increase the time interval between harvest and the end of storage to allow for microbial die-off, and/or adopt activities such as commercial washing that result in microbial removal as a mitigation measure. This proposed revision reflects our proposal to remove the pre-harvest microbial quality criteria and testing requirements from the produce safety regulation and would allow a covered farm to use microbial die-off or removal post-harvest (i.e., between harvest and end of storage, and during activities such as commercial washing) as a mitigation measure, provided the covered farm has adequate supporting scientific data and information.

We are not proposing to establish a specific microbial die-off rate(s) between harvest and end of storage or specific microbial removal rate(s) during postharvest activities such as commercial washing. The World Health Organization has attributed a 1-log reduction in microbial load to washing (Ref. 55). (See also 79 FR 58434 at 58446.) As discussed in the produce safety supplemental notice and final rule, we do not have sufficient information to support the derivation of appropriate, broadly-applicable microbial die-off or removal rate(s) for this purpose. While it is reasonable to expect some die-off during post-harvest storage, the rate and accompanying time interval would be highly dependent upon the conditions of storage. Covered farms would be able to more narrowly define die-off and/or removal rates associated with their specific production practices, and apply an appropriate time interval between harvest and end of storage and/or adopt activities such as commercial washing that result in microbial removal, as applicable to their circumstances. We are proposing to provide this option so that a covered farm may account for microbial die-off or removal during post-harvest activities (i.e., between harvest and end of storage, and during activities such as commercial washing), provided the farm has adequate scientific data or information to support the conclusions in accordance with proposed § 112.12.

In light of recent produce outbreaks (including the outbreaks described in section III.D.), we are proposing in § 112.45(b)(1) to require expedited mitigation for known or reasonably foreseeable hazards from animal activity, BSAAOs, or untreated or improperly treated human waste associated with adjacent or nearby lands.

For any other identified hazards, proposed § 112.45(b)(1) would require covered farms to implement mitigation measures as soon as practicable and no later than one year after the date of the agricultural water assessment (as required by proposed § 112.43). This requirement aligns with § 112.45(b) of the produce safety regulation, which requires mitigation measures to be implemented as soon as practicable and no later than the following year.

Proposed § 112.45(b)(2) would provide that if a covered farm failed to implement appropriate mitigation measures, or if the farm determined that the measures were not effective to reduce the potential for contamination of non-sprout covered produce or food contact surfaces with any known or reasonably foreseeable hazards, the farm must discontinue use of the pre-harvest agricultural water until it has implemented mitigation measures adequate to reduce the potential for such contamination, consistent with § 112.41.

We note that while not considered agricultural water for purposes of subpart E, indirect water application methods, such as the use of drip tape in a manner that water is not likely to contact the harvestable portion of the crop, remain subject to section 402 of the FD&C Act. That is, indirect water application may adulterate produce if, considering the water quality and the manner of its application, the use of the water causes produce to be prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or rendered injurious to health under section 402(a)(4) of the FD&C Act. For example, if a farm uses drip tape in a way that water does not normally contact the harvestable portion of the crop, unintentional contact may still occur if the drip tape begins to leak sprays water on the crop. Although not considered agricultural water for purposes of subpart E, the farm should consider whether the source of water may have caused the produce to become adulterated under section



402 of the FD&C Act (for example, the farm may consider the conditions described in proposed § 112.43(a)(1)) and, if so, dispose of the product appropriately.

*G. Records Requirements for Pre-Harvest Agricultural Water Assessments (Proposed § 112.50)*

We propose to amend the records requirements in § 112.50 of the produce safety regulation to conform with proposed subpart E and to add new requirements for records relating to pre-harvest agricultural water assessments and the optional testing that certain covered farms may elect to conduct under proposed § 112.43.

1. Records of Pre-Harvest Agricultural Water Assessments

Proposed § 112.50(b)(2) would require covered farms to maintain records of their agricultural water assessments, including written determinations on whether mitigation measures under proposed § 112.45(b) would be 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.

Effective water management includes records necessary to confirm that agricultural water is safe and of adequate sanitary quality for its intended use(s). Records of pre-harvest agricultural water assessments would be critical for a covered farm to maintain to ensure its own compliance with the requirements of proposed § 112.43. For example, records of agricultural water assessments would be helpful to a covered farm in determining whether changed conditions were sufficient to trigger the requirement to conduct a reassessment under proposed § 112.43(f)(2), prior to an annual reassessment.

