

PEER-REVIEWED ARTICLE

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Industry Reaction and Perceived Barriers to Implementation of the Preharvest Water Requirements (Subpart E) from the United States Food and Drug Administration Produce Safety Rule

ABSTRACT

The United States Food and Drug Administration proposed new Produce Safety Rule requirements for preharvest water in December 2021. It is unclear if growers are utilizing water treatment as a corrective or mitigation measure or perceive the proposed requirements as easier to implement. The objectives of this study were to describe fresh produce grower responses to the proposed rule for preharvest water management, query if growers are currently treating preharvest water, and identify the most significant barriers growers face when treating preharvest water. An anonymous survey was distributed via Qualtrics™ to various sectors of the produce industry from March to August 2023. Descriptive statistics were used to determine frequencies and distribution of responses. Ranking of barriers to effective preharvest water treatment were assessed by inversely weighting. Statistical analysis was conducted using RStudio version 4.2.3. Forty-six respondents completed the survey (n = 46), identifying primarily as growers (36/46; 78.3%). Approximately half of respondents

reported having read the proposed rule (15/32) and having a poor understanding of the requirements (20/40). The largest barrier identified was the impact of treatment on soil. Educational water treatment programs emphasizing practical implementation and decision-making strategies are needed to support grower use of water treatment as a corrective action or mitigation measure.

INTRODUCTION

To minimize the risk of consuming contaminated fresh produce, the Food Safety Modernization Act (FSMA) charged the U.S. Food and Drug Administration (FDA) with the task of developing and enforcing a rulemaking that is now known as the Produce Safety Rule (PSR; 21 CFR Part 112), the final rule of which was published on November 27, 2015. The PSR (35) includes requirements related to management of known sources or routes of contamination of foodborne pathogens to fresh produce, including worker health and hygiene (Subpart D); biological soil amendments of animal origin and human waste (Subpart F); domestic animals and wildlife intrusion

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(Subpart I); management of food contact surfaces (e.g., buildings, equipment, and tools (Subpart L); and preharvest and postharvest agricultural water (Subpart E).

The initial rule required the implementation of testing requirements to meet microbial water quality standards for water that was likely to, or intended to, contact fresh produce and food contact surfaces during preharvest (growing activities before harvest) and postharvest (harvesting and after harvest) activities. Initially, preharvest water needed to be tested for generic *Escherichia coli* concentrations and must have a calculated geometric mean ≤ 126 CFU/100 ml and statistical threshold value ≤ 410 CFU/100 ml [21 CFR § 112.44(b)]. The number of tests required for water varied for each source of agricultural water, from no sampling if municipal water was used, to twenty samples over a four-year period if surface water was used. After testing an agricultural water source, if the source did not meet these microbiological criteria, growers could use a different water source or continue to use the same water source with one of several corrective measures, including treating the water [21 CFR § 112.45(b)]. Agricultural water treatment was also identified as an activity that excluded growers from the rigorous testing required in the initial rule [21 CFR § 112.46(1)(3)].

During the federal comment period, the fresh produce industry voiced concern about complying with the microbial water quality requirements that would undoubtedly impact the practical implementation of the regulation in preharvest environments (4, 10, 21, 22, 26, 34), particularly related to the rigorous testing schedule and calculations that must be met for preharvest agricultural water. In response to these concerns, new requirements for agricultural water (21 CFR Part 112 Subpart E), specifically the management and use of preharvest water, were proposed in December 2021 (37). In the proposed legislation, the focus of preharvest Subpart E shifted from a rigid testing structure to an assessment-based decision-making model. Growers would be expected to perform a written Agricultural Water Assessment (AgWA) that would evaluate several factors related to preharvest water use, including the agricultural water system, agricultural water practices, crop characteristics, environmental conditions, and any other relevant factors (86 FR 69120). Any potential food safety hazards that emerged during the AgWA would need to be corrected or mitigated as appropriate prior to using that source as preharvest water (86 FR 69120). Water treatment is listed as both a potential corrective and mitigation measure.

Even if preharvest agricultural water treatment is utilized by fresh produce operations, water testing will still be an important part of a holistic approach to understanding the impact of microbial quality of the water on risk and verifying that food safety risks related to preharvest water are reliably managed. Growers are still required to implement water quality testing methods to meet certain buyer or audit standards (7, 25). While the PSR may be one reason that growers begin

treating agricultural water, audit standards, such as those defined by the CA and AZ LGMA that require the treatment of water used for overhead irrigation of crops within the 21 days of harvest (7), also impact water treatment decisions.

Although agricultural water treatment may appear to be a simple step that acts as both a risk mitigation measure and a means of achieving regulatory compliance, implementing a preharvest agricultural water treatment program is not a feasible option for all fresh produce operations. In addition to the complexity of managing the treatment chemistry or treatment device, the potential impact of agricultural water treatment on soil health (12, 16), the potential for development of disinfection by-products as a result of chlorine-based treatment (14), resource costs associated with the treatment itself and employee training, and the sensitivity of crops to the treatment (3, 27) have all been identified as challenges to effective implementation.

