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## The Food Safety Modernization Act

PSE 101 | April 9, 2020



## Overview

#### PART 1

- What's the big deal with food safety?
- Voluntary vs mandatory food safety assurances
- FSMA and "the Produce Rule"

#### Part 2

- Practical food safety on the farm
- Real-farm food safety plans
- The intersection between food safety and human wellness (in a time of COVID-19)



## Part 1 (this video)

### Make sure to watch Part 2 - it's a seperate video!



## What's the big deal with food safety?





Set in the meat packing and slaughter district of Chicago in the early 1900s.

Sinclair's focus was on the immigrant workers' experiences, however he "aimed at the public's heart, and by accident I hit it in the stomach."

aunched the nation's first food safety novement.



Photo from PBS



## Food adulteration

As canned and packaged foods became more widespread and popular, so did adulteration.

Chemical additions to food were widespread.

Plaster and dust were added to flour and watered down milk.

Dirt and leaves were added to spices.

Lead was added to beer and wine.

In one instance, soldiers fighting in the Spanish American War were sent "embalmed meat" that led to many illnesses and deaths among the troops.



LOOK BEFORE YOU EAT-AND SEE IF YOU CAN DISCOVER ANY UNADULTERATED FOOD.

6



## The "Poison Squad" of the USDA

Led by chemist Harvey Wiley

Experiments started in 1902

Motivated by the lack of control with the U.S. food supply: "How dangerous is our food?"

Treatments included formaldehyde, borax, salicylic acid (aspirin), copper sulfate, etc.





## Important federal legislation

1. **The Pure Food and Drug Act (1906)**: prohibited the sale of "misbranded or adulterated food and drugs." Led to the establishment of the modern Food and Drug Administration (FDA)

However, adulteration and misbranding were not defined in the legislation, so states were left to interpret for themselves.

Legislation was amended in 1938 to fix this ("The Food, Drug, and Cosmetic Act") - shifted the burden of proving food was NOT adulterated from the government to industry.

Authorized FDA inspections of processing facilities, prohibited false statements about food items, set labeling requirements, prohibited misleading packaging.



## Important federal legislation

2. **The Federal Meat Inspection Act (FMIA, 1906)**: prohibited the sale of "misbranded or adulterated livestock" and ensured sanitary conditions for livestock slaughtering and meat processing.

Animals must be inspected by the USDA prior to and after slaughter

Amended in the "Poultry Products Inspection Act" (1957, 1968)



## Produce and fresh vegetables

- Not included in previous food safety regulation
- A cause for concern?





## Pathogens of concern



#### Escherichia coli (E. coli)

- Warm temperatures
- High nutrient availability, low C to N ratio of fertilizer
- Low microbial diversity
- Moisture (soil available water storage, slow soil drainage, precipitation)
- Outbreaks peak in summer



#### Salmonella enterica

- Warm temperatures (incidence increases 5-10% for each one-degree of ambient temperature above 5 degrees C.)
- Moisture (soil available water storage, slow soil drainage, precipitation)
- Outbreaks peak in summer



#### Listeria (L. monocytogenes)

- Survives in cool temperatures, but can survive very hot temperatures as well.
- Moisture (soil available water storage, slow soil drainage, precipitation)
- Outbreaks peak in winter



## Pathogens of concern







- Uptick in number of outbreaks (from 2/year in 1970s  $\rightarrow$  16/year in the 1990s)
- Uptick in the median number of people who get sick during each outbreak (from 21-43 people per incident)
- In 2004, produce was the second leading cause of foodborne outbreaks (following seafood)

## A special shout out for *Escherichia coli*, E. Coli



- Found in the natural environment, generally a poor competitor
- Can produce Shinga toxin, which can cause kidney failure and death (immunocompromised, children and elderly most susceptible)
- Responsible for 8% of all bacteria-caused outbreaks attributed to produce

