RUTGERS
New Jersey Agricultural Experiment Station

The Food Safety Modernization Act: Where We Stand in 2015

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Food Safety Modernization Act

Signed into law on January 4, 2011

The most sweeping reform of food safety laws in 70+ years

PREVENTION of contamination

Five Proposed Rules Establish Food Safety Framework

- Produce Safety Standards
  - Final rule to be published October, 2015
- Preventive Controls for Human Food
  - Final rule to be published October, 2015
- Foreign Supplier Verification Program
  - Final rule to be published August, 2015
- Preventive Controls for Animal Food
  - Final rule to be published August, 2015
- Accreditation of Third Party Auditors
  - Final rule to be published 2016

FDA Proposed Rule on Produce Safety

Key Principles

- Considers risk posed by practices, commodities
- Science- and Risk-based
  - Focus on identified routes of microbial contamination
  - Excludes certain produce rarely consumed raw
  - Excludes produce to be commercially processed (documentation required)
- Flexible
  - Additional time for small farms to comply
  - Variances
  - Alternatives for some provisions

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

Who Would be Covered?

- Farms that grow, harvest, pack or hold most produce in raw or natural state (raw agricultural commodities)
- Farms and “farm” portions of mixed-type facilities
- Domestic and imported produce
- Farms with annual sales less than $25,000 per year are exempt
- Limitations on coverage are proposed

- 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

Covered Produce

- “Produce” defined as fruits and vegetables
- Produce includes mushrooms, sprouts, herbs and tree nuts
- Mixes of intact fruits and vegetables (such as fruit baskets)
- Produce does not include grains except for calculating sales in the exempt category

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

Requirements

- When a label is required by Federal Food, Drug and Cosmetic Act
  - Name and complete business address
- When label not required
  - Prominently display, at point of purchase name and complete business address
  - Electronic notice

Withdrawal of Exemption

- FDA would notify the farm as to the reason for withdrawing the exemption (warning letters, recall, administrative detention, etc.)
- There is an appeal procedure that has been proposed
- A procedure for reinstating the exemption is included in the latest proposal

Standards for Produce Safety

Focus on identified routes of microbial contamination

- Domesticated and wild animals
- Equipment, tools, buildings and sanitation
- Worker health and hygiene
- **Agricultural water**
- Growing, harvesting, packing and holding activities
- **Biological soil amendments of animal origin**
- Specific requirements for sprouts

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 that has potential or intent to come in **direct contact** with produce including sprays
- Frost protection is not agricultural water if does not contact harvestable product
  - Strawberries it is agricultural water
  - Blueberries probably not agricultural water

Agricultural Water

- Agricultural water must be microbially safe
- Inspection of water system at beginning of season and maintain sources
- If water is not safe (discontinue use):
  - Re-inspect system, make changes, test water OR treat water
- Alternatives permitted that provide same level of public health protection

