

# Collaborative Food Safety Forum

## Agricultural Water Standards and Testing Protocols: Summary

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*October 3, 2017  
Washington, D.C.*

### Background

[The Collaborative Food Safety Forum](#) (CFSF or Forum) is a platform for multi-sector engagement on issues critical to keeping our nation's food supply safe, jointly sponsored by The Pew Charitable Trusts (Pew) and the Robert Wood Johnson Foundation (RWJF). On October 3, 2017, representatives from the U.S. Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), the U.S. Environmental Protection Agency (EPA), Centers for Disease Control and Prevention (CDC), farms, academia, and food industry trade associations discussed potential revisions to the FDA Food Safety Modernization Act (FSMA) Produce Safety Rule's (PSR) microbial quality standards and testing requirements for agricultural water. This was the second meeting on agricultural water convened by the CFSF; the first was held in August 2013 during the proposed rule comment period. This second meeting followed FDA's announcement of a proposed rulemaking to extend compliance dates for agricultural water requirements and a constituent update regarding reassessment of water testing requirements. During this extension, FDA aims to address questions about the practical implementation of compliance with certain provisions and to consider how FDA might further reduce the regulatory burden or increase flexibility while continuing to achieve FDA regulatory objectives, in keeping with the Administration's policies. Discussion at the CFSF meeting included proposals 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.

### Updates from FDA on recent activities regarding agriculture water requirements

Samir Assar, Director of the Division of Produce Safety, and Mike Mahovic, Branch Chief, Fresh Produce Branch, Division of Produce Safety, at FDA updated participants on the status of the PSR's water requirements, saying that while agricultural water has been one of the most challenging components of the rule, FDA is committed to getting it right.

FDA has proposed to extend to January 2022 the compliance date for subpart E (which contains the agricultural water provisions), with additional time provided for small and very small businesses. With this extended time, FDA will consider approaches to addressing concerns raised by stakeholders regarding the agricultural water requirements. Concerns often cited include that: the prevalence and concentration of the current analyte (substance being tested for) used in the standard for water testing, generic *E. coli*, is not inherently meaningful for public health protection because it is not universally correlated with the presence or absence of human pathogens in agricultural water; the high cost of testing due to required sampling frequency; the need for more flexibility to share testing data to reduce the burden on individual farmers; and a desire for additional approved testing methodologies. With

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regard to the last, FDA has already identified [eight additional methods](#) as scientifically valid and equivalent in precision, sensitivity, and accuracy to USEPA Method 1603 which is the method explicitly accepted in the PSR.

As FDA seeks to address additional stakeholder concerns, any revisions or adjustments to the agricultural water regulations must meet four criteria. Any potential revisions or adjustments should be:

- 1) scientifically-based and valid;
- 2) commonly understood and able to be clearly interpreted by those who implement and those who enforce;
- 3) practical and cost effective for all parties; and
- 4) at least equivalent to the current framework as related to public health protection.

FDA's aim is to listen to stakeholders and seek solutions to their concerns while protecting public health. At this stage, FDA remains open to all proposed options for increasing the feasibility of the agricultural water requirements. However, Dr. Assar stressed that any changes to the current requirements would have to be supported by a strong rationale, including meeting the four criteria outlined above. The goal is to arrive at science-based requirements simple enough to engender wide buy-in and compliance, which do not present an overly steep learning curve or burden on growers, and protect public health. The rule must also continue to provide FDA with a clear basis for enforcement. Dr. Assar noted that as they work to reassess the agricultural water requirements, FDA has indicated to buyers that they should not impose the existing agricultural water requirements on suppliers during the extended compliance period.

### **Perspectives on agriculture water requirements and proposed future frameworks**

Jim Gorny, Produce Marketing Association, and Jennifer McEntire, United Fresh Produce Association, who shared an article they wrote on this issue, outlined their perspectives on the current agricultural water requirements, including challenges; an examination of water testing required by audit programs; and an analysis of the relative importance of water testing to achieving the overall goal of public health protection. The full presentation by these panelists may be found [here](#).

