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April 5, 2022

Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket ID 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,

The New York Farm Bureau (NYFB), New York State's largest general farm organization, appreciates the opportunity to comment on the Food and Drug Administration's Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water, referred to in these comments generally as the Agricultural Water Rule. Our members grow a large variety of specialty crop commodities, represent all size farms and represent the large variety of production methods from organic to conventional and everything in between. Food safety is of utmost importance to our food system in New York and the U.S., so implementing the Food Safety Modernization Act (FSMA) and the Produce Safety Rule in a meaningful and effective way for both farmers and consumers is essential to our members and to our country at large.

Farmers in New York are committed to food safety and participate in both voluntary Good Agricultural Practices (GAPs) and retailed-developed food safety programs. Also, because so many growers in New York have direct contact with their consumers – through farm markets, farm stands, Community Supported Agriculture (CSA) structures, direct restaurant sales and other innovative and modern local food distribution systems, farmers are directly accountable to these customers who know them by name and may even visit their farm. Therefore, on-farm food safety protocols are key to the reputation and success of the farm business. The U.S. is known for its high food quality standards, and while NYFB does not want to jeopardize this reputation, it is also important that farmers be able to meet standards and follow guidance with practicality and economics in mind especially when it comes to pre-harvest water requirements.

NYFB appreciates FDA's response to stakeholder concerns regarding the previously proposed microbial criteria water testing requirements and replacing the requirements with a more workable rule. NYFB recognizes the new workable approach outlined in the proposed agricultural water rule. As FDA explains, the proposed rule replaces "the microbial quality criteria and testing requirements with new provisions for conducting pre-harvest agricultural water assessments for hazard identification purposes (including consideration of agricultural water sources, distribution systems, and practices, as well as adjacent and nearby land uses, and other relevant factors)." Should this proposal be final, farmers will use, "the results of the assessments in risk management decision

making." With this approach, FDA allows for a testing option "for certain covered farms that elect to test their pre-harvest agricultural water for generic *Escherichia coli* (*E. coli*) (or other appropriate indicator organism, index organism, or analyte) to help inform their agricultural water assessments."

In light of this proposed update, NYFB would offer the following suggestions for ensuring the rule is workable for farmers based on actual New York farmer feedback.

Agricultural Water Assessment
The proposed rule would add the definition of an "agricultural water assessment" which would require growers to perform an assessment of the pre-harvest water systems on their operations. NYFB requests that if this definition is adopted in the final rule that FDA work with producers to clearly understand what would be required to conduct an agricultural water assessment and a list of items that inspectors would be looking for in that assessment. This way, there is clear understanding by all parties of what is required through the assessment.

Adjacent Land
In the proposal, FDA includes details concerning food safety outbreaks in recent years and often points to activities on adjacent lands contaminating water sources intended for use in the production of specialty crops. While NYFB can understand that off-farm activities such as animal agriculture or the use of soil amendments may pose a food safety threat, FDA's directive in this proposed rule concerning adjacent lands is vague. Should the proposed rule become final, and growers undertake the responsibility of compliance, FDA must provide a clear definition of adjacent lands so farms can accurately conduct their water assessments.

The concept of adjacent lands is also challenging for farmers to navigate, as neighboring property often belongs to another landowner. Covered farms may not know about the activities taking place on adjacent lands and, therefore, will not be able to properly identify supposed risks. FDA also suggests potential mitigations to an identified risk on adjacent lands. In determining potential hazards from animal agriculture on nearby lands, FDA suggests covered farms assess if "there may be additional factors to consider when evaluating the likelihood of introduction of hazards, such as whether the operation has any best management practices in place (such as to prevent overflow of manure lagoons), the locations of waste storage or composting operations relative to the canal, and animal and traffic patterns throughout the dairy that have the potential to spread contaminants."

However, FDA goes on to suggest that if farms "face uncertainty around evaluating factors like these where they are unable to obtain the relevant information, such as if adjacent or nearby land users are not willing to share information. Due to the nature of the risks associated with animal activity, in these instances, farms should consider accounting for the increased likelihood of hazard introduction to the water systems from adjacent or nearby lands when making decisions around the safe use of their water." NYFB is concerned that without a clear, appropriate understanding of what an adjacent land is, covered farms may be forced to assume risks are present on nearby property and impose potentially overly conservative and costly mitigation practices. Furthermore, NYFB recognizes under this proposed rule that farms may be forced to undertake mitigations even if no risk is present, but rather because there could be a risk on adjacent lands and the covered farmer cannot prove otherwise. Considering this, NYFB urges FDA to narrowly define what is considered an adjacent land. In addition, NYFB would also encourage FDA to provide details on the scope of water sources that would be considered adjacent and how those would be incorporated into the water risk assessment.