## Fecal contamination is most likely cause

- E. Coli often in the guts of cows, poultry
- Irrigation water contaminated with manure
- Crops which are difficult to clean are of concern (netted skin, splash up)
- Not all manure is equally risky - aged manure is much safer (120 days)



## Pathogen cycles through agroecosystems



Figure from Franz, E., van Bruggen, A.H.C., 2008. Ecology of E. coli O157:H7 and Salmonella enterica in the primary vegetable production chain. Crit. Rev. Microbiol. 34,15 143–161. doi:10.1080/10408410802357432



## Spinach contaminated in California (2006)

- Likely due to feral pigs and/or other wild animals
- Led to outbreaks in 26 states
- 199 people ill; 102 hospitalized; 3 deaths
- Cost the spinach industry \$100M in sales





## What's the relative risk?

Causes of death in the United States in 2017 (according to the CDC)

- Heart disease: 647,457
- Cancer: 599,108
- Accidents (unintentional injuries): 169,936
- Chronic lower respiratory diseases: 160,201
- Stroke (cerebrovascular diseases): 146,383
- Alzheimer's disease: 121,404
- Diabetes: 83,564
- Influenza and Pneumonia: 55,672
- Nephritis, nephrotic syndrome and nephrosis: 50,633
- Intentional self-harm (suicide): 47,173
- ...
- E. Coli contamination from leafy greens in 2017: 1 (in 2018 there were 5 deaths)



# The Good Agricultural Practices (GAPs) program

- Voluntary
- Market (wholesale buyer) driven
- Audit verified
- Administered by the USDA



## The Food Safety Modernization Act (FSMA)

- Passed by Congress in 2010, overwhelming bipartisan support
- Does NOT address food safety risks from GM organisms, pesticides, or antibiotic resistance
- DOES cover risks from pathogens (E. Coli 0157:H7, Salmonella, Shigella)
- Rules are NOT voluntary
- Consumer driven
- Inspection verified
- Administered by the Food and Drug Administration (FDA)





## Let's review the differences between GAPs and FSMA

#### <u>GAPS</u>

- Voluntary
- Market (wholesale buyer) driven
- Audit verified
- Administered by the USDA

#### <u>FSMA</u>

- NOT voluntary
- Consumer driven
- Inspection verified
- Administered by the Food and Drug Administration (FDA)



## FSMA - two important components

#### The Produce Rule

Applies to the production and harvesting of food "typically eaten raw"

#### The Preventative Controls Rule

Applies to the manufacturing, packaging, or holding food





#### STANDARDS FOR PRODUCE SAFETY Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.





## In other words, the law pertains a farm when:

- They generate more than \$500K a year in sales (averaged over 3 years)
- The majority of sales is NOT sold to the "end user" meaning it is sold into the wholesale market
- The produce is "likely to be eaten raw"





## Components of the Produce Safety Rule

- Worker health
- Soil amendments
- Wildlife and animals
- Agricultural water
- Postharvest handling
- Food safety planning





Grower Training Version 1.2





End of Part 1 Don't forget to watch the next video!



## Part 2: Food safety on the farm



## Practical food safety

Why care?

- Produce-related outbreaks increasing in prevalence
- New technology (bagged salads) are GREAT environments for microbes
- Distribution across states = broader impact of outbreaks (leads to public perception that fresh food is dangerous, which affects ALL growers)
- More people eating fresh fruits and veg
- More people living with compromised immune systems



## Components of the Produce Safety Rule

- Worker health
- Soil amendments
- Wildlife and animals
- Agricultural water
- Postharvest handling
- Food safety planning





Grower Training Version 1.2







## Worker health

Workers carry pathogens, and can spread them

- Fecal/oral route is most common mode of transmission (animal, human)
- Other modes: contact with contaminated surfaces (doorknobs), saliva, blood, mucus.

Training can help to reduce risk!

- Handwashing
- Limit where people eat and smoke etc.
- Have policies in place that make it clear workers should not be around produce when they are sick
- Give employees what they need to deal with injuries (cuts, etc.)
- Change clothes/boots when moving between animal/produce areas
- Clean equipment and tools



## Worker health

When is the right time to conduct a training? When workers start work (either at the beginning of the season, or whenever they start).