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

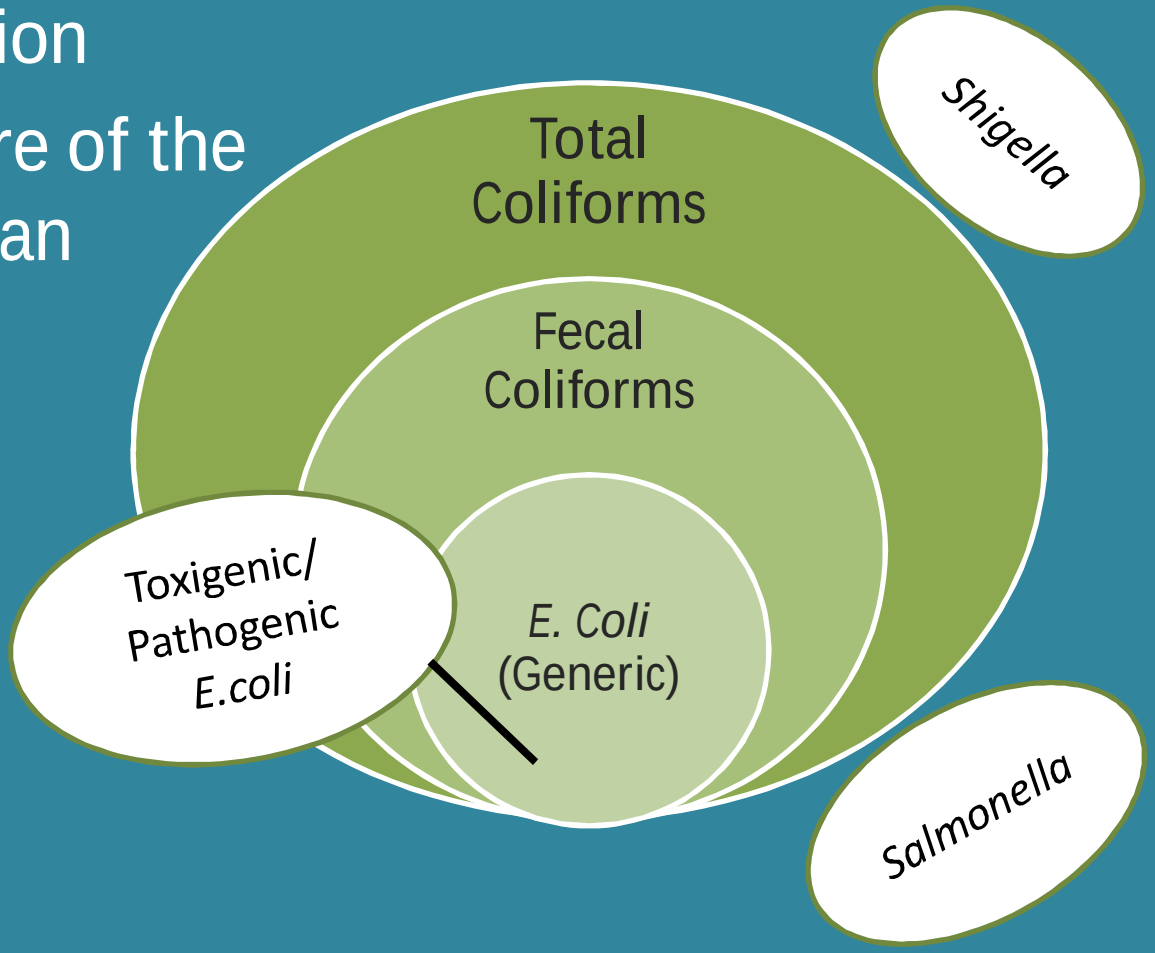
- IF water contacts the harvestable portion of the crop, risks may be reduced by maximizing the time between application and harvest
- Proposed FSMA Produce Rule outlines a microbial die-off rate of 0.5 log per day between the last irrigation event and harvest
  - *This will be important if your water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

Example

- Water sample 1000 cfu/100 ml
- 1 day with 0.5 log reduction
  - 330 cfu/100 ml
- 2 day
  - 106 cfu/100 ml

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



Evaluating Water Sources

- The only way to know the quality of your water is through testing
- Testing can help you:
  - Understand the quality of your source water
  - Establish a baseline water quality so you can best plan how and when to apply water
  - Determine if corrective actions, such as water treatment, are needed if the microbial contamination exceeds your established baseline or current indicator limits

Pre Harvest Water Testing

- When not required to test
  - When water from public water system is used and a copy of test results or compliance certificate is available
  - You treat the water

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:

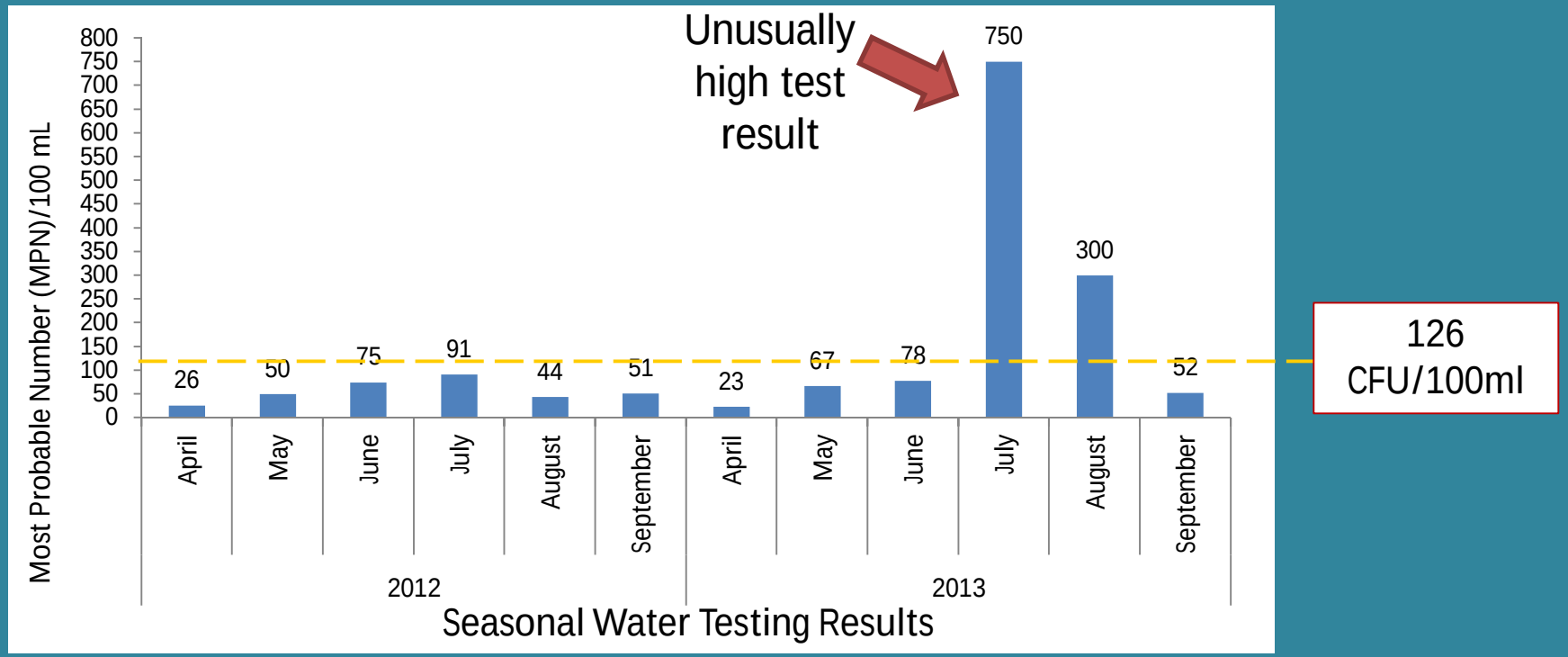
1. Time interval to achieve 0.5 log microbial die-off per day between water application and harvest
2. Time interval between harvest and end of storage to achieve microbial die-off
3. Other activities that may achieve microbial die-off, i.e. washing
4. Discontinue use

Reviewing Test Results

- If your baseline is higher than the proposed microbial water standards, take action!
  - Investigate water sources for possible causes
    - Manure application and runoff
    - Wildlife fecal contamination
    - Incorrect/inadvertent cross connections
    - Wellhead impacts
- Take corrective actions to reduce risk
  - Treat water source
  - Use a microbial die-off rate
    - Timing of water application
    - Other methods such as washing that reduce microbial populations

Visualizing Water Quality Trends

Comparing water test results to your baseline can help you identify possible risks in your water source.



