Produce Safety ALLIANCE

Cornell University

Food Safety Modernization Act (FSMA):

Produce Safety Rule and Exemptions

Produce Safety Rule: CFR 112

Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (effective rule date 1/26/2016)

- Growers
- Packinghouses – majority ownership by the grower whose product they pack
- Domestic and imported produce
- Produce for human consumption
- Sprouts – not covered in this talk

FSMA 101

Produce Safety Standard Rule

Farms with raw agricultural commodities

Preventive Controls Human Food Rule and GMP 21 *CFR117*

Preventive Controls Animal Food

Farms with some mixed-type activities may fall here as well

Foreign Supplier Verification Program Rule

Accredited 3rd Party Certification Rule

Sanitary Transport Human and Animal Food

Intentional Adulteration (Food Defense)

FDA Produce Safety Rule

The rule establishes science-based minimum standards for safe growing, harvesting, packing and holding of produce on farms

FSMA Produce Safety Rule

- Training requirements
- Produce safety standards (similar GAP standards)
  - Worker health and hygiene
  - Growing, harvesting , packing and holding
  - Equipment, tools, buildings and sanitation
  - **Domestic and wild animals**
  - **Agricultural water**
  - **Biological soil amendments of animal/human origin**
- Records

FSMA Produce Safety Rule: Training

- Supervisors
  - Requires farmer training—based on standard FDA approved training (Produce Safety Alliance curriculum): **Raw Agricultural Commodities**
  - Nationwide curriculum
  - Attendance required for compliance
  - Trained lead instructors
- Farm workers (by supervisors) -
  - All who handle **covered** produce or **food contact surfaces** as appropriate to duties
  - All – food hygiene and safety
  - Harvesters – what not to harvest, container cleanliness

Definitions to Know

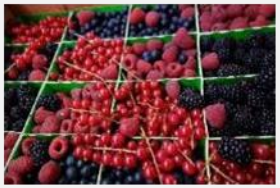
- Food
- Farm
- Covered Farm
- Covered Activity
- Covered Produce
  - RAC = Raw Agricultural Commodity
- Qualified Exemptions for Farms

Food

- 21 U.S.C. United States Code, 2010 Edition Title 21 - FOOD AND DRUGS CHAPTER 9 - FEDERAL FOOD, DRUG, AND COSMETIC ACT SUBCHAPTER II – DEFINITIONS
- Food means food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts:
  - (f) The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article

Raw Agricultural Commodity

- The term “raw agricultural commodity” (RAC) means any food in its raw or natural state, including all fruits and vegetables that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing

RACs	Not RACs
  	  

Covered Activity

- Growing, harvesting, packing or holding covered produce
- Activities within the farm definition

What is a farm?

Farm: Primary Production Farm

- Operation under **one management**, in general, but not necessarily contiguous location
  - Owner-operator, rented or cooperatively owned
  - Key = one management structure
- **Activities related to growing/harvesting/holding produce (RAC), or raising animals**

Farm: Primary Production Farm

- **Certain manufacturing** – limited categories
  - drying/dehydrating with labeling without additional process (i.e. slicing/cutting)
  - Treatment for ripening
  - Packing/labeling RAC when no additional processing
- **Personal/On-farm consumption - excluded**

Farm: Secondary Activities Farm

- Not located on primary production farm
- Can do same harvesting, packing or holding as primary
- Primary farm owns or jointly owns **majority** interest
- Allows offsite packinghouses managed by a business (e.g. cooperative) thus under Produce Safety Rule
  - Owner criteria must be met

Example: Secondary Activities Farms

- Four farms own packing shed located rented land 20 miles away
- Each farmer contributes 25% produce and holds 25% interest in operation
- Secondary activity farm – FDA registration as processing facility not required and produce rule applies

Example: Secondary Activities Farms

- Distribution operation
- Aggregates produce from multiple farms to sell institutional buyers
- Ownership structure where farmers provide 100% produce, but no ownership of packing/holding facility
- FDA registration as food processor required
  - Produce Rule does not apply
  - Prevention and Controls Human Food Rule applies

What are Covered Activities?

- Growing, harvesting, packing or holding covered produce
- Activities within the farm definition

Covered Activity: Harvesting

- Activities **traditionally** performed on farms to remove RACs from place grown to preparing for food
- Does not include activities that **transform** RACs.
- Includes: cutting (separating) edible portion of RAC from crop plant; trimming parts RAC (*e.g.* foliage, husks, roots, stems)

Covered Activity: Harvesting

Examples:

- Cooling
- Field coring
- Gathering
- Hulling
- Stem/husk removal
- Shelling
- Threshing
- Trimming outer leaves
- Washing

Example farm vs process:

- Cut lettuce out of field, wash and market = harvesting
- Chopping lettuce, wash and market = manufacturing/processing and no longer farm definition

Covered Activity: Holding

- Storage of food
- Includes activities performed for safe and effective storage
- Activities necessary for distribution (e.g. breaking down pallets)
- No changes from RAC to a processed product
- Other Examples:
  - Fumigating storage area
  - Blending same RACs different lots

Covered Activity: Packing

- Placing food in a container
- Repacking
- Examples:
  - Sorting, Culling, Grading, Weighing (for packing)
  - RACs with wax/oil/resin for storage or transport

Covered Produce: Risk Based

- Fruits/Vegetables grown, held or packed in raw agricultural state
- Includes herbs, mushrooms, tree nuts, sprouts, mixes of intact fruits and vegetables
- Covered products includes crops commonly consumed raw
- Mixes of intact fruits and vegetables (such as fruit baskets)

Examples of Covered Produce

- Almonds, apples, apricots, aprium, avocados, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carrots, cauliflower, celery, cherries, citrus, cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons, mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, shallots, snow peas, spinach, sprouts, strawberries, summer squash (such as patty pan, yellow and zucchini), swiss chard, tomatoes, walnuts, watercress, and watermelon
- **Not an exhaustive list**

Produce: Not Covered

- Low risk, rarely consumed raw
  - Examples:
    - Yams, winter squash, potatoes, sweet potatoes, sweet corn, brussel sprouts, cranberries, beets, pumpkin, asparagus, beans (black, kidney, lima, navy, pinto), cocoa and coffee beans, eggplants, figs,

Produce: Not Covered

- Grains, and cashews, pecans, peanuts (roasted)
- Destined for commercial processing – kill step (documentation required)
- Personal or on-farm use

Are you covered?

- **Not covered:**
  - Farms with **produce** sales of < $25,000
    - Rolling average, 3 years sales adjusted for inflation (2011 baseline)
      - Currently - $28,575
      - Bureau of Labor Statistics calculator

      https://www.bls.gov/data/inflation_calculator.htm

Do you fall under the exemption?

Qualified Exemption. Must satisfy **both** parts:

Part 1: 3 year average gross sales between $25,000 and $500,000 for **ALL** food sales adjusted for inflation (2011 baseline)

- Bureau of Labor Statistics calculator
- https://www.bls.gov/data/inflation_calculator.htm
- Current = $571,493

Do you fall under the exemption?

Qualified Exemption. Must satisfy **both** parts:

Part 2: Majority (over 50%) distribution to "qualified end users" – directly to a) consumer of food (not business) **or** b) restaurant **or** retail food establishment that has a distribution in state or Indian reservation or not more than 275 miles from the farm.

Are there other requirements?

Qualified Exemption: Modified Requirements

- **Packaging/Point of Sale** labeling or sign required : Name, complete business address of farm
- **Records (Subpart 0):** Demonstration of exemption criteria
  - Annual review and verification – 3 year rolling average
  - Begin keeping records ASAP – in line with compliance timelines
  - Subject to records requirements of the rule
    - Sales receipts, no initialing required – keep long enough

Qualified Exemption: Modified Requirements

- **Compliance/Enforcement (Subpart Q):** Still must apply controls for hazards as or in compliance with other state, local requirements. Prepared and packed in a sanitary manner
- **Withdrawal of Qualified Exemption (subpart R)**
- **General Provisions (Subpart B):** "Appropriate measures to minimize the risk of serious adverse health consequences or death from use of and exposure to, covered produce including measures …to prevent introduction of…hazards to produce…and not adulterated.."

Qualified Exemption: Example

- Farm with $475,000 in food sales. Includes $200,00 wholesale, $200,000 to a local restaurant and $75,000 to a local grocery store – qualified exemption applies
- However, the grocery store is in the next state, 300 miles from the farm: no qualified exemption

Quiz 1

A farm sells $19,000 in produce average over a 3 year period at a local farmer's market and through a CSA.

Is this farm covered by the FSMA Produce Safety Rule?

No

Quiz 2

A farm sells $35,000 in produce, and also sells $650,000 in other food products (3-year rolling average).

Do they satisfy the ‘qualified exemption’ requirements?