Drs. Gorny and McEntire emphasized that while the produce industry is concerned about the cost of water testing, it is more concerned about its *worth*. For many, the current PSR agricultural water testing requirements do not seem worthwhile because there is no broadly-accepted evidence that they will significantly improve public health outcomes above current routine practices by the produce industry. Gorny and McEntire underscored this by highlighting findings from the FDA Regulatory Impact Analysis for the PSR that the agricultural water provisions regarding pre-harvest agricultural water use are expected to be 55% effective. They suggested that FDA might construct more effective requirements for protecting public health, perhaps through the use of other indicator organisms, improving the sampling plan to account for greater variability, and/or opting for a long-term risk assessment-based approach to provide the FDA with more and better data to inform rulemaking.

The current numerical requirements for water testing limit the geometric mean (a measure of central tendency, based on 20 or more samples) to no greater than 126 CFU of generic *E. coli*/ 100 mL sample of

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water, and a statistical threshold value (STV; a measure of the variability) of no greater than 410 CFU of generic *E. coli*/100 ml of water. These values were derived from criteria set forth in the EPA's 1986 report [Ambient Water Quality Criteria for Bacteria and later supported by EPA's Recreational Water Quality Criteria \(2012\)](#). These numerical requirements apply for agricultural water used during growing, for direct water application methods, for all covered commodities across all climates and regions. However, the agricultural water requirements also incorporate flexibility in situations where growers use different numerical requirements, drawing on concepts outlined by the World Health Organization (WHO) regarding in-field die-off, postharvest microbial reduction practices, and alternative application methods of water. Additional information on the current requirements for agricultural water testing can be found [here](#).

On one hand, the numeric values codified in the PSR provide growers and regulators with a clear, enforceable quantitative standard. On the other, some have questioned the merit or appropriateness of setting so prescriptive a value – given that this EPA numeric standard was not developed nor intended for use in assessing public health risk associated with agricultural water used to grow, handle, or pack fresh produce, nor does it take into account the wide variety of water sources, crops, and growing situations across the world. If it remains codified in the rule (as opposed to in guidance), FDA will have less flexibility to adjust this requirement in response to emerging science and other new information.

There is language in the rule allowing for the use of alternatives if they provide the same level of public health protection as the specified requirements. The alternatives can be used, for example, in lieu of the required fecal indicator organism, or the required testing frequency for surface water. Alternatives are not required to be “cleared” or “approved” and growers are able to use them as long as there is sufficient scientific support for the use. However, Gorny and McEntire asserted that because there is no specified process whereby growers can confidently develop the scientific support and determine if the alternative is equivalent in public health protection, individual farmers are reluctant to exercise this option, effectively stymying its use. Gorny and McEntire also stated that stakeholders may feel more comfortable knowing that FDA has an approval process for alternatives and may post “approved alternatives” to the FDA website for others to access. As stated, earlier this year FDA identified eight other testing methods for assessing the adequacy of agricultural water microbial quality that are equivalent to Method 1603. Gorny and McEntire requested that FDA consider establishing a mechanism for evaluating and approving additional alternative testing methods and sampling schemes that take into account varied growing conditions and practices.

Finally, a number of agricultural water testing protocols are already in practice across the produce industry. For example, many farms test their water as part of regular audits required of them by buyers. Most of these audit programs, including USDA's Harmonized GAPs, PrimusGFS, and SQF, do not prescribe a specific testing method or required result value (like 126 CFU *E. coli* /100 mL), but rather provide flexibility for growers to determine an appropriate method and target range for their region and commodity (e.g., by working with cooperative extension or referencing other commodity-specific guidances). Participants discussed the idea that the protocols included in audit requirements might be acknowledged as satisfying the water testing requirements under FSMA, as a first step, until additional

science-based testing requirements tailored specifically to agricultural water use and demonstrated to enhance public health protection are developed.

