FSMA-What to Expect
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FSMA-What to Expect

• What are everyone’s current perceptions of FSMA-PSR?
Background-why FSMA

- Signed into law in 2011
- Due to food borne illness outbreaks related to produce
- Goal to establish more secure domestic and imported food sources—preventative vs reactive
- Regulations for law released January 2016
Is food secure in US?

Table 1. Deadly Multistate Outbreaks of Foodborne Illness in the U.S., 2006-2011

<table>
<thead>
<tr>
<th>Year</th>
<th>Pathogen</th>
<th>Food Source</th>
<th>Cases of Illness</th>
<th>Number of Deaths</th>
<th>Number of States</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>Listeria monocytogenes</td>
<td>Cantaloupes (Jensen Farms)</td>
<td>145</td>
<td>30\textsuperscript{a}</td>
<td>28</td>
</tr>
<tr>
<td>2011</td>
<td>Salmonella heidelberg</td>
<td>Ground turkey (Cargill)</td>
<td>136</td>
<td>1</td>
<td>34</td>
</tr>
<tr>
<td>2009</td>
<td>Escherichia coli 0157:H7</td>
<td>Ground beef (Fairbank Farms)</td>
<td>26</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td>2009</td>
<td>Salmonella typhimurium</td>
<td>Peanut butter (King Nut)</td>
<td>714</td>
<td>9</td>
<td>46</td>
</tr>
<tr>
<td>2008</td>
<td>Salmonella saintpaul</td>
<td>Jalapeño peppers (Mexico)</td>
<td>1,442</td>
<td>2</td>
<td>43</td>
</tr>
<tr>
<td>2006</td>
<td>Escherichia coli 0157:H7</td>
<td>Baby spinach (Dole)</td>
<td>199</td>
<td>3</td>
<td>26</td>
</tr>
</tbody>
</table>

\textsuperscript{a} One miscarriage was reported in a pregnant woman.  
Source: Reference 3.

- 2011 CDC estimated 47.8 million Americans contracted food-borne illness
- 55,961 hospitalized
- 1,351 deaths
Food Safety Outbreaks

2006 Spinach E-coli O157
• 205 illness
• 3 deaths

2011 Cantaloupe Listeria
• 147 illness across 28 states
• 30 deaths

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What’s the Consensus

• **You’re doing great!**
  – First and foremost, thank you!
  – Growers work incredibly hard, and the law is to protect those growers from financial loss from food borne illness.
What’s the Consensus?

• Through outbreaks we’ve learned valuable lessons:
  – Contamination sources on the farm & handling facilities
  – Practices for avoiding these contamination points
  – Let’s work together!
What is FSMA-PSR?

- **Food Safety Modernization Act, Produce Safety Rule**—Regulations for ensuring growers of a designated size and scope are employing practices to minimize food safety risks.
Who Influenced the Rules?

- Industry, FDA, USDA, and public comment have all played a role in developing standards
Standards are Based on:

- Science based standards
- Previous issues encountered
- What we’ve learned from previous outbreaks
- Prevention vs reaction
How Does this Impact You?

- Farm scopes include products commonly consumed raw. **Exempt crops include**: asparagus, beans; collards; sweet corn; cranberries; dates; dill (seeds and weed); eggplants; figs; horseradish; hazelnuts; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestasparagus; black beans, great Northern beans, kidney beans, lima beans, navy beans, and pinto beans; garden beets (roots and tops) and sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee nuts

- Food grains, including barley, dent- or flint-corn, sorghum, oats, rice, rye, wheat, amaranth, quinoa, buckwheat, and oilseeds (e.g. cotton seed, flax seed, rapeseed, soybean, and sunflower seed)
Exemptions Continued

• Produce that is used for personal or on-farm consumption

• Farms that have an average annual value of produce sold during the previous three-year period of $25,000 or less (gross income)

• This includes all produce, not just produce on the commonly consumed raw list
Exemptions Continued

• The rule provides an exemption for produce that receives commercial processing that adequately reduces the presence of microorganisms of public health significance, under certain conditions
Exemption example

- Tomato grower that is sending all crops to be processed into tomato sauce
- Still must maintain records that verify tomatoes are being sent for this processing
Qualified Exemption

• The farm must have food sales averaging less than $500,000 per year during the previous three years; and
• The farm’s sales to qualified end-users must exceed sales to all others combined during the previous three years. A qualified end-user is either (a) the consumer of the food or (b) a restaurant or retail food establishment that is located in the same state or the same Indian reservation as the farm or not more than 275 miles away.
However.....