Mitigation Efforts
Should risks be identified during the water assessment, FDA proposes that covered farms implement mitigation measures to manage potential risk. Mitigation measures include: repairs to address conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces; increasing the time interval between the last direct application of agricultural water and harvest of the covered produce to allow for microbial die-off; and/or conducting other activities, such as commercial washing, to reduce pathogens using appropriate microbial removal rates, except as supported by scientifically valid data and information, changing the method of water application to reduce the likelihood of produce contamination (such as by changing from overhead spray to subsurface drip irrigation of certain crops, treating the water, or an alternative mitigation measure. Under the rule as drafted, some mitigation measures could be implemented within a year to address concerns raised in the risk assessment. Given the current supply chain constraints limiting access to much-needed farm equipment and supplies, NYFB urges FDA to consider allowing two years for mitigations to be put in place to accommodate expected supply delays.

In the proposal, FDA suggests a four-day die off interval as an appropriate mitigation but allows for a farm to use less than four days if the farm has "scientifically valid data or information to support use of a die-off rate of 0.5 log per day for less than 4 days." As currently outlined, it is unclear what data FDA would consider ***scientifically valid***. Clear understanding of what FDA considers scientifically valid would also be useful in determining how frequently covered farms should test water sources should a farm elect to test their preharvest water. AFBF urges the FDA to provide clear guidance for this data in the final rule.

Regarding the use of a four-day die-off interval, producers of certain crops, including broccoli and baby leaf greens, indicated that a four-day interval would be too long. In the case of baby leaf lettuce or spring mix, moisture is often added to the crop before it is cut from the field. In the case of broccoli, producers indicated that they harvest the same field multiple times in a condensed time frame. Usually there are two-or three days in between each harvest. In these two–three-day time periods, the crop often requires overhead irrigation. Using the four-day interval would not be feasible in this circumstance. While NYFB understands the intent to provide flexibility in the die-off period by allowing for data to indicate shorter die-off intervals, it is unclear if data exists or meets the unknown standard of "scientifically valid" that would address these specific concerns and allow for shorter die-off intervals for these crops.

In the proposed rule, covered farms must also consider environmental risks including weather patterns when determining potential hazards. Considering the weather can be varied in different regions and from year to year, it is unclear how routine weather events compared to more rare weather occurrences should be factored into the annual water risk assessment. If rainfall and other weather events are a potential hazard, covered farms will need more guidance from FDA regarding how to assess this prospective risk.

The proposed rule also allows for consideration of individual crop characteristics when conducting preharvest water risk assessments. The language as proposed is too broad and does not clearly indicate how various crop characteristics minimize the risks of contaminated water.
While NYFB is appreciative that FDA has delayed enforcement of water testing provisions thus far, NYFB urges FDA to consider providing more time in between the publication of this final rule and

the time in which FDA plans to enforce its provisions. Covered farms will need to work with state departments of agriculture, industry associations, Extension agents and other food safety specialists to understand how these new requirements apply to their operations. Furthermore, it is imperative recordkeeping requirements align with existing food safety practices including those recognized under existing Good Agricultural Practices and/or the Global Food Safety Initiative. While NYFB appreciates the flexibility in the proposed rule, the options presented to farmers by conducting their risk assessments require additional educational outreach so that farms can achieve compliance.

Definition of Significant Change

The rule states that *"whenever a significant change occurs in your agricultural water system(s) (including changes relating to animal activity, the application of biological soil amendments of animal origin, or the presence of uncreated or improperly treated human waste associated with adjacent or nearby land uses.)"* While FDA does provide these examples, more references and guidance are needed for producers to know what is and isn't a significant change. Without clear guidance, both farmers and inspectors may interpret this differently and lead to confusion on how best to implement a "significant change" into an assessment.

Education and Outreach

NYFB hopes that FDA will work with farmers and with state departments of agriculture on best management practices that individual farms can utilize as part of their water risk assessment. In addition, NYFB requests that FDA work with states and the Produce Safety Alliance to offer educational trainings and draft risk assessment templates that farmers can utilize on their farms. It is of equal importance that guidance documents provide clarity and easily understandable in-field interpretation for farmers and their employees. As a state with many different sized produce farms, with varying levels of staff to handle food safety compliance, it is critical that resources and technical assistance be made available to help with compliance. NYFB would like to acknowledge the efforts made by the New York State Department of Agriculture and Markets (NYSDAM) to educate farmers in New York in the past through On-Farm Readiness Reviews, and we hope a similar approach will be taken during the timeframe in which producers have to conduct their initial risk assessments.

Conclusion

NYFB shares FDA's commitment to food safety and appreciates the opportunity to continued dialog and clarity on the Agricultural Water Rule and guidance for producers. New York farmers understand the immense responsibility they have to produce safe, nutritious food for consumers. Considering this, food safety requirements must be flexible yet precise so farmers can understand how to comply. NYFB looks forward to further engagement with FDA to ensure food safety requirements are workable for farmers and generate intended food safety outcomes for the general public.

Sincerely,

David Fisher
President, New York Farm Bureau