CENTER FOR
Science IN THE
Public Interest
The nonprofit publisher of
Nutrition Action Healthletter

April 5, 2022

Docket Clerk
United States Food and Drug Administration
Division of Dockets Management, HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Comment on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water (Docket No. FDA-2021-N-0471).

To Whom it May Concern,

The Center for Science in the Public Interest (CSPI)[1] and the undersigned respectfully submit these comments on the U.S. Food and Drug Administration's (FDA) above-referenced proposed standards for agricultural water, which are part of the agency's rule on produce safety.

We support the FDA proposing new agricultural water standards and are supportive of many aspects of the proposed standards, including that they allow for a more comprehensive approach to assessing water hazards, offer flexibility for implementation into different production systems, allow for water safety system improvements if science advances, and generally require scientifically supported hazard mitigation.

We have concerns, however, about certain aspects of the proposed standards. While we believe that in the long term, the standards will provide a strong framework for improving produce safety, the rule relies heavily on the produce industry to develop and implement effective, science-based best practices, in areas where such practices are currently lacking. We believe that the FDA has a critical role to play in incentivizing the development and implementation of such science-based practices through this rule.

Accordingly, we propose some concrete changes FDA can take to advance produce safety in the rule. First, the proposed standards could do more to ensure that hazards are prioritized based their level of threat to public health and establish stronger accountability for addressing the highest-risk hazards. Second, the standards should require validated microbial testing as part of the water assessments. Third, the water assessment requirement should extend to all water used throughout the agricultural process, including water that meets requirements for use in harvest, post-harvest, and sprouts. Fourth, standards should replace the safe harbor for certain agricultural practices with an approach that will encourage the use of best science and techniques. Finally, stakeholders may not be well-equipped to effectively implement these proposed standards and will require additional support and guidance from the agency to ensure

[1] CSPI is America's food and health watchdog. Since 1971, CSPI has worked to improve the public's health through better nutrition and food safety. The organization's work is supported by subscribers to its Nutrition Action Healthletter, one of the nation's leading health newsletters. CSPI is an independent organization that does not accept government donations or corporate funding.

the standards are effective. More detailed discussions of these aspects of the rule are included below.

I. Background on the Proposed Agriculture Water Standards

Produce can pose a threat to public health when it becomes contaminated with pathogens and can serve as a vector for disease transmission. The Interagency Food Safety Analytics Collaboration estimates that products covered by the produce safety rule caused 41.8% of *Salmonella* and 65% *E. coli* O157:H7 foodborne illnesses in 2019.[2] In recent years, certain produce products drew increased public attention to this food safety issue. For example, between 2019 and 2021, at least 9 multistate outbreaks linked to leafy greens occurred that prompted the Centers for Disease Control and Prevention to notify the public.[3]

Beyond directly affecting public health due to illness, concern over produce safety could have the adverse effect of turning consumers away from produce products, which are a core component of healthy diets. A diet rich in whole, unprocessed fruits and vegetables helps lower blood pressure and LDL ("bad") cholesterol, two key risk factors for heart attacks and strokes, which are major causes of death in America.[4-6] Yet nine out of ten Americans don't get the recommended amount of vegetables, and eight in ten aren't getting enough fruits.[7] Having confidence in the safety of our produce supply is critical if we are to begin to address this crisis.

Agricultural water can be a source of pathogens that contaminate produce and harm consumers. As the FDA stated in its preamble to the proposed agricultural water standards, investigations into recent large leafy greens outbreaks and an onion outbreak show water's potential role in compromising produce safety.[8] In some cases, the specific outbreak strain of the pathogen was identified in water sources on the farm. In other cases, pathogenic bacteria were found in water sources in close proximity to the farms, indicating that the water could have been a source of the outbreak bacteria.

Policymakers have long been aware of these risks, which is why Congress included a provision in the Food Safety Modernization Act (FSMA) of 2011 directing the FDA to create a rule protecting produce with "science-based minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, *and water*."[9] (emphasis added) The FDA initially finalized that rule in 2015 by publishing Standards for Growing, Harvesting,

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[2] Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2019 for Salmonella, Escherichia coli O157, Listeria monocytogenes and Campylobacter using multi-year outbreak surveillance data, United States. GA and D.C.: U.S. Department of Health and Human Services' Centers for Disease Control and Prevention and U.S. Food and Drug Administration, U.S. Department of Agriculture's Food Safety and Inspection Service. 2021.

[3] Lettuce, other leafy greens, and food safety. Centers for Disease Control and Prevention. Updated March 8, 2022. Accessed March 25, 2022. https://www.cdc.gov/foodsafety/communication/leafy-greens.html.