What kinds of training materials are effective? Include interactive and visual learning options. Present materials in the language spoken by workers.

Example: the \$0.10 hand-wash: https://youtu.be/JNgeS58iCOk





## Worker health







### ....But what about visitors?



## Visitor policies

Visitors must be aware of a farm's policies (including how to wash hands)

Farms must provide access to handwashing and bathrooms

Areas of the farm that are open to visitors must be carefully designated and signs must be visible

Visitors should not come to the farm when they are ill

Pets should stay at home

#### NC STATE



#### No pets in the fields

Leave your pet at home.



#### Why? Pets could contaminate the

fields by going to the bathroom and eating or licking the berries. They could accidentally damage crops or fields, too. Some customers may not feel comfortable around or may be allergic to certain types of animals.

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NC STATE

#### Don't work if you are sick

#### Why?



f and have completes and as Barries, wirding, masses. deferminal pairs or countes, and/ in fever, you may have a bodherne direas that could be read to others. Washing your ands with usap and water after using sock or using the batteria um field konst others from period with. It is first to star-teres as due 1 work with first it

Staying home can keep you from accidentally giving your illness to others.



#### NC STATE



#### Choose the **Ripe Berries**

Pick fully ripe, red berries straight from the plant that are free from cuts, bruises, mold, and bugs.



#### Why?

Can, braised, rothen, moldy and othersense damaged herries have wounds that make it easy for bacteria, vesses, and other harmful organisms to get inside. Bernies on the ground are not as fresh and worn't last as long.

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Images from NC State Extension



## Components of a training program

If you are employee, you may be asked to:

- Survey areas for animals or animal damage to crops
- Avoid harvesting produce that has been contaminated
- Avoid harvesting dropped produce
- Only use clean and dedicated packing containers
- Maintain personal cleanliness, use gloves, don't eat in production areas, not wear jewelry
- Stay home if sick ("If you're not in control of your bodily fluids, you can't be at work")
- Wash hands!




Training curriculum and records

Monitoring and restocking bathrooms/handwashing stations

Illness and injury reports

First aid kits (and restocking)

If it isn't documented, it didn't happen.



# Soil amendments

Soil amendments are "any chemical, biological, or physical materials intentionally added to the soil to improve and support plant growth and development." (PSA)

- Biological amendments (manure, processed or otherwise; bone, bloed meal, feather meal, fish emulsion) pose risk
- Chemical amendments also pose risk if not processed correctly
- Not all risks are equal
  - Type of amendment
  - Time between application and harvest
  - Mode of application (incorporation, injection, surface)
  - Frequency of application





Manure storage

- Minimize runoff, especially near cropping areas
- Keep raw and aged manure in seperate zones
- Minimize traffic (people and equipment) in and around manure storage areas
- Develop standard operating procedures (SOPs) for clearing equipment





Amendment source - manufacturer name and address, when and where you purchased, date purchased, lot, documentation of processing to ensure proper handling

Temperature and management records (compost or aged manure  $\rightarrow$  thermophilic composting)

- Aerated static compost systems, min 131 degrees F for 3 days min
- Aerobic turned compost systems, min 131 degrees F for 15 days min, 5 turnings

Application dates and rates of application/harvest dates

- Maximize time between application and harvest (currently no established guidelines)
- Don't contact harvestable portion of the crop during applications

Handling and sanitation practices (SOPs) that minimize risks



# Wildlife and domestic animals

Why be concerned? Fecal transmission of pathogens, of course.

What animals pose risks?

- Domesticated animals
- Wild animals (including birds)

Complete exclusion is not possible





# Wildlife and domestic animals

Strive for co-management of food safety and conservation

Monitor for fecal contamination

Consider deterrent strategies (fencing, decoys, netting, noise makers, relocation)

Assess risks before you site your field and plant your crop





# What about working animals?

Keep draft animals out of the field when harvestable produce is present.