Such records also are important for FDA to verify, for example, that the covered farm evaluated all the required elements of an assessment listed in proposed § 112.43(a), in support of a written determination, under proposed § 112.43(c), regarding whether mitigation 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 agricultural water used in growing non-sprout covered produce.

## 2. Records Relating to Testing Pre-Harvest Agricultural Water for Analytes Other than Generic *E. coli*

Under proposed § 112.50(b)(3), a covered farm that tests its pre-harvest agricultural water to inform its agricultural water assessment and uses an indicator of fecal contamination, index organism, or other analyte other than generic *E. coli*, would be required to retain records of the scientific data or information the farm relies on to support the use of such analyte. These records would be necessary for a covered farm to ensure, and for FDA to verify, that appropriate scientific methods are being used when the farm elects to test its pre-harvest agricultural water under proposed § 112.43(d) to inform its agricultural water assessment.

## 3. Records Relating to the Sampling and Microbial Criterion (or Criteria) Applied for Pre-Harvest Agricultural Water

Under proposed § 112.50(b)(4), a covered farm that tests its pre-harvest agricultural water would be required to maintain records of the scientific data or information it relied on to support the sampling and testing methods and the microbial criterion (or criteria) it applied. Records of sampling protocols, testing methods, and microbial criterion (or criteria) would be necessary for a covered farm that uses testing to ensure that the frequency of testing samples and microbial criteria applied are adequate to assist in determining, in conjunction with other data and information from their assessment, whether mitigation measures are reasonably necessary. Such records would allow FDA to help verify a covered farm's compliance with proposed § 112.43(d).

Additionally, we would amend § 112.50(b) of the produce safety regulation to:

- Move paragraph (b)(2) to proposed § 112.50(b)(5), and as a clarifying edit add the phrase, “including any testing conducted for purposes of §§ 112.43 and 112.44”;
- Move paragraphs (b)(3) through (b)(4) to proposed § 112.50(b)(9) through (b)(10);
- Move paragraph (b)(5) to proposed § 112.50(b)(8) and remove the phrase “, in accordance with § 112.45(b)(1)(ii)”;

- Move paragraph (b)(6) to proposed § 112.50(b)(7) and remove the phrase “in accordance with § 112.45(b)(1)(ii) and/or (b)(1)(iii)”;
- Move paragraph (b)(7) to proposed § 112.50(b)(6) and replace “§ 112.46(a)(1) or (2)” with “§ 112.44(c)(1) or (c)(2)”;
- Remove paragraph (b)(8); and
- Move paragraph (b)(9) to proposed § 112.50(b)(11).

*H. Conforming Changes (Proposed §§ 112.12, 112.151, and 112.161)*

As conforming changes in light of our proposal to remove 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) of the produce safety regulation, we would:

- Amend § 112.12 to replace “§ 112.49” with “§ 112.45(b)”;
- Amend the section heading of § 112.151 to replace “§ 112.46” with “subpart E”; and
- Amend § 112.151(b)(2) to replace “§ 112.49(a)” with “§ 112.43(d)”.

As an additional conforming change, we propose to revise the requirements of § 112.161(b) of the produce safety regulation to require supervisory review of records of pre-harvest agricultural water assessments and determinations, given the essential role of such records in establishing compliance with the requirements of proposed § 112.43 and in confirming that pre-harvest agricultural water is safe and of adequate sanitary quality for its intended use(s). Therefore, in § 112.161 of the produce safety regulation, we would replace “(b)(4), and (b)(6)” with “(b)(7), and (b)(10)”.

*I. Other Amendments (Proposed §§ 112.42, 112.44, and 112.46-112.49)*

1. Proposed § 112.42

To provide additional clarity around certain language, based on stakeholder feedback and questions, we would:

- Add descriptive headings to paragraphs (a) and (b);

- Consolidate the requirements for maintenance of agricultural water systems in § 112.43(b), (c), and (d) into § 112.42(b)(1)-(4); and
- Clarify the descriptions of possible maintenance measures for pooled water in § 112.42(b)(4).