No

Quiz 3

- A farm sells all of their $27,000 in produce annually to a distributor located more than 275 miles away and not in the same state of where the produce was grown. The farm grows potatoes, pumpkins, sweet corn, winter squash, and has a 1 acre of raspberries and strawberries.
- Is this farm covered by the Produce Safety Rule?

Yes

Exclusions & Exemptions: Summary

- Some growers may be **excluded** based on:
  - Commodities grown (e.g., rarely consumed raw)
  - Average annual produce sales
  - Personal/on-farm consumption
- Some growers may be **exempt** based on:
  - Processing activities that include a 'kill step'
  - Average annual food sales and to 'qualified end users'
- Ultimately, <u>all</u> growers should understand and take action to reduce food safety risks on the farm

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  - Average annual food sales and to 'qualified end users'

Exclusions & Exemptions: Summary

Ultimately, **all** growers should understand and take action to reduce food safety risks on the farm

What do buyers require?

NOT ME!!

Business Size	 Compliance Dates for Sprouts	 Compliance Dates For Most Produce	 Water Related Compliance Dates[1]	Compliance Date for Qualified Exemption Labeling Requirement [2]	Compliance Date for Retention of Records Supporting a Qualified Exemption
All other businesses (>$500K)	1/26/17	1/26/18	1/26/22	1/1/2020	1/26/16
Small businesses (>$250K-500K)[3]	1/26/18	1/28/19	1/26/23		
Very small businesses (>$25K-250K)[4]	1/28/19	1/27/20	1/26/24		

[1] According to the Proposed Rule issued 9/13/17, Compliance dates for Subpart E, Agricultural Water, allow an additional four years.
[2] A farm eligible for a qualified exemption must notify consumers as to the complete business address of the farm where the food is grown, harvested, packed, and held.
[3] A farm is a small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than $500,000.
[4] A farm is a very small business if, on a rolling basis, the average annual monetary value of produce sold during the previous 3-year period is no more than $250,000.

Before the compliance date, every covered farm that does not qualify for an exemption must have a supervisor (such as a farm owner/operator) complete a standardized food safety training program. You can find out more about food safety training from the Produce Safety Alliance. https://producesafetyalliance.cornell.edu/training

Revised 10/09/17

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SC Southern Center for Training, Education, Extension, Outreach, and Technical Assistance to Enhance Produce Safety

Business size based on produce sales

PSR vs. RI GAP

- Workshop good for both
- Some added material for
  - Clarification
  - GAP only
- PSR – regulatory
- RI GAP – voluntary, third party audit

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Module 1: Introduction to Produce Safety

Learning Objectives

- Develop a better understanding of produce safety on your fresh fruit and vegetable farm
- Identify types of human pathogens that can contaminate fresh produce
- Understand common ways that produce might become contaminated on the farm
- Describe strategies to prevent and reduce risks of contamination by human pathogens
- Understand the value of commitment to implementing food safety practices

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Relevance to the Farm

- You can prevent and reduce risks on the farm
- You know your farm and practices better than anyone, but you may not know the consequences of your current practices on food safety risks
- Your actions directly impact food safety and the financial viability of your farm

The Food Safety Modernization Act (FSMA)

- FSMA includes:
  - **Produce Safety Rule**
  - Preventive Controls for Human Food
  - Preventive 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
- Focused on prevention of food safety issues and encompasses the entire food system

FDA FOOD SAFETY MODERNIZATION ACT

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Produce Safety Alliance Curriculum

- Covers both FSMA Produce Safety Rule requirements and many produce safety practices including Good Agricultural Practices (GAPs)
- At least one supervisor from the farm must complete food safety training at least equivalent to the standardized curriculum
  - The PSA training satisfies this FSMA requirement
- Keep an eye out for the 'Section - §' symbol
  - This indicates a specific FSMA Produce Safety Rule requirement is presented on the slide or referred to in the slide notes
- Pay attention to the words 'must' and 'should'
- FSMA Regulatory Reference Table is provided to align the curriculum with the regulation
- Glossary terms are in **bold** throughout

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FSMA Produce Safety Rule

- First ever mandatory federal standard for growing, harvesting, packing, and holding of fresh produce
- Some growers may be eligible for an exemption or excluded based on:
  - Commodities grown (e.g., rarely consumed raw)
  - Processing activities that include a 'kill step'
  - Average annual produce sales
  - Average annual food sales and sales to 'qualified end users'
- Ultimately, all growers should understand and take action to reduce food safety risks on the farm

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Produce Safety Rule Compliance

Business Size	Years to Comply After Effective Date (1-26-16)*
All other businesses (>$500K)	2
Small businesses (>$250K-500K)	3
Very small businesses (>$25K-250K)	4

**Compliance dates for certain aspects of the agricultural water requirements allow an additional two years beyond each of these compliance dates.*

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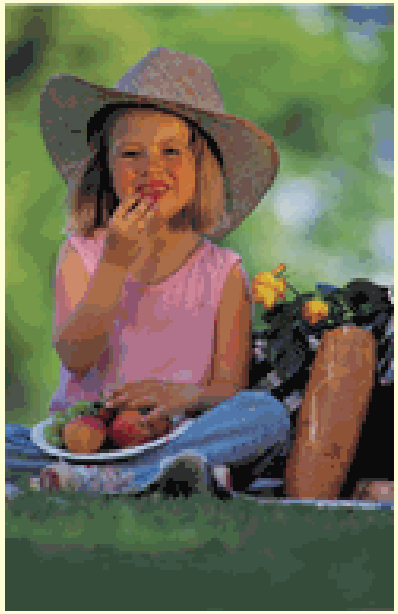
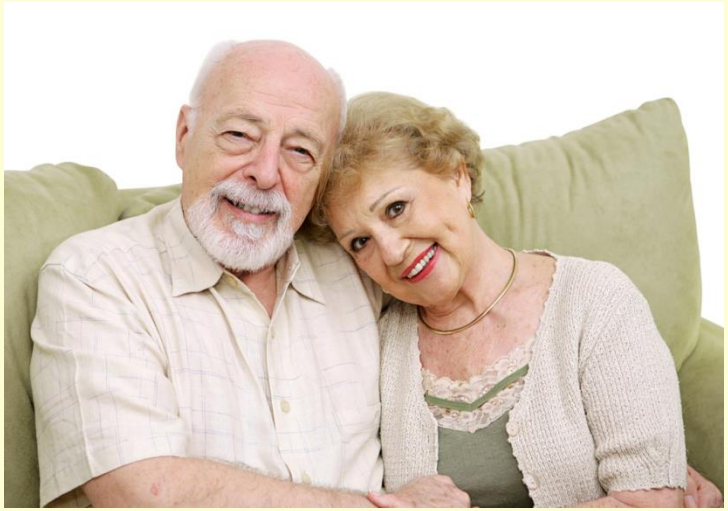
What is the Food Safety Problem?