Have SOPs for handwashing, cleaning equipment. Train employees to follow SOPs.





#### What about pets?

No pets should be allowed in produce fields (including those that belong to employees and visitors)





Observation logs looking for fecal contamination of any kind (pre-harvest risk assessments)

Corrective actions taken if feces are observed

- Suggested buffer zone around fecal matter where no produce is harvested
- Disposal of fecal matter

Deterrence actions taken

# If it isn't documented, it didn't happen.



## Agricultural water

Covers both:

- PRODUCTION WATER: in contact with produce while being grown, and can include irrigation, fertigation, foliar sprays, frost protection
- POST-HARVEST WATER: used after harvest for washing, cooling







#### Three risk factors to consider:

- 1. Water source and quality
  - a. Ground water, surface water, municipal
  - b. Testing frequency
- 2. Application method
  - a. Contact with edible portion of crop
- 3. Application timing
  - a. Wait periods for high risk crops





**Risk mitigation - GROUNDWATER** 

- Inspect wells (capping and grading)
- Install backflow preventers





Septic leakage/waste

**Risk mitigation - SURFACE WATER** 

- Assess upstream activities
- Assess runoff potential
- Monitor animal access to surface water, control if necessary and practical









contact with the harvestable portion of the crop?

Does the irrigation method cause "spash up"?



Q: When irrigation water comes into contact with harvestable produce, what do you do?

A: Implement a "wait period"

- Pathogens may die off or desiccate over time because of solar radiation, high temperatures, starvation or competition
- Pathogens that are protected may survive for longer
- Pathogens can "regrow" if conditions are right and they have something to eat





Water system inspection records (annual)

Debris, trash, or animals around water sources

Maps of water sources and distribution systems in farm files

Contamination records and corrective actions

Water test results (E. coli is the established indicator pathogen)



- Ground water: 4+ times during the growing season, collected close to harvest time
- Surface water: 20+ times over a period of 2-4 years; 5+ per year
- Municipal: Request records yearly

If it isn't documented, it didn't happen.



# What if you get a contaminated sample?

Apply a wait time for microbial die off between application and harvest (keep records) ~ 4 days

Apply a wait time between harvest and introducing the produce "into commerce" (keep records) ~ 4 days

Identify where things went wrong and correct - you could treat water (UV filters, etc.) (keep records)

If it isn't documented, it didn't happen.



#### Post-harvest water

Why does it matter?

- Post-harvest water can spread contamination
- It's impossible to control everything in the field

What does it include?

 Washing hands, cleaning and sanitizing "food contact surfaces", cooling, ice making, rinsing and washing, post harvest fungicides, etc.





#### Post-harvest water

What are the standards?

- No detectable E. coli per 100 mL water
- Includes water that touches produce, food contact surfaces, used to make ice, or used for handwashing
- No untreated surface water allowed

Testing requirements

- Ground water: 4+ per year, 1+ per year after initial year
- Public water supply: Keep a copy of municipal test results and update annually



#### Post-harvest water

Antimicrobial products

- They do not clean produce, but minimize spread
- Only use for label uses
- Some approved by NOP for organic use
- pH and temperature may affect efficacy (if temp is high, or pH low, may offgas and harm workers)
- Does not work when turbidity is high
- Monitor effectiveness using handheld sensors or indicator strips

#### ALWAYS FOLLOW THE LABEL

Photos from QC Supply and Sanidate





- Water test results
- Schedule for changing batch water/process for reducing organic matter buildup
- pH records
- Recorded use of antimicrobial products (and monitoring records)
- Calibration of thermometers and sensors
- Record of any water treatment

If it isn't documented, it didn't happen.



