FSMA'S PRODUCE SAFETY RULE

And How to Comply

March 2017

Our Learning Goals

- What is the Food Safety Modernization Act (FSMA)?
- What is FSMA's Final Rule on Produce Safety?
- Is my farm covered under the regulations?
- If I am covered, how do I comply?
- Why should I be concerned with Food Safety on my farm?
- What is a Food Safety Plan?

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Tools for Further Learning

- Useful Links for Farmers Complying with FDA's FSMA Rule for Produce Safety
- FSMA's Produce Coverage Flowchart
- List of covered produce and rarely consumed raw produce
- MDAR's AFSIP brochure

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Food Safety Modernization Act (2011)

- Focused on prevention of food safety issues and encompasses the entire food system:
  - *Produce Safety Rule*
  - *Preventative Controls for Human Food*
  - *Preventative Controls for Animal Food*
  - *Foreign Supplier Verification Programs*
  - *Accreditation of Third-Party Auditors/Certification Bodies*
  - *Sanitary Transportation of Human and Animal Food*
  - *Prevention of Intentional Contamination/Adulteration*

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FSMA Produce Safety Rule (2015)

- Exempt Farms
- Qualified Exempt Farms
- Fully Covered Farms
  - ***Ultimately all growers should understand and take action to reduce food safety risks on the farm***

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Exempt Farms

- Farms grossing <$25,000 (based on a rolling average of 3 years worth of sales and adjusted for inflation) on produce sales
- Not performing a covered activity – growing, harvesting, packing or holding covered produce on a farm
  - *Produce not covered includes: food grains, produce rarely consumed raw, produce that receives commercial processing with a kill step*
  - *Produce that is used for personal or on-farm consumption*
  - *Making cheese, other value added products not covered (see Preventative Controls Rule)*

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Qualified Exempt Farms – subject to modified requirements and compliance timelines

- Farms that gross between $25,000 - $500,000 in sales of all food (not just produce) based on a rolling 3 year average and adjusted for inflation…
- **AND** your sales to "qualified end users" exceeds your sales to all other purchasers:
  - *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 as the farm or not more than 275 miles away*

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Covered Farms

- Gross >$500,000 in total food sales and do more indirect sales than direct
- Subject to full suite of requirements

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Are you exempt, qualified exempt or covered??

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Exempt Farm Requirements

- **Record Keeping** – Written record that shows the farm is below the sales threshold
  - *Records must be detailed, accurate, legible, dated and signed by person performing documented activity*

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Qualified Exempt Farm Requirements

- **Labeling** – "Must include prominently and conspicuously on the food packaging label the name and complete business address of the farm where the produce was grown"
  - *If doesn't require a label, then must be displayed on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business. Internet sales must include electronic notice.*

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Qualified Exempt Farm Requirements continued

- **Record Keeping** – Written record that shows a) the farm is below the sales threshold, b) is selling more to qualified end users than not and c) that the purchaser is a qualified end user
  - *Records must be detailed, accurate, legible, dated and signed by person performing documented activity*
  - *Note: FDA can withdraw a qualified exemption in the event of an outbreak directly linked to your farm or if they deem necessary.*

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Covered Farm Requirements

- Nominate your Food Safety delegate and register for a Produce Safety Alliance training.

- Additionally, Covered Farms may opt to:
  - *Become GAP certified or*
  - *Become Commonwealth Quality Certified*

  - *Farm Food Safety Plan: A written document that outlines the farm's food safety practices and may include recordkeeping logs, Standard Operating Procedures, and other supporting documents that help growers implement food safety practices.* ***A Farm Food Safety Plan is not required for the FSMA Produce Safety Rule****, but is required for many third-party food safety audits.*

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Compliance Timeline

Business Size	Compliance Dates for Sprouts	Compliance Dates For All Other Covered Produce	Water Related Compliance Dates[1,2]	Compliance Date for Qualified Exemption Labeling Requirement [3]	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>$500K)	1/26/17	1/26/18	1/27/20	1/1/20	1/26/16
Small businesses (>$250K-500K)[4]	1/26/18	1/28/19	1/26/21		
Very small businesses (>$25K-250K)[5]	1/28/19	1/27/20	1/26/22		

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Why should I practice Food Safety if I am exempt?

- “From 1996-2014, ~172 produce related outbreaks occurred, resulting in 17,156 outbreak-related illnesses, 2067 hospitalizations and 68 deaths.” PSA
- Food safety is important no matter how large your business! You focus so hard on growing delicious, nutritious produce – why wouldn’t you want to make it just as safe for your customers?
- Personal liability and your farm’s viability – having insurance does not cover you for negligence. Record keeping is the only was to disprove negligence.
- If an outbreak were to occur on your small farm, it would affect all small farms and their reputation as well.

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What are we concerned about?

- **Human pathogens and foodborne illness outbreaks:**
  - *Bacteria – Salmonella, E.coli, Listeria*
  - *Viruses - Norovirus*
  - *Parasites – Girardia, Cryptosporidium*

Chemical and **Physical** hazards are less common and usually are responsible for fewer serious health consequences, but still should be taken into account.