[4] Appel LJ, Moore TJ, Obarzanek E, et al. A clinical trial of the effects of dietary patterns on blood pressure. DASH Collaborative Research Group. N Engl J Med. 1997;336(16):1117-1124.

[5] Appel LJ, Sacks FM, Carey VJ, et al. Effects of protein, monounsaturated fat, and carbohydrate intake on blood pressure and serum lipids: results of the OmniHeart randomized trial. JAMA. 2005;294(19):2455-2464.

[6] Heart disease and stroke. Centers for Disease Control and Prevention. Updated March 7, 2022. Accessed March 26, 2022. https://www.cdc.gov/chronicdisease/resources/publications/factsheets/heart-disease-stroke.htm

[7] U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary guidelines for Americans, 2020-2025. 9th Edition. December 2020.

[8] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," 86 *Federal Register* 231 (December 6, 2021), pp. 69120-69155.

[9] U.S. House. 111th Congress, 1st Session. *H.R.2751, FDA Food Safety Modernization Act*. Washington, Government Printing Office, 2011.

Packing, and Holding of Produce for Human Consumption, which included a section with agricultural water standards.[10] Those standards required that all agricultural water be "safe and of adequate sanitary quality for its intended use," and included specific generic *E. coli* testing requirements to measure water quality, which varied depending on the source (surface water, well water, or municipal) and the use (preharvest, harvest and post-harvest, and use in growing sprouts) of the water. The rule also required farms to inspect and maintain water systems annually.

The implementation of the testing requirements provided in the final rule, other than requirements for sprouts,[11] was delayed by the FDA due to concerns around administrability, and the requirements have never gone into effect.[12,13] Stakeholders within the produce industry also expressed substantial concerns about the water testing standards, including that they were overly prescriptive, too complicated, and would be difficult to implement.[14] This feedback, combined with FDA's recent experiences investigating outbreaks and associated farm agricultural water, has led the agency to propose a revision of the water standards.[15]

The new proposed standards replace the generic *E. coli* testing method used in pre-harvest water applications with a more comprehensive annual agricultural water assessment requirement in which producers are required to take into account all conditions that are "reasonably likely to introduce known or reasonably foreseeable hazards."[16] Farms are further required to determine whether corrective or mitigation measures are needed and put these measures in place.[17] The proposed water assessment requirement will not, however, apply to agricultural water that meets the source and testing requirements for use in harvest, post-harvest, or for growing sprouts, which will be subject to separate requirements.[18]

II. We Support the Comprehensive Water Assessment Requirements in Place of the Prior Narrow Water Testing Requirements

The proposed standards improve over the previous water standards by replacing the narrowly-focused, prescriptive, and imperfect specific generic *E. coli* testing requirement[19] for preharvest water with a more comprehensive water assessment that can be adapted to different environments and evolve with advancing science.[20]

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[10] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," 80 *Federal Register* 228 (November 27, 2015), pp. 74354-74568.
[11] FDA considers sprouts to represent a special food safety concern and made sprout-specific requirements in the Produce Safety Rule. See Food and Drug Administration. *Draft Guidance for Industry: Compliance with and Recommendations for Implementation of the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for Sprout Operations*. Washington, D.C: U.S. Department of Health and Human Services, FDA; 2017.
[12] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E," 84 *Federal Register* 52 (March 18, 2019), pp. 9706-9714.
[13] FSMA proposed rule on agricultural water. Food and Drug Administration. Updated March 21, 2022. Accessed March 27, 2022. https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-agricultural-water.
[14] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," 86 *Federal Register* 231 (December 6, 2021), pp. 69120-69155.
[15] Ibid.
[16] Ibid.
[17] Ibid.
[18] Ibid.
[19] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," 80 *Federal Register* 228 (November 27, 2015), pp. 74354-74568.
[20] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," 86 *Federal Register* 231 (December 6, 2021), pp. 69120-69155.

While validated microbiological testing remains an important part of that assessment, as we discuss in the next section, we agree with the agency that maintaining the original codified generic *E coli* testing criteria for preharvest water was not in the best interests of public health.

These criteria centered on requirements that a geometric mean and a statistical threshold value of generic *E. coli* in samples of each water source collected over years not be exceeded.[21]

There is not a strong correlation between these generic *E. coli* testing requirements and water safety. Pathogens may be present or absent regardless of generic *E. coli* counts.[22] For example, a 2014 review of 81 datasets found that the relationships between measured generic *E. coli* or thermotolerant coliforms in surface fresh waters and the concentrations of one or more of waterborne and food-borne pathogenic organisms were not significant in 65% of datasets.[23] The researchers concluded, "Standards of microbial water quality for irrigation cannot rely only on concentrations of indicators and/or pathogens, but must include references to crop management."