Throughout the discussion, participants echoed and built upon many of the points, questions, and concerns outlined above. Their comments highlighted the following diverse viewpoints and complexities:

- It was generally acknowledged that generic *E. coli* alone is an inadequate analyte to determine the adequacy of agricultural water and if possible better analytes or a portfolio of analytes, such as index organisms (that indicate the presence of pathogens), need to be identified to better assess the presence or absence of human pathogens in agricultural water. Generic *E. coli* can sometimes serve as an indicator of agricultural water fecal contamination but this provides limited insights on the degree of public health risk. In recognition of this situation, FDA attempted to provide flexibility in the standard by including corrective measures allowing for in-field die-off and microbial removal and allowing the use of alternative approaches for assessing water quality with the caveat that any alternative approach must be scientifically-based and provide the same level of public health protection as the established testing framework. However, translating from the risk-based *recreational water* quality standard to an agricultural water quality outcome, and the requirement to demonstrate equivalent public health protection, makes exercising this flexibility difficult for growers, in part because the existing PSR standards themselves have not been definitively shown to provide enhanced public health protection compared to current industry practices with respect to agricultural water. Participants added that, even with a robust testing method in place, safety cannot be “tested into a product.” Rather, testing should be used to validate a hazard analysis and critical control points (HACCP) approach.
- Demonstrating that alternative testing approaches provide public health protection equivalent to the current requirements is challenging. FDA acknowledged that in adopting the EPA recreational water criteria, they are accepting EPA’s illness-outcome rates. However, as several participants pointed out, exposure through recreational water is different from exposure through agricultural water (i.e., ingested volumes, die-off or growth rates, different pathogens, etc.), and thus may not be comparable in terms of likelihood of illness. Many participants questioned the scientific validity of basing a public health standard agricultural water on epidemiology related to recreational water. Given this concern, they resisted the notion that alternative methods must provide equivalent public health protection as the current requirements.
- Codification of a quantitative standard in the rule gives a firm, understandable and enforceable target, but the current FDA standard is difficult to update as agricultural water quality science evolves. By contrast, if the quantitative standard is not in the regulation (i.e., is in guidance), then it is relatively easier to update based on better science. The tradeoff is that a guidance document provides a less clearly enforceable standard (the regulation might just require “that all agricultural water be safe and adequate for its intended use.”)

- Growers are willing to invest time and money into meeting the PSR requirements, if they can be assured there is value in expending the resources. Value comes from either knowing they are reducing risks or generating valuable information that helps them manage practices to reduce risks. Because farming is not a static operation, growers need a sense of the value of, as well as some degree of flexibility in, meeting PSR agricultural water requirements. This flexibility should reflect the diversity of crops, growing conditions, and costs of meeting these requirements. The challenge from an outreach perspective is that too much variability makes a national program difficult to explain, comply with, and evaluate in terms of effectiveness.
- Increasing awareness of the importance of agricultural water quality is being spurred not only by the PSR, but also by programs such as GlobalGAP, CA and AZ LGMA, and other initiatives that require assessment or testing of agricultural water quality. Linking to or building on these efforts could help explain the value added, reinforce the importance of agricultural water quality, and increase adoption of requirements and compliance. However, not all programs are consistent, and there is little understanding of the extent of adoption and effectiveness of these programs to reduce the risk of microbial contamination and, ultimately, of foodborne illness. This understanding is important for linking PSR requirements to what growers are doing in other programs.
- Participants supported building the science base needed to develop agricultural water management practices that provide the highest possible level of public health protection. However, they recognized that development of this body of research could require significant time and resources, and growers are anxious now for an indication of what the rule will require and what steps they should be taking to come into compliance. Additionally, compliance deadlines – even extended ones - require the Agency to implement a program intended to advance prevention and improve public health outcomes. Thus, tension exists between the desires to methodically determine and put in place the most appropriate standards, and to relieve businesses of the uncertainty felt while the rule is being revisited, as quickly as possible. It should be stated again, that the market place has its own requirements, so growers are trying to streamline efforts to navigate both regulatory and buyer requirements.

### **Potential strategies for revising FDA's agricultural water testing frameworks**

Participants navigated these disparate points of views as they began to propose and discuss potential approaches to revising the PSR agricultural water requirements. Suggested proposals are intended to make requirements more effective and efficient for farmers while continuing to strive for more defined public health protection and more effectively meet the listed criteria. These options included approaches that could be reasonably enacted in the near-term and longer-term approaches that would require more extensive research and documentation. A combination approach was also discussed where short-term efforts were coupled with an aggressive research agenda, and linked to mechanisms ultimately putting into place a risk-based approach in a longer term plan. Additionally, participants assumed that testing, or validated and verified treatment, would continue to be part of any agricultural water requirements going forward, but thought that there was not enough scientific data to clearly define the best analyte for determining pathogen presence, how often testing should be completed, and what are the appropriate quantitative thresholds. Questions also remained around how to outline

appropriate flexibility for the range of variables at play on farms, and be sensitive to the additional costs and relative benefit of improved public health protection associated with a particular approach.