## 2. Proposed § 112.44

As part of the proposed reorganization of subpart E to group provisions of a similar nature (i.e., requirements specific to pre-harvest agricultural water, sprout irrigation water, and harvest/post-harvest agricultural water), we would:

- Revise the section heading of § 112.44 of the produce safety regulation by adding “and testing requirements” after “criteria” and by replacing “certain intended uses” with “sprout irrigation and for harvesting, packing, and holding covered produce”;
- Move § 112.46(c) of the produce safety regulation to proposed § 112.44(b), add a paragraph heading, “*Untreated ground water.*”, and replace “§ 112.44(a)” with “paragraph (a)” wherever it appears;
- Move § 112.46(a) of the produce safety regulation to proposed § 112.44(c) and add a paragraph heading, “*Exemptions.*” and replace “§ 112.43” with “§ 112.46”; and
- Move the text of § 112.48 of the produce safety regulation to proposed § 112.44(d) and add a paragraph heading, “*Additional management and monitoring practices.*”

## 3. Proposed § 112.46

As part of our reorganization of subpart E for clarifying purposes, we are proposing to move the treatment provision from § 112.43 of the produce safety regulation to § 112.46.

## 4. Proposed § 112.47

As clarifying edits, we would:

- In § 112.47(a) of the produce safety regulation, replace “§ 112.46” with “§§ 112.43(c)(4)(ii) and “112.44” and

- In § 112.47(b) of the produce safety regulation, replace “method as set forth in § 112.151” with “method set forth in § 112.151, as applicable”.

#### 5. Proposed § 112.48

As part of our reorganization of subpart E, we would move the requirements in § 112.48 of the produce safety regulation to proposed § 112.44(d), which would contain other requirements applicable to harvest and post-harvest uses of agricultural water, and reserve § 112.48.

#### 6. Proposed § 112.49

As part of our reorganization of subpart E, we would remove and reserve § 112.49 of the produce safety regulation that allows for various alternatives based on the pre-harvest agricultural water quality profile and testing requirements that we propose to remove from subpart E.

### VII. Online Tool

We recognize that covered farms would likely benefit from resources to assist them in complying with the proposed requirements, if finalized. As such, we are developing an online tool that would assist farms in developing the pre-harvest agricultural water assessments described in this proposed rule. We plan to provide additional information about this online tool in the near future.

### VIII. Proposed Effective and Compliance Dates

We are proposing that a final rule based on this proposed rule be effective 60 days after the date of publication of the final rule.

Covered farms currently are 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 covered farms (84 FR 9706). We intend to exercise enforcement

discretion for these subpart E requirements while pursuing a targeted compliance date rulemaking, with the goal of completing the rulemaking as quickly as possible.

In the meantime, covered farms (other than sprout operations, for which compliance dates have already passed) should focus their attention good agricultural practices to maintain and protect the quality of their water sources (Ref. 32). We note that produce remains subject to the other applicable provisions of the produce safety regulation and the applicable provisions of the FD&C Act.

#### IX. Preliminary Economic Analysis of Impacts

We have examined the impacts of the proposed rule under E.O. 12866, E.O. 13563, the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4). E.O.s 12866 and 13563 direct us to assess all costs and benefits 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). This proposed rule has been designated a significant regulatory action as defined by E.O. 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because we estimate that annualized costs will not be larger than 3 percent of revenue for any covered farms, we anticipate that the proposed rule will not have a significant economic impact on a substantial number of small entities. If the proposed rule is finalized, we may, if appropriate, certify that the final rule does not have a significant 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 an assessment of anticipated costs and benefits, before proposing “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 \$158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This proposed rule would not result in an expenditure in any year that meets or exceeds this amount.

We have developed a comprehensive Preliminary Economic Analysis of Impacts (PEIA) that assesses the impacts of the proposed rule (Ref. 79). We estimate costs of the proposed 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. We estimate cost savings of the proposed rule resulting from pre-harvest agricultural water testing and corrective measure provisions in the 2015 final rule that would be replaced by the proposed provisions for pre-harvest agricultural water assessments and mitigation measures. Our primary estimates of annualized net costs are approximately \$11.3 million at a 3 percent discount rate over 10 years and approximately \$11.2 million at a 7 percent discount rate over 10 years.

We estimate benefits of the proposed rule resulting from the dollar burden of foodborne illnesses averted, and we estimate forgone benefits of the proposed rule resulting from foodborne illnesses not averted due to the current pre-harvest agricultural water testing provisions. Our primary estimates of annualized net benefits are approximately \$9.9 million at a 3 percent discount rate and approximately \$9.6 million at a 7 percent discount rate. We discuss qualitative benefits of the proposed rule stemming from increased flexibility for covered farms to comprehensively evaluate their agricultural water systems. These changes to pre-harvest agricultural water provisions are being proposed, in part, to address practical implementation challenges of the current pre-harvest agricultural water testing requirements.

The full preliminary analysis of economic impacts is available in the docket for this proposed rule and at <https://www.fda.gov/about-fda/reports/economic-impact-analyses-fda-regulations>.