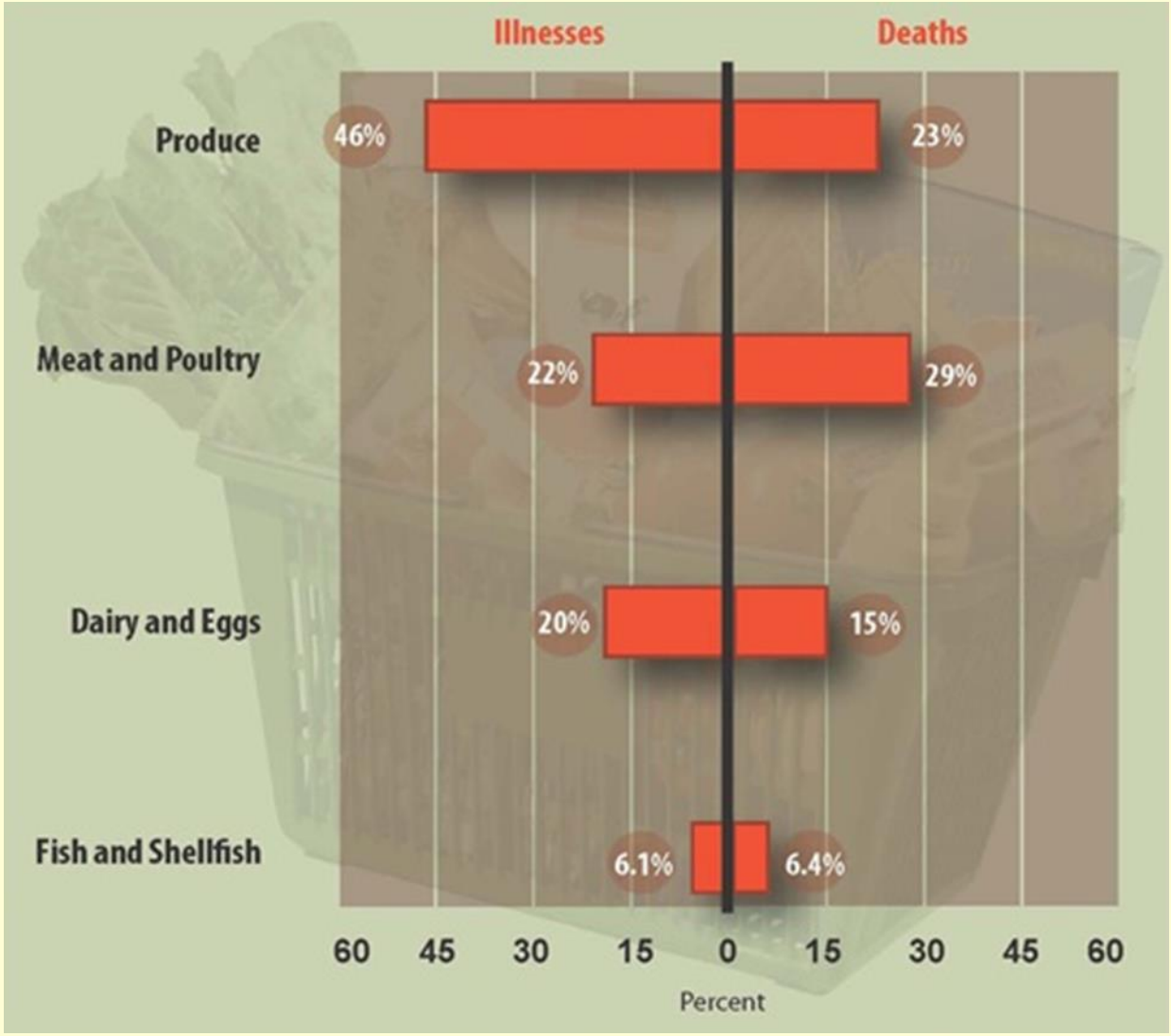




Foodborne Illness (2010): Dangers

- Cases: 48 million per year
- Hospital: 128,000 per year
- Deaths: 3,000 per year
- Cost: Billions per year

Contribution of different foods to domestic illnesses: 1998-2008 (CDC)



2006 – A Banner Year

- **Spinach – September, 2006:**
  - 204 cases *E. coli 0157:H7*
  - 31 cases HUS
  - 104 hospitalizations
  - 3 deaths
  - 26 states
  - Source – Salinas Valley, CA
  - Pigs
  - Shut down industry; Price fell

2006 Outbreaks/Recalls – A Banner Year

- **Shredded Lettuce (Taco Bell) – December, 2006:**
  - 71 cases *E. coli 0157:H7*
  - 8 cases HUS
  - 53 hospitalizations
  - 0 deaths
  - 5 states
  - Source – Central Valley, CA???

2006 Outbreaks/Recalls – A Banner Year

- **Lettuce Recall – October, 2006**
  - Nunes Lettuce, Salina, CA
  - Foxy Brand
  - *E. coli* contamination of irrigation water
- **Tomato – November, 2006**
  - 183 cases, Salmonella typhimurium
    - 21 states
    - Served in restaurants
  - 100 cases, Salmonella typhimurium
    - 19 states
- **Cantaloupe Recall – November, 2006**
  - Rio Vista, Ltd., Rio Rico, AZ
  - Llano, Nature's Partner brands
  - Salmonella

Salmonella Saint Paul -Jalapeno Peppers/2008

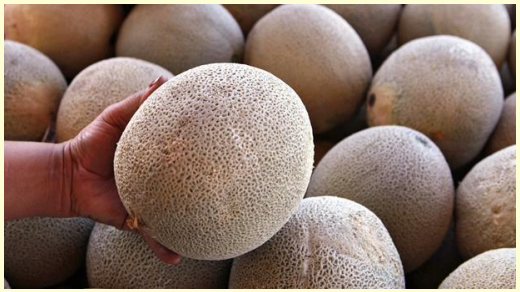
- 4/14/2008 –8/16/2008
- 1,442 ill, 43 states, DC and Canada
- June/July – FDA: Certain tomato types implicated. Specified areas to purchase from
- June/July – FDA lifts tomato advisory, implements Jalapeno pepper advisory
- August – Traceback – distributor in Texas, peppers from Mexico. Pathogen found in irrigation water
- **Cost to tomato industry – Approx. $100 million.**

Romaine Lettuce – Fall, 2011

- E. coli 0157 H7
- 58 people, 9 states
- 10/2011- 11/2011
- St Louis supermarket salad bar and shelves
- 33 hospitalized
- 3 hemolytic uremic syndrome (HUS)
- No deaths
- Single common lot of romaine lettuce/one farm
  - Contamination before grocery
  - By time origin figured out, farm not producing, not possible to determine route contamination
- Law suits

Cantaloupe Outbreak

- Jensen Farm, Colorado. **7/2011-12/2011**
- **147 hospitalized, 28 states, 33 deaths, 1 miscarriage**
- **Deadliest outbreak**
- Listeria monocytogenes. 50 days!!
  - 2/22/2012 – Victim dies after 5-month battle



Jensen Farm Cantaloupe Outbreak

What did they do wrong in **packing house**?

- Installed potato washer to wash cantaloupes
- Did not wash cantaloupes well, did not cool them down, not easy to clean
- Served as a source of contamination
- No cooling, warmer temperatures good growing conditions for Listeria on **outside** of produce
- Chlorine sanitizer spray system not operating

Jensen Farm Cantaloupe Outbreak:

- Brothers pleaded guilty six counts of selling adulterated food interstate

- Penalty/sentencing January, 2014
- Maximum sentence: Prison up to 6 years and up to $1.5 million fines
- Got 5 years probation, 6 months home detention, $150,000 fines
- Sued Primus Labs: farm a superior rating, 96%, July 2011, prior to shipping

Cucumbers – Spring, 2014

- Salmonella Newport
- 275 people, 29 states
- 5/2014-9/2014
- Virginia Eastern Shore –Delmarva region
- 48 hospitalized
- 1 death
- Cucumber typical shelf-life 10-14 days

2015 Outbreaks

- January 6, 2015- Bidart Bros., CA
  - Granny Smith and Gala apples
  - Lm in apple-packing facility
  - 35 people ill, 12 states, 3 deaths

- 7/3/2015-2/29/2016 – Andrew and Williamson Fresh Produce, CA. Cucumbers
  - Grown in Mexico, distributed in US
  - Salmonella Poona
  - 907 ill, 40 states, 204 hospitalized, 6 deaths
  - 49% < 18 years, 56% female