In addition to the poor correlation between generic *E coli* as an indicator for pathogens, the periodic nature of the sampling and reliance on a geometric mean reduced the potential usefulness of the testing method. Hazards can also be temporal (such as sewage overflow in a flooding situation), a situation that the periodic testing[24] required in the previous standards would be unlikely to detect. In addition, the use of geometric means[25] diminished the importance of individual tests when generic *E. coli* counts were especially elevated.

The testing method was also uniform across the country, regardless of environment and produce production system, when different methods of testing may have been better in particular systems.[26]

These shortcomings mean the original testing requirements may have had only limited value in assessing the critical question of whether the water was in fact "safe and of adequate sanitary quality for its intended use."[27] More concerning, by relying so heavily on testing as a measure of water safety, the standards promoted a false impression of safety, discouraging more comprehensive safety assessments in production systems where the testing thresholds were met. The uniform requirements also did not encourage the use or future adoption of better testing methodologies for specific systems.

Rather than maintain these narrowly-focused, prescriptive, and imperfect preharvest water testing requirements that may be poorly correlated with actual water safety, the new standards provide a more comprehensive framework for assessing hazards. This approach is supported by science and will better allow the rule to be adapted for diverse production systems.

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[21] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," 80 *Federal Register* 228 (November 27, 2015), pp. 74354-74568.
[22] Pachepsky Y, Shelton D, Dorner S, Whelan G. Can E. coli or thermotolerant coliform concentrations predict pathogen presence or prevalence in irrigation waters? Crit Rev Microbiol. 2016 May;42(3):384-93.
[23] Ibid.
[24] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," 80 *Federal Register* 228 (November 27, 2015), pp. 74354-74568.
[25] Ibid.
[26] McEntire J and Gorny J. Fixing FSMA's ag water requirements. *Food Safety Magazine*. August 15, 2017. Accessed March 27, 2022. https://www.food-safety.com/articles/5417-fixing-fsmae28099s-ag-water-requirements.
[27] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," 80 Federal Register 228 (November 27, 2015), pp. 74354-74568.

We agree with the new comprehensive water assessment requirements proposed in the rule. The proposed water assessment provisions will bring the produce safety rule more in line with the preventive framework envisioned in FSMA by requiring a comprehensive hazard assessment and mitigation measures.

The water assessment requirements are similar to the preventive framework laid out for manufacturers under FSMA, which specified that the owners of food production facilities must "identify and evaluate known or reasonably foreseeable hazards" and "identify and implement preventive controls" to minimize or prevent these hazards.[28]

The previous agricultural water standards implemented a much lower standard for produce, specifying only that growers conduct an at least yearly inspection of agricultural water systems.[29] There was a limited description of what these yearly inspections should entail or what should result from them, distinctly separating them from the requirements of food production facilities.[30]

In contrast, the proposed standards indicate, in essence, that produce growers should take a similar approach on their operations as the preventive controls approach employed in food production facilities. Under the proposal, produce growers will be expected to assess and mitigate hazards by conducting water assessments and determine the best measures to take to protect public health. Namely, the proposed standards detail the requirements of annual agricultural water assessments, considering the evaluations of each entire water system used for growing activities and the agricultural water practices associated with each water system.[31] In addition, the proposed standards require that measures must be taken to address the outcomes of these assessments within certain time frames, similar to the preventative control requirements of FSMA for food production facilities.[32] These requirements should better foster a food safety culture in growers as they will be required to comprehensively evaluate their systems for food safety, just like other food production facilities.

Thus, we support the new requirements that growers conduct comprehensive water assessments and determine testing systems that best work for their operation to ensure produce safety.

III. The Proposed Standards Should Be Amended to Require Hazard Prioritization and to Establish Standards and Accountability for the Highest-Risk Hazards

While the proposed standards do bring growers closer in line with conducting a hazard assessment like other food production facilities, the proposed rule offers little by way of guidance to growers or regulators to ensure the adequacy and quality of the hazard assessments conducted under the rule or establish clear standards and accountability for the highest-risk hazards. One way to help ensure that hazard assessments are useful and address the most substantial risks is to require a system of hazard prioritization, similar to the preventive controls

[28] U.S. House. 111th Congress, 1st Session. *H.R.2751, FDA Food Safety Modernization Act.* Washington, Government Printing Office, 2011.
[29] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," 80 *Federal Register* 228 (November 27, 2015), pp. 74354-74568.
[30] Ibid.
[31] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," 86 *Federal Register* 231 (December 6, 2021), pp. 69120-69155.
[32] Ibid.
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approach already utilized in food production facilities, and to have the agency identify more clearly the hazards that require water to be treated as a mitigation step.

