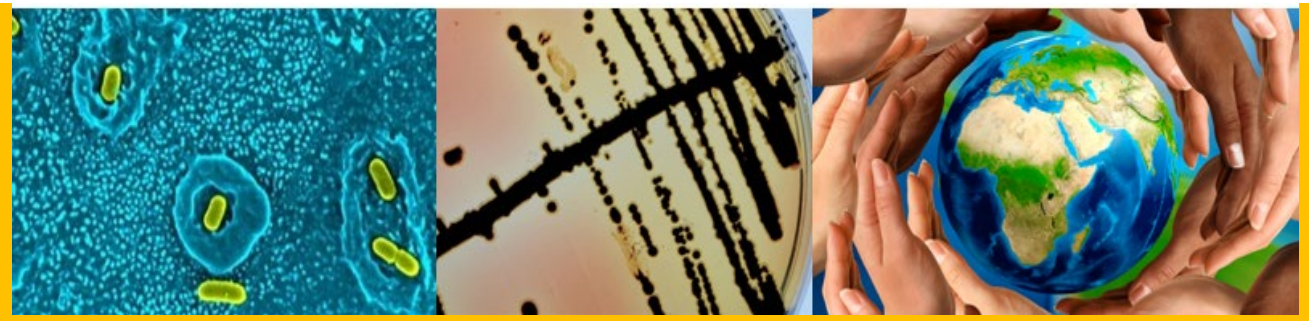


Food and Drug Administration Food Code
Produce Safety Rule of Food Safety Modernization Act

AGSC 5540: Food Policies and Regulations

11-4-2021

Tennessee State University, Nashville, TN

A. Fouladkhah: Faculty Director, Public Health Microbiology Laboratory

Sor far in the class

- **Policies for Consumers:** USDA DGA
- **Policies for State and Territorial Agencies:** CIFOR Guidelines of CDC
- **Policies for the Human Food Industry:** HACCP and PC Rule of FSMA
- **Policies for the Animal Food Industry:** PC Rule for Animal Food of FSMA

- Today we discuss:
- **FDA Food Code:** Retail and Restaurant operations and the food industry
- **Produce Safety Rule:** Raw agricultural commodities

- Food Code, Exercises 1 and 2
- Exercise 3, Food Safety challenges in the news
- Produce Safety Rule, Exercise 4

Remaining of the Semester

- After today we will have two more classes
- 11/11/2021: Nutrition Facts Labels and GRAS List
- 11/18/2021: Climate Change and Food Safety

- **11/18/2021: Final Paper Due**
- 11/18/2021: Take home exam provided to students
- 11/24/2021 (Wed): Final Take Home Exam Due
- 11/29/2021: Grades to be posted

- 11/08/2021: Optional Regional IFT Meeting
- 11/20/2021: Commencement
- 12/2/2021: Annual Competition (virtual)

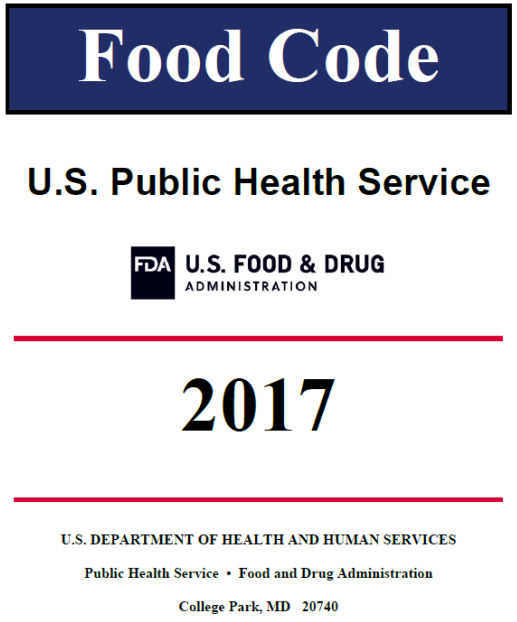
FDA Food Code

What is food code?

- Known as ***FDA Food Code***, is a publication of Food and Drug Administration
- Provides scientifically sound **technical** and **legal** basis for regulating Food Service:
  - **Restaurant industry**
  - **Grocery stores**
  - **Other institutions** *e.g.* nursing homes and campus dinning
  - Could be adopted as part of FSMA and HACCP

Other Uses of FDA Food Code:

- **State and local agencies** use the FDA food code to update their own rules
- **Producers** (farmers) and **processors** (food manufacturing) could utilize the document for:
  - **Validation of their operations**
  - **Determining process, sanitation, and allergen controls** in their food safety plan



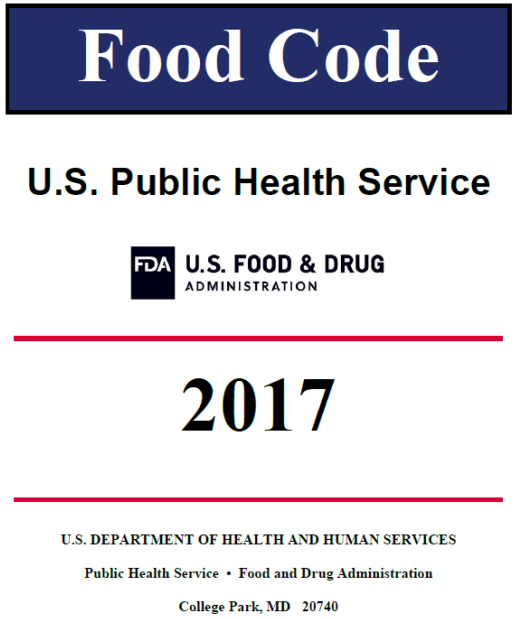
FDA Food Code

What is food code?

- First version introduced 1934
- Has been extensively revised since introduction
- Currently is revised **every four years**
- Is discussed extensive during **Conference for Food Protection**

(Conference for Food Protection and International Association for Food Protection Conference)

- Newest version released in 2017 (767 pages)



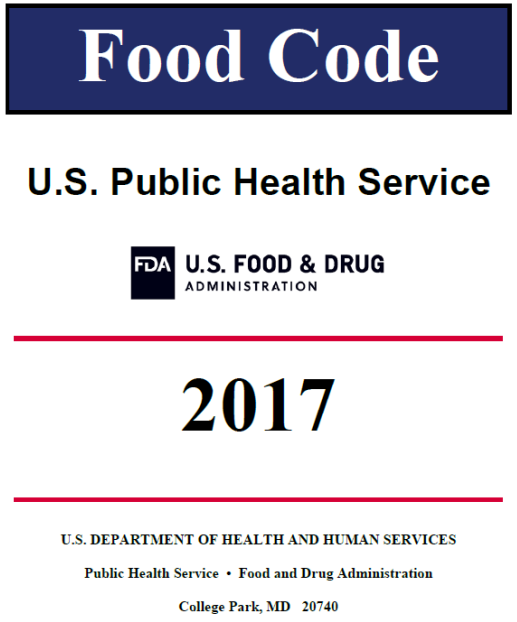
Purpose:

- Safeguarding **public health** (microbial, physical, and chemical hazards)
- Assuring honestly and **avoiding adulteration**
- Provide a **basis for each state to** develop and revise their regulatory document

FDA Food Code

Benefits of Food Code?