- Farm must still meet modified requirements even if exempt:
  - Business name and production address on the product label or at point of sale (compliance by Jan 1, 2020)
  - Maintain records that verify eligibility for exemption or qualified exemption (compliance by Jan 1, 2016)
Qualified Exemption Ex.

• Farm sells an annual average (over a three year period) of $200,000 in livestock sales, $50,000 of leafy greens via farmers markets, $100,000 in jams and salsas, and $150,000 in alfalfa hay.
When do I need to Comply?

PSR were finalized January 2016. Inspections will begin 1 year past each deadline

<table>
<thead>
<tr>
<th>Business Size</th>
<th>Compliance Dates for Sprouts</th>
<th>Compliance Dates For Most Produce</th>
<th>Water Related Compliance Dates¹</th>
<th>Compliance Date for Qualified Exemption Labeling Requirement ²</th>
<th>Compliance Date for Retention of Records Supporting a Qualified Exemption</th>
</tr>
</thead>
<tbody>
<tr>
<td>All other businesses (&gt;=$500K)</td>
<td>1/26/17</td>
<td>1/26/18</td>
<td>1/26/22</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Small businesses (&gt;=$250K-500K)³</td>
<td>1/26/18</td>
<td>1/28/19</td>
<td>1/26/23</td>
<td></td>
<td>1/1/2020</td>
</tr>
<tr>
<td>Very small businesses (&gt;=$25K-250K)⁴</td>
<td>1/28/19</td>
<td>1/27/20</td>
<td>1/26/24</td>
<td></td>
<td>1/26/16</td>
</tr>
</tbody>
</table>

¹ Water related compliance dates vary by category. ² Exemption labeling requirement dates vary by category. ³ Small businesses include $250,000-$500,000. ⁴ Very small businesses include $25,000-$250,000.
Compliance Dates Defined

- Very small: >$25,000 but < $250,000 average annual gross produce sales over 3 years (January 2020 effective date)
- Small: >$250,000 but < $500,000 average annual gross produce sales over 3 years (January 2019)
- All other farms (January 2018)
• Compliance for certain aspects of water quality will allow for an additional 2 years beyond overall compliance to fulfill testing and record keeping provisions.
Modified Exemptions Dates

- Labeling requirements January 2020
- Retention records supporting eligibility for modified exemption, effective date of the rule (January 2016)
Overview of the PSR

- PSR prioritizes on frequent biological risks associated with produce:
  - water quality
  - animal waste use
  - animal intrusion
  - health and hygiene practices
PSA-Agriculture Water Use

- Irrigation
- Fertigation
- Crop sprays
- Cooling
- Frost protection
- Dust abatement
- Other uses where water directly contacts produce
Three main impact points for produce safety risks related to production water are:

1. Production water source and quality
   - Public water supply, ground water, surface water
   - Testing frequency and sampling location

2. Application method
   - Water that does not contact the harvestable portion
   - Water that contacts the harvestable portion of the crop

3. Timing of application
   - At planting or close to harvest
PSA-Probability of Contamination

Lower Risk

Public Water Supply  
Treated

Ground Water

Surface Water  
Open to Environment

Higher Risk
PSR—Potential Sources of Surface Water Contamination

- Agricultural Runoff
- Septic Tank Leakage
- Waste Water Discharge
- Urban and Environmental Runoff
- Manure Application/Composting Operations
- Wildlife & Domesticated Animal Feces
- Things We Never Thought Of
• **Assess nearby land use and upstream water activities to identify risks**
  – Work with neighbors and local watershed groups to understand and minimize identified risks

• **Assess and address runoff risks**
  – Develop diversion ditches, berms or containments to minimize environmental runoff, runoff from manure and compost piles, or runoff from livestock feeding areas

• **Monitor and control animal access to irrigation water sources where practical** (e.g., irrigation reservoirs)
PSR-Methods of Irrigation

• **Overhead (sprinkler)**
  – Higher risk: A direct water application method resulting in contact with produce

• **Flood (surface, furrow)**
  – May avoid direct contact with produce
  – Consider risk of contact with contaminated soil during harvest or from splash

• **Drip (trickle, subsurface, micro, under canopy)**
  – Lower risk: Produce generally not in direct contact (except root crops), reduces foliar diseases, improves water use efficiency
Local Challenges

Irrigation sources may vary annually
• How does a grower determine which sources to develop a water profile?
• This concern has been expressed to FDA

Discussion on what concerns growers

What resources can NDA and UNR provide? (highlight survey)
PSR-Less Contact with Water = Lower Risk

A key question for evaluation of risk is:
“Is the water applied using a direct water application method?”