The annual water assessment requirement under the proposed standards specifies that farms "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."[33] As discussed supra, this water hazard assessment is similar to what is generally required under FSMA for other food production facilities.[34] Under FDA regulations for other food production facilities, though, preventative controls must be put into place after a hazard analysis, "which includes an assessment of the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls."[35] This element of the analysis helps firms to focus on and address the hazards that pose most substantial risks to public health.

The proposed standards for agricultural water do not specify hazard prioritization based on the probability of the hazard occurring and the level of harm. Instead, they specify, in essence, a three-tiered system of pre-harvest water hazard ranking and consequent mitigation requirements. These are summarized by the FDA as follows:[36]

If you determine	**Then you must**
that your agricultural water is not safe or is not of adequate sanitary quality for intended use(s)	• Immediately discontinue use (s) ***And*** • Take corrective measures before resuming use of the water for pre-harvest activities
there is one or more known or reasonably foreseeable hazards related to animal activity, BSAAOs, or untreated or improperly treated human waste for which mitigation is reasonably necessary	• Implement mitigation measures promptly, and no later than the same growing season
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	• Implement mitigation measures as soon as practicable and no later than the following year ***Or*** • Test water as part of the assessment and implement measures, as needed, based on the outcome of the assessment

The proposed rule distinguishes between tier 1 and tiers 2 and 3 not only in terms of timing (tier 1 hazards must be addressed immediately, whereas tier 2 and 3 hazards may be addressed within

[33] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," 86 *Federal Register* 231 (December 6, 2021), pp. 69120-69155.
[34] U.S. House. 111th Congress, 1st Session. *H.R.2751, FDA Food Safety Modernization Act.* Washington, Government Printing Office, 2011.
[35] "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food," 80 *Federal Register* 180 (September 17, 2015), pp. 55908-56168.
[36] FSMA proposed rule on agricultural water. Food and Drug administration. Updated March 21, 2022. Accessed March 27, 2022. https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-agricultural-water.

the growing season or year), but also in terms of the response required. For tier 1 hazards, the water cannot be used again until the grower has taken effective "corrective measures", which consist of either making changes to the water system to address the conditions that created the hazard, or treating the water. Hazards that fall into tiers 2 and 3, by contrast, receive "mitigation measures that are reasonably necessary to reduce the potential for contamination," which can include the corrective measures already described, as well as additional options like changing the method of water application or allowing for a "die off" period.

This hazard ranking system leaves the determination up to the growers whether a hazard warrants immediate action, and what level of response is needed to correct or mitigate the hazard. It also differs from the approach applied under the preventive controls rule for other food production facilities in that it does not require produce growers to analyze and document the severity of the illness or injury and the probability of occurrence, as is required for other food production facilities. Employing such as simplified system may result in many hazards being ranked in the same tier.

This creates a problem both of 1) how to ensure hazards will be assigned to the correct tier and addressed with appropriate measures, such as water treatment, and 2) how to prioritize resources within a tier that includes many hazards.

With respect to the first problem, the rule currently provides no framework for determining when a hazard falls into the first tier warranting immediate action. As an additional source of confusion, tier 2 is the only tier to offer specific criteria for determining whether a hazard qualifies for that tier. Namely, "hazards related to animal activity, BSAAOs, or untreated or improperly treated human waste for which mitigation is reasonably necessary" fall into tier 2. Yet some of these hazards could also potentially make water not "safe or of adequate sanitary quality for its intended use" warranting inclusion in tier 1.

In addition, regardless of the tier assigned, the rule is vague about what corrective or mitigation measures might be considered adequate, stating in particular that the farm may either treat the water or take several alternate approaches to correct or mitigate hazards. A grower may, for example, avoid treating the water as a corrective measure, and instead opt re-inspect, "make necessary changes," and "take adequate measures to determine if your changes were effective." But the rule fails to explicitly state the conditions under which water treatment would be required as the only effective option. While it may be implied that water treatment is required if other effective options are not available, the rule fails to explicitly state this. There is thus no standard in the rule for the FDA to interpret to require treatment under specific high-risk circumstances.