- Promotes **uniform national standards**, reduce complexity, and better ensure compliance.
- Ensures food safety regulations are **science- and evidence-based**
- **Protecting the consumer and the industry** from foodborne diseases
- **Provides** extensive **supporting documents and training**
- Allows for **standardization of inspections and inspectors**
- **Reduces complexity and the paperwork** burden for industry and government alike.
- **State and local agencies usage of FDA interpretations** of Food Code reduces the work load
- Reduces **industry food safety training costs**



FDA Food Code

Adoption in Tennessee Department of Health

Tennessee Department of Health:

Document entitled "**Food Service Establishment**"

Revised : **July 2015 (129 pages), eight sections**:

- 1200-23-01-.01 Definitions
- 1200-23-01-.02 Management and Personnel
- 1200-23-01-.03 **Food**
- 1200-23-01-.04 Equipment, Utensils, and Linens
- 1200-23-01-.05 Water, Plumbing, and Waste
- 1200-23-01-.06 Physical Facilities
- 1200-23-01-.07 Poisonous or Toxic Materials
- 1200-23-01-.08 Compliance and Enforcement

RULES
OF
TENNESSEE DEPARTMENT OF HEALTH
BUREAU OF HEALTH SERVICES ADMINISTRATION
DIVISION OF GENERAL ENVIRONMENTAL HEALTH

CHAPTER 1200-23-01
FOOD SERVICE ESTABLISHMENT

TABLE OF CONTENTS

1200-23-01-.01	Definitions	1200-23-01-.05	Water, Plumbing, and Waste
1200-23-01-.02	Management and Personnel	1200-23-01-.06	Physical Facilities
1200-23-01-.03	Food	1200-23-01-.07	Poisonous or Toxic Materials
1200-23-01-.04	Equipment, Utensils, and Linens	1200-23-01-.08	Compliance and Enforcement

1200-23-01-.01 DEFINITIONS.

(1) Accredited Program.

(a) "Accredited program" means a food protection manager certification program that has been evaluated and listed by an accrediting agency as conforming to national standards for organizations that certify individuals.

FDA Food Code

Adoption in Tennessee Department of Agriculture

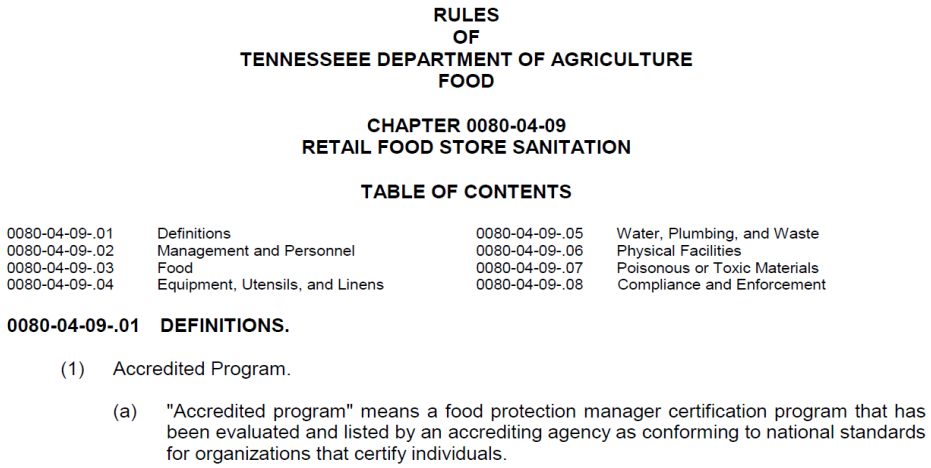
Tennessee Department of Agriculture:

Document entitled "**Retail Food Store Sanitation**"

Revised : June 2017 (125 pages), **eight sections**:

- 0080-04-09-.01 Definitions
- 0080-04-09-.02 Management and Personnel
- 0080-04-09-.03 Food
- 0080-04-09-.04 Equipment, Utensils, and Linens
- 0080-04-09-.05 Water, Plumbing, and Waste
- 0080-04-09-.06 Physical Facilities
- 0080-04-09-.07 Poisonous or Toxic Materials
- 0080-04-09-.08 Compliance and Enforcement

Both documents similar in content and derived from FDA food code



RULES
OF
TENNESSEEE DEPARTMENT OF AGRICULTURE
FOOD

CHAPTER 0080-04-09
RETAIL FOOD STORE SANITATION

TABLE OF CONTENTS

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FDA Food Code

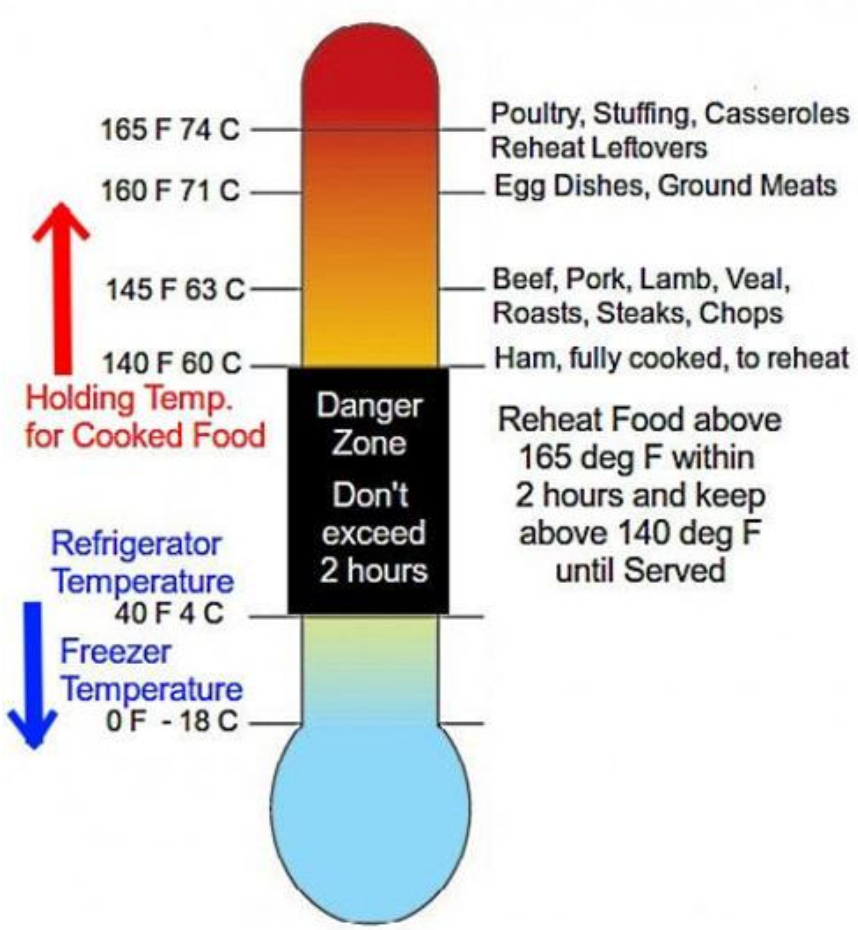
Adoption in Tennessee Department of Health 1200-23-01-.03 Food

Food section has several sub-sections for example

Temperature.