Despite the changes to the proposed preharvest Subpart E and efforts related to enhancing water treatment efficacy, it is unclear how growers (i) perceive the preharvest Subpart E requirements' impact on their operations and (ii) are utilizing water treatment programs. Therefore, the objectives of this study were to conduct a baseline assessment to describe fresh produce grower responses to the rule for preharvest water management, query if growers are currently treating preharvest water and why, and identify the most significant barriers growers face when treating preharvest water.

MATERIALS AND METHODS

Survey development and dissemination

A survey instrument was developed to understand the fresh produce industry perceptions of FDA FSMA PSR preharvest Subpart E proposed regulation (86 FR 69120) and preharvest water treatment (Supplemental Material 1). Survey questions were developed by produce industry experts across five academic institutions and reviewed independently by representatives of four industry groups prior to widespread dissemination in a similar structure to previous work (5). Questions were screened and approved by Institutional Review Boards at the University of Arizona (STUDY00002560), University of Florida (PROJECT00000044), Rutgers University (PRO2023000020), and Virginia Tech (23-056).

The survey was designed to anonymously capture feedback from various sectors of the produce industry. No identifying information was collected beyond the respondent's self-identified demographics. Using a method similar to what was previously described in Bakin et al. 2023 (5), respondents were asked to select their individual role in the produce industry from a pre-determined list (i.e., buyer, grower, packer, allied industries, consultant) or write-in "other" text box. If a respondent selected multiple roles of which "grower" was a role selected, those respondents were classified as growers for statistical analysis. While not every individual

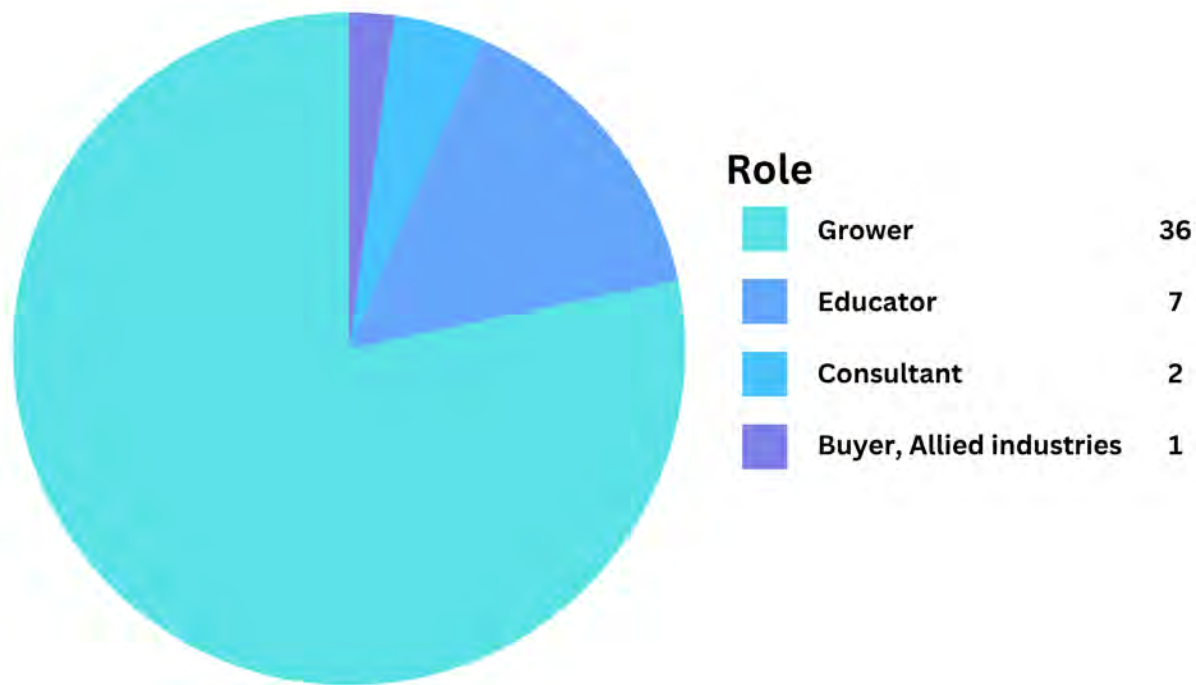


Figure 1. Preharvest water survey respondents by role.

who could be responsible for water treatment would identify as a “grower”, this study focused on capturing water treatment practices of individuals who identified as fresh produce industry growers (i.e., if a grower role was not selected, the individual was not asked questions about water treatment). Respondents were also given the option to not answer any of the questions. In such cases, those responses were not included in the statistical analysis.

The survey was disseminated online via a link to Qualtrics™ through multiple proprietary email lists across industry groups (e.g., Western Growers, Center for Produce Safety), social media platforms (e.g., Instagram, Twitter), membership organizations (e.g., International Fresh Produce Association, Florida Fruit and Vegetable Association), food safety media outlets (e.g., *Food Safety News*), and local cooperative Extension offices. Data were collected from March through August 2023.

