



April 4, 2022

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

Submitted electronically via www.regulations.gov

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 Sir or Madam:

FMI- The Food Industry Association (FMI) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) proposed rule "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Relating to Agricultural Water." As the food industry association, FMI works with and on behalf of the entire industry to advance a safer, healthier, and more efficient consumer food supply chain. FMI brings together a wide range of members across the value chain — from retailers that sell to consumers, to producers that supply food and other products, as well as the wide variety of companies providing critical services — to amplify the collective work of the industry. www.FMI.org.

Produce safety has been a top priority for retail and wholesale members of FMI for years. With frequent outbreak investigations, recalls and public health advisories, retailers and wholesalers are all too familiar with the importance of produce safety and the necessity of high safety standards through FDA regulations. All produce needs to be safe independent of size of company or where the product is grown.

We support FDA in promulgating the proposed rule on produce safety and specifically agricultural water. We are supportive of science based and flexible regulations to support food safety. We have some specific thoughts as well as some questions about the agricultural water proposed rule.

Most importantly, we support the flexibility in the proposed regulation that recognizes different types of production systems in different regions. There is not a one size fits all approach and the proposed rule recognizes the varied nature of produce production systems. The Produce Safety Rule (PSR) helped provide a framework for evaluating the food safety hazards for growing. The agricultural water rule when finalized, will complete the majority of requirements for the PSR and provide the industry with information needed to help ensure the safety of their products.

Scope of Agricultural Water Rule

FDA should provide more clarity around the definition of *agricultural water*. Whether water is characterized as agricultural water depends on whether the “water is intended to, or is likely to, contact covered produce or food contact surfaces.”¹

Growers using water not considered agricultural water as defined in the PSR are not required to comply with the proposed regulations.² We encourage FDA to provide clear guidance on what is agricultural water and what is not agricultural water. Furthermore, FDA should clarify what is expected of growers in terms of inspecting and assessing water considered outside the scope of agriculture water to ensure any water used for growing, harvesting, packing or holding covered produce is of adequate quality to minimize the likelihood of contamination.

Additionally, we ask FDA to provide clarity on what is considered the harvestable portion of the crop and whether the use of drip or furrow irrigation for low growing crops that grow close to the ground, (e.g., leafy greens) would be considered an indirect or direct water application method. In response to comment 178 in the final PSR, FDA clarified that “drip irrigation of tree crops that grow high above the ground and are not likely to touch the ground, is not agricultural water because the irrigation water is neither intended to nor likely to contact covered produce³. In this response, FDA also notes that drip irrigation of root crops, for example carrots, agricultural water” and the definition of “direct water application method” because the drip irrigation “is intended to filter through the soil and contact the carrots growing underground.”⁴ The application method of the irrigation water should not impact the decision of whether a farm needs to assess the water used for the growing, harvesting, packing or holding of produce.

¹ 21 CFR 112.3

² *Federal Register* Vol 80, No 228, November 27, 2015 Page 74370

³ *Federal Register* Vol 80, No 228, November 27, 2015 Page 74429

⁴ *Federal Register* Vol 80, No 228, November 27, 2015 Page 74429

In the preamble of the agricultural water proposed rule⁵, FDA notes that for water “not considered agricultural water for purposes of subpart E, indirect water application methods, such as the use of drip tape in a manner that water is not likely to contact the harvestable portion of the crop, remain subject to section 402 of the FD&C Act. FDA acknowledges that “indirect water application may adulterate produce.” Furthermore, for water not considered agricultural water under subpart E, FDA suggests farms assess the water and consider the conditions described in proposed § 112.43(a)(1). We agree that farms should assess water used for growing, harvesting, packing or holding covered produce to identify conditions that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces. We ask FDA to clarify what water assessment is required under § 112.43(a)(1) for water outside the scope of agricultural water.

In food safety standards for produce, such as Harmonized GAP and GFSI standards, there is no differentiation between water and the assessment of water is not determined based on the practice (e.g., direct water application). The measures and controls put in place to protect sources of water and minimize the risk of contamination are determined based on the findings of a hazard analysis and risk assessment (i.e., water assessment). For example, irrigation of tree fruits via drip tape is very different than irrigation of leafy greens via drip tape. While both use the same irrigation method, they have very different risk profiles and with differing hazards and risks that need to be considered. In both examples, the irrigation water is perceived to fall outside of the definition of agricultural water.

Several recent outbreak investigation findings outlined in Section D⁶ of the Agricultural Water proposed rule highlighted the role the water quality potentially played in produce safety and the potential for water to serve as a source or route of contamination in produce outbreaks. Moreover, in several examples provided, the water identified as likely serving as the source or route of contamination of produce was water that did not meet the definition of *agricultural water* in the Produce Safety Final Rule.⁷ Examples follow.

⁵ *Federal Register* Vol 86, No 231, December 6, 2021 page 69145

⁶ *Federal Register* Vol 86, No 231, December 6, 2021 pages 69125-69127

⁷ *Federal Register* Vol 80, No 228, November 27, 2015 page 74353

Example 1: Spring 2018 *E. coli* O157:H7 Outbreak Linked to Romaine Lettuce from the Yuma Growing Region

- “Investigators found the outbreak strain in water samples from three locations along a 3.5-mile stretch of an open irrigation canal adjacent to a Concentrated Animal Feeding Operation (CAFO). One of these samples was collected immediately downstream from where shallow ground water is pumped into the irrigation canal. The Environmental Assessment investigators also found an area where ground water may have been seeping directly into unlined sections of the canal within the 3.5-mile stretch where the outbreak strain was detected. Although no obvious route of contamination was determined, the investigators identified onsite wells at the CAFO as a potential route of ground water contamination from the CAFO.”⁸
 - Furrow irrigation is the primary method of irrigating leafy greens grown in the Yuma, AZ growing area and growers typically rely on water from the open irrigation canal as the water source. Water delivered via furrow irrigation is not intended to contact the edible portion of the leafy greens. Therefore, in this example, the irrigation water would not meet the definition of *agricultural water*.