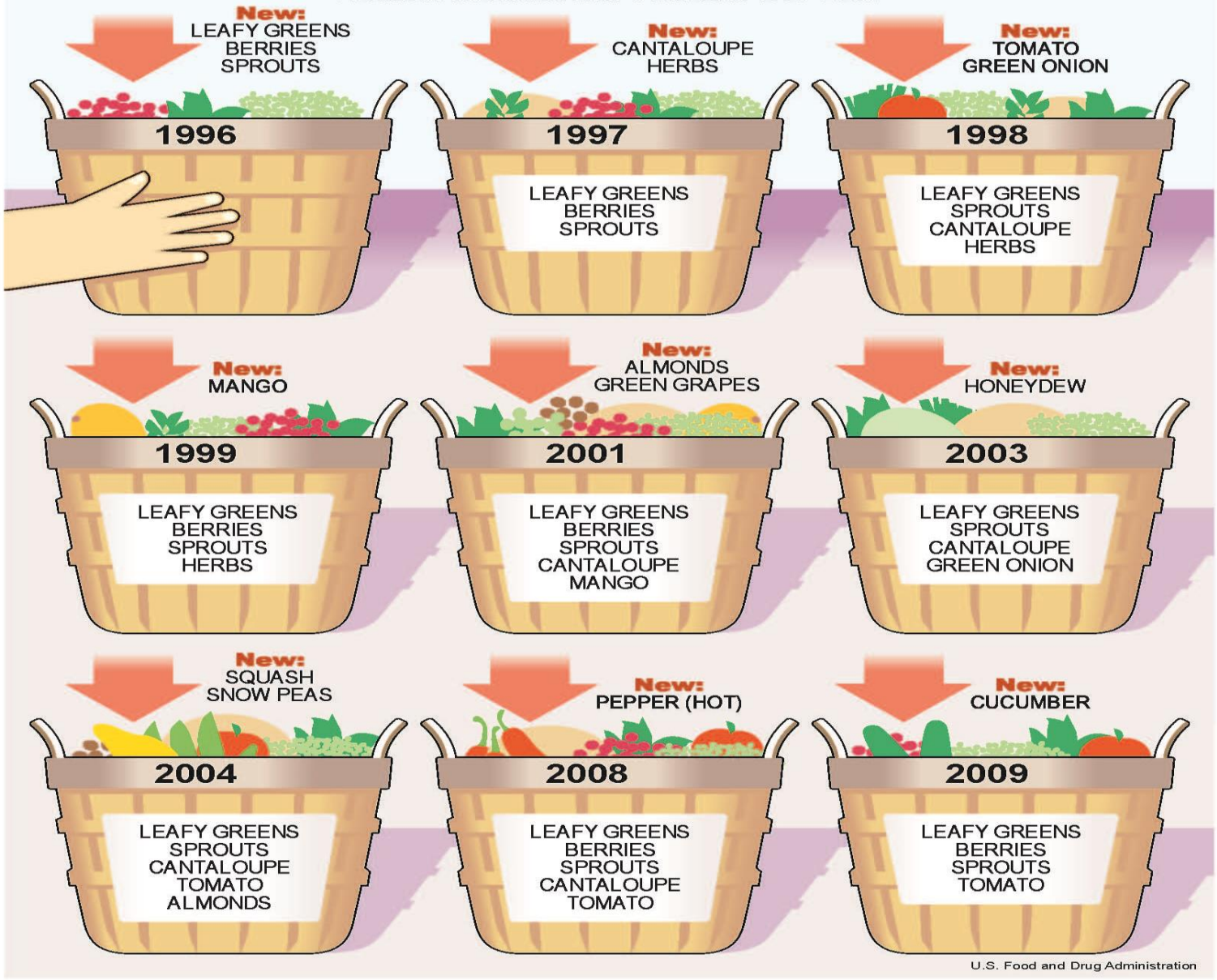
Ongoing Challenges

- **Leafy Greens**
- **Tomatoes**
- **Green Onions**
- **Cantaloupe**
- **Parsley, Cilantro**

From R. Buchanan presentation. FDA

Commodities Related to Outbreaks Change Frequently

Why doesn't the proposed Produce Safety Rule only target fruits and vegetables that are known to have caused outbreaks of foodborne illness? Why include produce that has not been involved in outbreaks of foodborne illnesses? As you can see here, new players join the cast regularly. The below infographic shows produce-associated outbreaks that occurred between 1996 and 2009. It only shows the years a new type of produce was related to outbreaks during that time period. Because we cannot anticipate with certainty which foods could be contaminated in the growing, harvesting or production process, the rules that we propose would cover a variety of produce.



Hazelnuts - 2016

- Salmonella Typhimurium
- Schmidt farm – Oregon – roadside stand
  - 20% at farm stand
  - 80% wholesale for roasting
  - Notified customers not to eat raw; how to roast
- 80 acres of hazelnuts
- Only 5 documented illnesses; nuts long shelf-life

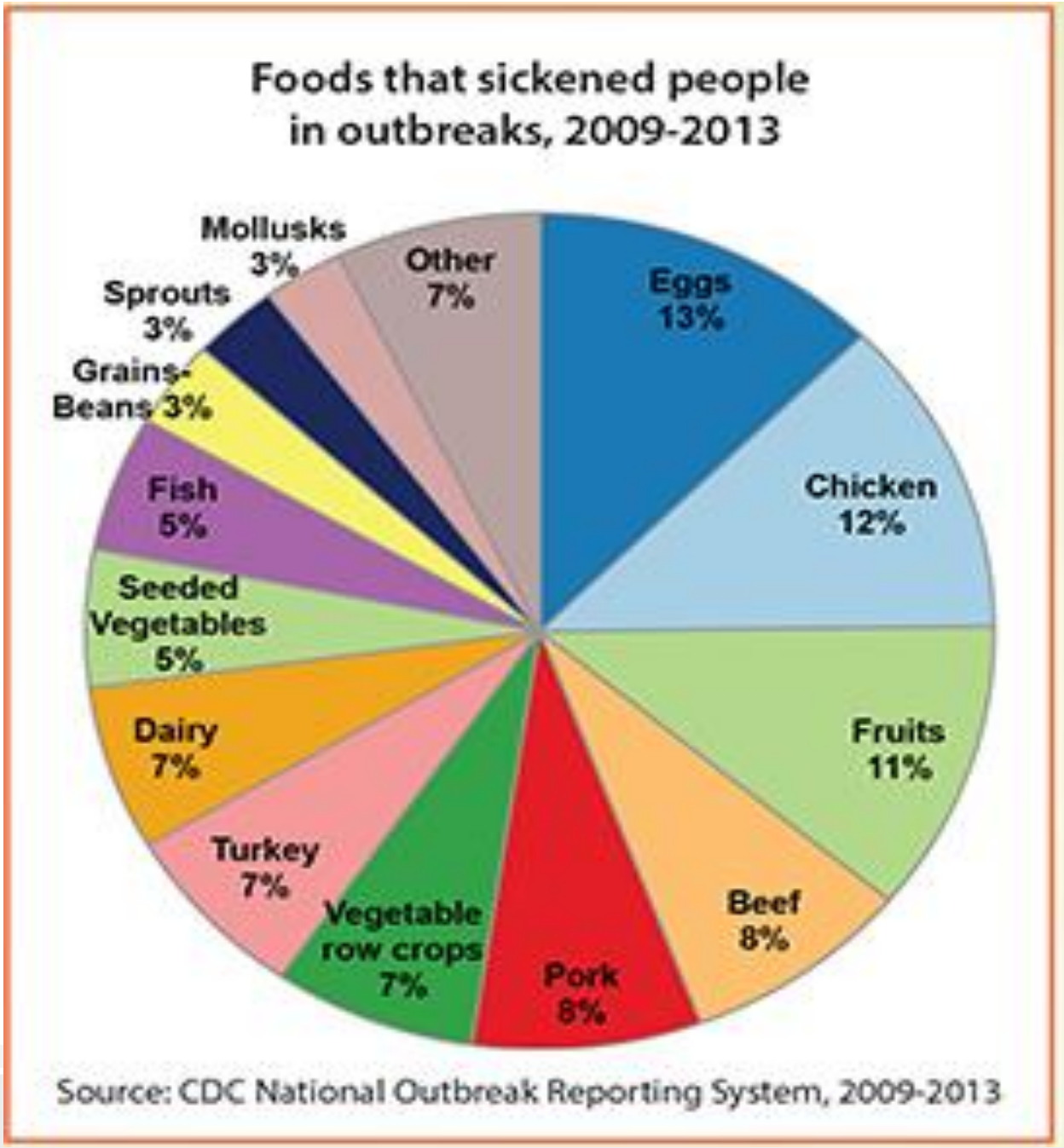
Romaine Lettuce: E. coli 0157 H7

- **4/2018-6/2018**
  - 210 people, 36 states
  - 96 hospitalized; 27 HUS
  - 5 deaths
  - One farm – Yuma AZ growing region
    - **Trace back problems**
- **11/2018-1/2019**
  - 62 people, 16 states
  - 25 hospitalized; 2 HUS
  - No deaths
  - On-farm reservoir- Santa Maria, CA
  - Contact after harvest or washing/rinsing surfaces
    - **Trace back problems**