## X. 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. 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 (Refs. 80-81). Under FDA's regulations implementing the National Environmental Policy Act (21 CFR part 25), an action of this type would require an EA under 21 CFR 25.31a(a) (an abbreviated EA under 21 CFR 25.31a(b)).

## XI. Paperwork Reduction Act of 1995

This proposed 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.

FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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



*Description:* The proposed rule would replace current recordkeeping requirements (found in 21 CFR part 112, subpart E) associated with sampling and testing of pre-harvest agricultural water for non-sprout covered produce with revised requirements to prepare and maintain documentation of written agricultural water assessments for certain pre-harvest agricultural water.

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

We estimate the burden of the information collection as follows:

Table 5.--Cumulative Average Annual Burden, Covered Farms of All Sizes

21 CFR part 112, subpart E: Requirements that apply regarding records	Total 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 (proposed § 112.50(b)(2))	8218	1.1	9040	4	36160
Agricultural Water Assessment and Records Maintenance--Small covered farms (proposed § 112.50(b)(2))	1613	1.1	1774	8	14192
Agricultural Water Assessment and Records Maintenance--All other (Large) Covered Farms (proposed § 112.50(b)(2))	4283	1.1	4711	9	42399
Cumulative totals for covered farms of all sizes	14114	3.3	15525	7.0	92751
Cumulative average 7.0 burden hours per covered farm annually					

Covered farms using pre-harvest agricultural water for non-sprout covered produce would prepare and maintain records of their agricultural water assessments unless excluded under proposed § 112.43(b). We estimate that a total of 14,114 covered farms (8,218 very small farms, 1,613 small farms, and 4,283 other (large) covered farms) would be subject to information collection requirements under the proposed rule, consistent with figures in our current approval and our PRIA (Ref. 79) for this proposed rule and informed by a 2018 USDA survey of covered farms' irrigation practices (Ref. 82). We are estimating 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.

To ensure that comments on information collection are received, OMB recommends that written comments be submitted through [reginfo.gov](http://reginfo.gov) (see ADDRESSES). All comments should be identified with the title of the information collection.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), we have submitted the information collection provisions of this proposed rule to OMB for review. These information collection requirements will not be effective until FDA publishes a final rule, OMB approves the information collection requirements, and the rule goes into effect. FDA will announce OMB approval of these requirements in the *Federal Register*.

## XII. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13132. We have determined that the proposed 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.

## XIII. Consultation and Coordination with Tribal Governments

We have analyzed this proposed rule in accordance with the principles set forth in E.O. 13175. We have tentatively determined that the rule does not contain policies that would have a substantial direct effect 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. We invite comments from tribal officials on any potential impact on Indian Tribes from this proposed action.

## XIV. 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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### **List of Subjects in 21 CFR Part 112**

Dietary foods, Food grades and standards, Foods, Fruits, Incorporation by reference, Packaging and containers, Reporting and recordkeeping requirements, Safety, Vegetables.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, we propose that 21 CFR part 112 be 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 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
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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(e) (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 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 the location and nature of the water source (whether it is ground water or surface water), the type of water distribution system (for example, open or closed conveyance), and 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 you can demonstrate that the water:

(1) 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;

(2) Meets the requirements in § 112.44(c) for water from a Public Water System or public water supply; or

(3) Is treated in accordance with § 112.46.

(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 discontinue use of the water and take corrective measures under § 112.45(a) before resuming such use(s);

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

(3) If you have identified no 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 for assessment purposes.* 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 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, 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 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, 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, or 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 (with a minimum interval of 4 days between application and harvest, except as supported by test results conducted under § 112.43(d), or other scientifically valid data or information in accordance with § 112.12);

(iii) Increasing the time interval between harvest and the end of storage using an appropriate microbial die-off rate, and/or conducting other activities, such as commercial washing, to reduce pathogens using appropriate microbial removal rates, provided you have scientifically valid supporting data and information;

(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, 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; 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.

(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 *Escherichia coli* (*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. With respect to any time interval applied in accordance with § 112.45(b)(1)(ii) and/or (iii), such documentation must include the specific time interval (or log reduction, if applicable), how the time interval or log reduction was determined, and the dates of corresponding activities such as the dates of last application and harvest, the dates of harvest and end of storage, and/or the dates of activities such as commercial washing;

(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 activities (such as commercial washing) that result in microbial removal in § 112.45(b)(1)(iii);

(9) 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);

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

(11) 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 (10), 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: November 24, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.