Statistical analysis

Statistical analysis was conducted using RStudio version 4.2.3. Incomplete surveys (i.e., surveys that respondents initiated but did not complete and submit) were removed prior to statistical analysis. Responses were compared between respondents who identified as a grower and all other roles. Descriptive statistics were used to determine frequencies and distribution of responses. Ranking of barriers to effective preharvest water treatment were assessed using the method described in Bakin et al. (2023) by

inversely weighting rankings by 5, 4, 3, 2, and 1 to ranked priorities 1, 2, 3, 4, and 5, respectively. A weighted score was calculated for each priority by summing weighted rankings across responses.

RESULTS AND DISCUSSION

Of the 90 survey responses initiated, 46 were completed and included a response to the role question (51.1%). Respondents identified predominantly as growers (36/46; 78.3%), followed by educators (7/46; 15.2%), consultants (2/46; 4.3%), and a buyer or member of an allied industry (1/46; 2.2%; *Fig. 1*). Only respondents who self-identified as growers were asked survey questions related to preharvest water treatment.

Response to preharvest water proposed legislation

When asked if growers had read the proposed preharvest Subpart E, their responses were split between “yes” (15/32; 46.9%), “no” (15/32; 46.9%), and “unsure” (2/32; 6.2%), with four growers choosing not to answer this question. Growers also showed mixed responses to their reported level of understanding of this proposed rule (*Fig. 2*), with some indicating they did not understand at all how to comply (8/36; 22.2%) and others reporting they understood very well what they were being asked to do (6/36; 16.7%). Despite this split in level of understanding of proposed requirements, most growers indicated they were already in compliance with the proposed regulation (11/36; 30.6%; *Fig. 3*), which was

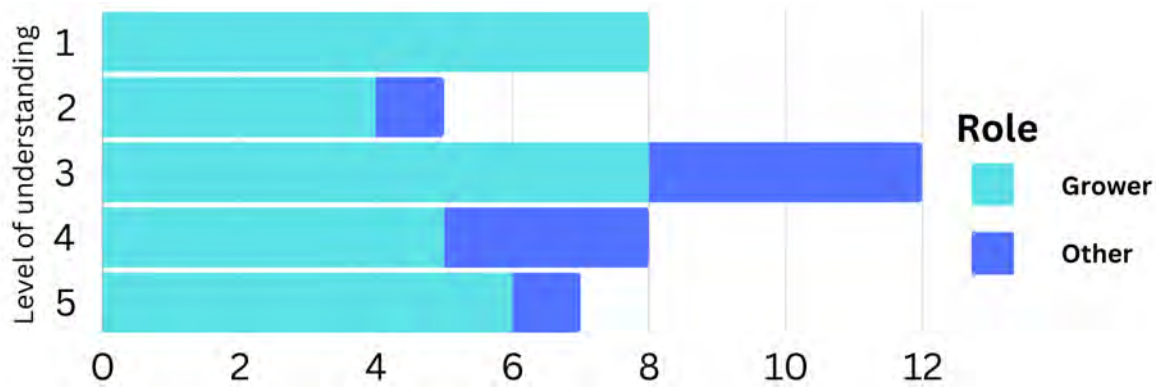


Figure 2. Industry responses (n = 40) to “How well do you understand what FDA is asking growers to do in response to proposed Subpart E?” question. Level of understanding 1 = I don’t understand at all; 5 = I understand very well what I am being asked to do.

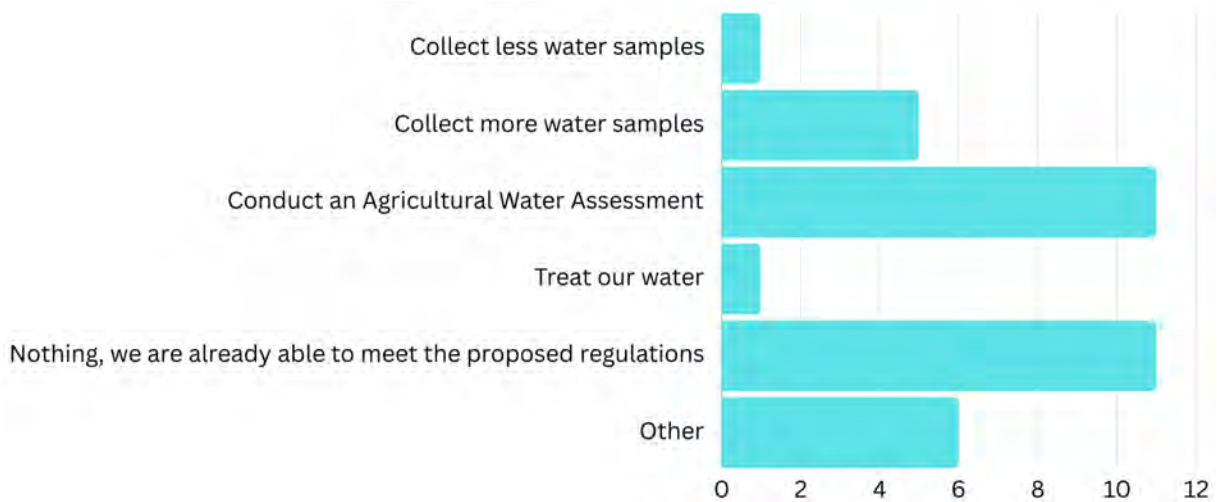


Figure 3. Grower responses (n = 35) to “What do you intend to do in response to the proposed subpart E language?” question.