- *(i) Except as specified in subpart 1.(ii) of this subparagraph,* ***refrigerated,***
- *time/temperature control for safety food shall be at a temperature of* ***5°C***
- ***(41°F) or below when received****. (P)*
- *(iii)* ***Raw eggs*** *shall be received in* ***refrigerated equipment that maintains*** *an*
- *ambient air temperature of* ***5°C (41°F) or less.*** *(P)*
- *(iv)* ***Time/temperature control*** *for safety food that is cooked to a temperature*
- *and for a time specified under 1200-23-01-.03(6)(a)1.- 3. and* ***received hot***
- *shall be at a temperature of* ***57°C (135°F) or above****. (P)*
- *(v) A food that is labeled* ***frozen and shipped frozen*** *by a food processing plant*
- ***shall be received frozen****. (Pf)*
- *(vi)* ***Upon receipt****, time/temperature control for safety food shall be free of*
- *evidence of* ***previous temperature abuse****.(Pf)*

USDA FSIS Danger Zone



FDA Food Code

Adoption in Tennessee Department of Health

1200-23-01-.03 Food

- ***Additives.*** *Food may not contain* ***unapproved*** *food additives or additives that*
- ***exceed amounts*** *specified in 21 CFR Parts 170-180 relating to food additives,*
- ***generally recognized as safe*** *or prior sanctioned substances that exceed*
- *amounts specified in 21 CFR Parts 181-186, substances that exceed amounts*
- *specified in 9 CFR Subpart C § 424.21(b) Food ingredients and sources of*
- *radiation, or* ***pesticide residues*** *that exceed provisions specified in 40 CFR Part*
- *180* ***Tolerances and exemptions*** *for pesticide chemical residues in food. (P)*
-
- ***Juice*** *- Commercially Processed: Pre-packaged juice shall:*
- *(i).* ***Be obtained from a processor with a HACCP system*** *as specified in 21*
- *CFR Part 120 Hazard Analysis and Critical Control (HACCP) Systems; (Pf)*
- *and*
- *(ii). Be* ***obtained pasteurized*** *or otherwise* ***treated to attain a 5 log reduction*** *of*
- ***the most resistant microorganism of public health significance*** *as specified*
- *in* ***21 CFR § 120.24 Process Controls****. (P)*

RULES
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FDA Food Code

Adoption in Tennessee Department of Agriculture

0080-04-09-.02 Management and Personnel

Supervisor Responsibilities

- *1. Complying with these rules by **having no violations** of priority items during the **current inspection**; (Pf)*
- *2. Being a **certified food protection manager** who has shown proficiency of required information through passing a test that is part of an accredited program; (Pf) or*
- *3. **Responding correctly to the inspector's questions** as they relate to the specific food operation. The areas of knowledge include:*
- *(i) Describing the **relationship between the prevention of foodborne disease and the personal hygiene** of a food employee; (Pf)*
- *(ii) Explaining the responsibility of the person in charge for preventing the transmission of foodborne disease by a **food employee who has a disease or medical condition** that may cause foodborne disease; (Pf)*
- *(iii) Describing the **symptoms associated with the diseases** that are transmissible through food; (Pf)*
- *(iv) Explaining the significance of the relationship between maintaining the time and temperature of **time/temperature control for safety food** and the prevention of foodborne illness; (Pf)*
- *(v) **Explaining the hazards involved in the consumption of raw or undercooked meat**, poultry, eggs, and fish; (Pf)*

RULES
OF
TENNESSEEE DEPARTMENT OF AGRICULTURE
FOOD

CHAPTER 0080-04-09
RETAIL FOOD STORE SANITATION

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FDA Food Code

Adoption in Tennessee Department of Agriculture

0080-04-09-.02 Management and Personnel

Example of Employee Responsibilities

- *10. Consumers are notified that **clean tableware** is to be used when they **return to self-service areas** such as **salad bars and buffets** as specified under 0080-04-09-.03(3)(d)6; (Pf) [S. aureus and other pathogens]*
- *11. Except when approval is obtained from the commissioner as specified in 0080-04-09-.03(3)(a)1(v), employees are preventing cross-contamination of **ready-to-eat food** with **bare hands** by properly using suitable utensils such as deli tissue, spatulas, tongs, single-use gloves, or dispensing equipment; (Pf)*
- *12. Employees are **properly trained in food safety**, including food allergy awareness, as it relates to their assigned duties; (Pf) and*
- *6. Employees are **properly cooking time/temperature control** for safety food, being particularly careful in cooking those foods known to cause severe foodborne illness and death, such as eggs and comminuted meats, through daily oversight of the employees' routine monitoring of the cooking temperatures using appropriate temperature measuring devices properly scaled and calibrated as specified under 0080-04-09-.04(2)(c) or 0080-04-09-.04(5)(b); (Pf)*
- *7. Employees are using proper methods to **rapidly cool potentially time/temperature control** for safety foods that are not held hot or are not for consumption within four hours, through daily oversight of …*

RULES
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FOOD

CHAPTER 0080-04-09
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ServSafe®

Exercise 1

- **What is FDA Food Code and what area of the food industry it targets?**
- **What are four benefits of FDA Food Code?**
- **What are the two documents derived from FDA Food Code that mandate the food safety regulatory compliance in Tennessee? What are the eight sections of the documents? When was the last time they were revised?**
- **Please name three temperature-related requirements that Tennessean Food Service Establishments would need to follow based on "Food Service Establishment" document from Tennessee Department of Health.**
- **Please name five supervisor and employee responsibility that Tennessean Food Service Establishments would need to follow based on "Retail Food Store Sanitation" document from Tennessee Department of Agriculture?**
- **According "Food Service Establishment" document from Tennessee Department of Health, what type of food additives are permitted in food establishments? What is the required temperature for storing shell eggs? What are the requirement for juices that could be sold to customers?**

FDA Food Code

The Main Document

Current Burden of Foodborne Diseases:

- 48 million illnesses (1 out 6 individuals)
- 128,000 hospitalizations
- More than 3,000 deaths
- Around 1000 reported outbreak per year
- Economic burden: $10 -$83 billion/year

(*Pain and suffering, reduced productivity, and medical costs*)

Major change in trends from 1970s:

Advances in **pasteurization** and **canning** operations eliminated food safety concerns such ***Clostridium botulinum*** ***[sporadic cases of infant botulism]***

Food Code

U.S. Public Health Service

FDA U.S. FOOD & DRUG ADMINISTRATION

2017

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service • Food and Drug Administration

College Park, MD 20740

Current Significant foodborne pathogens…

- **Leading etiological agents for illnesses**: *Norovirus* (58%), Nontyphoidal *Salmonella* serovars (11%), *Clostridium perfringens* (10%), and *Campylobacter* spp (9%).
- **Leading etiological agents for hospitalization:** Nontyphoidal *Salmonella* serovars (35%), *Norovirus (26%), Campylobacter* spp (15%), and *Toxoplasma gondii* (8%).
- **Leading etiological agents for death:** Nontyphoidal *Salmonella* serovars (28%), *T. gondii* (24*%), Listeria monocytogenes* (19%), and *Norovirus (11%).*

Signs and Symptoms of Foodborne Diseases

- Mild illness (no medical care sought)
- **Guillain–Barré syndrome** (*Campylobacter* and *Salmonella*)
- **Post-infectious irritable bowel syndrome** (*Campylobacter* and *Salmonella*)
- **Reactive arthritis** (*Campylobacter* and *Salmonella*)
- **Haemolytic uraemic syndrome** (*E. coli* O157)
- **End-stage renal disease** (*E. coli* O157)
- Death

Significant foodborne pathogens…
based on Scallan et al., 2015 study

- **Disability adjusted life year** (DALY). *DALY: Loss of life and health due to illness*
- Non-typhoidal *Salmonella* (329000)
- Toxoplasma (32700)
- *Campylobacte*r (22500)
- Norovirus (9900)
- *Listeria monocytogenes* (8800)
- *Clostridium perfringens* (4000)
- *Escherichia coli* O157 (1200)