– If the answer is “never”, the risk from water is very low
– If the answer is “yes”, the type of commodity, quality of the water and the timing of the application should be reviewed to assess risks
Environmental conditions can influence die-off rates including:
- Desiccation (drying out)
- Sunlight (ultraviolet irradiation)
- Temperature and humidity
- Starvation and competition

Some pathogens may be ‘protected’ on the plant and survive for extended periods of time.
Under some conditions, pathogens can even regrow on a plant so avoiding contamination is best.
PSR-Inspect Agricultural Water Sources and Water Distribution Systems

• Water can be contaminated at the source, or at the distribution system
• Mapping all water distribution systems is recommended
• Water sources and distribution systems must be inspected at least annually
• Must keep water sources free of debris, trash, domesticated animals, and other hazards
• **Testing is the only way to quantitatively evaluate the microbial quality of the water**

• **The water quality profile can help:**
  – Understand the long-term quality of source water
  – Understand appropriate uses for each source
  – Determine if corrective measures are needed if the microbial water quality profile exceeds numerical GM and STV criteria in the FSMA Produce Safety Rule
SR-Generic *E. coli* is an Established Indicator

- **Generic *Escherichia coli* (E. coli)** is an indicator of fecal contamination
- **E. coli** is not a direct measure of the presence of human pathogens
- **E. coli** is the indicator used to measure water quality in the FSMA Produce Safety Rule
PSR-Water Quality Criteria for Water Used During Growing Activities

- Apply to water used with a direct water application method to covered produce
- Each source of production water must be tested to evaluate whether its water quality profile meets the following criteria (*which is under review*):
  - 126 or less colony forming units (CFU) generic *E. coli* per 100 mL water geometric mean (GM)
  - AND
  - 410 or less CFU generic *E. coli* per 100 mL water statistical threshold value (STV)
### PSR-Microbial Water Quality Profile: Survey of Ground Water Sources

<table>
<thead>
<tr>
<th>Source</th>
<th>Initial and Annual Testing Requirement</th>
</tr>
</thead>
</table>
| Ground | 4 or more times during the growing season or over the period of a year  
1 or more samples rolled into profile every year after initial year |

- Profile samples must be representative of use and must be collected as close in time as practicable to, but before, harvest.
<table>
<thead>
<tr>
<th>Source</th>
<th>Initial and Annual Testing Requirement</th>
</tr>
</thead>
</table>
| Surface | 20 or more times over a period of 2 to 4 years  
5 or more samples rolled into profile every year after initial survey |

- Profile samples must be representative of use and must be collected as close in time as practicable to, but before, harvest
PSR-Where Do I Collect Samples?

• **Surface water and ground water:**
  - Take a representative sample appropriate for the water source

• **Municipal/public water supply:**
  - No sample required if testing reports obtained from the water utility, treatment plant, or lab
  - Optional sampling at different points in the distribution system can be useful
Three types of corrective measures are allowed if the microbial water quality profile does not meet water quality criteria:

1. Apply a time interval for microbial die off
   i. Between last application and harvest
   ii. Between harvest and the end of storage and/or removal during activities such as commercial washing

2. Re-inspect the water system, identify problems, and make necessary changes and confirm effectiveness

3. Treat the water
The 2017 Winter Policy Meeting for the National Association of State Departments of Agriculture provided an update from FDA on water quality standards testing. FDA visited numerous farms and your message has been heard. FDA has indicated that they intend to simplify the water testing standards. No specifics on what this will entail was released.
PSA-Soil Amendments & Food Safety Risks

- Biological soil amendments, especially those that include untreated (raw) manure, pose significant microbial risks.
- Synthetic (chemical) soil amendments can also impact food safety, if not prepared and applied properly.
- Risks should be assessed when selecting and applying all soil amendments on produce fields.
PSA-Assessing Your Risks

• What type of soil amendments do you use?
  – Raw manure, composted manure, chemical, etc.
• What crops receive soil amendments?
  – Fresh produce or agronomic crops
• When do you apply them?
  – Days to harvest, time of year
• How do you apply them?
  – Incorporated, injected, surface applied
• How much and how often do you apply them?
  – Excessive application can lead to environmental impacts
• Human waste is prohibited for use on produce crops, unless it meets the EPA regulation for biosolids (40 CFR part 503)
• Untreated human waste may contain pathogens, heavy metals, or other contaminants
• May not be accepted by produce buyers
• Management of biosolids not discussed because use is infrequent in fresh produce production
PSA-Non-Manure Based Soil Amendments of Animal Origin

