The Food Safety Modernization Act: Update 2015

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Definitions

• Farm – an establishment under one ownership in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood)
  – Pack or hold raw agricultural commodities
  – Pack or hold processed food that is consumed on that farm or another under the same ownership
  – Manufacture/process food (not consumed on farm)
    • Drying/dehydrating to create a distinct commodity
    • Packing and labeling raw agricultural commodities when no additional manufacturing/processing is involved
Definitions

• Very small business (farm)
  - Average annual value of *produce* sold >$25,000, but not more than $250,000 during the previous three years

- Small business (farm)
  - Average annual value of *produce* sold >$250,000, but not more than $500,000 during the previous three years
• Farm or mixed-type facility
  – Average annual monetary value of produce sales of $25,000 or more
  – Farm will not need to register as a food facility merely because it packs or holds raw commodities grown on another farm under a different ownership
    • These activities would fall under the produce rule not the preventive controls rule
Proposed Exemptions

• Farms may be exempt if they:
  o Average annual monetary value of **food sold** in previous 3 years is <$500,000 AND
  o Sell to qualified end users either*:
    A. Direct to consumer
    B. Restaurant, retail food establishment in same state or within 275 miles of where produce was grown

*Sales must exceed the annual monetary value of all food sold to other buyers in the same time period
Agricultural Water - Subpart E

• Water that is intended to or likely to contact produce or food-contact surfaces including:
  – Irrigation when applied direct
  – Water used in pesticide applications
  – Growing sprouts
  – Washing or cooling produce
  – Making ice
  – Preventing dehydration
Water Quality Criteria For Direct Contact With The Crop

• Applies to water used in *direct contact* with the harvestable portion of the crop

• **All water must be:**
  - \(< 126 \text{ CFU/MPN} \) generic *E. coli* per 100 ml geometric mean
  - and/or
  - \(< 410 \text{ CFU/MPN} \) generic *E. coli* per 100 ml statistical threshold value
Water Application and Timing

- **IF** water contacts the harvestable portion of the crop, risks may be reduced by maximizing the time between application and harvest.
- Proposed FSMA Produce Rule outlines a microbial die-off rate of 0.5 log per day between the last irrigation event and harvest.
  - *This will be important if your water does not meet standard criteria!*
Generic *E. coli* Is An Indicator Organism

- Generic *E.coli* is intended to indicate the likelihood of fecal contamination
- It is not a measure of the presence of human pathogens
Establishing a Baseline for Untreated Surface Water

• Establishing a baseline of water quality can help identify when you may have a problem with your water source

• The proposed Produce Safety Rule requires a minimum 20 samples collected as close to harvest as practical over 2 years to establish a geometric mean (GM) and a statistical threshold value (STV)
Establishing a Surface Water Quality Profile

**START:**
Establish water quality profile
Take 20 samples over two years

**ANNUALLY AFTER START:**
Take 5 samples
Compare to established water quality profile

**SAMPLING DOES MATCH PROFILE:**
Continue to test 5 samples annually

**TEN YEAR RE-EVALUATION:**
Take 20 samples to establish a new water quality profile

**SAMPLING DOES NOT MATCH PROFILE:**
Use the 5 annual samples, plus an additional 15 new samples (20 total) to establish a new profile

**APPLY ALTERNATE METHODS:**
1. Time interval to achieve 0.5 log microbial die-off per day between water application and harvest
2. Time interval between harvest and end of storage to achieve microbial die-off
3. Other activities that may achieve microbial die-off, i.e. washing
4. Discontinue use
How Often Should You Test Ground Water Sources?

4 times during the growing season or over the period of a year. If the test has no detectable level of generic E. coli per 100 mL or a geometric mean of 126 cfu per 100 mL then once a year.

You must resume testing at least four times per growing season or year if any annual test fails to meet the standard.
Post Harvest Water

- Water change schedules for re-circulated water
- Minimize potential contamination of product and food contact surfaces
- Visually monitor the quality of water in dump tanks, flumes, wash tanks and hydrocoolers for build up of organic material
- Monitor temperature to minimize the potential for infiltration of microorganisms.
Minimum Application Intervals Biological Soil Amendments of Animal Origin

• There are no application intervals for raw manure outlined in the proposed Produce Safety Rule
• FDA continues to encourage use of NOP guidelines
• **Untreated Soil Amendments**
  – FDA is currently pursuing further research to support quantitative application intervals for raw manure
• **Treated Soil Amendments**
  – 0 day application interval for compost treated by a scientifically validated process
Final Rule Published: Oct 2015

Large growers comply: Dec 2017
2 years

Small growers comply: Dec 2018
3 years

Very small growers comply: Dec 2019
4 years

Effective date (60d): Dec 2015

Complete Implementation: Dec 2021
One More Thing You Need!

• Proposed Produce Safety Rule:
  Each farm must have at least one person who has successfully completed food safety training
• Must be from a course recognized as equivalent to FDA training
More Information Available

- Web site: http://www.fda.gov/fsma
- Subscription feature available
- Send questions to FSMA@fda.hhs.gov