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New Rules: Navigating Produce Safety's Changing Landscape

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New/Updated Regulations Impacting Produce

- Produce Safety Rule Subpart E (Agricultural water)
- Food Safety Modernization Act's Traceability Rule (FSMA 204)

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Agricultural Water Background

- The FSMA PSR, including Subpart E (agricultural water) was published in 2015
- Subpart E was revised in 2024
  - The standard for production water (preharvest agricultural water) changed
  - The standard for postharvest water did not change
- The revised Subpart E moved from testing preharvest water to an agricultural water assessment of the whole water system

Produce Safety Rules Definitions

- **Agricultural water** - water used in covered activities on covered produce where water is intended to, or is likely to, contact covered produce or food contact surfaces
- **Agricultural water assessment (AgWA)** – evaluation to…
  - Identify any condition(s) that are reasonably likely to introduce known or reasonably foreseeable hazards…
  - Determine whether measures are reasonably necessary to reduce the potential for contamination… with such known or reasonably foreseeable hazards

Risk V Hazard

- A **hazard** is a biological, chemical, or physical agent that could cause harm
- **Risk** is the likelihood of a hazard causing harm.

AgWA Exemptions

1. Is the same quality as harvest and postharvest agricultural water
   - No detectable generic *E. coli* in 100 mL and meets other postharvest agricultural water testing requirements
   - Is not untreated surface water
2. Is received from a public water system or supply
3. Is treated in accordance with FSMA PSR

- Reasonably likely the water quality will not change prior to use
- Each exemption condition requires supporting records

Parts of the AgWA

- Agricultural water system
- Agricultural water practices
- Crop characteristics
- Environmental conditions
- Other relevant factors (e.g., water test results)

Agricultural Water System

- The location and nature of the water source
  - Surface water vs groundwater vs municipal water
- The type of water distribution system
  - Open vs closed
- The degree to which the system is protected from possible sources of contamination

Public Water Supply

Treated

Ground Water

Surface Water

Open to Environment

Risk Related to Degree of Protection

Adjacent > Nearby > Proximity

Agricultural Water Practices

- Application Method**
  - Overhead/foliar vs furrow/flood vs drip
- The interval between application and harvest
  - Close to harvest vs further from harvest

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Crop Characteristics

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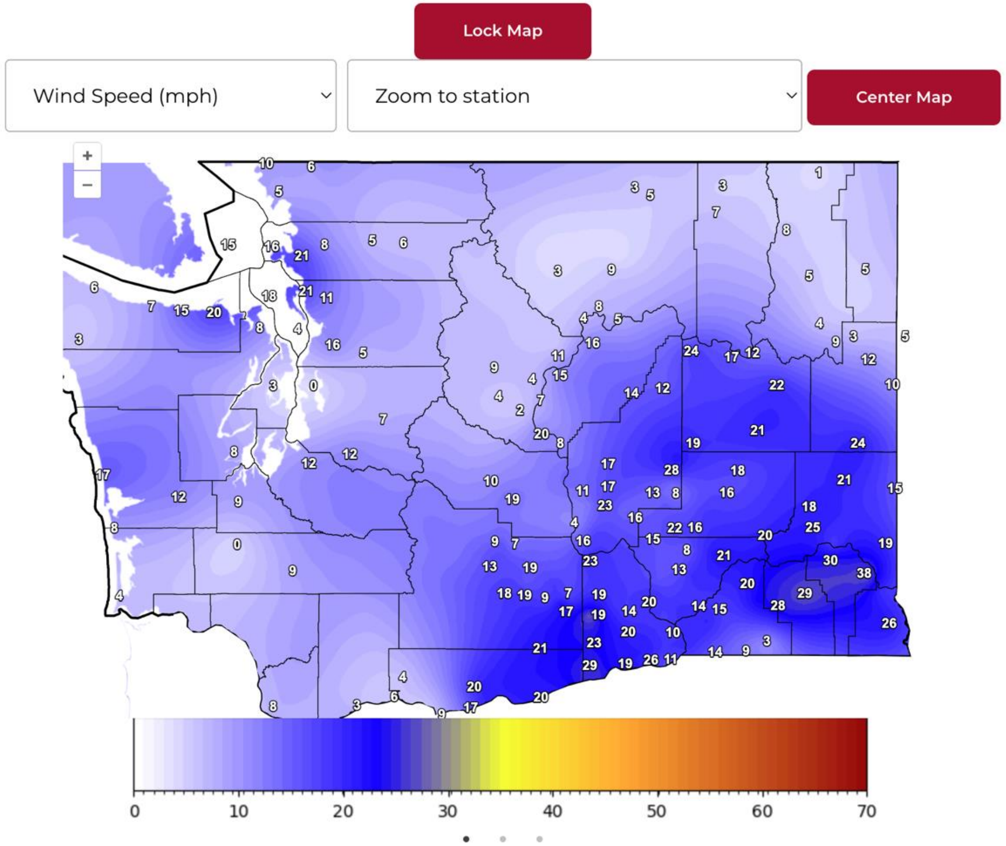
Environmental Conditions