This framework allows several opportunities for growers to defer necessary water treatment, either because they consider the hazard to be of lower risk (tiers 2 or 3 as opposed to tier 1), and/or because they make changes to their production system short of water treatment that they deem sufficient to correct or mitigate the hazards.

In contrast to the vague framework proposed by the FDA, a subset of the produce industry has already established a more clear and accountable standard for determining whether water treatment is required for leafy greens production. Following the 2018 romaine lettuce outbreaks, growers participating in Leafy Greens Marketing Agreements (LGMA) committed to avoid

using untreated surface water in overhead irrigation systems in the three weeks leading up to harvest, with the understanding that such water is of lower microbial quality and is applied directly to the edible portion of the crop, creating unacceptable risks.[37] If an overhead irrigation system is used, the water in that system must be treated when irrigating in the final three weeks before harvest.[38]

With respect to the second problem of sorting hazards within a category, this simplified three tier hazard ranking could create challenges for farms conducting a water assessment when deciding which hazards to prioritize addressing when most hazards are in the same tiers. This may lead firms to devote insufficient resources towards addressing priority hazards, or to focus limited resources on areas that will not address the most critical hazards.

In addition, the lumping together of many hazards within a tier negatively impacts the ability of regulators to enforce the standards. Rather than being able to expect and evaluate a clear and comprehensive hazard analysis with public health justifications as to which mitigation steps were prioritized, water assessments may be muddled with hazards of relatively less importance. For example, the rule fails to require producers to distinguish between the amount of attention that should be given in water assessments and mitigation plans to potential flooding events in a drier climate area that may be very unlikely to occur versus omnipresent run-off and seepage from neighboring fields, when the latter issue could be much more impactful in that particular system to produce safety.

To augment this tiered approach, the standards should include the following changes:

- A requirement that farms conduct a similar food safety hazard analysis to what other food production facilities already perform. Namely, they should be required to assess the severity of harm from the hazard and the probability that the hazard will occur, prior to determining the tier and implementing corrective or mitigation measures. This will strengthen the framework by providing farms with a risk analysis to determine whether immediate action is warranted, as well as facilitate prioritization within categories.

- An explicit standard requiring water treatment water as a corrective measure. This standard should require water treatment where changes other than water treatment would not effectively ensure that the water is of safe or of adequate sanitary quality for its intended use. Likewise, the rule should include an explicit standard requiring water treatment as a mitigation measure where changes other than water treatment would not adequately mitigate the known or reasonably foreseeable hazards. While all such conditions need not be enumerated in the text of the rule, the FDA could provide examples of what conditions would warrant water treatment. One of these conditions could be surface water applied to the edible portion of a leafy greens crop in proximity to harvest, reflecting the practice which, as noted above, has been adopted in the leafy greens industry. Additional examples could be developed over time as part of agency guidance and the advancement of best practices within the industry.

[37] New water management standards for leafy greens. Western Growers Association. Published May 07, 2019. Accessed April 4, 2021. https://www.wga.com/blog/new-water-management-standards-leafy-greens.
[38] Commodity specific food safety guidelines for the production and harvest of lettuce and leafy greens. California Leafy Green Marketing Association. August 20, 2020.

These recommendations could be implemented through the following changes to the text of the rule:

§ 112.3

Agricultural water assessment means an evaluation of an agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) related to growing activities for covered produce (other than sprouts) to:
(1) Identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces, assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur; and
(2) Determine whether measures are reasonably necessary to reduce the potential for contamination of covered produce or food contact surfaces with such known or reasonably foreseeable hazards.

…

§ 112.43

(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, and assess the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur, based on an evaluation of the following factors:

…

§ 112.45

(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) If changes other than water treatment would not effectively ensure that water is of safe or of adequate sanitary quality for its intended use (for example, if the water system applies surface water to the edible portion of a leafy greens crop in proximity harvest), 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:

…

(v) If the mitigation measures other than water treatment would not adequately mitigate the known or foreseeable hazards, tTreating the water in accordance with § 112.46;

In addition to these changes to the text of the rule, we urge the agency to provide clearer guidance in the preamble to the final rule discussing the circumstances under which water will be considered to fall under tier 1. FDA should clarify, in particular, that an activity can fall into tier 1 irrespective of whether it relates to the categories described in tier 2 (in other words, hazards involving, for example, human waste or animal activity can present tier 1 hazards), using specific examples based on real-world conditions.