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 fest fails to meet the standard

Post Harvest Water Testing

- Must test agricultural water using
  - Quantitative or presence-absence method
  - No detectable generic *Escherichia coli* in 100 mL of water
    - Sprout Irrigation
    - Direct contact during or after harvest
    - Making ice that will contact food or food-contact surfaces
    - Hand washing during and after harvest

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.

Biological Soil Amendments of Animal Origin – Subpart F

- Biological soil amendments of animal origin may contaminate produce with pathogens
  Requirements include:
  - Standards for handling, conveying and storing
  - Treatment methods, application methods, and application intervals
- Alternatives permitted that provide same level of public health protection

Untreated Soil Amendments

- Untreated soil amendments are considered the highest risk since they have not been treated to reduce or eliminate pathogens
- All of the following soil amendments would be considered untreated:
  - Raw manure
  - ‘Aged’ or ‘stacked’ manure
  - Untreated manure slurries
  - Compost teas made with raw manure
  - Any soil amendment mixed with raw manure

Composting as a Treatment

- Composting is a controlled biological process that decomposes organic matter and reduces pathogens
- Temperature is the primary method of pathogen reduction; however, there are other factors that contribute to pathogen die-off
- Only an approved, scientifically valid composting process ensures adequate pathogen die-off
- Monitoring and recordkeeping is critical to ensuring the compost is safe

Composting Options

- Select a scientifically valid process outlined in the proposed Produce Rule:
  1. Static composting: aerobic, minimum 131°F (55°C) for 3 days, followed by curing with proper insulation (e.g. six inch covering or other management to ensure elevated temperatures throughout all materials)
  2. Turned composting: aerobic, minimum of 131°F (55°C) for 15 days, minimum 5 turnings, followed by curing
  3. Other scientifically valid, controlled composting processes

Minimum Application Intervals

- 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

Recordkeeping: Soil Amendments

- Type and source of soil amendment
- Rates and dates of application
- Treatments, certificates of analysis and any microbial test results
- Handling and sanitation practices used to reduce risks

Storage Area Considerations

- Minimize run-off, leaching, and wind drift to prevent contamination of crops, water sources, and handling areas
  - Cover piles
  - Build berms to prevent run-off
- Do not store uphill or close to water sources
- Keep raw manure and finished compost in separate areas to prevent cross-contamination

Worker Health and Hygiene
Subparts C and D

- Pathogens may be transmitted from person to food
- Requirements Include:
- Training
  - If a farmer sells the entire field pre-harvest, food safety training is the responsibility of the new owner or if crew is hired the crew leader is responsible
- Preventing contamination by ill persons

Workers Are A Food Safety Concern Because They…

- Can carry human pathogens
  - *Shigella*, Hepatitis A, Norovirus, and others
- Can spread human pathogens
  - Harvest and pack with their hands
  - Fecal-oral route
- Require training to reduce risks
  - Proper hand washing
  - How to handle injuries

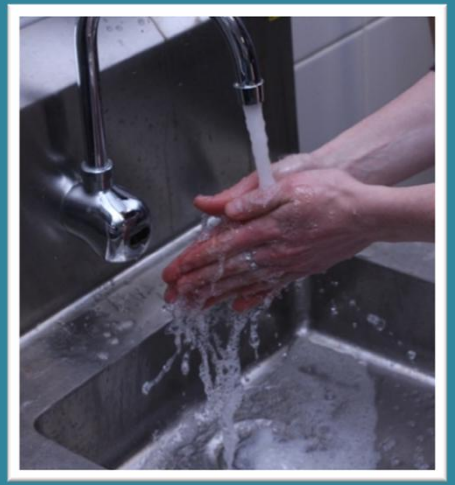
Employee Training

- Everyone who works on a farm needs to be trained!
  - Workers (office and field)
  - Seasonal volunteers, interns
  - Contracted personnel
  - Family members
- Must be trained at the beginning of the season and periodically thereafter
- Must be conducted in a manner that is easily understood

