

April 5, 2022

Dr. Robert Califf

Commissioner

U.S. Food and Drug Administration

*Submitted electronically*

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

Dear Commissioner Califf:

Consumer Federation of America appreciates your consideration of these comments on the U.S. Food and Drug Administration’s Proposed Rule to amend the agricultural water standards of the produce safety rule. As we indicated in our joint comments with the Center for Science in the Public Interest, we commend FDA for moving forward in implementing this important part of the Food Safety Modernization Act, and we support aspects of the Proposed Rule that will require growers to conduct comprehensive, scientifically sound hazard analysis and mitigation related to agricultural water use. However, the lack of enforceable, prescriptive standards in the Proposed Rule raises a significant concern that many food safety hazards will evade remediation, if not detection, and that government inspectors will not have adequate tools to hold noncompliant growers accountable. CFA writes separately here to urge FDA to provide clearer directions for growers and inspectors alike in the final rule. In particular, FDA should clarify that water assessments required under the Proposed Rule must incorporate validated microbial testing, and that growers must treat water in certain high-risk circumstances.

Background

As the proposed rule details, numerous produce outbreaks have rattled consumer confidence in recent years. Indeed, produce may represent the most important source of foodborne illness in the United States. According to the most recent foodborne illness attribution data, over half (55.9%) of *E. coli* O157 illnesses were attributable to “Vegetable Row Crops (such as leafy greens),” while “Fruits,” “seeded vegetables (such as tomatoes)” and “Other Produce (such as fungi, herbs, nuts and root vegetables),” accounted for over a third (33.4%) of foodborne *Salmonella* infections.[[1]](#footnote-1)

In addition to the suffering of foodborne illness victims, produce outbreaks have wide-ranging impacts on public health. Ironically, to the extent that food safety concerns lead consumers to avoid produce and opt for less healthy foods, they may end up increasing the burden of foodborne illness, because food safety risk is tied to nutrition: studies show that eating healthier foods boosts individuals’ immunity to infections from foodborne pathogens.[[2]](#footnote-2) More generally, produce outbreaks threaten to exacerbate unhealthy dietary trends that have created a tsunami of diet-related disease and now cause hundreds of thousands of premature deaths each year.[[3]](#footnote-3)

FDA is therefore justified in imposing rules on growers that entail substantial costs, provided those rules result in safer produce and healthier diets. Congress recognized as much when it directed FDA in Section 105 of the Food Safety Modernization Act to promulgate “science-based minimum standards related to . . . water.” 21 U.S.C. § 350h(a). The proposed rule, however, does little to establish such “science-based minimum standards,” opting instead to give the industry discretion to regulate itself.

This approach contrasts sharply with the agricultural water standards that FDA finalized in 2015. Under those standards, microbial quality criteria and testing requirements defined what the agency considered “safe.” As the Proposed Rule points out, industry balked at these requirements, complaining that they were “too complicated to understand,” and did not “sufficiently allow for a variety of water uses and availabilities.” Under the Proposed Rule § 112.41, FDA now simply requires that “[a]ll agricultural water must be safe and of adequate sanitary quality for its intended use.” However, the Proposed Rule leaves open to interpretation what exactly this means.

FDA Should Require that Water Assessments Include Validated Microbial Testing

Bright line, numerical, microbial water quality criteria have their advantages. As CFA wrote in comments on FDA’s first effort to promulgate water standards, back in 2013, a numerical standard is appropriate where the effectiveness of individual measures, such as the protection of agricultural water sources from contamination, is not complete or fully known. It is also appropriate because the quality of a particular water source (such as surface water) may be outside the control of the farm. A numerical standard also provides some objective evidence that the water system is functioning adequately and corrective actions employed by the farmer are working as intended. Finally, we noted that the numerical standard specified in the regulation would provide FDA with a clear and enforceable way to hold farmers accountable for checking and maintaining their water systems.

To be sure, if a testing regime and related numerical standards lack a meaningful correlation to safety, they may provide mere false assurances. As noted in our joint comments, recent evidence, and outbreak experiences, have called into question the extent to which growers can rely on generic *e.coli* testing to validate safety protocols. Nevertheless, FDA should not go so far as to abandon a microbial testing requirement altogether. At the very least, the agency should direct growers to incorporate some form of validated microbial testing into the annual water quality assessment required under the Proposed Rule.