Discussion centered around three primary short-term approaches:

1. Leaving the current agriculture water standard in a regulation while defining “FDA approved alternatives” in a guidance document. The “FDA approved alternatives” specified in guidance would, if met, demonstrate a comparable level of risk reduction and demonstrate compliance with the PSR agricultural water requirements.
2. Replacing the current quantitative requirements specified in the regulation with a qualitative standard and defining “safe harbors” in guidance. A “safe harbor” in this context is an approach that demonstrates comparable risk reduction and provide comparable compliance to the current agricultural water regulation. *Note: “safe harbor” was used in this forum as defined above and is not intended to carry any additional legal connotation as it might in other contexts.*
3. Recognizing (or perhaps codifying) the current private industry agricultural water quality standards, as a baseline of appropriate control, until a definitive science-based standard or approach is identified and validated.

And one long-term approach:

4. Performing a multiyear quantitative microbial risk assessment collecting data from across key produce production areas looking at indicators, human pathogens, and using next generation sequencing microbiome analysis to identify a portfolio of index organisms that correlate with the prevalence of human pathogens and potential risk.

These four proposals are detailed further below, along with key questions, challenges and other considerations raised by participants related to each concept. Again, participants noted that these should not be thought of as mutually-exclusive options; a final approach could include elements of all four proposals. For instance, a short-term approach could be implemented while simultaneously initiating a long-term risk assessment.

### **1. Leaving the current agriculture water testing requirements in the rule while defining “FDA approved alternatives”**

FDA’s current water requirements establish a standard for assisting growers in determining whether the microbial quality of water used in produce operations is adequate for its intended use. Participants expressed concern over the rigidity and universality of these provisions that apply across growing regions, climates, water sources, and distribution systems. This one-size-fits-all approach, they maintained, fails to account for the dynamism of growing conditions and practices across the country and the globe that impact the relative “adequateness” of the microbial quality of agricultural water. In some cases, the current regulation could cause farmers to employ a standard that is inappropriate for, or to take steps unreasonable for, their particular circumstances. For instance, farmers who grow covered produce on rotating fields may have difficulties complying with current long-term testing requirements. Farmers must also continue testing with the same frequency even if years of sampling data have shown a water source to be consistently compliant.

As stated, the rule does allow flexibility to use alternative approaches for assessing water quality, provided that they provide the anticipated same level of public health protection as current requirements. Given the technical complexity of developing and quantitatively defending a different way to assess water quality and its public health impact and the lack of clarity of the public health impact of the current testing requirements, many in industry believe that these criteria do not actually provide growers realistic latitude for advancing alternative approaches or ameliorate concerns of over-prescriptiveness.

Rather than rely on a single, quantitative standard, participants proposed that FDA work with stakeholders to develop a compendium of qualitative criteria likely to ensure adequate water quality based on categories of farm and water-source characteristics. If met, these criteria would allow farms to follow less burdensome testing requirements yet to be defined, or be exempted from them. These “FDA-approved alternatives” would be defined in guidance (e.g., businesses that meet the characteristics described under category A and satisfy criteria X, Y, and Z are in compliance with the PSR agricultural water requirements). “FDA approved alternative” would be developed by FDA with input from stakeholders. For example, farmers and other stakeholders could submit proposed processes or criteria for their growing situation, which FDA would then evaluate and approve or reject. Alternatively, FDA could develop broad categories that combine growing situations and water sources and identify water standards and testing requirements for each by relying on examples submitted by stakeholders.

