RUTGERS
New Jersey Agricultural Experiment Station

The Food Safety Modernization Act: Update 2015

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FDA Proposed Rule on Produce Safety

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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:**
  - Average annual monetary value of **food sold** in previous 3 years is <$500,000
    AND
  - 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 CFU/MPN** generic *E. coli* per 100 ml geometric mean

  and/or

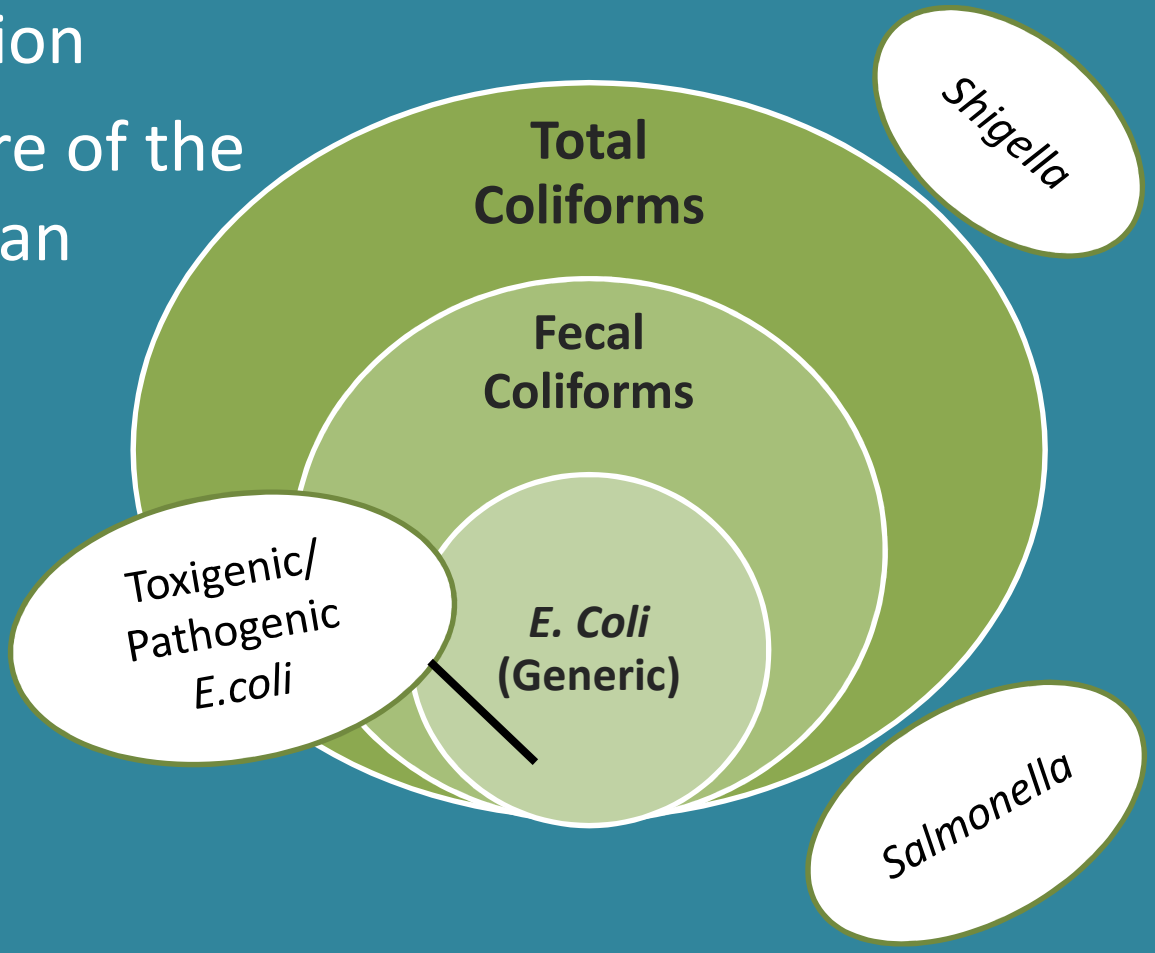
  ≤ **410 CFU/MPN** generic *E. coli* per 100 ml statistical threshold value