FDA may grant flexibility in how test results are interpreted, but even where growers themselves have discretion to specify the microbial criteria that determines whether water is safe for its intended use, a requirement that water assessments rely on validated microbial testing offers many of the benefits associated with the numerical microbial standard that FDA now seeks to formally abandon. Like a numerical standard, a validated testing requirement will compensate for inherent uncertainty in the water assessment. For example, the Proposed Rule justifiably requires covered farms to “consider adjacent and nearby land uses related to untreated or improperly treated human waste,” including “whether any portable toilet facilities on adjacent and nearby lands are appropriately located away from water sources and distribution.” But since growers are not entitled to inspect their neighbors’ lands for portable toilets or other hazards, many water assessments will necessarily omit such considerations. Microbial testing provides a check for overly optimistic assumptions about nearby land use. A testing requirement similarly may expose ineffective remediation, and in some cases, may provide the grounds for FDA or state government inspectors to take enforcement action. In contrast, by declining to specify that growers must incorporate microbial testing into agricultural water assessments, the Proposed Rule may actually create a perverse incentive for some growers to avoid testing water, lest the results show a need for treatment or other mitigation.

FDA Should Better Identify High-Risk Water Use Scenarios

In addition to a validated microbial testing requirement, FDA should also establish non-microbial standards to direct how growers use and treat water. In particular, the Proposed Rule can strike a better balance between flexible and administrable standards related to high-risk water use scenarios. As we point out in our joint comments with CSPI, the Proposed Rule currently provides no framework for determining when a hazard requires a grower to immediately discontinue water use. The Proposed Rule cites the example of where “a covered farm finds that there is a dead and decaying sheep in the canal upstream and at a close distance from where it draws water.” Apart from this extreme circumstance, however, the Proposed Rule leaves ambiguous what type of information might lead a grower to determine that “agricultural water is not safe or is not of adequate sanitary quality for intended use(s).” By implication, some “hazards related to animal activity, BSAAOs, or untreated or improperly treated human waste” do not require immediate attention (rather, they require “mitigation measures within the same growing season as the assessment.”). But the Proposed Rule does not delineate what factors separate these hazards from the dead sheep scenario.

FDA should do more to help growers identify circumstances in which water is not likely to be safe for its intended uses. As the proposed rule points out, “[t]here is a significant likelihood that U.S. surface waters will contain human pathogens, and surface waters pose the highest potential for contamination and the greatest variability in quality of the agricultural water sources.” This significant likelihood has led growers participating in the Leafy Greens Marketing Agreements (LGMA) to discontinue use of untreated surface water in overhead irrigation systems in the three weeks leading up to harvest.[[4]](#footnote-4) FDA could similarly specify certain uses for which untreated surface water is unacceptable.

Conclusion

Given the reaction to FDA’s previous attempt to implement FSMA’s agricultural water standard requirement, the agency’s reluctance to promulgate bright line rules is understandable. However, the Proposed Rule puts too much responsibility on growers to devise the optimal approach to managing food safety risk. Many growers lack the expertise to manage agricultural water hazards effectively. Moreover, so long as foodborne illness surveillance remains imperfect, the free market’s pressure to cut costs wherever possible will reliably erode investment in food safety. FDA plays a critical role in countering this trend, and here, FSMA gives FDA a clear mandate to set agricultural water standards that protect consumers. FDA should use its FSMA authority, and the expertise gained over a decade of implementing the law, to better protect consumers.

Thank you for your consideration of these comments.

Sincerely,

Thomas Gremillion

Director of Food Policy

Consumer Federation of America

1. <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2019-report-TriAgency-508.pdf> [↑](#footnote-ref-1)
2. In particular, researchers have found that poor nutrition among the elderly, who are among the most susceptible to foodborne illnesses, increases food safety risk. See, e.g. Smith, J. L. (1998, September 01). Foodborne Illness in the Elderly. <https://meridian.allenpress.com/jfp/article/61/9/1229/168212/Foodborne-Illness-in-the-Elderly>. Animal studies indicate that an important mechanism linking poor nutrition to foodborne illness may be reduced gut health, which has been show to reduce the body’s ability to fight off infections by pathogens such as *Salmonella*. *See* Brown, E. M., et. al. (2015, August 4). Diet and specific microbial exposure trigger features of environmental enteropathy in a novel murine model. <https://pubmed.ncbi.nlm.nih.gov/26241678/>. [↑](#footnote-ref-2)
3. *See* US Burden of Disease Collaborators. The State of US Health, 1990-2010: Burden of Diseases, Injuries, and Risk Factors. JAMA. 2013;310(6):591–606. doi:10.1001/jama.2013.13805 [↑](#footnote-ref-3)
4. <https://lgmatech.com/wp-content/uploads/2020/08/CA-LGMA-Metrics-August-2020_Final_Clean_9-18-20.pdf> [↑](#footnote-ref-4)