# Postharvest handling

Think about all surfaces, containers, and people that come into contact with produce including (but not limited to):

- Packing and picking containers
- Packing equipment
- Hands and clothing
- Post-harvest water
- Buildings, coolers, storage areas
- Transport vehicles





#### Food contact zones





# Containers

An example of a Zone 1 surface (direct contact with produce)

Cleanable; Separate based on use (harvesting vs. cleaned product)











# Postharvest handling

Cleaning and sanitizing food contact surfaces, tools, and equipment

- 4- step process (remove debris, clean w/detergent, rinse, sanitize)

Worker training around clothing, eating, handwashing, and minimizing risks

Eliminate pest and debris

- Repair holes and cracks in walls, floors, ceilings
- Remove trash daily
- Keep windows and doors closed whenever possible
- Monitor pest presence (keep records)

Minimize standing water

- Watch for condensation
- Monitor cooler temps at beginning and end of each day



#### Packing areas

Reduce animal and wildlife entrance into the cleaning and packing area

Keep it organized

Take the trash out every day (or more often if needed)

Separate places for employees to take breaks/eat

What about unenclosed packing areas? Industry standard is moving towards enclosed areas.



These guys shouldn't be visiting your packing area!



#### Holding areas

Reduce standing water

Elevate storage containers off the floor

Use construction materials and shelves that can be easily cleaned

Store bins far enough away from the wall to allow visual inspection for pests, etc.





## Vehicles and transportation

Vehicles that transport clean produce need to be inspected and cleaned prior to loading.

If you pay someone else to deliver your produce, make cleaning and sanitizing and record keeping part of the contract.





Records for:

- Cleaning and sanitizing tools, equipment, delivery vehicles
- Pest management and corrective actions
- Worker training on cleaning and sanitizing SOPs
- Packing area cleaning and monitoring



# Real examples: Footprint Farm, Starksboro VT

Farmers: Taylor Hutchinson and Jake Mendel

In business since: 2013

Acres: 2.5

Sales bracket: \$100K-\$250K

Old wash pack operation:

- Triple bay wash (greens) and converted washing machine salad spinner
- Barrel drum washer (roots)
- Bunch washing on spray table





# Real examples: Footprint Farm, Starksboro VT

#### Investment in a new packshed

- New slab-on-grade construction
- 36' x 48' (1,782 sq ft)
- Mixed use: wash/pack, storage, egg cleaning, cooler, break areas, workshop, residential space







# Real examples: Footprint Farm, Starksboro VT

Flow of product to minimize backtracking

Separation of crew/customer zones









### For more...




## Food safety SOPs and COVID-19

- Current SOPs often designed to control viruses like nora viruses, which are <u>unenveloped</u>
- COVID-19 and other corona viruses are enveloped



### COVID-19 is not a foodborne disease

It's likely that the low pH in your stomach will deactivate the virus if you ingest it.



# What should farms do differently considering COVID-19?

Produce safety goal - keep food consumers safe from <u>foodborne pathogens</u>.

**COVID-19 management goal** - keep customers, farmers, farmworkers (EVERYONE) safe from a pathogen spread through <u>respiratory transmission</u>.

In other words - different goals, but some of the same SOPs will apply (with tweaks)

## What do farmers need to do manage COVID-19 this summer?

- 1. Share information about COVID-19 with employees, customers, etc.
- 2. Monitor the health of anyone working on the farm
  - a. Follow specific guidelines if someone on the farm tests positive
  - b. Contact the Health Dept. if an employee tests positive (required), and map where that employee was on the farm
    - i. clean  $\rightarrow$  disinfect  $\rightarrow$  rinse  $\rightarrow$  sanitize (United Fresh Produce Association/CDC)
- 3. Provide fully functional hand washing facilities
  - a. Potable water (not necessarily hot); single use paper towels, soaps, trash can with a liner
  - b. If soap and water is not available, you can use an alcohol based hand sanitizer (only if hands are not visibly dirty). Not a normal food safety SOP, doesn't help control Salmonella or norovirus.
- 4. Limit access to the farm and packing areas
  - a. Don't let people come into packing areas, practice social distancing, clean the areas in which customers and staff are regularly
  - b. Post signage for customers
  - c. Use gloves when handling money, credit cards, or otherwise coming into contact with customers
- 5. Clean and sanitize food contact surfaces, non-food contact surfaces, and disinfect high touch surfaces



Clean and sanitize food contact surfaces, non-food contact surfaces, and disinfect high touch surfaces

**Clean** - physical removal of soil and food residue - use clean water and detergent - on all surfaces. Use detergents for cleaning.