62% bacterial agents; 29% parasitic agents; 9% viral agents

FDA Food Code

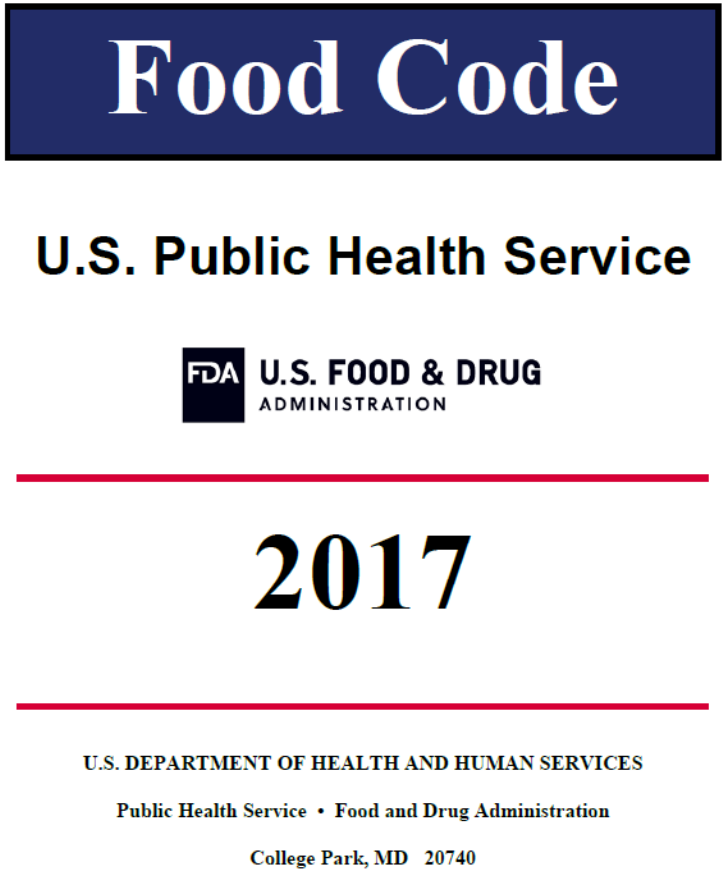
Five Major Risk Factors

5 major risk factors for food safety

- Improper **holding temperatures**
- **Inadequate cooking**, such as undercooking raw shell eggs,
- **Contaminated equipment**
- Food from **unsafe sources**
- Poor **personal hygiene**

5 key public health interventions to protect consumer health.

- **Demonstration of knowledge** (PC QI and ServeSafe)
- **Employee health** controls
- Controlling **hands as a vehicle of contamination**
- **Time and temperature parameters** for controlling pathogens
- The **consumer advisory**



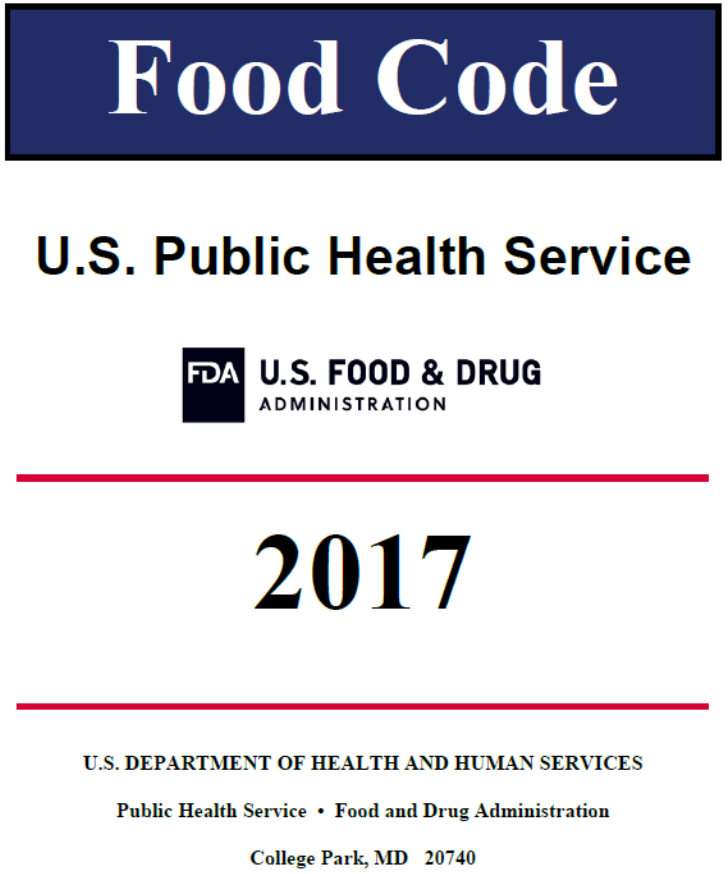
FDA Food Code

Content of the document

- CHAPTER 1: PURPOSE AND DEFINITIONS
- CHAPTER 2: MANAGEMENT AND PERSONNEL
- CHAPTER 3: FOOD
- CHAPTER 4: EQUIPMENT, UTENSILS, AND LINENS
- CHAPTER 5: WATER, PLUMBING, AND WASTE
- CHAPTER 6: PHYSICAL FACILITIES
- CHAPTER 7: POISONOUS OR TOXIC MATERIALS
- CHAPTER 8: COMPLIANCE AND ENFORCEMENT

Applying for Variance: Variance Committee if Food Code Requirement is not met:

"Variance" *means a written document issued by the REGULATORY AUTHORITY that authorizes a modification or waiver of one or more requirements of this Code if, in the opinion of the REGULATORY AUTHORITY, a health HAZARD or nuisance will not result from the modification or waiver.*

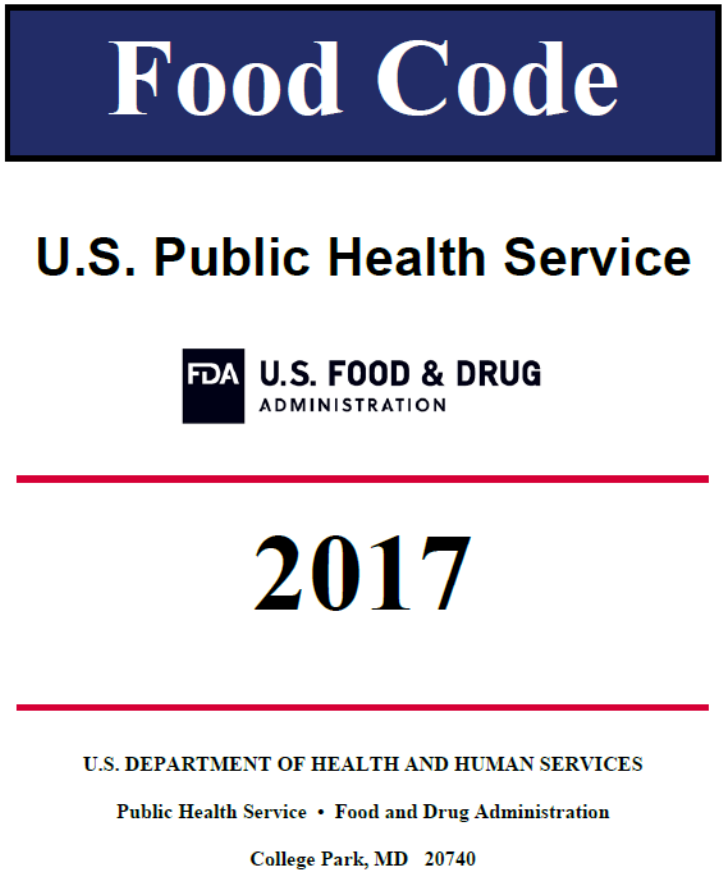


FDA Food Code

CHAPTER 3: FOOD

- **8 sections discussed in Food Chapter:**
- **Characteristics**
- Sources, specifications, and original containers and records (**standards of identity**)
- **Protection from contamination** after receiving (**storage**)
- **Destruction of organisms** of public health concern
- **Limitation of growth** of organisms of public health concern
- Food **Identity, presentation, and on-premises labeling**
- **Contaminated foods**
- **Special requirements for highly susceptible populations**