Worker Training Programs MUST Include:

- How to properly use toilets and wash hands
- Importance of personal cleanliness
- What to do when injured or ill
- How to implement practices to reduce food safety risks while working (such as inspecting containers and equipment)
- How to communicate food safety risks with managers/supervisors

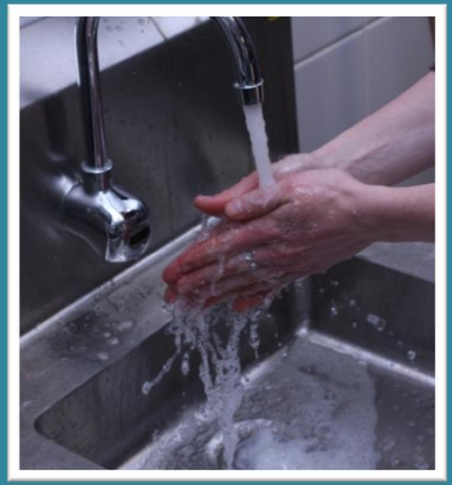
Proper Hand Washing



1. Wet hands with water.
2. Apply soap and lather. Be sure to wash the front and backs of hands as well as in between the fingers. Rub hands together for AT LEAST 20 seconds.
3. Rinse hands thoroughly with clean water
4. Dry with a paper towel (turn off faucet with used towel)
5. Throw the paper towel in a trash can.

Antibacterial hand sanitizers CANNOT replace handwashing.

Proper Hand Washing



1. Before Starting Work
2. Before Putting on Gloves
3. After using the toilet
4. Upon returning to work
5. As soon as practical after touching animals
6. Any other time when the hands may have become contaminated

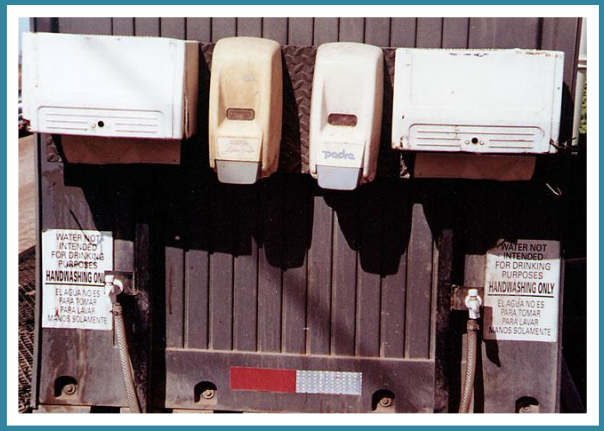
Note: If gloves are used they must be maintained in an intact and sanitary condition

Visitors

Everyone (except personnel) is considered a visitors; must be aware of policies and have access to toilet and hand washing facilities

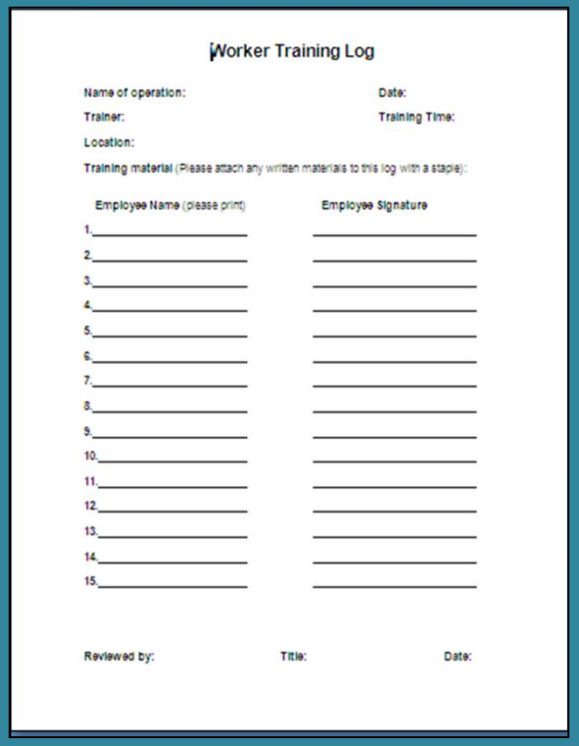
Resources That MUST Be Provided:

- Toilets
- Toilet paper
- Soap
- Clean water
- Paper towels
- Garbage cans
- First Aid Kit
- Break Areas



Recordkeeping

- Example of documenting worker training
  - Date
  - Name of trainer
  - Materials/information covered
  - Printed names & signatures of attendees
  - Manager signature



Worker Training Log

Name of operation: Date:

Trainer: Training Time:

Location:

Training material (Please attach any written materials to this log with a staple):

Employee Name (please print)	Employee Signature
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	
14.	
15.	

Reviewed by: Title: Date:

Equipment, Tools and Buildings Subpart L

- Requirements include:
  - Equipment/tools must be designed and constructed to allow adequate cleaning and maintenance
  - Food contact surfaces of equipment and tools must be inspected, maintained, cleaned and sanitized as necessary
  - Buildings must be designed and constructed to allow adequate cleaning and reduce potential for contamination
  - Must have adequate, reasonably accessible toilet and hand washing facilities in or adjacent to the building

Not All Packing Areas Are The Same

Open

Open to the environment, with some open sides

Closed

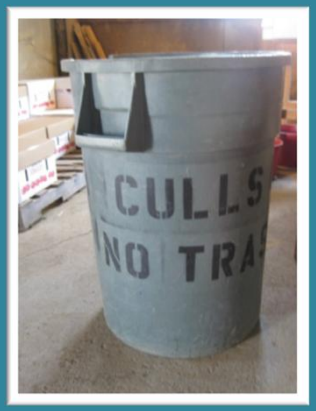
Has doors with some ability to control entry into the building

Keeping Things Clean

- Keeping things clean during postharvest handling and reducing contamination risks is essential
- Consider everything that touches or impacts produce
  - Packing containers
  - Packing equipment
  - Hands and clothing
  - Postharvest water
  - Buildings (i.e. coolers, storage areas)
  - Transport vehicles

Reduce Risks in All Packing Facilities!

Keep it clean



Proper facilities & break areas for workers

Pest management

Avoid standing water

Keep it organized

Domesticated/Wild Animals Subpart I

- Requirements apply if there is a reasonable probability that animals will contaminate covered produce (FDA looking for fecal material not animals)
- Requirements include:
  - Wait an adequate amount of time between grazing and harvesting
  - If working animals are used in a planted growing area, take measures to prevent pathogens from being introduced onto the produce
  - Monitor for animal intrusion and if observed, evaluate for harvest (no harvesting of visibly contaminated covered produce)

Animals Are A Produce Safety Concern Because They:

- Can carry human pathogens
  - e.g. *E.coli* O157:H7, *Salmonella, Listeria,* and more
- Can spread human pathogens
  - By depositing feces in fields
  - By spreading fecal contamination as they move
- Are a natural part of the growing environment
  - If fencing is used, even the best fence can be breached
  - Birds and small animals travel unnoticed
  - Complete exclusion is impossible

Assessing Risks: Wildlife

- Do you find wildlife feces in your produce fields?
  - How often? Is it widely distributed? Is it in contact with produce?
- Is your farm in an area that large numbers of animals visit (e.g. flocks of migrating birds, herds of deer)?
- What management practices can limit wildlife contamination of produce fields and water sources?

Assessing Risks: Domestic Animals

- Are domestic animals allowed in the field while the crop is present as part of the production process?
- Is run-off likely to flow from pastures, corrals or manure storage locations into production or packing areas?
- Is pet access to the fields and packing areas controlled?
- Are workers aware of cross-contamination risks from fecal contamination of hands, clothing, shoes, and equipment after handling animals or fecal material?
- Do animals graze culls or crop residues in the field?
- Is the production ground rotated into grazing land?