released in December 2021 (six years after the publication of the initial rule). Most of the growers who reported that they were already in compliance were either large (6) or exempt (3) farms. This confidence could be attributed to the fact that the compliance dates for large farms was January 26, 2018, for covered activities and January 26, 2022, for activities related to the management of harvest and postharvest agricultural water; meaning that, at the time this survey was conducted, those farms were expected to be compliant with other aspects of the rule as verified through inspection. Inspections and assessments (such as On-Farm Readiness Reviews [OFRR] (33)) provide opportunities for growers to engage with regulatory authorities or other support about practical application of the requirements, questions related to compliance, and the status of requirements under enforcement discretion, such as those related to preharvest Subpart E. OFRRs, in particular, have

improved participant understanding of PSR requirements and developed teams of assessors (such as through Cooperative Extension) across the country to effectively evaluate farm readiness for inspection (18). Produce operations that are exempt from the requirements of the PSR would not experience changes to their operation because of the enactment of a final rule for preharvest Subpart E.

Growers also mentioned that they would conduct an AgWA (11/36; 30.6%), collect more water samples (5/36; 13.9%), and implement other actions (6/36; 16.7%), such as “Leave the business Sell farm” (Supplemental Material 4), and treating their water (1/36; 2.8%) or collecting less water samples (1/36; 2.8%). Most growers (17/30; 56.7%) reported having conducted an AgWA (or similar) before; although, most also reported not having looked at or used the AgWA tool provided by the FDA (28/32; 87.5%; (28)).

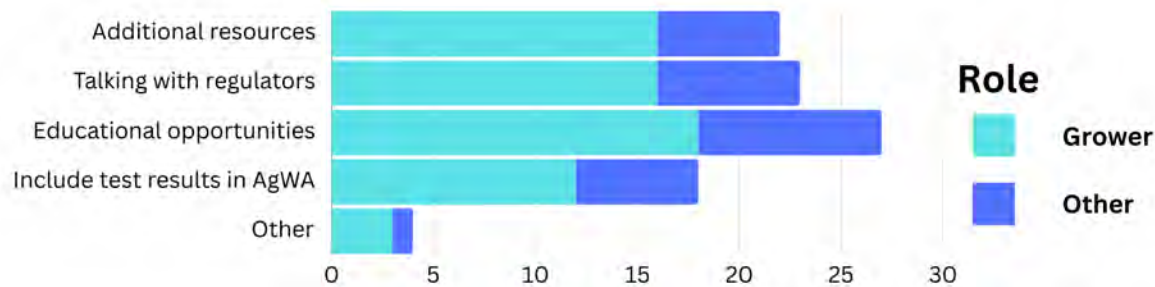


Figure 4. Industry responses (n = 36) to “What would make it easier for growers to comply with the proposed Subpart E rule language?” question.

When asked which version of the rule was preferred, most growers were unsure (14/30; 46.7%), with 43.3% of growers reporting that the new preharvest Subpart E was more difficult to implement than the previous version (which required testing; 13/30). Growers reported that educational opportunities (e.g., workshops) to learn how to conduct an AgWA (18/36; 50.0%), speaking with regulators about the challenges of conducting an AgWA (16/36; 44.4%), additional resources (e.g., fact sheets, videos, case study examples; 16/36; 44.4%), and the allowance of results from water testing to be included in the assessment would all reduce the burden of compliance with the new rule (12/36; 33.3%), in addition to other examples (3/36; 8.3%; Fig. 4). The AgWA structure currently allows for water test results to be included in the “Other relevant factors” section (32).