We discuss two sections briefly in class…



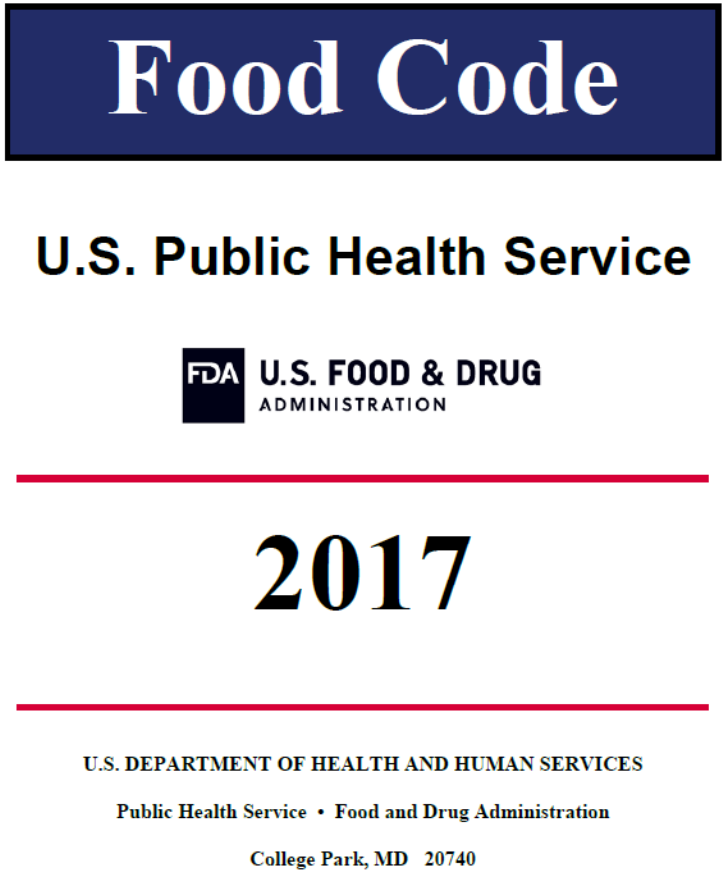
FDA Food Code

CHAPTER 3: FOOD

Destruction of organisms of public health concern

Destruction of organisms of public health concern

- 3-401 Cooking
- 3-402 Freezing
- 3-403 Reheating
- 3-404 Other Methods



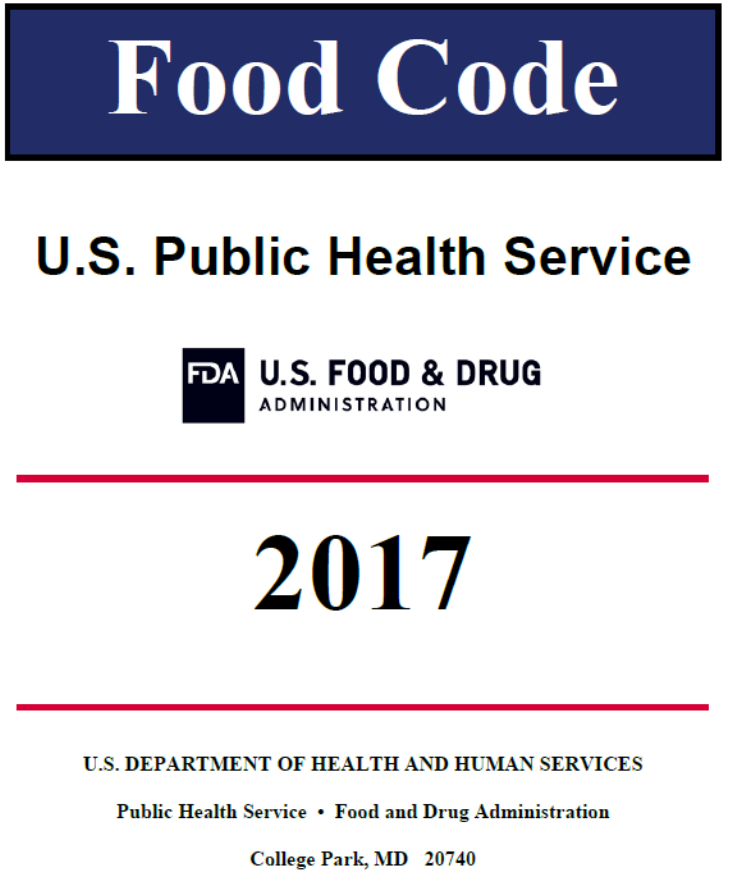
FDA Food Code

CHAPTER 3: FOOD

Destruction of organisms of public health concern

Destruction of organisms of public health concern: 3-401 Cooking

- ***(1) 63°C (145°F) or above for 15 seconds*** *for:*
- *(a)* ***Raw EGGS*** *that are broken and prepared in response to a CONSUMER'S order and for immediate service,* [P] *and*
- *(b) Except as specified under Subparagraphs (A)(2) and (A)(3) and ¶ (B), and in ¶ (C) of this section,* ***FISH and INTACT MEAT including GAME ANIMALS*** *commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1) and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2);* [P]
- ***(2) 68°C (155°F) for 17 seconds*** *or the temperature specified in the following chart that corresponds to the holding time for* ***RATITES, MECHANICALLY TENDERIZED, and INJECTED MEATS****; the following if they are COMMINUTED: FISH, MEAT, GAME ANIMALS commercially raised for FOOD as specified under Subparagraph 3-201.17(A)(1), and GAME ANIMALS under a voluntary inspection program as specified under Subparagraph 3-201.17(A)(2); and raw EGGS that are not prepared as specified under Subparagraph (A)(1)(a) of this section: [about 75% meat from carcass in sold as nonintact meat, terndloin, T-bone, ribeye, New York strip etc.] [Sterility of center]*
- ***(3) 74°C (165°F) or above for < 1 second*** *(instantaneous) for* ***POULTRY, BALUTS, wild GAME ANIMALS*** *as specified under Subparagraphs 3-201.17(A)(3) and (4), stuffed FISH, stuffed MEAT, stuffed pasta, stuffed POULTRY, stuffed RATITES, or stuffing*
- *(B) Whole* ***MEAT roasts*** *including beef, corned beef, lamb, pork, and cured pork roasts such as ham shall be cooked:*