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

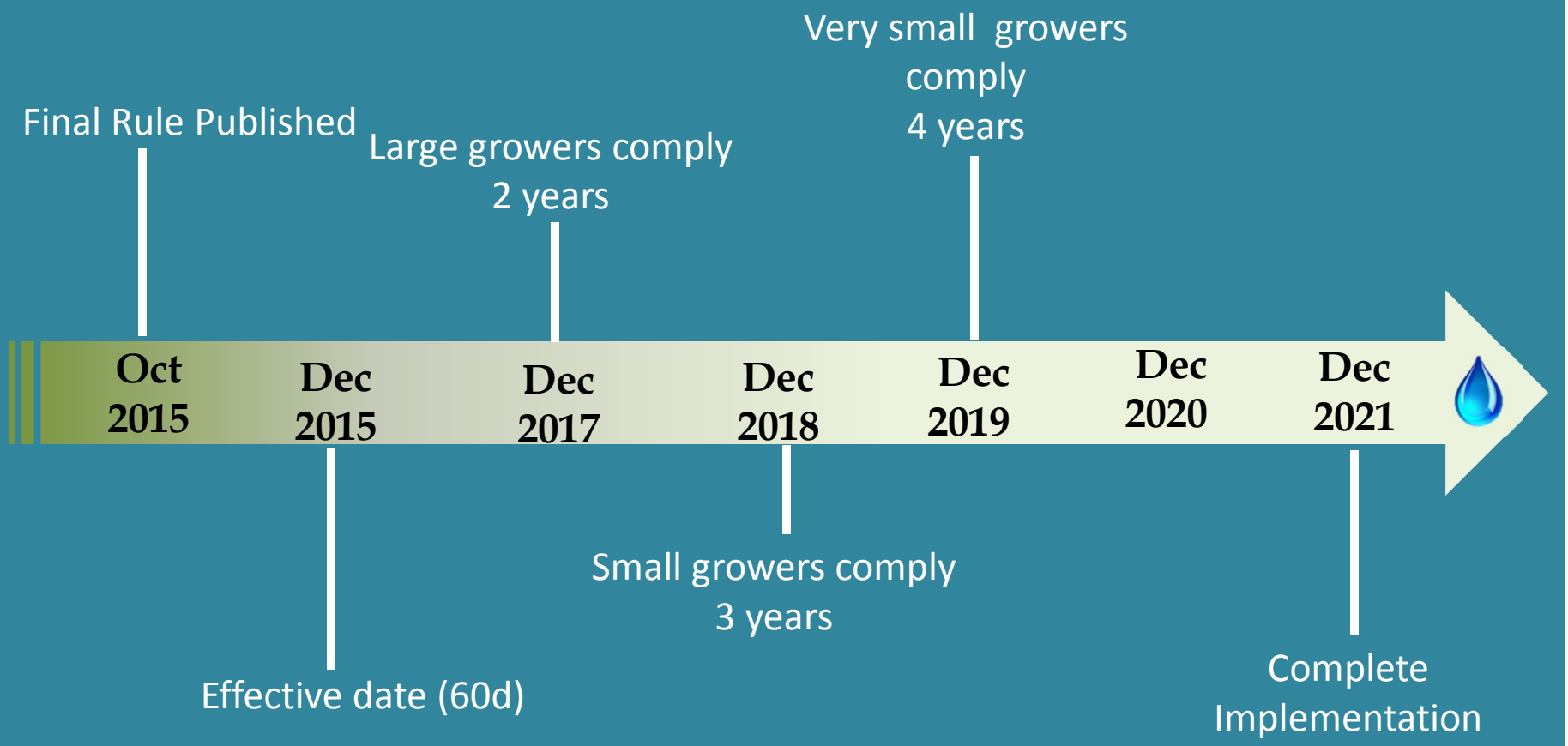
Post Harvest Water

- 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

Time Frame…in Theory!



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

FDA FOOD SAFETY MODERNIZATION ACT

More Information Available

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