• Should be processed to eliminate pathogens or must be considered untreated biological soil amendments of animal origin

  - Bone meal
  - Blood meal
  - Feather meal
  - Fish emulsion
Verification from Suppliers

Soil Amendments of Animal Origen
• Suppliers should be providing treatment verification
• Have a repour with your supplier-they should have treatment records
• If applying raw manure-maintain a record of when applied and when crops began to be harvested.
• Do not apply directly to produce when plant has budded (side-dress or apply prior to budding)
• *Once plant buds it is considered whole fruit (study on salmonella)
PSA-The Value of Manure

• Increases soil tilth, fertility, and water holding capacity
• Sound nutrient management and waste utilization for those with animal production or partnering with other farms who have animals
• Widely available and cost effective
PSA-Pathogens in Animal Manure

- All manures can carry human pathogens
- Some animals tend to be reservoirs for certain pathogens
- Many things can affect animals shedding pathogens in their manure
  - Age
  - Rearing practices
  - Diet
  - Season
  - Environmental conditions
• Untreated biological soil amendments of animal origin-high risk since no treatment to reduce pathogens
• All of the following soil amendments would be considered untreated:
  – Raw manure
  – ‘Aged’ or ‘stacked’ manure
  – Untreated manure slurries
  – Untreated manure teas
  – Agricultural teas with supplemental microbial nutrients
  – Any soil amendment mixed with raw manure
• Aqueous Solution: Applying a compost mixed with microbially safe water prior to applying (must be applied within 60 min)
• Compost Tea: Brewing this mixture longer than 60 minutes.
• Cannot apply compost tea foliarly, but must be applied to minimize bud contact
• If adding molasses to fully composted manure it reverts to untreated soil amendment.
PSA-Reducing Soil Amendment Risks

- Selection
- Treatment
- Application Timing

- Application Methods
- Handling and Storage
- Recordkeeping
PSA-Composting Options

Must use a scientifically valid process:

1. Aerated static composting: aerobic, minimum 131°F (55°C) for 3 days, followed by curing with proper 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, control composting processes
Steps you should take to reduce risks:

• Maximize the time between application and harvest

• Do not contact the edible (bud) portion of the crop during application.

• Minimize risks to adjacent produce crops if you are field spreading manure
Recordkeeping: Soil Amendments

Soil amendments can introduce microbial risks, so you should document:

- Type and source of soil amendment
- Rates and dates of application
- Handling and sanitation practices used that reduce risks

There are a few records required for treated biological soil amendments of animal origin within the Produce Safety Rule

- Some details are outlined on the next few slides
Key factors in the composting process must be documented. These may include the following steps depending on the process used:

- Time
- Temperatures
- Turnings
- Other processing steps
PSA-Recordkeeping: Soil Amendments Supplied by a Third Party

**Documentation should be kept of:**

- The name and address of the supplier
- What soil amendments were purchased
- The date and amount purchased
- Lot information, if available

**Documentation must be collected from the supplier:**

- To ensure the supplier has used scientifically validated treatment processes and monitoring during the production of the treated amendment (including compost)
- To ensure proper handling requirements have been met
PSA-Manure Summary

- Soil amendments can introduce produce safety risks, especially those that contain raw manure.
- To reduce risks associated with soil amendments:
  1. Apply untreated manure to non-produce fields.
  2. Treat raw manure using a scientifically validated, controlled process.
  3. Extend the time between application of raw manure and harvest.
- Make sure storage areas do not contaminate fields, water sources, or packing areas.
- Train workers who handle and apply soil amendments.
- Develop sanitation steps for tools and equipment.
- Keep records of soil amendment applications and treatments.
Wildlife, Domesticated animal, land use
Animals Are A Produce Safety Concern Because They:

• **Can carry human pathogens**
  – e.g., *E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*

• **Can spread human pathogens**
  – By depositing feces in fields
  – By spreading fecal contamination as they move

• **Are very difficult to control**
  – Birds and small animals travel unnoticed
  – If fencing is used, even the best fence can be breached
  – Complete exclusion is not possible
Managing Food Safety on the Farm Can Be a Complex Issue!