Romaine Lettuce – Impact

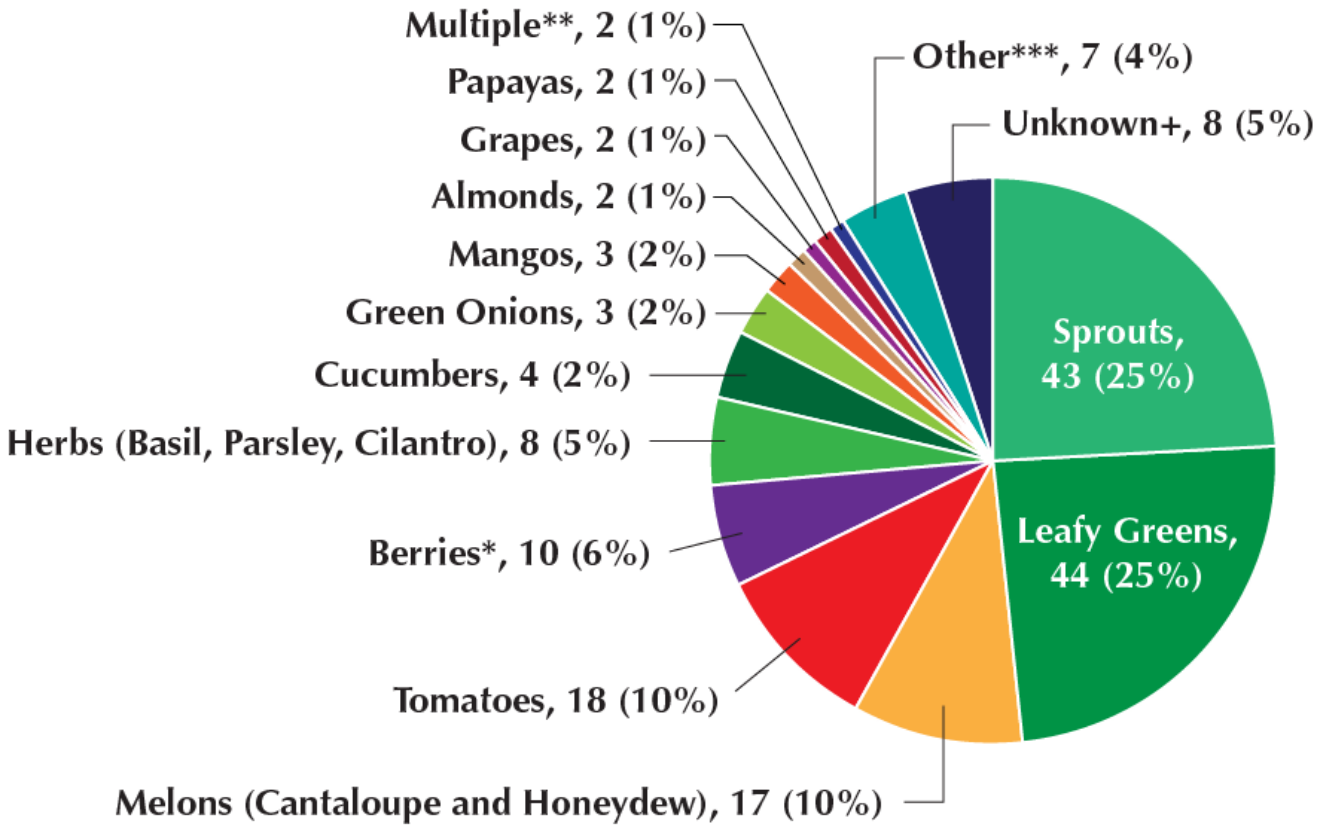
- **FDA urging labeling:**
  - All individually packaged romaine products to identify growing region and harvest date for romaine; and
  - Point of sale for the growing region when cannot be package labeled (e.g. unwrapped whole heads of romaine lettuce available in retail stores).
- **Trace-back Questions**
- **Abundance of caution**: All leafy lettuce removed from store shelves during outbreak

26% of outbreaks attributed to produce – fruits, vegetables, sprouts.



Outbreaks Associated with Produce

FDA Outbreaks Linked to Produce Contamination Likely Prior to Retail: 1996–2014



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Cost – one estimate

Produce (fresh, canned, processed) – 19.7 million illnesses, $1,960/case (higher then average) and $39 billion annually economic losses (CDC survellience system)

Source: produce safety project.org

So – Is it only the big farms?

- 2005-80 people in Oregon and Washington were sickened by E. coli O157:H7 from small Oregon parsley grower
- 2008-13 people fell ill from spinach grown by a small grower in Washington.
- 10 other outbreaks traced to small growers/processors in Oregon since 2005

Strawberries – Northwest Oregon, 2011

- **Jaquith Strawberry Farm**
  - E. coli 0157 H7
  - Sold locally – supermarkets, pick your own, roadside stands, farmers markets
  - Local counties
  - 15 ill, 1 death
  - Deer confirmed source

Cantaloupe Outbreak

- Chamberlain Farms Produce, Indiana
  Organic, 100 acres used for cantaloupes
- August 22, 2012 announcement, CDC
- July-September
- 261 ill, 24 states, 94 hospitalized, 3 deaths,
- Salmonella typhimurium, Salmonella newport.
- Recall – Mostly Indiana,
  some Illinois,/Kentucky

Cantaloupe Outbreak

What went wrong? Per FDA:

- Poor sanitation
- Environmental swabs positive
- Cantaloupe cardboard bin – positive
- Food contact surfaces not constructed for cleaning
- Lack of cleaning, standing water in packing shed
- Failure to remove waste, litter, harborage for pests

Large vs. Small

- Large farms have issues (i.e. mingling of sources, many hands touch the product before it gets to the consumer) and huge product reach—an outbreak has a bigger impact.

Large vs. Small

- **Small farms – hard to trace, hard to notice illnesses**
- Small farmers beginning to be proactive. Training to change practices
  - Small farms with advantages
    - More control over what they are producing
    - Easier to keep track, records (farmer, produce alliance)
    - Don't ship as far
- **Most important – when berries OR. had E.coli, berry growers in neighboring states were fearful that outbreak could impact them**.

Why is this so hard to find?
Why don't you know? Believe?

Why is this so hard to find?
Why don't you know?

- **The Food that Made You Ill Is Probably Not the Last Food that You Ate**
- Incubation Period
  - Norovirus 12-48 hours
  - Salmonella 6 to 72 hours
  - E. coli O157:H7 1 to 10 days
  - Listeria 3 to 70 days

From E. Julian talk, 2012, Food Safety conference

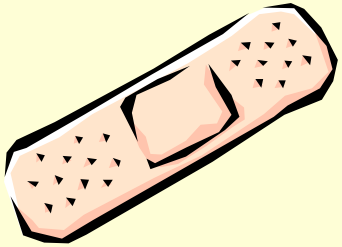
Foodborne Illness: The Symptoms

- Nausea
- Vomiting
- Diarrhea
- Headache
- Fever

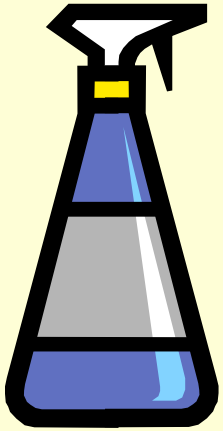
Mathematics of an outbreak

- A report first needs to be made
- Minimum of 2 illnesses = outbreak or cluster
- 1 out of 31 reports illness
- If 200 illnesses documented = 6000 actually sick

Food Safety Hazards:
3 Types of Contamination



Physical



Chemical

Biological

Physical Food Safety Hazards

- Wood
- Plastic
  - Golf balls and potatoes
- Metal
  - Needles in strawberries
- Glass
- Tools
- Gloves, bandages, pens and other personal items

Chemical Food Safety Hazards

- Cleaning chemicals, sanitizers
- Lubricants, other plant chemicals
- Heavy metals, such as lead
- Allergens, such as milk protein
- Toxins, such as patulin - apples
- Pesticides
  - USDA/Pesticide data program-2017
    - 99% well below EPA tolerances and 53% no detectable
    - ~72% domestic, 26% imports
    - Of 10,541 samples, ~83% fresh/processed produce
    - Regulations and monitoring

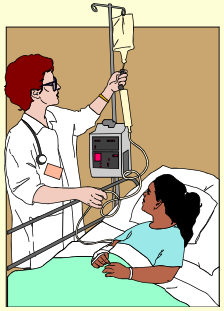
The goal of an on-farm food safety program is to reduce microbial risks in fresh or minimally processed fruits and vegetables—making produce safer.

