CR ConsumerReports™

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

To Whom it May Concern:

Consumer Reports (CR)[1] submits these comments on the U.S. Food and Drug Administration's (FDA) proposed rule on standards for the growing, harvesting, packing, and holding of produce for human consumption relating to agricultural water, which are part of the agency's rule on produce safety.

CR is generally supportive of the overall concepts outlined in the FDA proposed new agricultural water standards, including the allowance of a more comprehensive approach to assessing water hazards. We also recognize the importance of offering flexibility for implementation into different production systems.

However, we do feel changes are necessary to certain aspects of the proposed standards, in order to strengthen consumer protections and reduce food-borne illness rates.

- First, **the proposed standards leave too much to the discretion of the farmer**. In its attempt to provide greater flexibility for implementation, the FDA may have overcorrected itself and swung the regulatory pendulum too far in the other direction; this new proposal transformed from being too prescriptive into one that is potentially more lenient than existing voluntary industry standards.

  FDA should be more assertive about the definition of various terms, such as "safe and of adequate sanitary quality" or "necessary measures" to mitigate hazards, and should establish stronger standards for the highest risk hazards.

- Second, **the proposed standards should require validated microbial testing as part of the agricultural water assessment and as a way to verify the effectiveness of mitigation measures taken**.

- Third, while we support the record requirements for the agricultural water assessment, **we believe that all the data, especially the results of microbial testing, should be available to FDA during an inspection**, whether the inspection is in person or is virtual.

These points are discussed in a bit more detail below.

Background on Agriculture Water Standards

Produce contaminated with pathogens that can serve as a vector for disease transmission poses a threat to public health. The Interagency Food Safety Analytics Collaboration estimates that produce commodities cause 65 percent of foodborne *E. coli* O157:H7 illnesses and over 40 percent of foodborne *Salmonella* illnesses. IFSAC attributed approximately 56 percent of E. coli O157 illnesses to vegetable row crops (such as leafy greens) and approximately 9 percent to fruits and other types of produce.[2]

Agricultural water can clearly be a source of pathogens that contaminate produce and harm consumers. FDA investigated five outbreaks involving leafy greens and onions that occurred between spring of 2018 and summer of 2020 and showed the potential for agricultural water to contaminate produce with pathogens.[3] 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 the water as a potential source of the outbreak bacteria.

Policy makers have recognized the risks, which is why Congress included a provision in the Food Safety Modernization Act (FSMA) of 2011 to develop a rule to protect produce safety, which establishes science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption. In 2015, the FDA initially finalized this proposed rule when they published Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption[4], which had a section on agricultural water standards. The regulation focused on biological hazards and major routes of microbial contamination—including *agricultural water*; biological soil amendments; domesticated and wild animals; worker health and hygiene; and equipment, buildings, and tools.[5] (italics added). The produce safety regulation included a general requirement that all agricultural water must be "safe and of adequate sanitary quality for its intended use," and included specific testing requirements for generic *E. coli* to measure microbial quality of the water, which depended on the source (surface water, groundwater, municipal water) and the use (preharvest, post-harvest, and use in growing sprouts). Indeed, the required microbial testing (for generic *E. coli*) had to be done on each individual water source used on the farm with multiple samples taken on each water source each year.

FDA delayed the implementation of the microbial testing requirements (other than for sprouts) due primarily to concerns raised by stakeholders within the produce industry, who expressed substantial concerns about the microbial testing standards, including that they were "too complex, overly prescriptive, and not practical to implement, urging FDA to reconsider the 'one-size-fits-all' approach of the produce safety regulations that they state is not risk-based or adaptable based on future research."[6] As a result of these stakeholder concerns, FDA proposed a revision of these testing standards.

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 to identify known or reasonably foreseeable hazards. Farms would use the results of the agricultural water assessment to determine whether corrective or mitigation measures are needed and put these measures in place. Some farms may also do microbial testing to help inform their agricultural water assessment.

New Comprehensive Water Assessment is Better But Enhancements are Necessary

We agree with FDA that the previous water standard, particularly the specific generic *E. coli* testing requirement[7] for preharvest water, was too narrowly-focused and too prescriptive. In contrast, the present proposed water standards, particularly the agricultural water assessment, take a more system-level (or holistic) approach that can be adapted to different farms in different environments and can evolve with advancing science.

The proposed standard involves requiring farmers to annually conduct an "agricultural water assessment" involving the farm's "agricultural water system." The FDA defines "agricultural water assessment" as "an evaluation, conducted by a covered farm, of its agricultural water system used during growing activities for non sprout covered produce, its agricultural water practices for such pre-harvest water, crop characteristics, environmental conditions, and other relevant factors (including test results, where appropriate) to: (1) Identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces and (2) determine whether corrective or mitigation measures for pre-harvest agricultural water are necessary to reduce the potential for contamination with such known or reasonably foreseeable hazards."[8]

They define "agricultural water system" as "a source of agricultural water, the water distribution system, any building or structure that is part of the water distribution system (such as a well house, pump station, or shed), and any equipment used for application of agricultural water to covered produce during growing, harvesting, packing, or holding activities."[9]

We agree that the definitions of "agricultural water assessment" and "agricultural water system" are good definitions. Clearly, the agricultural water assessment provides broad, science-based flexibility to be applicable to farms of all different sizes, and different production systems, in different environments.