IV. The Proposed Standards Should Require Validated Microbial Testing as Part of the Water Assessments

While we support the elimination of a specific, codified testing requirement in favor of a more comprehensive and adaptive approach, we are concerned that the proposed rule fails to require any form of microbial testing as part of the water assessment. We urge the agency to indicate in the rule that validated microbial testing should be a part of the water assessment unless the grower can verify, through scientifically valid means, that such testing is not necessary to identify potential hazards.

Industry has already recognized microbiological testing as a critically important source of information for assessing hazards. For example, the California Leafy Green Marketing Association Food Safety Guidelines include microbial testing for baseline microbial assessments, initial microbial water quality assessments, and routine system assessments.[39]

[39] Commodity specific food safety guidelines for the production and harvest of lettuce and leafy greens. California Leafy Green Marketing Association. August 2, 2021.

In contrast, the proposed standards, while maintaining microbiological testing requirements for water used for sprouts and post-harvest, only require testing as a possible further assessment of hazards in pre-harvest water.[40]

A requirement for a scientifically valid testing regimen could specify that testing is expected as a default as part of the annual assessment, and that the testing regimen must be scientifically valid, including following the criteria laid out in 112.43(d) of the proposed standards regarding sampling and selection of indicator organisms.

Section 112.43(d) could also potentially be enhanced to require preplanned scheduled testing at specific events or times (e.g., as close to harvest as reasonably possible) to limit "cherry-picking" for good testing times and results. It could also require that the grower needs to include individual test result microbial load thresholds in their testing regimen, to emphasize the short temporal nature of many microbial hazards and ensure that corrective measures will be immediately undertaken if these thresholds are exceeded. This would further separate the proposed standards from the previous standards, where an individual test result showing high water microbial contamination levels did not necessarily indicate immediate action be taken as the geometric means threshold of 126 colony forming units of generic *E. coli* per 100ml of water, based on a minimum of 20 test results over 4 years, could still be met.[41]

Every farm need not develop and validate its own unique testing method to comply with this requirement. First, FDA could specify in the preamble to the final rule and in other guidance that specific methods already validated by the FDA or others, are considered valid methods under paragraph (d) across a range of production systems. This would provide a set of default options for farms that have no means to validate a more tailored testing method. Second, acknowledging the diversity of the growing systems covered by the standard, including both regional and produce characteristics, regional- and produce-specific stakeholder committees organized by the FDA or other groups could undertake the work of validating specific testing methods for use by growers within a particular type of production system in their region.

Finally, the rule can specify that growers opting not to conduct microbial testing must describe in their risk assessment an alternative and provide adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as testing.

To implement these recommendations, we ask you to amend § 112.43 as follows:

> (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

[40] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," 86 *Federal Register* 231 (December 6, 2021), pp. 69120-69155.
[41] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," 80 *Federal Register* 228 (November 27, 2015), pp. 74354-74568.

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:

…

(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,t~~ The assessment must include results of ~~any~~ testing conducted pursuant to paragraph (d) of this section, unless an alternative to such testing is established in accordance with § 112.12; and
(6) Any other relevant factors impacting the analysis.

We also encourage you to amend § 112.43(d) to provide more specific criteria covering testing times, and testing microbial loads to emphasize the short temporal nature of the hazards.

V. The Water Assessment Requirement Should be Extended to Include All Agricultural Water

The proposed standard contains a number of exemptions from the written water assessment requirement. Though the water covered under these exemptions would be expected to be relatively safe based on its source and testing requirements, hazards can be introduced even in growing operations using these relatively safe sources of water. We therefore do not support exemptions to the requirement for a written assessment for any water used in agricultural operations.

The proposed standard requires a written water assessment for "water that you apply to covered produce (other than sprouts) using a direct application method during growing activities."[42]

The exceptions to this water assessment requirement for agricultural water used in growing activities pertain if the water is from the following relatively safe sources[43]:

1) If the water meets the requirements for agricultural water used as sprout irrigation water or in the harvesting, packing and holding of covered produce,
2) If the water comes from a public water system or supply, and
3) If the water is treated.

In addition, the new standard does not require a written water assessment for agricultural water used as sprout irrigation water or in the harvesting, packing and holding of covered produce, which already meets additional safety requirements.[44]

[42] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," 86 *Federal Register* 231 (December 6, 2021), pp. 69120-69155.
[43] Ibid.
[44] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," 86 *Federal Register* 231 (December 6, 2021), pp. 69120-69155.

The exemptions may enable incomplete hazard analysis and mitigation measures that can affect public health.