Foodborne Illness:
People at Greatest Risk

- Infants & Children

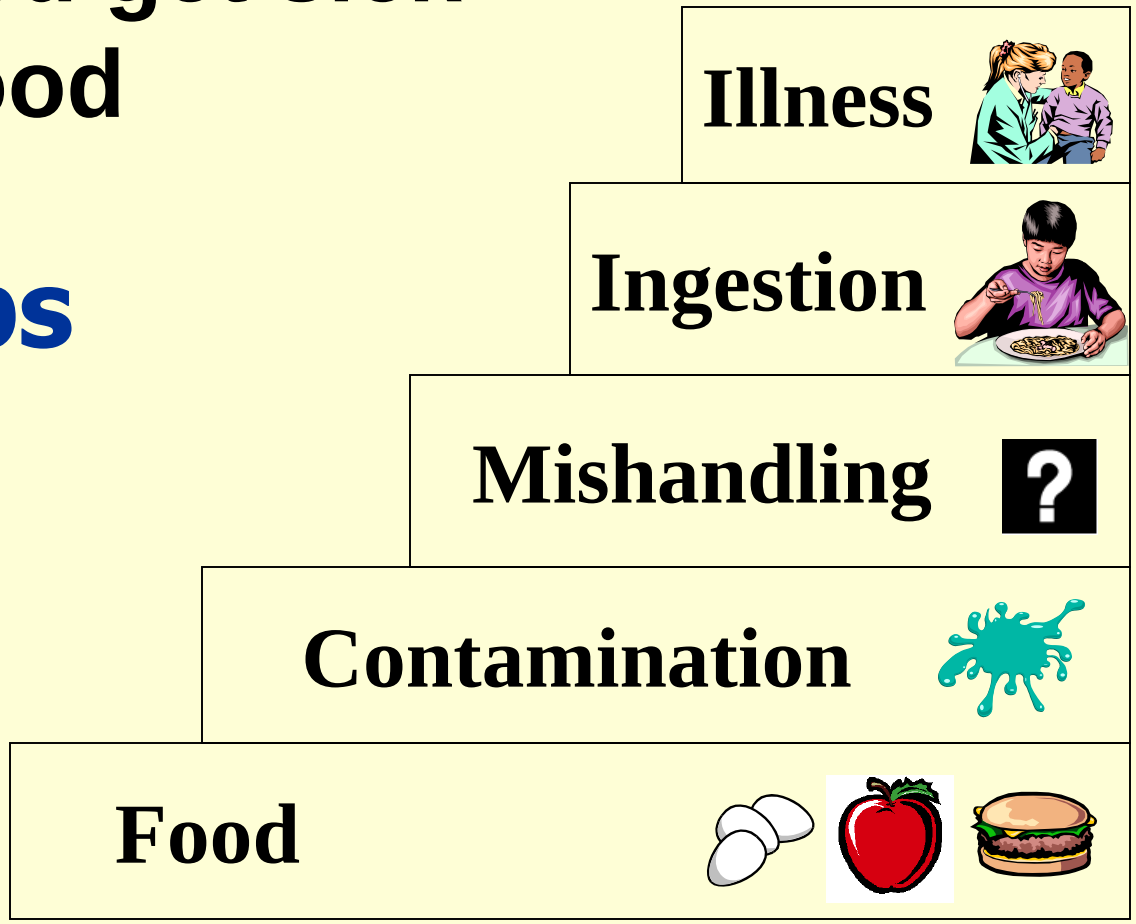
- Elderly

- People with weakened immune systems – cancer, diabetes, HIV/AIDS



Foodborne illness: How you get sick from food

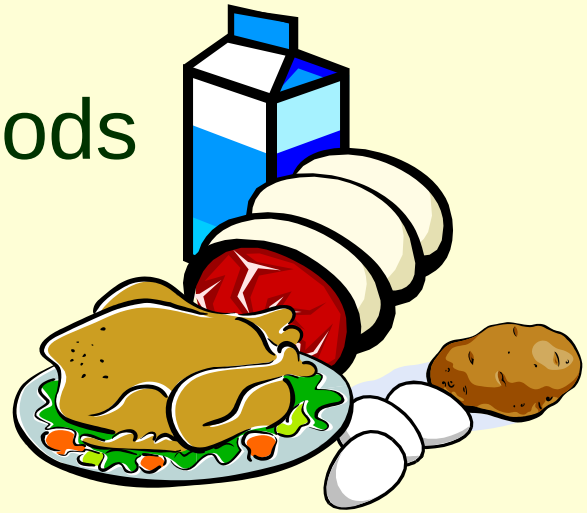
5 Steps



Foodborne Illness:
Most likely sources

- Ready to Eat Foods

- Potentially Hazardous Foods



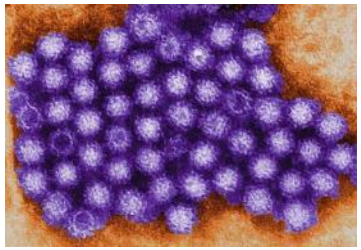
Foodborne illness: From Farm to Table

- Food Safety Hazards can be present at any point from the farm to the table
  - Growing
  - Harvesting
  - Processing
  - Storage
  - Distribution
  - Retailing
  - Final Preparation by the consumer or foodservice operation

Farm: Produce Food Safety Challenges

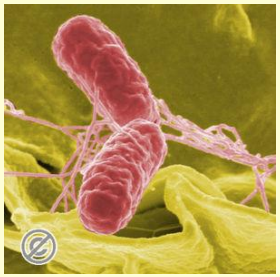
Microorganisms of Concern in Fresh Produce

- Bacteria
  - *Salmonella,* toxigenic *E. coli, Shigella, Listeria monocytogenes*
- Viruses
  - Norovirus, Hepatitis A
- Parasites
  - *Giardia lamblia*, *Cryptosporidium parvum, Cyclospora cayetanensis*



Some Frequent Contributors

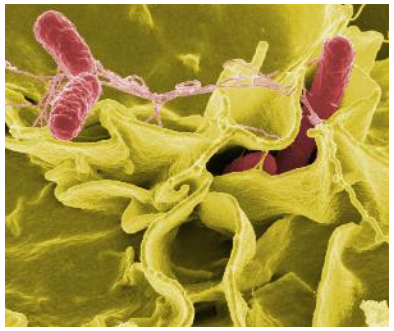
- Salmonella
  - cantaloupes, tomatoes, sprouts
- E.coli 0157:H7
  - leafy green vegetables
- Cycolspora (parasite)
  - raspberries
- Hepatitis A (virus)
  - green onions
- Listeria
  - cantaloupes



Salmonella

Listeria

Bacteria in the Farm Environment



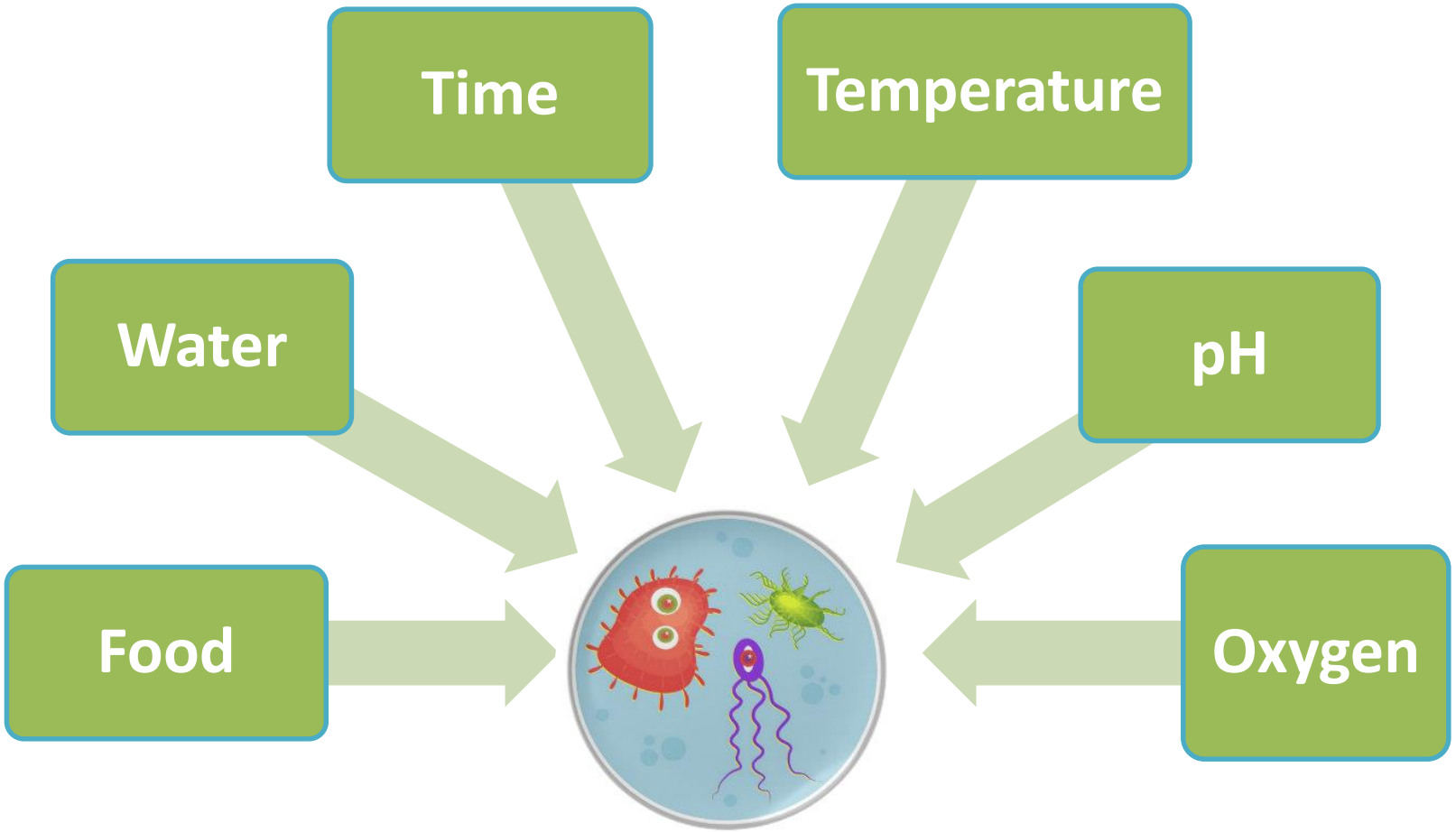
- Bacteria are microorganisms that can multiply both inside and outside of a host
- Bacteria include pathogens such as *E. coli* O157:H7, *Salmonella*, and *Listeria monocytogenes*
- Bacteria can multiply rapidly given the right conditions: water, food, and the proper temperature
- Good Agricultural Practices can reduce risks by minimizing situations that support bacterial survival and growth