Growers’ mixed reactions to preharvest Subpart E suggest that compliance with preharvest water requirements is not currently growers’ highest food safety priority. This aligns with previous assessments of food safety priorities of the fresh produce industry that reported similarly discordant prioritization of preharvest water across industry roles, i.e., that fresh produce industry community members ranked preharvest water as the seventh highest food safety priority, while respondents in upper management positions ranked preharvest water as the second-most important food safety concern currently (5). One reason for this may be that, since the enactment of FSMA, growers have prioritized rule requirements with more recent compliance dates. Other studies examining the impact of PSR requirements on the fresh produce industry note differences in preparedness, perception of hazards, and overall compliance rates across regions, commodities, operation sizes, and market channels (1, 8, 13, 17, 40). Agricultural water also remains a topic growers consistently struggle with in PSR training knowledge gain assessments (19, 24). Delayed federal implementation dates for Subpart E, coupled with commodity-specific buyer requirements (e.g., the Arizona and California Leafy Greens Marketing Agreements), have undoubtedly contributed to the confusion and inconsistent priority rankings reported. This is further compounded by many fresh produce growers’

reluctance to adhere to additional practices before that compliance is mandatory (31), suggesting that the fresh produce industry does not currently fully grasp the intent of the preharvest Subpart E requirements to push growers who utilize surface water toward water treatment as a risk mitigation measure.

While more than half (16/27; 59.3%) of respondents ranked lower confidence (“1,” “2”) in regulators to regulate the proposed rule (Fig. 5), respondents ranked higher confidence (9/26; 36.4%; “4,” “5”) in Extension’s ability to educate industry about how to meet the requirements in the proposed legislation, the highest ranking across all roles. Respondents showed a mixed response to confidence in the industry to technically (“1” = 28.6% [8/28]; “2” = 17.9% [5/28]; “3” = 21.4% [6/28]; “4” = 21.4% [6/28]; “5” = 10.7% [3/28]) and financially (“1” = 39.3% [11/28]; “2” = 17.9% [5/28]; “3” = 21.4% [6/28]; “4” = 7.1% [2/28]; “5” = 14.3% [4/28]) comply with the proposed requirements (Fig. 5).

Voluntary adoption of preharvest Subpart E requirements prior to the release of a final rule and in the wake of continually changing priorities relies heavily on outreach and education efforts from trusted sources, such as Extension services (1, 13). Respondents’ confidence in Extension’s ability to educate the industry about how to meet the rule’s requirements is consistent with a previous study that found producers’ confidence in Extension’s ability to train on FSMA content was not a barrier to regulatory compliance (20). However, respondents showed a strong lack of confidence in the ability of regulators to regulate the preharvest agricultural water rule. This may be due in part to the subjective nature of the assessment-based decision-making model, which would require an individual to rely on their own personal knowledge and experience to conduct an AgWA, as opposed to the previous version of the rule, which relied heavily on achieving metrics (water quality microbial indicator thresholds). At the time this survey was conducted, the preharvest water requirements under preharvest Subpart E were not yet final, so regulators were utilizing enforcement discretion for Subpart E requirements (86 FR 69120). The

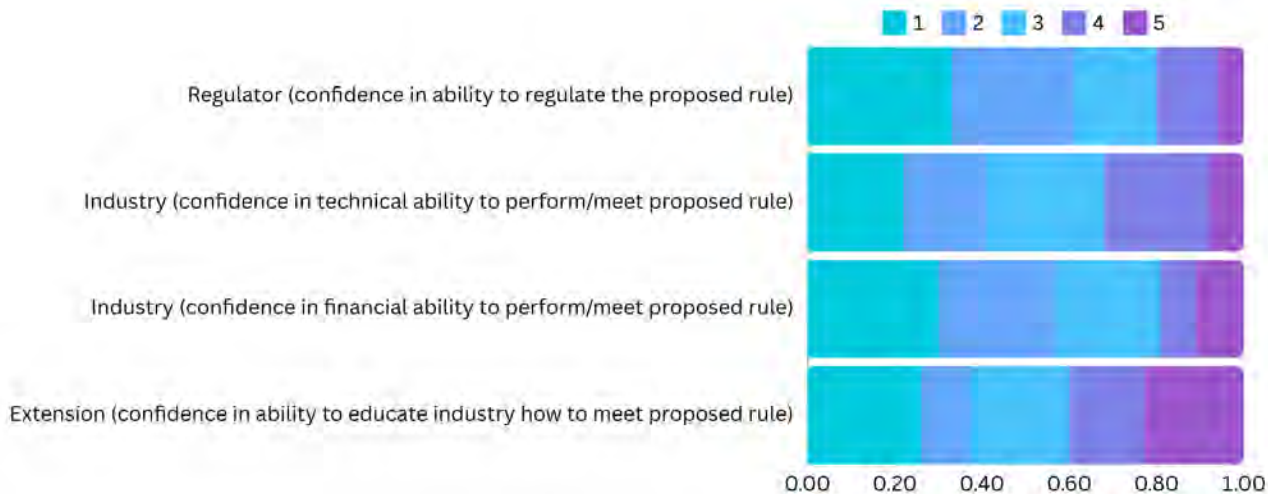


Figure 5. Industry responses to “Rate your confidence for each of the three groups as it relates to the proposed Subpart E rule” 1 = low confidence, 5 = high confidence

FDA announced the posting of a final rule in the Federal Register on May 2, 2024 (38), with the final rule released widely on May 6, 2024. The notice outlined requirements that integrate components of the initial rule, proposed rule, and public comments to support preharvest water management through changes to the requirements for preharvest agricultural water assessments (for fresh produce commodities other than sprouts) and mitigation measures; clarification related to timing and exemptions of preharvest agricultural water assessments; flexibility related to time interval-based mitigation measures; and revisions to records requirements. The final rule related to production water requires “systems-based assessments, with required testing in certain circumstances, that focus on key risk factors for contamination by preharvest agricultural water” (38), which are very similar to the requirements addressed in this survey.