*Rationales for this proposed approach included:*

- This approach would better account for and accommodate the wide variety of water sources and growing situations, and would provide farmers with flexibility to use an approach specifically suited to their region and water sources.
- Many growers already use water quality controls reflective of those that would likely be incorporated into the criteria for any “FDA approved alternatives” because these would be defined by the current state of knowledge. This approach would affirm that many farmers are already implementing quality control measures rather than impose a shift in practice and associated costs.
- Such criteria would likely be easier for farmers to understand and translate to practice.
- Establishing “FDA-approved alternatives” in guidance would take the burden of demonstrating the scientific merit and public health impact of alternative approaches off of individual growers.
- Defining these “FDA approved alternatives” in a guidance document would be more easily updateable and therefore more responsive to emerging science, new technologies, changing practices and climate, and other evolving factors.
- The current requirements would remain in regulations as an option for those who cannot or do not wish to conform to an “FDA-approved alternative” option. Moreover, putting “FDA-approved alternatives” in guidance would reduce or eliminate the need to provide a rationale for changes in the regulation.

*Challenges and drawbacks associated with this proposed approach included:*

- While one-size-fits-all requirements may not be appropriate, it is also unreasonable to expect FDA to develop and enforce individualized requirements for each farm and growing situation. Additionally, the adoption of and compliance with individualized requirements could be very complex and difficult. What is the appropriate balance between flexibility and standardization? How many categories or “alternative approaches” would have to be defined? These considerations will affect the feasibility and timeline of this approach.
- FDA is committed to maintaining a level playing field. This does not necessarily preclude setting different requirements for different types of operations, but FDA must avoid disparate rules and guidance, and it must be cognizant of the potential to unduly disadvantage some operations relative to others.
- Growers in the US may understand that adherence to guidance is strongly recommended, but growers in other countries that export to the U.S. may not. Similarly, guidance may provide alternatives that are relevant to some domestic farms but not others. Because of this these growers may be held to different requirements, if “FDA-approved alternatives” are defined in guidance.
- This approach does not address fundamental concerns raised by participants: 1) that the current standard of risk for agricultural water claims scientific validity based on epidemiology related to EPA’s recreational water standard; 2) that generic *E. coli* indicates presence of fecal contamination, without indicating whether that contamination carries human pathogens; and, 3) lack of evidence for the level of public health protection provided by the current provisions, and thus, for the requirement that proposed alternatives provide equivalent protection.

## **2. Replacing the current quantitative standard in regulation and outline situation-specific “safe harbors” defined in guidance**

Given concerns with the effectiveness, cost, and efficiency of the current agricultural water quality standard and testing requirements, participants proposed moving the current requirements wholesale from a regulation to a guidance document. The regulation would include a “qualitative” standard, with the current requirements becoming just one example of an acceptable quality standard and monitoring program, along with other standards and testing methods (all of which would become “safe harbors”) This would be accomplished through a process similar to the one described in approach #1. This approach could be supplemented or replaced by new, more effective requirements once an agricultural water-specific risk assessment was performed.

### *Rationales for this proposed approach included:*

- If the current requirements and public health standard remained in the rule, participants were concerned that they would continue to be the *de facto* requirements even if “safe harbors” were defined in guidance. This approach runs counter to the intention of developing approaches for situations in which the current standard may be inappropriate. Moving the current provisions to guidance would help to alleviate these concerns.
- Removing the universal quantitative standard from the rule would clearly signal to farmers and other stakeholders that their concerns about the current agricultural water requirements have been heard and seriously considered.



- This approach would better account for and accommodate the wide variety of water sources and growing situations, and would provide farmers with flexibility to use an approach specifically suited to their region and water type.
- Many growers already use water quality controls reflective of those that would likely be incorporated into the criteria for any “safe harbors.” This approach would affirm that farmers are already implementing quality control measures rather than impose a shift in practice and associated costs.
- Such criteria would likely be easier for farmers to understand and translate to practice.
- This approach would take the burden of demonstrating the scientific merit and public health impact of alternative approaches off of individual growers and researchers.
- Defining these “safe harbors” in a guidance document would be more easily updateable and therefore more responsive to emerging science, new technologies, changing practices and climate, and other evolving factors.
- Leaving the current requirements in the rule would make them harder to modify in response to new science, technologies, and other factors.