For example, there is no requirement for a written plan that non-single-pass postharvest produce washing water be treated or changed at an adequate frequency or inspected vigorously enough to detect organic contamination. Farms should have to explicitly acknowledge and address scenarios like an initial lot of pathogen-contaminated crop being washed and the wash water then potentially contaminating subsequent lots.

A 2021 multistate outbreak of *Salmonella* Typhimurium that sickened over 30 people, associated with products from a hydroponic leafy green facility, demonstrates that the water covered by these exemptions to the water may introduce hazards to produce and should be included in water assessments.[45] The hydroponic facility associated with the outbreak used water sourced from a municipal water supply that was further treated on-site through a four-stage sand filtration and UV system.[46] The pond water was also tested weekly for generic *E. coli*.[47]

Despite the municipal water source, protected indoor hydroponic environment, and water treatment, outbreak investigators found *Salmonella* Liverpool (not a strain associated with the outbreak) in an active production pond, indicating that water contamination was occurring.[48] When the firm performed water treatments with hydrogen peroxide and peracetic acid to address a previous finding of generic *E. coli*, it did not have a procedure or a systematic approach to ensure adequate treatment.[49] In addition, investigators also found the outbreak strain of *Salmonella* Typhimurium in a stormwater retention basin adjacent to the operation.[50]

Under the proposed standards, the water used in this hydroponic facility would be exempt from written water assessment requirements because it was both from a municipal water source and treated. As demonstrated by the *Salmonella* Liverpool, *E. coli* findings, and the nearby presence of the outbreak strain, though, this could be a gap in assessing water safety.

Thus, the FDA should require written assessments for all agricultural water and ensure that growers are evaluating hazards throughout the entire produce production process.

VI. The Proposed Standard Should Not Codify a Mitigation Period of Four Days Between Water Application and Harvest

The standards specify that a hazard mitigation measure may be increasing the time interval between the last direct application of agricultural water and harvest to allow for microbial die-off and that this interval should be "a minimum of 4 days between application and harvest, except as supported by test results conducted under § 112.43(d), or other scientifically valid data or

[45] U.S. Food and Drug Administration. Investigation Report: Factors Potentially Contributing to the Contamination of Packaged Leafy Greens Implicated in the Outbreak of Salmonella Typhimurium During the Summer of 2021. Updated January 14, 2022. Accessed March 28, 2022. https://www.fda.gov/media/155402/download.
[46] Ibid.
[47] Ibid.
[48] Ibid.
[49] U.S. Food and Drug Administration. Investigation Report: Factors Potentially Contributing to the Contamination of Packaged Leafy Greens Implicated in the Outbreak of Salmonella Typhimurium During the Summer of 2021. Updated January 14, 2022. Accessed March 28, 2022. https://www.fda.gov/media/155402/download.
[50] Ibid.

information in accordance with § 112.12."[51] This effectively creates a safe harbor for a 4-day die-off, placing the burden on regulators to develop evidence justifying why a longer die-off is necessary for specific conditions.

The FDA derived the 4-day limit from estimating a linear 0.5 log die-off rate per day considering a "broad range of variables including pathogen characteristics, environmental conditions, crop type, and watering frequency."[52] This estimated die-off rate results in an approximately 99% microbial load reduction after 4 days.[53]

The 4-day minimum time interval hinges on the assumption that for all agricultural systems 4 days would be sufficient to ensure adequate die-off. Yet as noted by the FDA, the microbial die-off rates can be dependent on many factors, like "various environmental factors, including sunlight intensity, moisture level, temperature, pH, the presence of competitive microbes, and suitable plant substrate."[54]

Certain systems and specific microbial hazards could conceivably need a longer interval to achieve an adequate die-off or other measures. A recent field trial study conducted in several geographic regions examined the die-off rates of inoculated *Salmonella* and *E. coli* on baby spinach and lettuce.[55] The results indicated that the die-off followed a segmented log-linear pattern rather than the log-linear pattern set by the FDA, and die-off rate ranges that included die-off rates below 0.5 log per day. The researchers concluded, "the use of a single die-off rate, as proposed by FSMA, is likely not appropriate, and instead the regulation should consider the effect of weather, bacteria, and produce type on microbial die-off."

Pathogens may also vary drastically in their susceptibility to die-off due to their life cycle. *Cyclospora,* for example, needs to be in the environment for days to weeks to sporulate and become infectious after being passed in feces.[56] Depending on a 4-day die off for this pathogen would seem to be inadequate for this hazard.

In addition, some pathogens only require a small dose to cause human illness, such as *E. coli* O157:H7 that has an estimated infectious dose in the range of only 10-100 cells.[57,58] Thus, depending on the pathogen hazard a farm is addressing and the expected initial contamination levels, a 99% die-off may not be sufficient.