Monitoring Wildlife Activity

- During the growing season:
  - Monitor for feces and evidence of intrusion
  - Evaluate the risk of fecal contamination on produce (e.g. tree vs. root crop)
  - Consider past observations

- Immediately prior to harvest
  - Scout for fecal contamination, signs of animal activity (trampling, rooting, feeding, tracks)
  - Assess risk and decide if the crop or a portion of the crop can be safely harvested

Working Animals

- Limit work animal access to fields when edible portion of crop is present
  - Establish draft animal paths to minimize contact with produce
- Anyone working with the animals should understand risks and be trained to minimize risks
- Develop SOPs for animal and manure handling
  - e.g. hand washing, cleaning and sanitizing tools, practices to complete after handling animals

Pets

- Should be excluded from produce fields, especially close to harvest
- Should be excluded from packing areas to prevent the contamination of food contact surfaces
- Visitors to the farm or U-Pick businesses should be instructed to leave their pets at home

Pre-Harvest Assessment

- A formal, documented process to assess fields before harvest can help you determine if:
  - Fecal contamination is present, or signs indicate a risk (e.g. tracks, trampling, rooting, feeding)
  - Fresh produce has been contaminated and if any corrective actions, such as buffer zones, are necessary
  - Harvest can safely proceed

Growing, harvesting, packing and holding activities – Subpart K

- Proposal includes science-based, minimum standards related to growing, harvesting, packing and holding
- Requirements include:
  - There must be a food contact sanitation step between covered and excluded produce during packing
  - Not distributing covered produce that drops to the ground before harvest unless it receives commercial processing
  - Food-packing material must be appropriate for use

- Wood containers, canvas bags are acceptable, but must be sanitary
- Any sanitizer or disinfectant used must have an EPA pesticide label

Records, Compliance and Enforcement

- The proposed rule would require certain records
  - Example: agricultural water testing results and conformance documents
- Records already kept for other purposes need not be duplicated
- Growers will need to be able to trace their product
- All records must be kept for 2 years
- FDA has authority to shut a farm if they are producing adulterated product.

Alternatives Permitted

- Farms may establish alternatives to certain requirements related to water and biological soil amendments of animal origin
- Alternatives must be scientifically established to provide the same amount of protection as the requirement in the proposed rule without increasing the risk of adulteration