While enforcement discretion provides regulators, educators, and the food industry as a whole time to understand, educate about, and comply with requirements, it has also resulted in a level of ambiguity across the industry that impedes successful implementation and may have also impacted the industry’s reported confidence in its own technical ability to meet the requirements of the proposed rule. Further, it is unclear what the financial cost will be to production water users under the proposed rule. Previous estimates of the costs associated with compliance with the PSR expected expenditures per acre to reduce with farm size, resulting in a greater per acre cost to small and very small farms compared to large farms (2). The FDA has estimated that “no additional costs will be incurred by state, local, and tribal governments or the private sector as a result of” extending compliance dates for Subpart E, but the agency had also only factored in activities related to specific

subsections (Table 1) to result in a cost (36). Due to the highly individualized nature of the proposed AgWA, it is expected that additional training costs related to education about conducting appropriate AgWAs will be warranted.

Growers treating preharvest water

When asked whether they were treating their preharvest agricultural water, 25.0% (9/36) of the growers surveyed said they were treating (Fig. 6), 77.8% (7/9) of which reported growing leafy greens (Fig. 7). Most growers were not (17/36; 47.2%); however, 8.3% (3/36) said they were considering it. Two respondents (2/36; 5.6%) admitted they did not know if they were treating their water, and four respondents did not respond to this question.

Of the growers who treat their preharvest agricultural water, most (6/8; 75.0%) are doing so for general risk management, followed equally by buyer and regulatory requirements (5/8; 62.5%). Less common drivers in the decision to treat water included water sampling test results (2/8; 25.0%) and consumer perception (1/8; 12.5%). The main drivers for grower decisions to treat preharvest agricultural water are shown in Fig. 8. One grower who treats their preharvest agricultural water did not respond to this question.

Training will remain an important part of ensuring current and future compliance with PSR requirements, especially related to treating preharvest water. Most of the growers who reported treating their water sold leafy greens and were operating in Arizona and California, states heavily impacted by the Arizona and California Leafy Greens Marketing Agreements’ requirements for treating preharvest water (7). Although this survey did not ask about specific audit or buyer requirements of growers, most growers who treated water

TABLE 1. Activities related to specific subsections of the Produce Safety Rule anticipated by FDA to result in a cost

Subsection	Subsection title or content
§ 112.42	What requirements apply to my agricultural water sources, water distribution system, and pooling of water?
§ 112.44	What specific microbial quality criteria apply to agricultural water used for certain intended purposes?
§ 112.45(a)(2)	Treat the water in accordance with the requirements of § 112.43
§ 112.45(b)(3)	Treat the water in accordance with the requirements of § 112.43
§ 112.46(b)	If you have determined or have reason to believe that your microbial water quality profile no longer represents the quality of your water (for example, if there are significant changes in adjacent land use that are reasonably likely to adversely affect the quality of your water source), you must develop a new microbial water quality profile reflective of the time period at which you believe your microbial water quality profile changed.
§ 112.46(c)	If you use untreated ground water for the purposes that are subject to the requirements of § 112.44(a), you must initially test the microbial quality of each source of the untreated ground water at least four times during the growing season or over a period of 1 year, using a minimum total of four samples collected to be representative of the intended use(s). Based on these results, you must determine whether the water can be used for that purpose, in accordance with § 112.45(a). If your four initial sample results meet the microbial quality criteria of § 112.44(a), you may test once annually thereafter, using a minimum of one sample collected to be representative of the intended use(s). You must resume testing at least four times per growing season or year if any annual test fails to meet the microbial quality criteria in § 112.44(a).