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What are our Produce Safety Challenges?

- Many fruits and vegetables are consumed raw
- Contamination is usually sporadic and affects only a small portion of the crop
- Difficult to know if contamination has occurred because microorganisms can not be visually detected.
- Contamination may be difficult to detect through product testing.
- Hard to remove from rough surfaces (cantaloupes), folded surface areas (leafy greens) and stem scars (tomatoes)

Focus on Prevention!!

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Where can contamination come from?

- Humans (Workers, Visitors)
- Soil Amendments
- Animals (Domestic and Wild) and Land Use
- Water (Production and Post-harvest)
- Harvest and Post-Harvest Buildings, Equipment and Tools

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Worker Hygiene and Training

- Humans can carry and spread pathogens (fecal matter, saliva, blood)
- Hands, Clothing, Footwear, Tools and Equipment, and Illness and Injuries
- Growers must train workers, volunteers and visitors to recognize and prevent hazards
- Growers must provide:
  - *Proper bathroom and handwashing stations (and how to properly use)*
  - *First aid kits*
  - *Break areas*
  - *Record when each worker receives food safety training*

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Soil Amendments

- Biological soil amendments, **particularly raw manure or amendments that contain components of animal origin** can spread human pathogens.
- Growers must
  - *assess the type of amendment being used for risks on a particular crop (agronomic vs. fresh produce)*
  - *Properly store or treat manure and other animal products – keep records of treatment*
  - *Properly store treated amendments to avoid cross contamination*
  - *Review the application method and timing for risks, and record all applications*
    - Increase the interval between application and harvest (NOP's 90/120)
    - Do not apply to edible portion of crop
    - Do not side dress with raw manure
    - Minimize risk to adjacent produce crops
    - Develop SOP's to avoid contamination from application equipment to fresh produce
    - Train workers to recognize methods of contamination; clothing, footwear, gloves, tools, handwashing

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Animals and Land Use

- Animals can transmit pathogens to produce through direct fecal contamination
- Animal movement through fields can spread contamination
- Animals can contaminate water sources used for production
- Manure runoff can contaminate fields, water sources and crops
- Growers must
  - *Monitor for feces and evidence of intrusion*
  - *Assess Risk and decide if produce can be harvested*
  - *Deter wildlife as best as possible*
  - *Assess the risk of allowing domestic/working animals in the fields*
  - *Train workers to wash hands after handling animals and to avoid contamination from clothing, footwear, and tools*
  - *Never harvest produce contaminated with feces*
  - *Eliminate pets from fields*
  - *Keep manure storage and unfinished compost away from production fields*
  - *Design farm uphill and properly distanced from possible contamination sources*

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Water – Production, Post Harvest and Flooding

- Water can carry and spread human pathogens over entire fields or large amounts of products through production water (irrigation, crop sprays), post harvest water (cooling, washing, ice) and unexpected events such as flooding and runoff
- For **Production Water**, Growers must:
  - *Know what their sources are (surface, ground or public)*
  - *Inspect and Test water sources and water distribution systems regularly and document*
  - *Address sources of contamination and take necessary corrective actions*
  - *Assess the risk associated with your method of irrigation*
  - *Assess timing of applications in regards to harvest (allow for die off if needed)*

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Water continued…

- For **Postharvest Water**, Growers must:
  - *Use water with no detectable generic E.coli*
  - *Know and prevent routes of cross-contamination*
  - *Understand difference between clean and sanitize*
  - *Know how to properly use sanitizers in wash water (follow label)*
  - *Know how pH, temperature and turbidity effect microbial growth*
  - *Have SOP's and documentation of what is done in your packing shed*

Note – any produce that has been impacted by a flood is considered adulterated and can not be sold.

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Post Harvest Handling – Buildings, Equipment and Tools

- Consider everything that touches and impacts produce – harvest bins, packing equipment, hands and clothing, buildings, transport vehicles
- Growers must:
  - *Know the difference between cleaning and sanitizing*
  - *Never harvest or distribute dropped produce*
  - *Keep packing areas and coolers clean and organized, free of pests and void of standing water. Minimize amount of soil brought in.*
  - *Replace existing equipment with sanitary designs whenever possible*
  - *Store packing materials (either single use or clean, reusable containers) in a covered area away from contamination*
  - *Clean vehicles before hauling produce*
  - *Provide SOP's to workers so that sanitary procedures are easy to follow*

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Food Safety Plan

- Efficient and effective use of your time by prioritizing most important risk reduction steps
- Parts could include:
  - *Farm name and address, map*
  - *Farm description, policies*
  - *Name and contact info for food safety manager*
  - *Risk assessment practices and environmental conditions on your farm that impact food safety*
  - *Practices to reduce food safety risks, SOP's*
  - *Records that document practices (trainings, water tests, supplier and buyer info, soil amendment applications, harvest sheets, traceability and recall plans)*
  - *Lot codes*

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