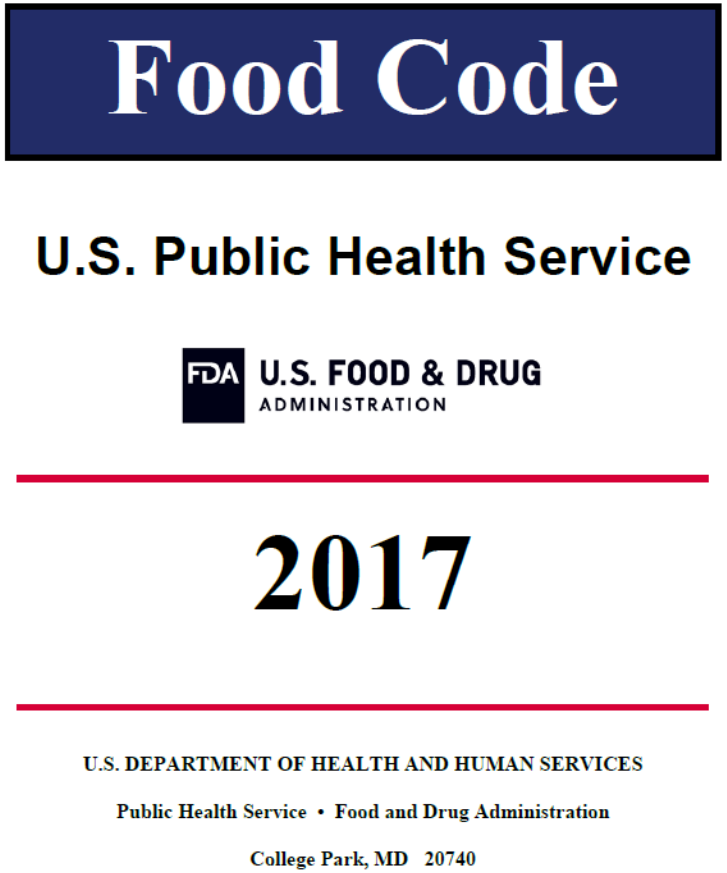


FDA Food Code

CHAPTER 3: FOOD

Destruction of organisms of public health concern

- **Destruction of organisms of public health concern**: 3-402 Freezing
- ***3-402.11 Parasite Destruction.***
- *(A) Except as specified in ¶ (B) of this section, before service or sale in **READY-TO-EAT form, raw, raw-marinated, partially cooked, or marinated-partially cooked FISH shall** be:*
- *(1) **Frozen and stored at a temperature of -20°C** (-4°F) or below for a minimum of **168 hours (7 days)** in a freezer;* [P]
- *(2) **Frozen at -35°C (-31°F) or below** until solid and stored at -35°C (-31°F) or below for a minimum of **15 hours**;* [P] *or*
- *(3) **Frozen at -35°C (-31°F) or below until solid** and **stored at -20°C** (-4°F) or below for a minimum of **24 hours**.* [P]



FDA Food Code

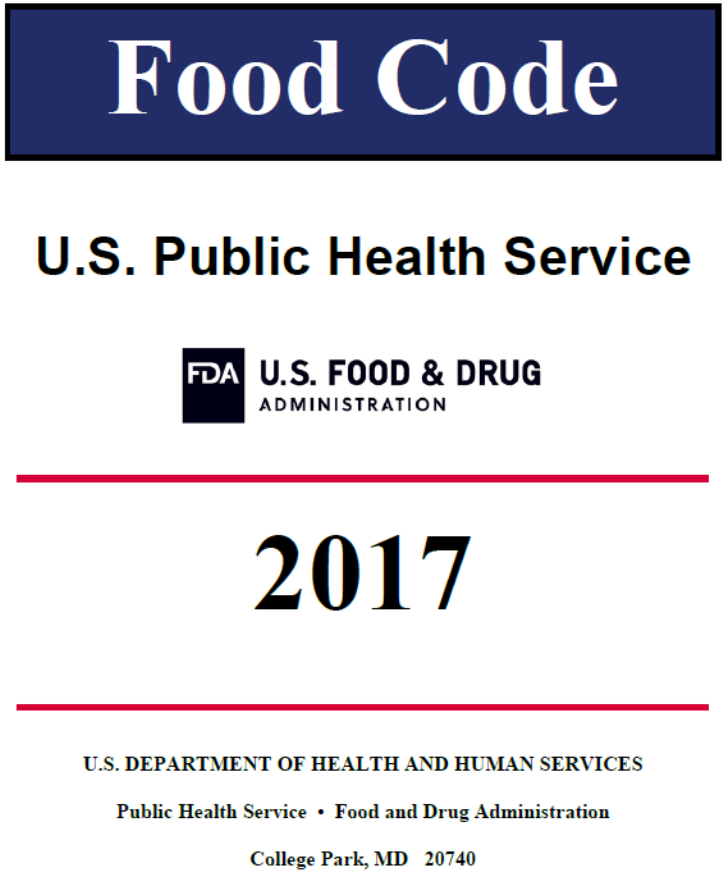
CHAPTER 3: FOOD

Destruction of organisms of public health concern

- ***Destruction of organisms of public health concern***:
- **3-403 Reheating**

- (A) Except as specified under ¶¶ (B) and (C) and in ¶ (E) of this section, **TIME/TEMPERATURE CONTROL FOR SAFETY FOOD** that is **cooked, cooled**, and reheated for hot holding shall be reheated so that all parts of the FOOD reach **a temperature of at least 74°C (165°F) for 15 seconds**.

- (C)**READY-TO-EAT TIME/TEMPERATURE** CONTROL FOR SAFETY FOOD that has been commercially processed and PACKAGED in a FOOD PROCESSING PLANT that is inspected by the REGULATORY AUTHORITY that has jurisdiction over the plant, shall be heated to a temperature of **at least 57°C (135°F) when being reheated for hot holding**.

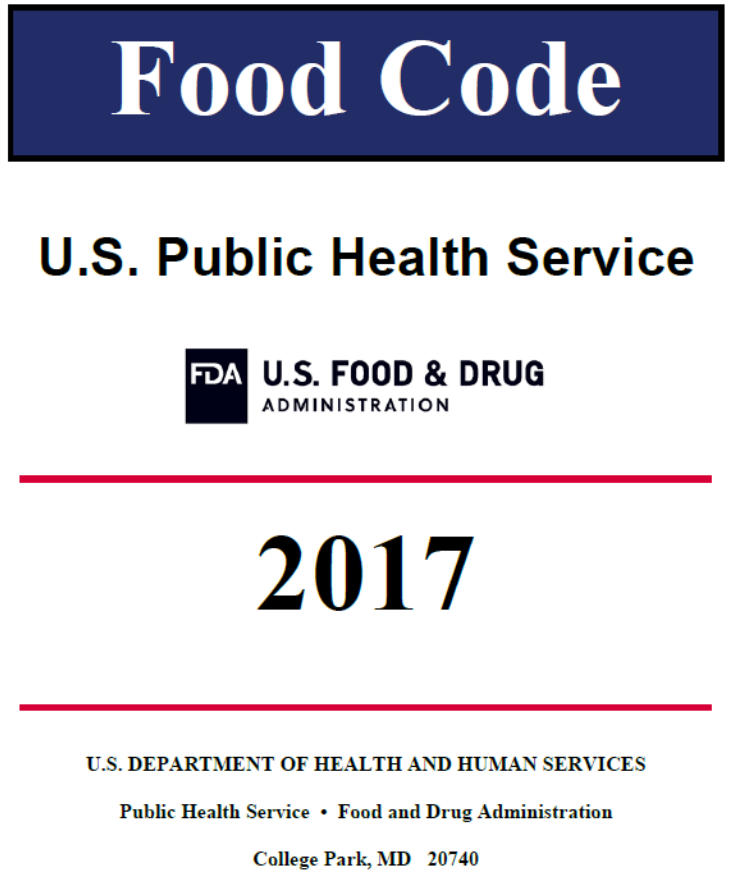


FDA Food Code

CHAPTER 3: FOOD

- **Special requirements for highly susceptible populations**

- *(A) The following criteria apply to **JUICE:***
- *(1) For the purposes of this paragraph only, **children who are age 9** or less and receive FOOD in a school, day care setting, or similar facility that provides custodial care are included as HIGHLY SUSCEPTIBLE POPULATIONS;*
- *(3) **UnPACKAGED JUICE** that is prepared on the premises for service or sale in a **READY-TO-EAT form** shall be **processed under a HACCP PLAN** that contains the information specified under §8-201.14 (C) -(E) and as specified in 21 CFR Part 120 – Hazard Analysis and Critical Control Point (HACCP) Systems, Subpart B Pathogen Reduction, 120.24 Process controls.* [P]
- *(B) **Pasteurized EGGS or EGG PRODUCTS shall be substituted for raw EGGS** in the preparation of:*
-
- *(C) The following **FOODS may not be served** or offered for sale in a READY-TO-EAT form:* [P]
- *(1) Raw animal FOODS such as **raw FISH, raw-marinated FISH, raw MOLLUSCAN SHELLFISH**, and **steak tartare**,* [P]
- *(2) **A partially cooked animal FOOD** such as lightly cooked FISH, rare MEAT, soft-cooked EGGS that are made from raw EGGS, and meringue; and*
- *(3) **Raw seed sprouts**.* [P]
- *(D) **FOOD EMPLOYEES may not contact READY-TO-EAT FOOD** as specified under ¶¶ 3-301.11(B) and (E).*[P]



