

April 5, 2022

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

Docket No. FDA-2021-N-0471

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

Dear Mr. Clark,

Thank you for this opportunity to provide comment on the Food and Drug Administration (FDA) [Proposed Rule](#) to amend the requirements for pre-harvest agricultural water for produce (other than sprouts) of the Produce Safety Rule under the Food Safety Modernization Act (FSMA). “Pre-harvest agricultural water” refers to water used in direct application to produce during growing activities.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to **promote and protect ORGANIC** with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary of OTA Positions:

- ✓ OTA is a long-time advocate for a safe organic food supply and food safety regulations that do not conflict with or put unnecessary burden on organic producers and handlers.
- ✓ We agree with FDA’s initial conclusion that this proposed rule does not conflict or duplicate the requirements of USDA Organic certification. However, we are concerned that the ambiguity of the proposed rule may cause undue burden on producers.
- ✓ We support the development and distribution of organic-specific resources, educational tools, and technical assistance to help organic operations understand and comply with FDA’s final rule.

We offer the following more detailed comments:

Support for Food Safety Regulation

The Organic Trade Association (OTA) is a long-time advocate for a safe organic food supply and continues to fully embrace FDA’s efforts to strengthen food safety regulation. We believe that **every** food producer has an obligation to supply safe food to the public.

OTA was an early supporter of food safety reform and was fully engaged in the legislative process that resulted in the enactment of the Food Safety Modernization Act (FSMA), as well as the implementation of the act through various regulatory rulemaking actions. A history of our engagement is documented in the public record over the last 13+ years.

Impacts for Certified Organic Operations

The Organic Trade Association (OTA) advocates for food safety regulations that *do not duplicate or conflict* with organic standards or *put unnecessary burden* on organic producers and handlers.

We agree with FDA’s initial conclusion that this proposed rule does not conflict or duplicate the requirements of organic certification under USDA’s National Organic Program standards (7 CFR 205). The proposed rule has *removed* the prescriptive microbial quality criteria and testing requirements for pre-harvest agricultural water that had been cited by stakeholders as inflexible, complex, and challenging, and *replaced* them with comprehensive risk-based assessments and mitigation measures. There does not appear to be any required use of inputs or practices in the proposed rule that could conflict or preclude organic operations from complying with the requirements for organic certification.

However, we are concerned that the ambiguity of the proposed rule may cause undue burden on producers. Under the proposed rule, farms would conduct an agricultural water assessment to identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces. Then farms would need to use findings from the assessment to determine whether measures are reasonably necessary to reduce the potential for contamination and implement corrective or mitigation measures as needed to ensure water is safe and of adequate sanitary quality. (Summary provided in Appendix A).

Organic farms are highly diverse and so the assessment of each individual crop can become numerous and highly complex for diversified farms that produce a large number of different crops per season. There will be unique decisions in each scenario for *if* and *which* mitigation measure are needed. On one hand, the flexibility of the rule is a strength for operations to customize and implement risk-based mitigation measures. On the other hand, the lack of specificity creates a lot of questions and uncertainty about what actually is required to comply, and whether robust and validated mitigation measures will actually be implemented.

We support the development and distribution of organic-specific resources, educational tools, and technical assistance to help organic operations understand and comply with FDA’s final rule. The rule requires a high level of technical knowledge to conduct a robust agricultural water assessment and identification of appropriate mitigation measures. FDA should provide information resources, tools, and technical assistance that embraces organic agricultural systems and the unique practice standards and restricted inputs that organic farmers must comply with. FDA must not exclude or preclude organic farmers from accessing and utilizing any further guidance or information provided by FDA to support the implementation of the final rule.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.



Respectfully submitted,

Johanna Mirenda

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
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APPENDIX A

Summary of Proposed Procedure for Agricultural Water Assessments

1. Conduct the Assessment – Evaluate the following factors to identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards into or onto covered produce or food contact surfaces:

- ✓ **Agricultural Water Systems** (sources, facilities and equipment for distribution and application)
- ✓ **Agricultural Water Practices** (pre-harvest timing and method of application)
- ✓ **Crop Characteristics** (physical traits, growth traits, and surface properties)
- ✓ **Environmental Conditions** (rainfall patterns, temperature, sunlight exposure, and extreme weather)
- ✓ **Other Relevant Factors**

2. Evaluate the Outcomes & Implement Corrective or Mitigation Measures – Use findings from your assessment to determine whether measures are reasonably necessary to reduce potential for contamination:

If you determine	Then you must
that your agricultural water is not safe or is not of adequate sanitary quality for intended use(s)	Immediately discontinue use(s) and take corrective measures before resuming use of the water for pre-harvest activities. Corrective measure include: <ol style="list-style-type: none"> 1. Re-inspecting the entire affected agricultural water system under the farm’s control and, among other steps, making necessary changes; or 2. Treating the water in accordance with the standards outlined in the Produce Safety Rule.
there is one or more known or reasonably foreseeable hazards <u>related to</u> animal activity, BSAAOs, or untreated or improperly treated human waste for which mitigation is reasonably necessary	Implement mitigation measures promptly, and no later than the <u>same growing season</u> . Mitigating measure include: <ol style="list-style-type: none"> 1. Making necessary changes (such as repairs) to reduce the risk 2. Increasing the time interval <u>between application and harvest</u> (minimum 4 days, except as supported by test results conducted under proposed § 112.43(d), or other scientifically valid data or information in accordance with proposed § 112.12) 3. Increasing the time interval <u>between harvest and end of storage</u> using an appropriate microbial die-off rate, 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 4. Changing the method of water application to reduce the risk 5. Treating the water in accordance with the rule 6. Alternatives in accordance with the rule
there is one or more known or reasonably foreseeable hazards not <u>related to</u> animal activity, BSAAOs, or untreated or improperly treated human waste, for which mitigation is reasonably necessary	Implement mitigation measures (same list as above) as soon as practicable and no later than the <u>following year</u> OR Test water as part of the assessment and implement measures, as needed, based on the outcome of the assessment
that there are no known or reasonably foreseeable hazards for which mitigation is reasonably necessary	Inspect and adequately maintain the water system(s) regularly, and at least once each year