Will Suckow
PSA-Wildlife on the Farm

• Can be a natural and valuable part of the landscape and farm environment
• Depending on species, management options may be limited by county, state, or federal law
• May be resident or transient (e.g., migrating species)
• Wildlife with close association to human activities may pose greater risks
  – e.g., seagulls feeding at dumps, starlings feeding in cattle feedlots
PSA-Co-Management: Striking a Balance

• Farmers must address food safety requirements, but should keep the conservation of natural resources in mind
• Farmers also have stewardship, aesthetic, and business objectives of their own
• Co-management considers both food safety and conservation of natural resources
PSA-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 and wildlife attractants

- **Immediately prior to harvest**
  - Monitor for fecal contamination, signs of animal activity (e.g., trampling, rooting, feeding, tracks)
  - Assess risks and decide if the crop or a portion of the crop can be safely harvested
PSA-Deterring Wildlife

Decoys

Fencing & Netting

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PSA-Deterring Wildlife

Visual Deterrents

Noise Deterrents  Tactile Repellent  Relocation

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PSA-Domesticated Animals on the Farm

• Domesticated animals, such as livestock and pets, may harbor human pathogens
• Domesticated animals are sometimes used in fields
  – As draft animals
  – As wildlife management (i.e., dogs)
  – To graze crop residues/culls
• **Assess the risk if animals are allowed or are likely to enter your production fields**
• Are domesticated animals allowed in the field while the crop is present as part of the production process?
  – Are they working animals?

• Are workers aware of cross-contamination risks from fecal contamination of hands, clothing, shoes, and equipment after handling animals or fecal material?

• Are production fields rotated into grazing land?
  – If manure is present on the ground, one recommendation is to extend the period of time between when animals were grazed and when produce can be planted.
Pets

• Should be excluded from produce fields
• Visitors to the farm should be instructed to leave their pets at home
• Farms with petting zoos should have handwashing sinks available and signage instructing visitors of the food safety policies
A process to assess fields before harvest to help determine if:

- Fecal contamination is present, or signs indicate a risk (e.g., tracks, trampling, rooting, feeding)
- Fresh produce has been contaminated and cannot be harvested
- Corrective actions, such as no-harvest buffer zones, are necessary
- Harvest can safely proceed
PSA-Recordkeeping

Records must be kept for:
  • Worker training

Records should be kept for:
  • Pre-plant land assessments
  • Monitoring for animal activity
  • Actions taken to reduce the risks related to animal intrusion into crop (domesticated animals and wildlife)
  • Pre-harvest risk assessments
  • Intrusion and contamination events
  • All corrective actions taken
Worker/Visitor Health & Hygiene
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 handwashing
  – How to handle illnesses and injuries
Routes of Contamination

- Feces
- Footwear
- Clothing
- Hands
- Tools & Equipment
- Illness & Injury

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Importance of Training Workers

• Fresh fruits and vegetables often receive no additional processing (such as cooking); contamination with a pathogen can result in illness when the produce is consumed.

• Workers need to use food safety practices to reduce produce safety risks.

• Food safety practices are learned so training is key to successful implementation.
Potential Training Challenges

- Time for training
- Language
- Literacy level
- Training mid-season
- Variation in hygiene practices and expectations
- Misconceptions/misperceptions
Ensuring training methods are effective
Visitors

• **Growers must:**
  – Make visitors aware of the farm’s food safety policies
  – Provide access to toilet and handwashing facilities

• **Other key information for visitors should include:**
  – Areas of the farm they are allowed to visit
  – The importance of not visiting the farm when ill
  – How to wash their hands
  – Instructions to keep pets at home
Training Programs Must Include

• Principles of food hygiene and food safety
• Recognizing symptoms of foodborne illness and the importance of personal hygiene for all personnel and visitors
• Other training relevant to the worker’s job
Worker Illness

• Workers who are sick or show signs of illness can contaminate fresh produce
• Ill workers must not handle fresh produce
• Symptoms of illness can include:
  – Nausea
  – Vomiting
  – Diarrhea
  – Fever
  – Jaundice
Resources
Resources

• NDA and DFI applied for a cooperative agreement with FDA
• Trainings are scheduled for February-April 2018 and will be ongoing for 2-3 years
• This will include trainings for those that must comply and for those simply interested
PSR Oversight

• NDA will be developing a regulatory program in conjunction with FDA

• In the meantime, ongoing trainings, on-site field assessments, on-line tools, etc will be established to help produce growers
Resources

• We need to find out how best to help you
• Surveys will be issued to identify the range of produce grown, education preferences, specific needs, etc.
• The producer certificate registration program will be used as a tool for obtaining this information
• Will also help with capturing state statistics on specialty crop production
Resources

• DFI will serve as a working model on how to comply with FSMA, PSR
• We will collaborate in creating resources and hosting class-room and field trainings
• We are here to help and are grateful for all you do!
Contact Info

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