Exercise 2

- **What is the burden of foodborne pathogens and what is the reason for major changes in food safety trends since 1970s?**
- **What are current significant foodborne pathogens?**
- **According to FDA food Code what are the 5 major risk factors for food safety and what are the 5 recommended public health interventions?**
- **What is a variance and what is a variance committee?**
- **Please name three approved time and temperature combinations associated with thermal processing of food according to food code.**
- **Please name three approved time and temperature combinations associated with freezing of food to inactivate parasites according to food code.**

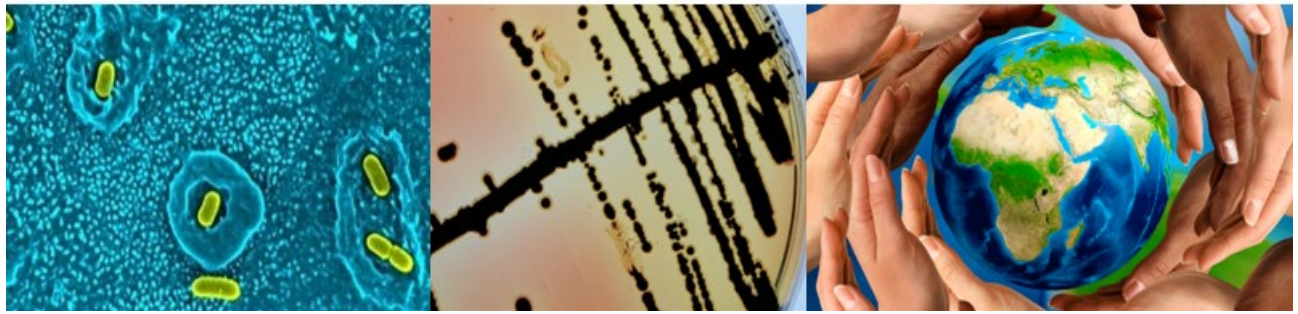
Exercise 3

- ***Exercise 3***
- Please answer the below questions after reading the news release of Food and Drug Administration (November 1, 2018) entitle "*Statement from FDA Commissioner Scott Gottlieb, M.D., on findings from the romaine lettuce E. coli O157:H7 outbreak investigation and FDA's efforts to prevent future outbreaks*"

- **What was the causative agent for the outbreak?**
- **What was the product involved in the outbreak?**
- **What was the potential source of contamination?**
- **What is the main challenge for investigating leafy greens outbreaks?**
- **What is the FDA response to prevent similar events in future?**

Please read the brief article "Two California food companies warned over violations (November 2, 2020)"

- **What was the violation in the food companies?**



Summary of:
Produce Safety Rule of Food Safety Modernization Act

Based on Curriculum of Produce Safety Alliance

Food Safety Modernization Act
Produce Rule

FSMA was signed into law on **January, 2011**

Regulations were supposed to be finalized within one to two years of enactment (roughly **January 2012 and January 2013**)

Revised implementation dates: (all drafts are currently publically available)

- **Preventative controls**: FSMA §103(a) and(c): August 30, 2015
- **Foreign supplier verification program**: FSMA §301(a): October 31, 2015
- **Accreditation of third party auditors**: FSMA §307): October 31, 2015
- **Produce safety Rule:** FSMA §105(a): October 31, 2015
- **Sanitary transportation practices for food and feed**: FSMA §111: March 31, 2016
- **Intentional adulteration of food**: FSMA §106(b): May 31, 2016.

Produce and Preventive Rules and Land-grant Institutions

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (**Produce Rule**): **Producers**
- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (**Preventive Rule**): **Processors**

- Large producers and processors
- Small and medium size producers and processors
- Very small (hobbyists) producers and processors (local and cottage industry)

- Many of small and medium size entrepreneur will require assistance from the nations 75 land-grant institution for **safe and economical access to market**.

Produce Rule: Overview

- Regulate "**farms**," and "**farm-type facilities**"
- Emphasizes on regulating fruits or vegetable to be consumed raw (**high risk produce**) *e.g. berries, celeries, most leafy greens, tomatoes, peppers, etc.*
- Certain vegetables and fruit (**low risk produce**) are except, those requiring preparation as "kill step," before consumption *e.g. pumpkins, potatoes, squash, green beans etc.*
- **Sprouts** are subjected to "special rule," requiring seed treatment, and a frequent pathogen testing
- Low and high risk categories have been subject of criticism, and had been a moving target throughout the revisions.

Requirements of Produce Rule

- Worker's training (similar to HACCP pre-requisite program, supervisor and workers)
- Health and hygiene training (similar to HACCP GMP's)
- Agricultural water (monthly test of sub-surface and weekly test of surface water; treatment and monitoring of water source)
- Biological soil amendment of animal origin (treatment, no visible contamination, harvest time)
- Domesticated and wild animals (waiting period for grazing during harvest time, required fence)
- Equipment, tools, buildings, and facilities (storage, pathogens, and extensive documentation)
- Sprout rule (seed treatment and enhanced pathogen testing for irrigation water)

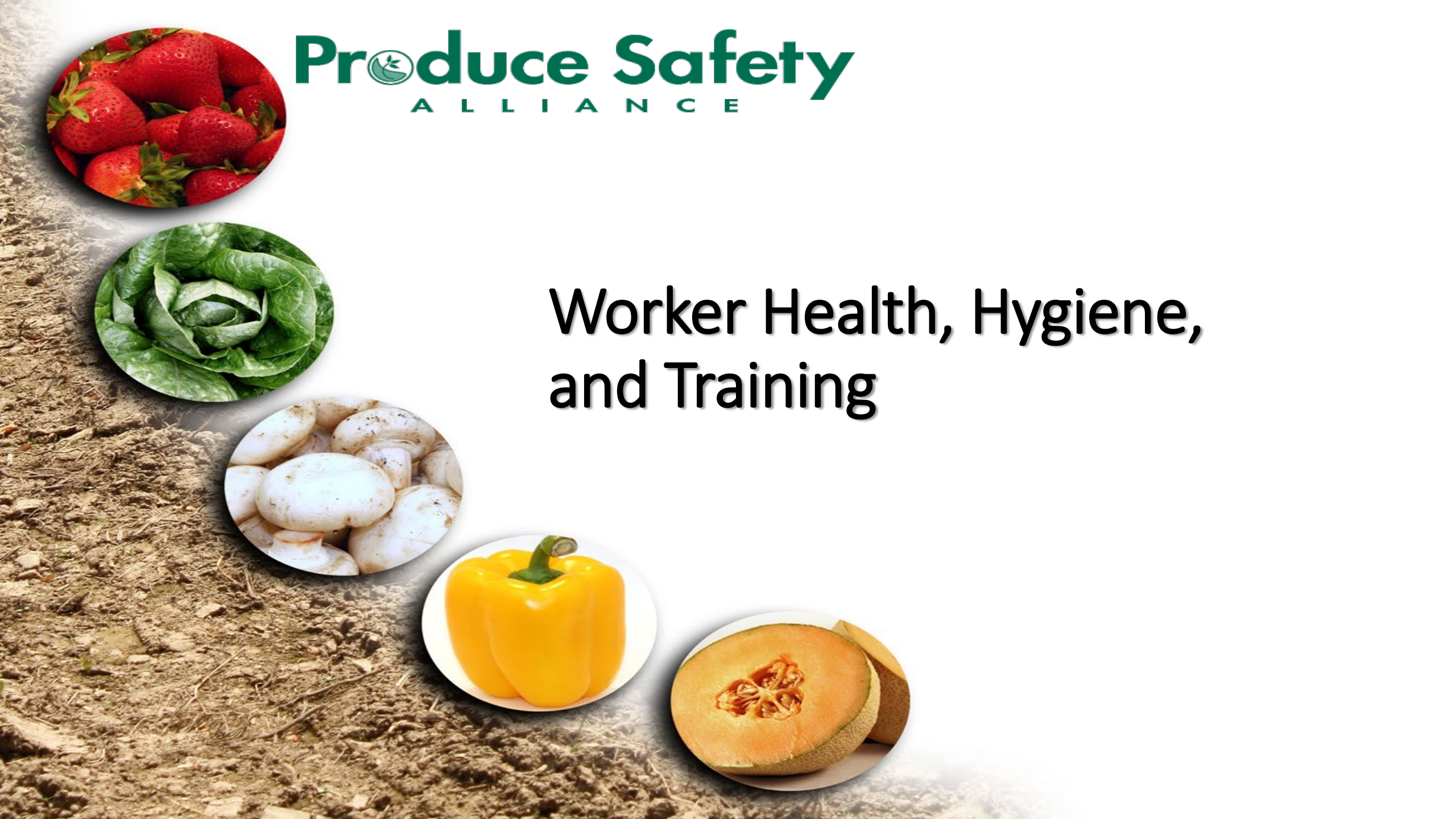
Produce Rule: Implementation and compliance dates