- Rain
  - Intensity
  - Quantity
  - Duration
- Air Temperatures
  - survival of pathogens in water sources decreases with increasing temperatures
- Wind
  - Speed
  - Direction
- Sun (UV) exposure
- Relative Humidity



Other…

- Water testing
  - Tested for:
    - generic *E. coli*
    - another “scientifically valid indicator organism, index organism, or analyte”
  - Frequency:
    - “Scientifically valid and appropriate”
  - Microbial criterion
    - “Scientifically valid and appropriate”
- Justify your actions/decisions
- Tests cannot be used as the only basis for water use decisions

If…	*Then…*
Ag water not safe or not of adequate sanitary quality	Immediately discontinue use **AND** Take corrective measure(s) before use at pre-harvest
Condition(s) on adjacent or nearby land uses pose risk related to animal activity, BSAAO, or human waste	Implement mitigation measures promptly, and no later than the same growing season
Other conditions that may introduce known or reasonably foreseeable hazards, not related to animal activity, BSAAO, or human waste on adjacent or nearby lands	Implement mitigation measures as soon as practicable, and no later than the following year **OR** Test water as part of the agricultural water assessment and implement measures as needed
No known or reasonably foreseeable hazards for which mitigation is necessary	Inspect and maintain water system regularly and at least once a year

Corrective measures	• Re-inspecting the entire affected agricultural water system under the farm's control and, among other steps, making necessary changes **OR** • Treating the water in accordance with the standards in FSMA PSR
Mitigation measures	• Making necessary changes such as repairs • Increasing time interval between last direct application and harvest (microbial die-off) • Increasing time interval between harvest and end of storage (microbial die-off) • Other activities that result in die-off or removal • Changing water application method • Treating water (PSR standards) • Taking alternative mitigation measures supported by scientific information

What is I have multiple…

Risk is Subjective!

Impact →

Likelihood ↑	Negligible	Minor	Moderate	Significant	Severe
Very Likely	Low Med	Medium	Med Hi	High	High
Likely	Low	Low Med	Medium	Med Hi	High
Possible	Low	Low Med	Medium	Med Hi	Med Hi
Unlikely	Low	Low Med	Low Med	Medium	Med Hi
Very Unlikely	Low	Low	Low Med	Medium	Medium

FSMA 204

- Final Rule published November 21, 2022
- The compliance date was originally set for January 20th, 2026
- Compliance was delayed by 30 months to July 20th, 2028
- Foods subject to the final rule requirements appear on the Food Traceability List (FTL)

Cucumbers (fresh)	**Leafy greens (fresh-cut)**	**Sprouts (fresh)**	**Peppers (fresh)**
Herbs (fresh)	**Leafy greens (fresh)**	**Tomatoes (fresh)**	**Vegetables other than leafy greens (fresh-cut)**

Critical Tracking Events (CTE)	Key Data Elements (KDE)	
Harvest	– Location description of farm – Location description of recipient – Name of the field harvested	– Reference document # – Commodity harvested – Date of harvest – Amount harvested
Initial Cooling	– Location description of cooler – Location description of recipient – Location description of farm	– Reference document # – Commodity cooled – Date of cooling – Amount cooled
Initial packing	– Traceability lot code assigned – Product description as packed – KDEs from Harvest CTE – KDEs from any Cooling CTE	– Reference document # – Date packed – Amount packed – Location description of initial packing
Shipping Receiving Transformation	– Traceability Lot Code – KDEs for the current CTE – Next receiver information	– KDEs from prior CTEs • Harvest, Cool, Pack, Prior Shipping, Receiving, Transformation

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