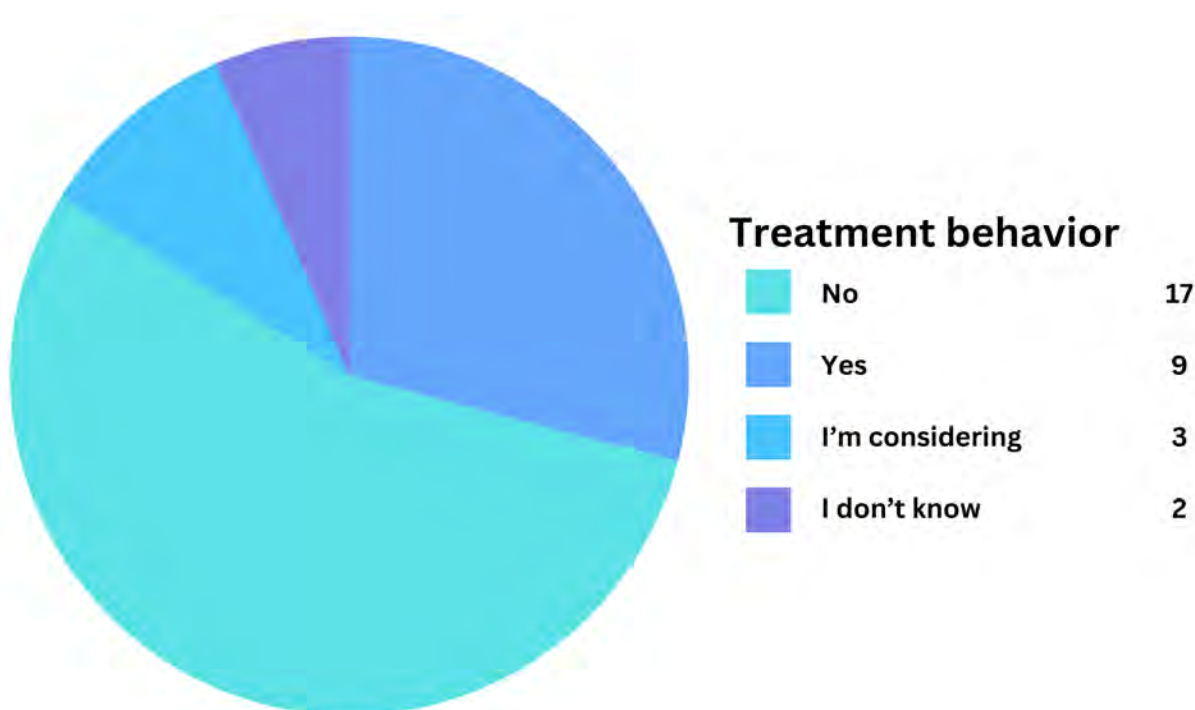


Figure 6. Grower responses to “Do you conduct preharvest agricultural water treatment on your farm?” question.

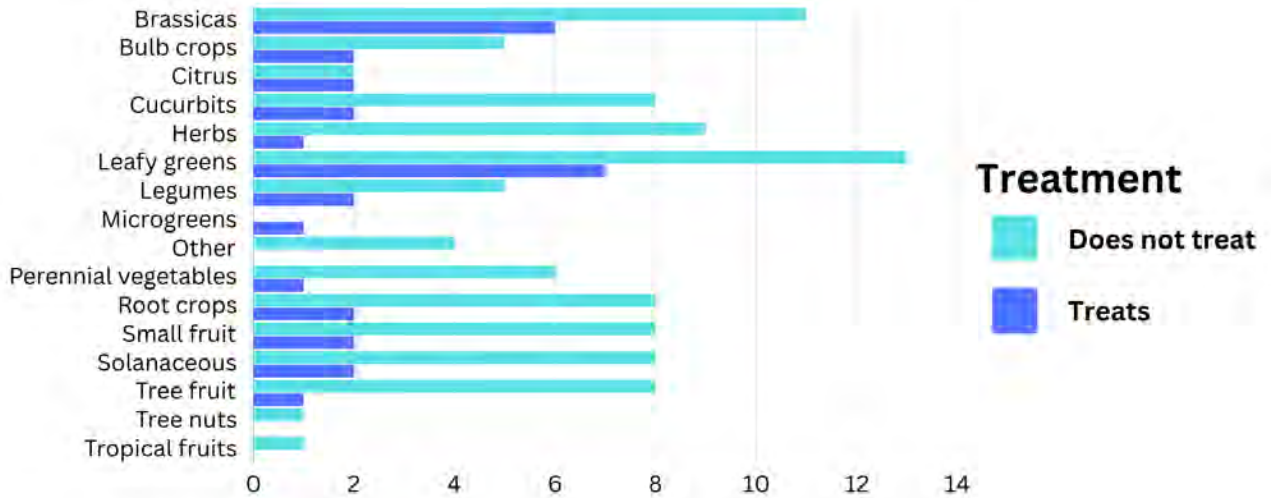


Figure 7. Comparison of reported crops grown by growers who do and do not treat their preharvest agricultural water (n = 36). One grower that reported treating water did not identify crops grown.