Bacteria

- If conditions are ideal, bacteria can multiply once every 20 minutes
- It is unlikely you'll ever start with just ONE bacterium
- Some pathogens can make people sick with a dose of 10 cells or less
- What conditions are optimal?
  - Food source
  - Moisture
  - Right temperature

Time	# of Bacteria
20 min	2
40 min	4
1 hour	8
80 min	16
100 min	32
2 hours	64
4 hours	4096
6 hours	262,144
8 hours	16,777,216

Conditions for Bacterial Growth



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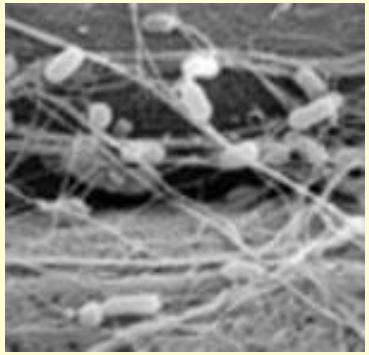
Survival of Bacteria

- Impacted by temperature, pH, sunlight exposure, source of contamination, other microflora and organism of interest

  E.coli, Salmonella spp., Listera, Shigella

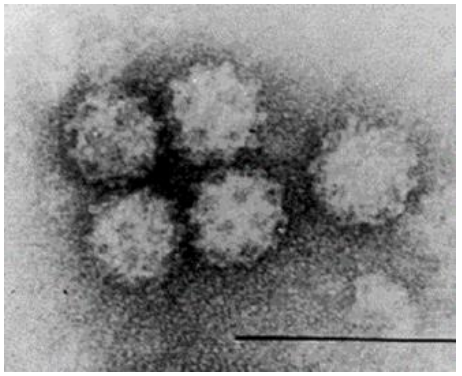
- Studies show different survivals of pathogens depending on commodity, surface soil or water, and viability/survival vs. growth

Salmonella spp.



E. coli

Viruses



- **Viruses** are small particles that multiply only in a host, not in the environment or on produce
- Contamination most often linked to an ill worker handling fresh produce (fecal-oral route) or contaminated water
- It only takes a few virus particles to make someone ill
- Can be very stable in the environment
- Prevention is the key to reducing viral contamination
- Limited options for effective sanitizers

NoroCORE Food Virology
Collaborative for Outreach, Research & Education

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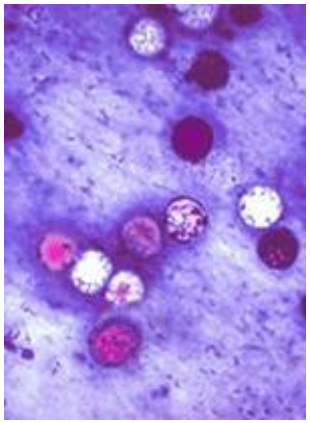
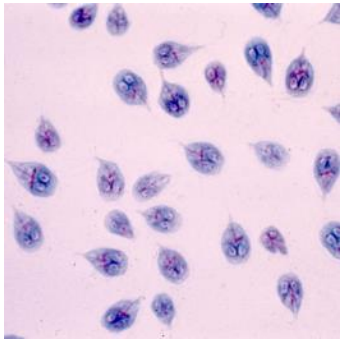
Parasites

- **Parasites** are protozoa or intestinal worms that can only multiply in a host animal or human
- Commonly transmitted by water
- Can be very stable in the environment; often not killed by chemical sanitizers
- Can survive in the body for long periods of time before ever causing signs of illness





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Health Impacts by Pathogen Type

FDA Outbreaks Linked to Produce by Pathogen Types: 1996–2014

Pathogen Type	Outbreaks (% of total)	Illnesses (% of total)	Hospitalizations (% of total)	Deaths
Bacterial	148 (85.55)	11,377 (66.28)	1,844 (89.21)	65
Parasitic	21 (12.14)	4,786 (27.88)	67 (3.24)	0
Viral	3 (1.73)	993 (5.79)	156 (7.55)	3
Total	173*	17,164	2,067	68

*The total also includes chemical hazards not identified in this table (e.g., a Curcurbitacin toxin outbreak associated with squash).

Pathogen Summary

Presence, Growth, Survival depends on:

- Microflora characteristics
- Available nutrients
- Environmental conditions
- Internalization

Jahid and Ha, 2012, Review of microbial biofilms. Compr. Rev. in Fd. Sci.

Internalization: Control More Difficult

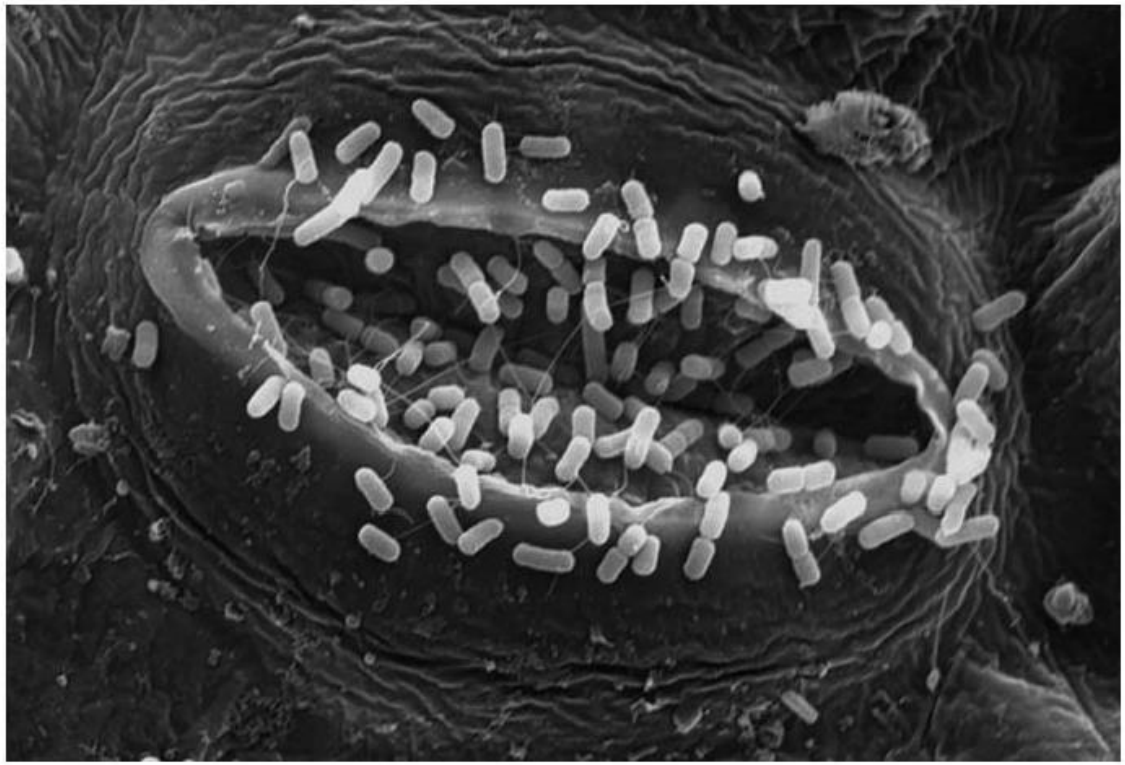

Fig. 4. Internalization of *E. coli* in leaf stomata (from Berger et al., 2010).

Olaimat and Holley. 2012. Factors affecting microbial safety fresh produce: a review. Food Micro. 32(1-19.

Internalization: How Does This Happen?

- Stomata, calyx, stems, damage to cuticle
- Damaged/cut edges produce/physiological disorders
- Roots or seeds – internalized during sprouting
- Might be inaccessible to water, disinfectants
- High temperatures, excess humidity during sprouting
  - conditions “ripe” for foodborne pathogen internalization
- Photosynthesis and light – stomata open?
- Sanitizing agents in wash/cooling water to avoid cross-contamination and internalization.
  - Lodge in stomata, crevices of produce exposed to contaminated water, postharvest

Jahid and Ha, 2012, Review of microbial biofilms. Compr. Rev. in Fd. Sci
M. Erickson, 2012. Ann. Rev. Food Sci. Technol. 2012.3:283-310.
Olaimat and Holley. 2012. Factors affecting microbial safety fresh produce: a review. Food Micro. 32(1-19.

Produce Safety Challenges

- Fresh produce is often consumed raw (i.e., not cooked)
- Microbial contamination on produce is extremely difficult to remove once present
  - Natural openings, stem scars, bruises, cuts
  - Rough surfaces, folds, netting
- Contamination is often sporadic
- Bacteria can multiply on produce surfaces and in fruit wounds, provided the right conditions are present

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Contamination Sources

Humans

Soil

Produce

Animals

Buildings
Equipment
Tools

Water

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How Contamination Is Spread

- **Humans**

  Workers can spread pathogens to produce because they directly handle fruits and vegetables.