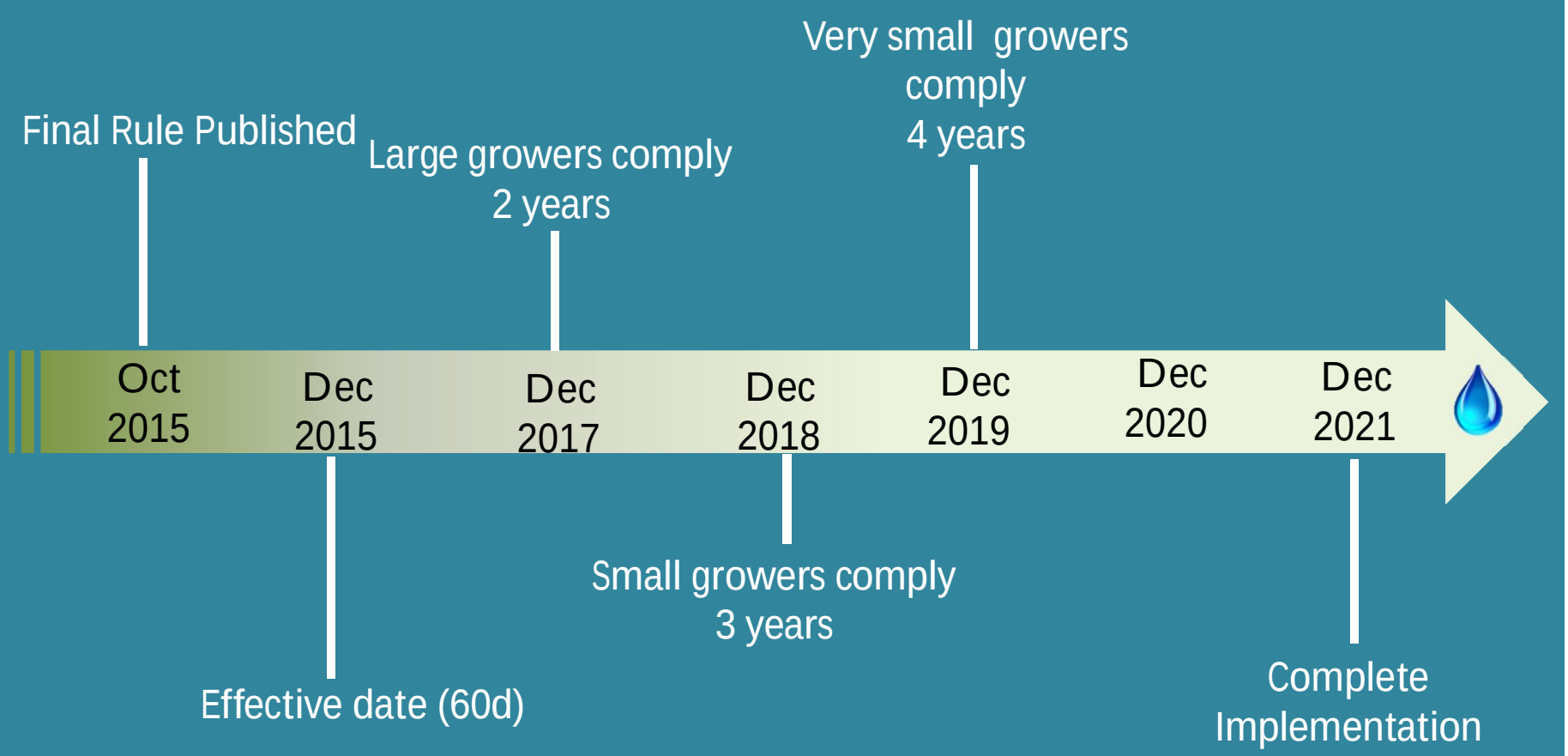
Variances Provide Flexibility

- A state, region or foreign country may petition FDA for a variance from some or all provisions if deemed necessary in light of local growing conditions.
- Practices under the variance would need to provide the same level of public health protection as the proposed rule without increasing the risk of adulteration.

Compliance Dates

- **Very small farm**
  - Average annual value of produce sold >$25,000, but not more than $250,000
  - Would have four years after the effective date
- **Small farm**
  - >$250,000, but not more than $500,000
  - Would have three years after the effective date
- **Other covered farms**
  - Other covered businesses would have two years
- **Compliance dated for water quality standards, testing and recordkeeping would have additional two years**

Time Frame…in Theory!



Estimated Annual Cost per Farm

- Very Small - $4,697
- Small - $12,972
- Large - $30,566

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

Preventive Controls for Human Food

Summary of Requirements

- Hazard Analysis and Risk-Based Preventive Controls
  - Each facility would be required to implement a written food safety plan that focuses on preventing hazards in foods
  - Corrective action procedures
  - Verification procedures
  - Recall plan
- May require FDA registration of packinghouse
- Updated Good Manufacturing Practices

More Information Available

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

Technical Assistance

- Alliances
  - Produce Safety
    - www.producesafetyalliance.cornell.edu
  - Preventive Controls
  - Sprouts Safety
    - www.iit.edu/ifsh/alliance
- Guidance documents
- National technical assistance network

Partnerships will be essential

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Questions

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