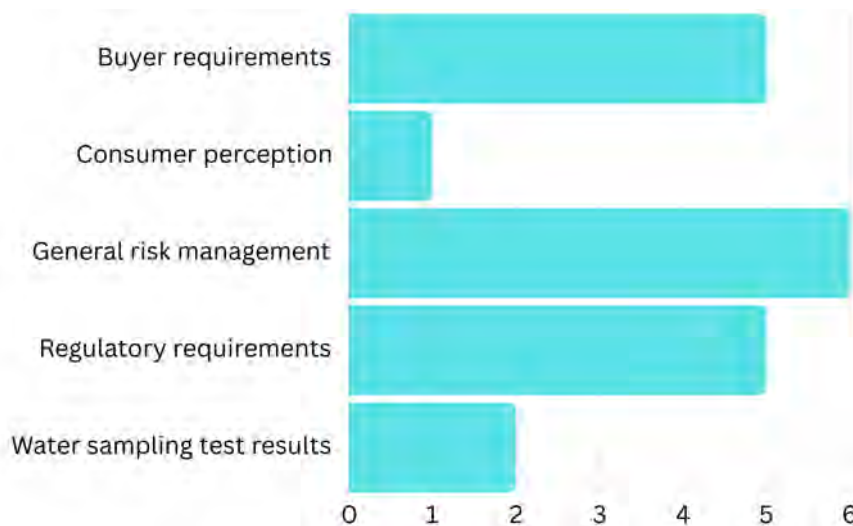


Figure 8. Grower responses to “What are the main drivers for your decision to treat your preharvest agricultural irrigation water?” question.

reported growing crops beyond leafy greens, and growers who reported not treating water also reported growing leafy greens, it is possible that the CA and AZ LGMA requirements influenced grower responses to the water treatment questions in this survey.

Of the 13 barriers included in the survey, the largest reported barrier that growers identified when treating preharvest water was the impact of that treatment on soil health, followed by treatment and reducing bacterial indicators, among others (Fig. 9). These reported barriers showed an emphasis on a variety of practical and technical

implication concerns. Growers showed a primary concern about the impact of the treatment on soil health, but there does not appear to be sufficient evidence to support that the treatment residual would result in damage to the health of the soil environment. A study evaluating the effect of chlorine used in irrigation water found that, even after 14 days of continuous chlorine treatment, no significant lasting effects on soil microbial community diversity or composition were observed (39). While some metabolic functions in the rhizosphere were impacted slightly by the treatment, function fully recovered after treatment discontinued (39). Another



Figure 9. Grower responses to “Please pick the top 5 challenges you face in implementing successful preharvest agricultural water treatment on the farm. (Drag and drop your selections into the box at the right. You can order them from 1 to 5, 1 being the greatest concern you have.)” question.

study found that the use of chlorine in drip irrigation systems impacted the microbial community structure in the soil, but that this did not impact crop yield (30). One study showed that free chlorine could have a negative impact on the soil environment in lettuce grown in pots, but this study was conducted in a small-scale laboratory setting that did not reflect the production structure or volume in commercial operations (15). A study has shown that peroxyacetic acid (PAA) and chlorine treatments impacted soil microbiomes, with PAA providing the more significant impact, but it is unclear if this resulted in a direct change in soil health (28). Additional research is necessary before this finding could be applied across the commodities, soils, and practices used in the fresh produce industry (28).

One of the second-highest barriers reported was the capability of water treatment strategies to reduce bacterial indicators; however, reducing pathogens was one of the lowest reported barriers to successfully treating preharvest water. This highlights an important disconnect between industry understanding and regulatory emphases (e.g., utilizing water treatment methods for the purpose of reducing risks associated with foodborne pathogens). This may be due, in part, to the emphasis placed on testing preharvest water sources for microbial water quality indicator organisms (i.e., generic *E. coli*) in the initial rule which, in the absence of a final rule, has been perpetuated in PSR and other water-related training activities.

CONCLUSIONS

Despite the previously uncertain climate surrounding preharvest water requirements, some fresh produce growers have been treating preharvest water to meet buyer and audit requirements. Educational water treatment programs

emphasizing practical implementation and decision-making strategies are needed to support grower use of water treatment. Training needs will likely also be impacted by specific grower commodities and regions in which they plan to sell their crops. Additional educational materials addressing food safety hazards, environmental concerns, and integrating food safety programming with existing programs will be necessary to support evidence-based decision-making related to completing the highly individualized AgWA, such as a risk ranking tool (29).

It is not currently known, nor has it been published as queried, how many growers are actively treating preharvest agricultural water as a reliable corrective or mitigation measure to comply with 21 CFR Part 112 Subpart E. This may be due to a combination of societal factors (e.g., unwillingness to share individual grower practices) as well as experimental design constraints. Given the inconsistency of expectations that accompanied changing agricultural water requirements, it is possible that respondents were not aware of regulatory requirements at the time of data collection, further shown by these data that less than half of respondents reported reading the rule (14/33). At the time of this survey, there were no sanitizers approved by the EPA to treat human health pathogens in agricultural water, which may have also impacted not only the practice of agricultural water treatment for this purpose but also the willingness of respondents to admit to potentially off-label uses of existing products. Lastly, survey fatigue (either due to survey length or the number of requests to complete surveys) likely impacted the response rate, as has been discussed extensively since the beginning of the COVID-19 pandemic (6, 9, 11, 23). Therefore, while the sample size observed in this study was smaller than what was expected, this study provides an important baseline

assessment of use and perceptions of Subpart E requirements (particularly related to treatment of preharvest water) that can be used to guide future hypothesis generation and priority setting for programmatic outreach, education and possible interventions to meet industry compliance needs.

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