  – Improper health and hygiene practices
    - Lack of adequate training and handwashing practices
    - Lack of or inadequate toilet facilities

  – Illness or injury
    - Working while sick
    - Injuries that result in blood contacting fresh produce

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How Contamination Is Spread

- **Animals**

  Domesticated and wild animals can carry and transmit human pathogens to produce.

  – Field intrusion may result in direct fecal contamination of crops and fields
  – Animal feeding, rooting, and movement through fields may spread contamination
  – Animals can contaminate water sources used for produce production
  – Manure runoff can contaminate fields, water sources, and crops

How Contamination Is Spread

- **Water**

  Water can carry and spread human pathogens, contaminating entire fields or large amounts of produce.

  – Production water
    - Irrigation, crop sprays, frost protection
  – Postharvest water
    - Fluming, cooling, washing, waxing, cleaning
  – Unexpected events
    - Flooding, runoff

How Contamination Is Spread

- **Soil Amendments**

  Raw manure and other soil amendments can be a source of contamination if not properly handled and applied.

  - Application too close to harvest
  - Improper/incomplete treatment
  - Improper storage
  - Runoff
  - Wind spread
  - Cross-contamination due to improper sanitation procedures

How Contamination Is Spread

- **Surfaces, equipment, tools, and buildings**

  Any unclean surface that contacts produce can harbor pathogens and serve as a source of contamination.

  – For example, not having an established schedule for cleaning or sanitizing food contact surfaces, including tools

  Facility management can also impact risks

  – Areas outside buildings that are not kept mowed or clean can serve as pest harborage areas

  – Standing water or debris present in the packinghouse can become a source of cross-contamination

Cleaning vs. Sanitizing

What is the difference and why does it matter?

- **Cleaning:** Physical removal of dirt (soil) from surfaces which can include the use of clean water and detergent
- **Sanitizing:** Treatment of a cleaned surface to reduce or eliminate microorganisms

Important point: You cannot sanitize a dirty surface.

Cleaning always comes first!

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Produce Safety Begins With Your Commitment

- Identifying produce safety risks on your farm
- Supporting the implementation of food safety policies and practices to reduce risks
- Providing equipment and facilities necessary to implement practices that reduce risks
- Supporting effective food safety training so everyone can actively be involved in reducing risks
- Setting a good and consistent example on your farm

Produce Safety ALLIANCE

Steps Towards Produce Safety

1. Assess Produce Safety Risks
2. Implement Practices
3. Monitor Practices
4. Use Corrective Actions
5. Keep Records

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Wes Kline, From
Rutgers NJ Agricultural
Experiment Station

Assessing Risks

- **Assess your farm and practices**
  - Location of farm, fields, and adjacent land activities that may represent risks to the crops you grow
  - Fecal contamination risk from domesticated or wild animals
  - Use of water and manure in crop production
  - Worker training programs and hygiene facilities
  - Practices used to grow, harvest, pack, or hold produce and the tools and equipment
  - Typical and atypical (e.g., flooding) situations

Implementing Practices to Reduce Risks

- Focus on preventing contamination
  - Cannot reliably remove contamination
- Address risks most likely to have the biggest impact on produce safety first
- May require modification of current practices and additional training for farm employees
- May require capital investment
- You may already be doing the right thing!
- Ask for help and seek training if you are unsure

Good Agricultural Practices (GAPs)

- This curriculum will focus on GAPs and provide information on how growers can comply with the FSMA Produce Safety Rule
- Key areas will be reviewed as well as practices that can be implemented to reduce risks including:
  - Worker training programs
  - Water monitoring, testing, and treatment
  - Manure and compost management
  - Wildlife and animal monitoring
  - Sanitation programs

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Standard Operating Procedures (SOPs)

- **A written document defining how to complete a specific food safety practice.**
- **SOPs include:**
  1. Step-by-step instructions to ensure that even a person who has never done a practice before can complete the practice correctly by following the instructions
  2. Location and name of any supplies needed to complete the practice
  3. When and how often the practice should be completed
  4. What records are needed/necessary

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Monitoring

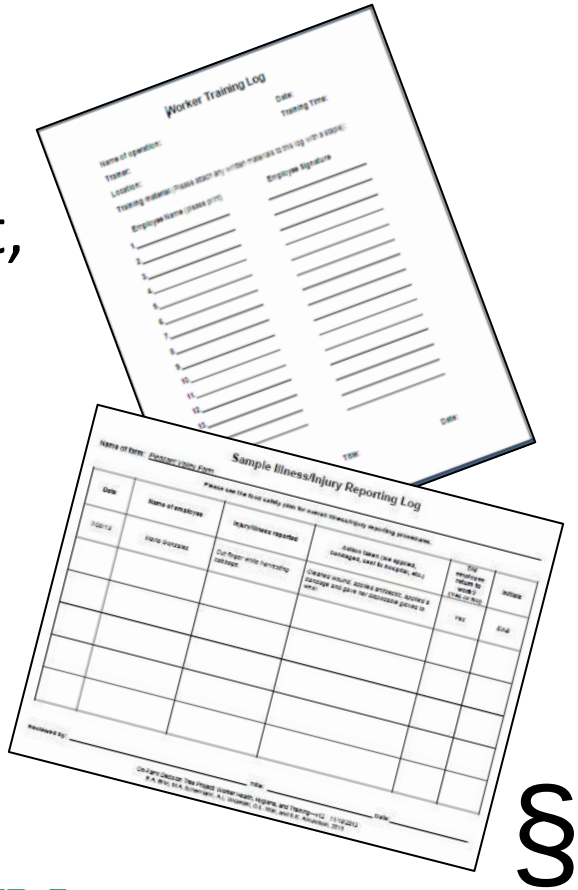
- Performed on a schedule or during a specific activity
- Allows you to verify practices are being completed properly
- Helps identify problems before they impact safety
  - Frequent high generic *E.coli* counts in water test results
  - Evidence of animal intrusion and fecal contamination
  - Improper cleaning and sanitation practices resulting in dirty equipment and tools

Corrective Actions

- Can be established in advance
  - Negative consequences for workers not following practices
  - Plans for a spilled portable toilet
- Fix problems that are identified during monitoring
  - Restocking toilet and handwashing facilities
  - Retraining supervisors and farm workers
- May require short and long term planning
  - Establishing sanitation programs (short term)
  - Replacing equipment (long term)

Recordkeeping

- Recordkeeping includes documenting practices, monitoring, and corrective actions
- There are many templates available
- Recordkeeping should be convenient, or else it will not get done
- Records must be signed and dated after they are reviewed
- Keep all records for at least 2 years



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Recordkeeping Benefits

- You can verify practices were done
  - And done properly!
  - Assures you that everyone is sticking to the food safety policies
- Look for trends or outliers and eliminate potential problems
- May be required for certain activities
  - Regulatory (i.e., FSMA Produce Safety Rule requirements)
  - Third party audits

Recordkeeping Basics

- Records can be handwritten (pen & paper) or electronic (handheld data entry or scanner)
- Invest in tools that make it work
  - Clip boards
  - Pens tied to long pieces of string attached to a clipboard with the recordkeeping logs
  - Plastic page sleeves
  - Duct tape
- Use technology to your advantage
  - Phones, apps, tablets, computer software

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Recordkeeping Tips

- Establish record keeping schedules that make sense for the record keeper and the action
  - When does it need to be recorded?
  - Who is in charge of documenting it?
  - How often does it need to be documented?
- Build recordkeeping into normal routines
  - Place recordkeeping logs in accessible areas with necessary supplies (e.g., pens, paper)

PSR vs RI GAP

Records

What records to keep vs required?

- Employee hygiene training
- Commercial processing
- Alternative measures
- Water – inspection, source, treatment, monitoring, corrections ☑
- Temperature control-when needed ☑
- Cleaning and Sanitation of Equipment ☑
- Maintenance toilet and hand washing facilities
- Pest control ☑
- Transportation
- Traceback/Recall
- Inspection - facility, production area
- Harvest logs
- Produce sold
- Fertilizer/compost/manure applications ☑
- Animal intrusion

A Farm Food Safety Plan

- Gets you thinking about YOUR farm and practices
- Keeps you organized so you can focus your time and resources more effectively
- Gives you a plan to follow and assure everyone is involved
- Documents your progress
- Is required by third part audits and some buyers
- Is not required by the FSMA Produce Safety Rule, but is a good idea!

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Summary

- Produce safety impacts your farm
- Microorganisms are the primary produce safety concern
- Your commitment is critical to success
- Produce safety includes:
  - Assessing risks, implementing practices, monitoring practices, using corrective actions, and keeping records
  - Providing the necessary resources to get it done
- A written Farm Food Safety Plan guides your produce safety efforts

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