Example 2: Fall 2018 *E. coli* O157:H7 Outbreak Linked to Romaine Lettuce from California

- The Environmental Assessment investigators “concluded that the water from the on-farm water reservoir where the outbreak strain was found most likely led to contamination of some romaine lettuce consumed during this outbreak.”⁹
 - Drip irrigation is a common method of irrigating leafy greens grown in California growing regions. While in this example, contamination of the on-farm water reservoir led to contamination, water delivered via drip irrigation is not intended to contact the edible portion of the leafy greens. Therefore, in this example, the irrigation water would not meet the definition of *agricultural water*.

These examples concern us since they fall outside of the definition of agricultural water and would not be subject to the proposed regulation.

⁸ *Federal Register* Vol 86, No 231, December 6, 2021 page 69126

⁹ *Federal Register* Vol 86, No 231, December 6, 2021 page 69126

Alternative Production Environments

Alternative production methods are quickly expanding based on land use and consumer expectations and demand for fresh produce items. Controlled Environment Agriculture (CEA), hydroponic, indoor agriculture and/or vertical farming operations are appearing in cities as well as suburban and rural areas. FDA should clarify the applicability of the PSR and the proposed agricultural water regulations to all types of produce production.

One recent outbreak investigation and recall was linked to product produced in a greenhouse farm in 2021. While the results of the investigation were inconclusive, water was a factor in the investigation and a sample matching the outbreak strain of *Salmonella* Typhimurium was found in a stormwater retention pond.¹⁰ We encourage FDA to provide guidance for CEA, indoor farming and vertical farming environments that addresses the hazards as well as clear guidance for this rapidly growing sector.

Traditional Farming Methods

As this rule applies consistently to all growers of covered produce, we acknowledge and respect all types of produce production and encourage the FDA to provide guidance to specific categories of growers to provide risk-based recommendations for the type of agriculture production. We respect traditional farming methods used by Amish and Mennonite farmers and do not want or expect changes in practices. We find that farmers using traditional methods are responsible stewards of the land and have utilized sustainable methods for years. We encourage FDA to allow traditional farming methods and provide practical guidance to facilitate continued agriculture production.

Questions about the requirements in the proposed rule

How should growers make the determination whether or not water is intended to or likely to contact the harvestable portion of the produce?

What is an adequate inspection?

What is an adequate assessment?

What are adequate mitigation strategies?

¹⁰ <https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-packaged-leafy-greens-implicated-outbreak-salmonella>

What are requirements regarding water that is not in the control of the grower? The proposed rule states that inspection of agricultural water systems is required to the extent the system is under the control of the grower. This is mentioned in proposed section 112.42, but it is not clear how water systems are inspected and assessed if they are outside of the growers' control. As we know, pathogens are not aware of property lines. We encourage FDA to clarify what is required for the inspection and assessment of the agricultural water system.

What are FDA's expectations when water is not safe to use? We encourage FDA to provide clear guidance to produce growers regarding making decisions if water is determined to not be safe to use or if the assessment identifies concerns.

There is benefit in developing tools and providing examples to industry but we are concerned that the availability of specific tools and resources may create a food safety mindset that is more of a check the box mentality rather than a systematic approach. Will use and/or completion of the Agricultural Water Assessment Builder referenced as an online tool as in the proposed rule well as at the public meeting be sufficient to demonstrate compliance?

Inspections and enforcement

FMI encourages FDA to focus enforcement efforts on the establishment who is responsible for the activity and controlling the hazards. For most produce, this happens at the farm level. The entity subject to the rule should be the focus of inspections and enforcement.

We encourage FDA to clarify relationships when enforcement might be contracted or delegated to other regulatory agencies. Due to the scope of the PSR and the proposed agricultural water regulations, we anticipate that FDA will need to work with state agencies. FDA will need to train federal and state inspectors on how to assess the agricultural water used for growing, harvesting, packing and holding covered produce. Training should be standardized, and inspections and enforcement actions should be consistent between all agencies inspecting and enforcing the regulations.

Grower Education and Outreach

Grower education and outreach is critical to ensure successful implementation of the rule. FDA and state partners will need to help growers understand what a good water assessment is; how to properly conduct one; how it should be documented (e.g., What does good look like?). Similarly, these resources should provide additional information surrounding mitigations including examples and expectations (e.g., What does good look like for mitigation?)

Grower outreach and education should include growers outside the U.S. and should include resources and tools in various language.

Importance of Risk Based Policies

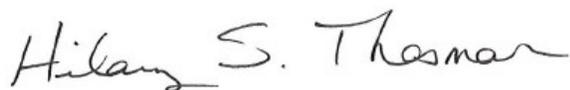
We commend FDA for proposing a rule that is flexible and risk based. Production practices vary widely across the country and internationally. Practices differ for commodities as well as regionally.

Summary

Given the size of the produce industry and the consumption of produce, we support FDA in moving forward with rulemaking based on the Food Safety Modernization Act. Recurring outbreaks in produce are a significant public health issue and need to be addressed. We need to improve root cause investigations and openly share findings from investigations that identify known and newly identified hazards. FMI is committed to working with FDA and the produce industry to improve the safety of products for consumers.

Thank you for this dialogue and we look forward to future engagement with the agency.

Sincerely,

A handwritten signature in black ink that reads "Hilary S. Thesmar". The signature is written in a cursive, flowing style.

Hilary S. Thesmar, PhD, RD, CFS

Chief Science Officer and Senior Vice President Food Safety