*Challenges and drawbacks associated with this proposed approach included:*

- There is no generally accepted public health standard derived specifically for agricultural water quality. If the current standard were removed from the rule, against what standard would “safe harbors” or other alternatives be assessed? A new (preferably quantitative) standard would have to be developed, evaluated, and verified, a process likely not accomplishable within a short period of time.
- The current framework containing discrete criteria benefits farmers by providing a “bright line” marker for compliance and for when additional action is necessary. Moving to a guidance-based approach would blur this line and potentially make it more difficult for farmers and regulators to say definitively whether an operation is in alignment with FDA’s promulgated practices.
- Removing the current regulation could have a higher administrative and potential political cost than simply providing additional guidance, and might have a cascading impact on businesses. Providing rationale for the transition from the current provisions to this approach would be more difficult for the agency to explain – specifically with regard to being charged with developing and enforcing a prevention-based rule, while moving away from a clear standard.
- A chief challenge to approach #2 is the implications for FDA’s regulatory enforceability of the PSR requirements. Enforcing language put forth in guidance is much more challenging than standards codified in rules. Certainly, many produce operations may follow guidance for water quality control, but FDA would have limited ability to compel those that did not. Strictly speaking, there would be no enforceable agricultural water quality standard. Relying on a purely qualitative standard, such as one that might be characterized as a “safe harbor,” also presents a regulatory enforcement challenge. More subject to interpretation than a qualitative standard, qualitative standards create gray areas that may only be revealed as problematic after there is a contamination event.

- Participants pointed out that FDA still retains its pre-FSMA authority to prosecute businesses that introduce adulterated food into commerce under the Federal Food Drug and Cosmetic Act. In this sense, FDA would still have the ability to take corrective action even if there were no explicit water quality standard and testing requirements. While true, reliance on this authority runs counter to the intended, prevention-based spirit of FSMA. Responding to food safety failures only after they have caused illness is not a preventive strategy. Moreover, rather than defining adequacy standards, it places the onus on FDA to prove inadequacy on a case-by-case basis, which is a lengthier and more difficult undertaking.

*Others considerations:*

- Participants stressed the need for reference tools to determine comparability with any agricultural water quality standard that FDA sets, as well as clear actionable risk-assessment tools to determine and rank hazards associated with their site and procedures. Participants pointed to several tools already in development that could be adapted or serve as a model for this purpose, and added that such tools should be validated and updated as necessary based on a strong research agenda:
  - The EPA is developing a sanitary survey tool to help assess risk levels on a given site, based on the presence of fecal sources. EPA believes this tool will be ready in about six months, but could potentially share a draft version with FDA as it revisits the PSR.
  - Trevor Suslow and the Postharvest Center at University of California Davis are developing a series of decision trees to assist growers in qualifying irrigation water sources and responding when water is found to be non-complaint.

**3. Recognizing current private industry standards as a beginning baseline of control for risks associated with agriculture water quality**

Participants noted that the proposed process for defining “FDA-approved alternatives” or “safe harbors” with the PSR agricultural water standard resembled the process used to develop Harmonized GAPS and other audited schemes, and suggested that a defined agricultural water microbial standard is already included in some of these programs. Use of private standards across the industry has increased steadily, driven by buyer expectations. If “FDA-approved alternatives” or “safe harbor” criteria would not be substantially different from these requirements already followed by many growers, why not simply accept or codify these program standards? This question seems particularly pertinent, participants added, in the absence of strong evidence that the current PSR requirements will provide improved public health protection.

Given these factors, participants proposed that FDA could recognize through guidance current private agricultural water standards as a baseline for a PSR agriculture water microbial quality standard and allow reliance on them while additional research is done. This approach could be supplemented or replaced by new, more effective requirements once an agricultural water-specific risk assessment was performed.

*Rationales for this proposed approach included:*

- As stated, many farms already undergo regular audits related to private water quality standard requirements. Some audits also require sanitary surveys of water sources or other practices that help growers understand the risks posed by their agricultural water. With this widespread practice, many in industry see the current PSR agricultural water requirements as simply added cost without demonstrated value. Participants discussed their interest in encouraging greater understanding of the role agricultural water quality plays in producing safe food, and to increase use of practices that involve greater awareness of agricultural water quality along with strategies for improving it. Reinforcement of activities already being adopted could help meet these objectives.
- It is clear that more research is needed to more accurately assess the risk of agricultural water for specific uses. This approach offers a low-burden, interim measure that would allow time for additional research while following existing practices. Relying on current private standards would also be a less taxing process for both the agency and stakeholders than developing “safe harbor” criteria for multiple situation types.
- This approach would better account for and accommodate the wide variety of water sources and growing situations, and would provide farmers with flexibility to use an approach specifically suited to their region and water type.
- This approach would affirm that farmers are already implementing quality control measures rather than impose a shift in practice and associated costs.
- Such criteria would likely be easier for farmers to understand and translate to practice.
- This approach would take the burden of demonstrating the scientific merit and public health impact of alternative approaches off of individual growers and researchers.