The new standards overall emphasize nonprescriptive comprehensive hazard assessments and justifiable mitigation steps to prevent these hazards. The same approach should be taken for the microbial die-off hazard mitigation option. The 4-day minimum time interval in the standards

[51] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," 86 *Federal Register* 231 (December 6, 2021), pp. 69120-69155.
[52] Ibid.
[53] Bihn E, Fick B, Pahl D, et al. Geometric means, statistical threshold values, and microbial die-off rates. Produce Safety Alliance. February 17, 2017.
[54] "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water," 86 *Federal Register* 231 (December 6, 2021), pp. 69120-69155.
[55] Belias AM, Sbodio A, Truchado P, et al. Effect of weather on the die-off of Escherichia coli and attenuated Salmonella enterica serovar Typhimurium on preharvest leafy greens following Irrigation with contaminated water. *Appl Environ Microbiol*. 2020;86(17):e00899-20.
[56] Parasites - Cyclosporiasis (Cyclospora infection). Centers for Disease Control and Prevention. Updated June 1, 2018. Accessed March 28, 2022. https://www.cdc.gov/parasites/cyclosporiasis/biology.html
[57] Hara-Kudo Y, Takatori K. Contamination level and ingestion dose of foodborne pathogens associated with infections. *Epidemiol Infect*. 2011;139(10):1505-1510.
[58] Food and Drug Administration. *Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins*. Second Edition. 2012

should be replaced with a requirement for farms to ensure that any die-off period utilized is validated for the conditions of their operation and the specific hazards that are being targeted.

We urge the agency to adopt this recommendation through amending § 112.45 as follows:

> (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);

FDA may specify in the preamble to the rule or in guidance that the 4-day minimum is supported under a broad range of conditions, but that producers should ensure there is adequate support for use of this period within their system, as there may be conditions under which a longer die-off is necessary. This will maintain the burden on growers to ensure that the die-off period is validated for their production system.

VII. FDA Needs to Elaborate on the Resources Needed and the Process for Implementation of the Proposed Standard

Compared to the previous more prescriptive standards, the new proposed standards put a much greater responsibility on growers to individually assess their water to identify and address hazards.

While some segments of the produce industry have worked to develop more advanced water safety assessments and protocols due to recent outbreaks, like leafy greens, others may not be as prepared to conduct comprehensive water assessments.[59] There may not even be enough experts in agricultural water in the United States to enable comprehensive water assessments and training across the entire produce industry, as the standards require.

In a similar fashion, state regulators will bear a large part of the burden of implementing the proposed standards; compared to the previous standards there will be much greater variability in possible manners to comply with the regulations in lieu of having uniform testing standards. Regulators will often be the primary people in charge of educating growers on the standards and will also have to ensure that they themselves have the expertise to evaluate water assessments.

There is a need for more detail on the specific components that should be included in a water assessment, the format they should be in, and mitigation steps which should take place. This could originate from the FDA or from stakeholder groups, similar to the process for developing microbial testing standards discussed *supra*. This will be useful to both farmers attempting to comply with the standards and to regulators in ensuring compliance, as more specificity would add a layer of objectivity to judge adequacy.

On top of the burden for these stakeholders, there are no existing extensive datasets of what effective written water assessments and mitigation measures look like. In the early years of this

[59] Commodity specific food safety guidelines for the production and harvest of lettuce and leafy greens. California Leafy Green Marketing Association. August 2, 2021.

standard implementation, the evidence base for what constitutes a proper water assessment and risk mitigation will be limited and many aspects of complying with the proposed standards may initially be subjective. The FDA will be in a unique position to create a repository of effective water assessments over time. The planned method of data collection and housing, analysis, and means to distribute knowledge from this dataset, including the best methods to conduct, record, and evaluate water assessments is unclear.

Accordingly, the FDA should outline the resources that the agency itself and industry will have available to assist with the new water assessment requirements and better ensure that this regulation is achievable. Resources for implementation could include additional funding for universities, other nongovernmental organizations, and non-federal government regulators and personnel to assist with outreach. The agency should also outline how it will evaluate the dataset of water assessments over time and ensure that best practices that arise from the dataset are disseminated to stakeholders.

VIII: Conclusion

While the proposed standards have areas that could be improved, we are optimistic that if these issues are addressed the standards will be beneficial to public health. We look forward to continuing to work with the FDA on these standards as they are finalized.

Sincerely,

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