Furthermore, there are a number of terms in proposed standards that are not adequately defined. For example, the agricultural water used pre-harvest must be "safe and of adequate sanitary quality," yet there is no definition for what is meant by "safe" or "adequate sanitary quality." The farmer must also determine what measures are "necessary" to mitigate identified hazards, yet there is no real definition on what constitutes "necessary measures."

As referenced earlier, another drawback of the proposed standard is that it appears to swing the regulatory pendulum too far in the other direction and, instead of being too prescriptive, it is now too flexible. While the old water standard was too prescriptive in terms of microbial testing, the new standard leaves too much discretion to the farmer. Indeed, the farmer can decide for themselves whether to do microbial testing or not and also decide what kind of mitigation measures, if any, to take.

In a real sense, all major decisions are being left up to the farmer, with insufficient guidance or input from FDA. **We think FDA should be more assertive on what components constitute a good agricultural water assessment and setting some sharp distinctions on what constitutes "necessary measures" for mitigation particularly for the highest risk situations and when such measures should be taken.**

For example, FDA could declare that use of surface water for preharvest uses is a high-risk situation and that such water must be treated (with a compound to kill pathogens) before being used unless the farmer has data to show pathogens have not been present in the water for the past few growing seasons. FDA could also assert that spraying water from any source on leafy greens in the three weeks before harvest also constitutes a high-risk situation and that such water must be treated prior to use. This would be consistent with the position of the Leafy Greens Marketing Agreement (LGMA), which requires treatment of overhead application water used within three weeks of harvest.[10]

Validated Microbial Testing Should be Part of the Agricultural Water Assessment

The failure of the proposed rule to require any form of microbial testing as part of the pre-harvest agricultural water assessment is problematic. We urge FDA to require validated microbial testing as part of the pre-harvest water assessment unless the grower can verify, through scientifically valid means, that such testing is not necessary to identify potential hazards.

Microbial testing of pre-harvest agricultural water is already considered important for determining microbial hazards. The California Leafy Green Marketing Association (CA LGMA) Food Safety Guidelines include microbial testing for baseline microbial assessments, initial microbial water quality assessment, and routine system assessments.[11] The proposed standards do not require any pre-harvest testing of agricultural water but merely suggests it as part of the assessment to help detect hazards.

Microbial testing is already required for water used in sprouts and for post-harvest purposes, as found in §§ 112.44(b) and 112.46(b) of the produce safety regulation. Microbial testing done for assessment purposes must follow the criteria laid out in 112.43(d) of the proposed standards regarding sampling frequency and selection of indicator organisms.

In addition, microbial testing should also be required as a way to verify the effectiveness of mitigation measures taken. After all, how can it be determined if a mitigation measure has removed the problem of microbial contamination without microbial testing?

We urge FDA to assert that an adequate agricultural water assessment will include microbial testing that follows the criteria laid out in 112.43(d) of the proposed standards. If a farmer decides not to do microbial testing as part of the assessment, the rule should require them to provide a detailed outline on the alternative approach/method they are using 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. FDA should also require that microbial testing also be done to validate that specific mitigation measures have been successful.

Make Records Available to FDA During Inspection, Whether in Person or Virtual

We are fully supportive of the Records Requirements for Pre-Harvest Agricultural Water Assessments (Proposed § 112.50), which would require the farms to keep records at the farm of their pre-harvest agricultural water assessment. For the issue of microbial testing, we are particularly supportive of the records relating to the test results themselves, as well as Testing Pre-Harvest Agricultural Water for Analytes Other Than Generic *E. coli* (proposed § 112.50(b)(3)) and Records Relating to the Sampling and Microbial Criterion (or Criteria) Applied for Pre-Harvest Agricultural Water (proposed § 112.50(b)(4)).

The farms should keep these records on farm for at least 2 years and such records should be made available to FDA during inspections. **We think FDA should make clear that all records must be kept on farm and made available to FDA during inspections, whether they are in person or virtual. The FDA also should subject high-risk facilities to more frequent inspections.**

Conclusion

While the proposed agricultural water assessment is a good science-based holistic framework, we feel that it could be improved by FDA being more assertive on what constitutes an adequate agricultural water assessment, what is meant by specific terms (such as "necessary measures" to mitigate a known/suspected risk); requiring validated microbial testing as part of the agricultural water assessment and as a way to verify the effectiveness of mitigation measure taken; and by stating that all records kept on the farm shall be available to FDA during inspections—whether virtual or in person.

Yours,

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[1] Founded in 1936, Consumer Reports (CR) is an independent, nonprofit and nonpartisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, CR advocates for laws and company practices that put consumers first. CR is dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to 6 million members across the U.S.

[2] 87 Fed. Reg. 69120 (December 6, 2021).

[3] 87 Fed. Reg. 69125-69127

[4] 80 Fed. Reg. 228 74354-74568 (November 27, 2015).

[5] 87 Fed. Reg. 69122

[6] 87 Fed. Reg. 69125

[7] 80 Fed. Reg. 74354-74568 (November 27, 2015).

[8] 87 Fed. Reg. 69132.

[9] *Ibid.*

[10] Pg. 36 California Leafy Green Marketing Association (CA LGMA). 2021. Commodity specific food safety guidelines. August 2, 2021 At: https://lgma-assets.sfo2.digitaloceanspaces.com/downloads/August-2021-CA-LGMA-Metrics_FINAL-v20211208_A11Y.pdf

[11] CA LGMA. 2021. *Op cit.*