*Challenges and drawbacks associated with this proposed approach included:*

- There has been a rash of illnesses linked to produce in recent years. While it is unclear whether the PSR agricultural water requirements offer increased public health protection, or whether contaminated water was at issue in any of the outbreaks, the produce industry is experiencing an ongoing public health problem. This seems to illustrate a need for additional standards or safety requirements to enhance public health protection, even beyond the private standards currently adopted by many growers.
- There is no established framework for evaluating private standards. Some private standard schemes require some sort of a risk assessment and water testing, but there is no assurance of the soundness of the methods used. Participants acknowledged that even when testing water is required under private standards, some guidance borrows from USEPA’s body of knowledge related to recreational water because there are few if any other criteria available.

#### **4. Performing a multiyear risk assessment of agricultural water**

Proposals #1 - #3 represent approaches to revising the PSR’s provisions for agricultural water quality that remain essentially within the rule’s current framework and are implementable in the relatively near term. They do not, however, address the underlying lack of understanding around the relative risk of agricultural water microbial quality as a source of illness, contamination pathways, and around effective

ways to measure the presence of human pathogens in agricultural water across a broad range of conditions. There has not been a long-term risk assessment performed for agricultural water. Nor has an analyte been identified that reliably correlates with the presence or the amount of human pathogens associated with fecal contamination in agricultural water. Given the irregular occurrence of pathogens in fecal sources that contaminate agricultural water, it is possible one may never be found. Such gaps originally led to the use of EPA's recreation water-based risk standard and reliance on monitoring (testing) generic *E. coli* as a preventive control that sparked concern among stakeholders. Participants agreed these are pressing research gaps, and that filling them would likely be a long-term (i.e., beyond the time frame of the onset of compliance) process.

Participants proposed that FDA (and other research entities such as the Center for Produce Safety, academic institutions, etc.) invest in long-term quantitative microbial risk assessments (QMRA) to potentially identify a suite of index and/or indicator organisms and characterize the risk associated with agricultural water quality across a variety of commodities, growing conditions and water sources. Or, absent such a suite, developing probability distributions of pathogen occurrence in relation to *E. coli* densities to inform risk assessments. New science and more effective sampling programs could be drafted into guidance as they become available. Perhaps, eventually, these characterizations could then be used to classify tiers of risk for different types of water sources, crops, and regions, and define sampling schedules for each tier (higher risk = higher sampling/testing burden).

*Rationales for this proposed approach included:*

- This approach addresses the fundamental lack of scientifically-based, agricultural water microbial quality standards and testing requirements, believed to be hamstringing the current agricultural water requirements. It focuses on the foundational need to gain a better understanding of the risks associated with agricultural water quality and associated risk management strategies to mitigate them.
- One of the challenges of developing alternative approaches to the current water testing requirements is the lack of standards to evaluate them against and tools/mechanisms to draw that comparison. Additional research could contribute to the development of these resources or index the quantitative risk to existing standards based on quantitative risk (e.g., the USEPA risk-based recreational water criteria). This is one way to reliably demonstrate public health protection and compare approaches.

*Challenges and drawbacks associated with this proposed approach included:*

- Characterizing the risk of agricultural water is complicated significantly by the high degree of variation across and within water sources and the use of that water on different crops and under different growing conditions. Weather events, climate shifts, animal activity, upstream contamination, and other uncontrollable factors can quickly and dramatically affect the contamination levels of a given water source and the likelihood that contaminants will persist. Because of this, a "baseline" risk profile, or even a series of profiles for different source types, would not be consistently informative.
  - However, participants added that so long as growers are incentivized to remain highly conscious of such events and their potential risks, having even an approximate baseline would help them determine whether changes have occurred and whether additional action is necessary to reduce risk and assure water quality.

