April 5, 2022

Dockets Management Staff (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

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

Dear FDA Staff,

The California Farm Bureau Federation (CAFB) appreciates the opportunity to comment in response to the Food & Drug Administration's (FDA) proposed rule on changes to the agricultural water requirements outlined in the Food Safety Modernization Act (FSMA).

For background, CAFB is a voluntary, non-profit organization made up of over 31,000 members across 53 counties and is the largest farm organization in the state. Established in 1919, we work for the betterment of family farmers and ranchers in California and help support up to 2.5 million jobs and over $56 billion in crop value. As a significant provider to hundreds of commodities distributed across the US and world, our members have always understood the importance of ensuring the safety and wellbeing of the products our consumers so critically rely on.

As outlined in this notice of proposed rulemaking (NPRM), FDA is seeking to make changes to the agricultural water requirements under the Produce Safety Rule. In assessing feedback from years of partnering with public and private groups on the feasibility of the original requirements, FDA concluded that the previous standards in Subpart E were inflexible, too complicated to understand (particularly on finding geometric mean and statistical threshold values), and difficult to implement for farms that rely on multiple pre-harvest water sources. CAFB largely agrees with these assessments and appreciates the FDA's willingness to reexamine the practicality of Subpart E; however, we have identified several areas in which we believe additional analysis is required.

Adjacent & Nearby Lands

One of these areas of concern includes identifying what constitutes "adjacent and nearby lands." Within the NPRM, there is substantial emphasis placed on covered farmers to examine lands and other farms in close proximity to their own. However, the NPRM fails to

define or even suggest a definition for what sort of proximity or zone producers will be required to inspect for their systems-based agricultural water assessment. In one of the historical examples provided in the rulemaking, the FDA highlights a Fall 2019 *E. coli* outbreak in Salinas, CA in which contamination was sourced to a point nearly two miles upslope from the impacted farms. CAFB has serious concerns regarding the potential radius of land surrounding farming operations and requests additional clarity to be provided with the consultation of involved entities at the producer level.

As acknowledged in the FDA's own assessment of the original water microbial testing requirements, a "one size fits all" approach was impractical to broadly apply to farms in completely different regions and climates. Even within a single county there can be a great variance between topological and/or climatic conditions from one end to the other. We understand that it can be beneficial to allow some regulatory flexibility by not providing an overly prescriptive definition or requirement in a particular rule; however, we feel that additional clarity on what constitutes "adjacent and nearby lands" will give covered farmers a better understanding on how to best comply with the rule.

Environmental Factors

Another area we also have concerns about are on the environmental condition factors that are expected in any assessment. Although the FDA has cited the potential role extreme weather and climate conditions can play in the spread of pathogens, they have not explicitly laid out how these events will be factored in on a region-by-region basis. If this is not addressed in the final rule, it would seem unreasonable to expect that farmers in one area of the country be required to account for "potential" weather events that are completely foreign to their region.

In addition, while there has been some evidence provided by the FDA as to the potential risks associated with certain weather events, we believe that any decisions regarding the extent to which environmental condition factors are determined should be grounded in exhaustive research. Given the limited degree to which some pathogens are able to travel in varied environments, it is unclear how common some of the provided examples provided are. We would encourage the FDA to examine these potential impacts more closely in order to better gauge how much weight these factors should carry in any assessment.

Scientifically Valid Collection and Testing

Although the FDA is proposing to switch away from mandated microbial testing, they do suggest that such testing could be helpful in identifying potential hazards and risks in a covered farm's assessment. Unfortunately, the NPRM has failed to outline a clear definition for what will be considered "scientifically valid" collection and testing methods. Given the vast variety in crops and commodities grown here in California and across the US, we realize

it might be impractical to provide an exhaustive list of testing platforms available for meeting this "scientifically valid" threshold; however, there should be some guidance provided on what will be acceptable to utilize in a water assessment. We recommend that the FDA find a way to clearly define the scope of what tests and methods would be considered legitimate options in order to help farmers as they look to ensure safety and quality for their commodities.

Education & Compliance Flexibility

Lastly, CAFB believes that any final rule should take into consideration the substantial amount of education, training, and guidance that will be needed for covered farmers as they look to carry out their systems-based agricultural water assessments, should this rule pass with most of these provisions intact. Historically, our members have routinely cited FSMA compliance as a significant challenge due to the inherent complexity of the law. Since it originally passed over a decade ago, the law continues to receive major changes, delays, and updated guidance, which can leave many farmers often confused about whether the most recent information they have is actually up to date.

To this end, we ask for the FDA to establish a compliance period that considers the outreach and education that will be required in order to effectively carry out the goals laid out under this proposed rule. While our members have always been firmly committed to ensuring the overall safety and well-being of the communities they help feed, these assessments of their farms will require a significant amount of time, money, and expertise to identify and mitigate potential contamination for pre-harvested agricultural water. This will also be more acutely felt if the final rule fails to address a number of the concerns we have highlighted above.

Conclusion

We appreciate the FDA's interest and willingness in making this rule more practical for farmers to comply with. While we still believe that there are several challenges with FSMA more broadly, we understand the importance and responsibility in keeping our foods safe for consumers and communities across the globe.

We appreciate opportunities like this to provide feedback as we know they are crucial to FDAs rulemaking process in gathering stakeholder input that provides meaningful, practical feedback that should result in a regulatory system that is feasible for growers, measurable for inspectors, and protective for consumers.

As the FDA looks to finalize this rule, we ask that the concerns raised above be taken into consideration and that the agency continue to engage in public-private partnerships to better understand the impacts and feasibility of subsequent changes.

Thank you for the opportunity to provide these comments—and please don't hesitate to reach me directly at either (916) 561-5612 or mviohl@cfbf.com if you believe we can be of additional assistance.

Regards,



Matthew Viohl
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California Farm Bureau Federation