**Sanitize** - treatment of a cleaned surface to <u>reduce</u> the number of microorganisms. Looking for a 99.99% reduction of pathogens on non-food contact surfaces within 1 min. Sanitizers are EPA-registered and approved for specific uses.

**Disinfect** - treatment of a clean surface to <u>destroy or inactivate</u> ALL infectious organisms on high touch surfaces, after an incident with a infected person, within 10 min. Disinfectants are EPA-registered and approved for specific uses.

- Definitions from the EPA, sources from NC State

## The difference between sanitizers and disinfectants?

### **Sanitizers**

- Intended for food contact surfaces
   (and non food contact surfaces)
- Reduces bacterial load by 99.99%
- Only tested against bacterial pathogens (E.coli, salmonella, staphylococcus)
- Used throughout the food industry
- Lower concentration and shorter contact time (1 min)

### **Disinfection**

- Intended for non-food contact surfaces
- Destroys/inactivates all infectious microorganisms (such as bacteria and virus, and fungi. Does not work on bacterial spores
- High concentrations and contact time (10 min)
- Used in settings with high-people to people contact (hospitals etc.)



## <u>Some</u> sanitizers can be used as disinfectants AT DIFFERENT CONCENTRATIONS





## <u>Some</u> sanitizers can be used as disinfectants AT DIFFERENT CONCENTRATIONS

Product	Active Ingredients as Received	Labeled Concentration for Wash Water Treatment	Labeled Concentration for Sanitizing Hard Surfaces	Labeled Concentration for <u>Disinfecting</u> Hard Surfaces
Ultra Clorox Brand Regular Bleach	6.0% sodium hypochlorite	<b>25 ppm</b> free chlorine 1/2 cup per 75 gallons 2 minute submersion time	200 ppm 1 tbsp per 1 gallon of water. 2 minutes contact time.	<b>2700 ppm</b> ¾ cup per gallon of water. 5 minutes contact time.
Sanidate 5.0	5.3% peroxyacetic acid (PAA) and 23.0% hydrogen peroxide	<b>27-96 ppm PAA</b> 59.1-209.5 fl. oz. per 1000 gallons of water	147-500 ppm PAA 1.6-5.4 fl. oz. per 5 gallons water. 2 minutes contact time.	230-1000 ppm PAA 0.5-2.2 fl. oz. per gallon of water. 10 minutes contact time.
Tsunami 100	15.2% peroxyacetic acid (PAA) and 11.2% hydrogen peroxide	30-80 ppm PAA 2.5-6.7 fl. oz. per 100 gallons of water	150-270 ppm PAA 1.0-1.8 ounces (product) per 8 gallons of water 1 minute contact time.	Not Labeled
Vigorox SP-15	15.0% peroxyacetic acid (PAA) and 10.0% hydrogen peroxide	<b>45 ppm PAA</b> 0.54 fl. oz. per 16 gallons of water	85 ppm PAA and 57 ppm hydrogen peroxide 3.1 fluid ounces per 50 gallons of water. 1 minute contact time.	<ul> <li>800 ppm PAA and 530 ppm hydrogen peroxide.</li> <li>3.0 fluid ounces of the product per 5 gallons of potable water.</li> <li>5 minutes contact time.</li> </ul>



### Common themes

What food safety plans and COVID-19 plans have in common:

- They both depend on clear communication, good training, good signage, and BUY-IN.

Farmworkers are designated as essential employees. They are not always safe (concern about those w/out health insurance, no sick leave, living paycheck to paycheck, no childcare, no immigration paperwork to protect them)