- Participants also noted that risk assessments could be used to distinguish between commodities with clearly different risk profiles, without requiring exact values. This information could be used to develop different water requirements for various commodities (e.g., the risk associated with spinach is orders of magnitude higher than onions, so testing requirements for spinach should be more stringent.)
- Epidemiological data are not currently available to conduct a QMRA for agricultural water. However, EPA has established illness rates associated with the current criteria for people who use water recreationally; these illness rates could be adapted for fresh produce by accounting for different volumes of water consumed. These data must be produced, which as noted, would likely be an extended process. Results of such studies may not be available in time to inform current rulemaking and to meet compliance deadlines. However, if flexibility and mechanisms to incorporate emerging data were incorporated into the regulations, QMRA results could be drafted into guidance for the PSR at a later date.
- Initiating a risk assessment at this stage would not provide industry with direction for how to prepare to comply with the current requirements. Growers will still require guidance in the near-term that this approach alone will not supply. A short term approach and accompanying guidance would be needed while a risk assessment was completed.

### **Other considerations:**

In addition to the four proposed approaches framed above, participants surfaced a number of other topics with implications for FDA as it works to revise the water testing requirements in the PSR.

#### *Data sharing to increase awareness of water testing already being done and reduce redundant testing*

The EPA, state and municipal agencies, irrigation districts, private companies, and other entities are already responsible for monitoring a large number of the public water sources across the country. Participants questioned why this testing data is not systematically shared with growers to reduce the testing burden on individual farms and businesses, beyond the explicit sharing allowed in the PSR related to public drinking water supplies. It seems duplicative and unnecessarily costly to test water when that data are already held by a public entity. Participants suggested that interagency coordination could be improved to aggregate and institutionalize the sharing of public water testing data. FDA representatives agreed, while stating that it would be easier for FDA to support such an initiative between federal agencies than at the state or local levels. Participants recognized that opportunities to leverage public water data would not be available to all farms or regions. Participants also noted that there is a database that exists currently, the [Water Quality Portal](#), with data on water sources in the United States.

It was suggested that data sharing could be one of the topics addressed at the Agriculture Water Summit scheduled for early 2018, or that a separate summit/deliberative process be held specifically around this issue.

#### *Further guidance for current provisions*

Though much of this discussion focused on ways to revise the water quality standards and testing requirements or alternative approaches to them, participants also highlighted areas in need of further guidance within the current water testing framework. These areas included:

- 1) Whether and how testing data could be pooled or shared between growers to minimize the testing burden on individuals.
- 2) Guidance on where samples should be drawn to increase relevance to public health protection.
- 3) Clarification on “prior to harvest” wording on farms that harvest multiple commodities throughout an extended farming season.
- 4) Guidance on how to interpret testing results.

Participants did not discuss these issues in depth, but emphasized they should be addressed FDA is considering whether to revise the PSR agricultural water standards, and particularly if the current testing provisions remain in place.

#### *Issues of perception*

Those with opportunities to attend forums and interact with FDA know the agency has heard and is seriously considering stakeholders’ concerns. However, participants reported that many other stakeholders do not share this perspective. With the compliance dates now twice deferred and the water testing requirements open to revision, stakeholders have little firm direction to prepare to comply with future provisions. This uncertainty has stirred stakeholder anxiety and lessened the industry’s confidence in the regulatory process. Participants asserted there would be value in FDA clearly indicating what direction it will pursue as soon as possible to both signal that stakeholder feedback has been influential and to alleviate uncertainty. Growers, too, are wary of how a substantial course correction by FDA might affect public perception. Industry faces potential consumer backlash if changes to the rule are perceived as an attempt to duck or lessen safety regulations, potentially at the expense of public health.

These considerations underscore why changes to the PSR agricultural water requirements must be rolled out along with explanation of why they are consistent with the specific requirements in FSMA to establish science-based standards (a standard the current rules do not meet) and meet the spirit of FSMA as a prevention-based law. The rationale describing how any changes will continue to meet the four criteria mentioned before will help align growers, the FDA, and consumers on the path forward.