- **Implementation date:** October 31, 2015
- **Compliance date:**
  - Very small farms ($25*k and below): Exempt
  - Small farms ($25k-250K): 4 years
  - Medium farms ($250-500K): 3 years
  - Large farms ($500k and above): 2 years

Water testing requirements will be effective after additional 2 years.

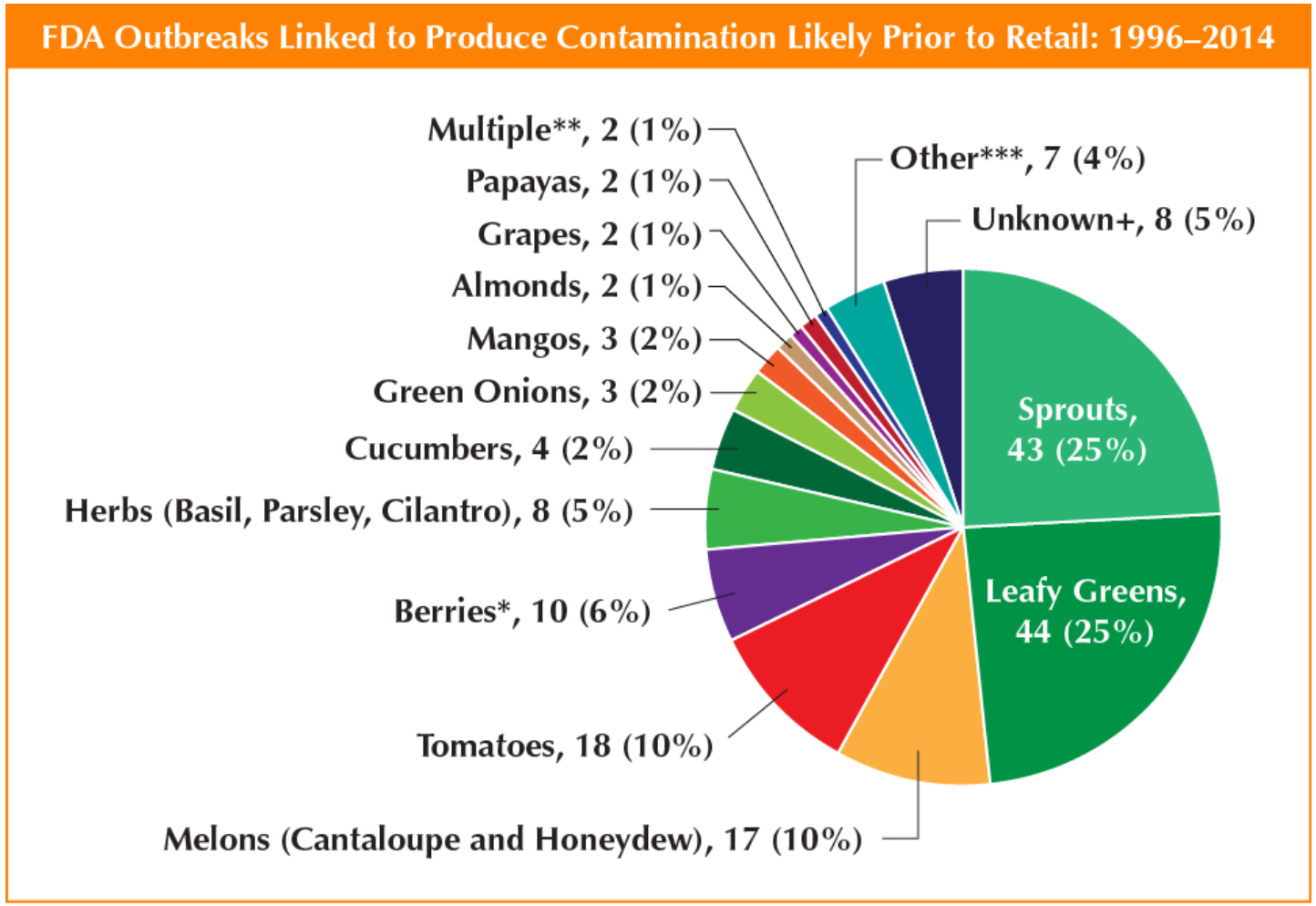
Effective dates are 60 days after implementation dates

***three-year average revenue**; *categories are no longer based on number of employee*, the categories differ in preventive and produce rules.



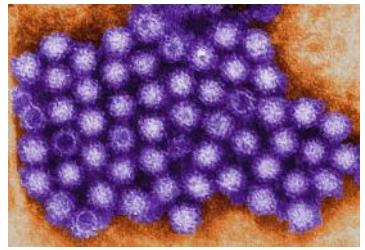
Worker Health, Hygiene, and Training

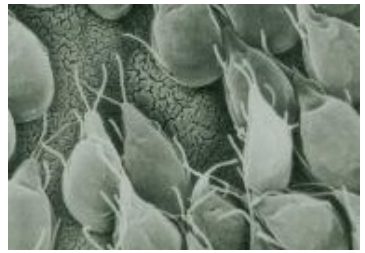
Outbreaks Associated with Produce

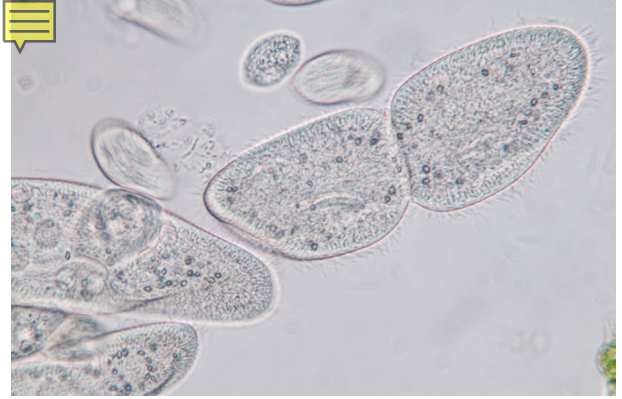


Microorganisms of Concern in Fresh Produce

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



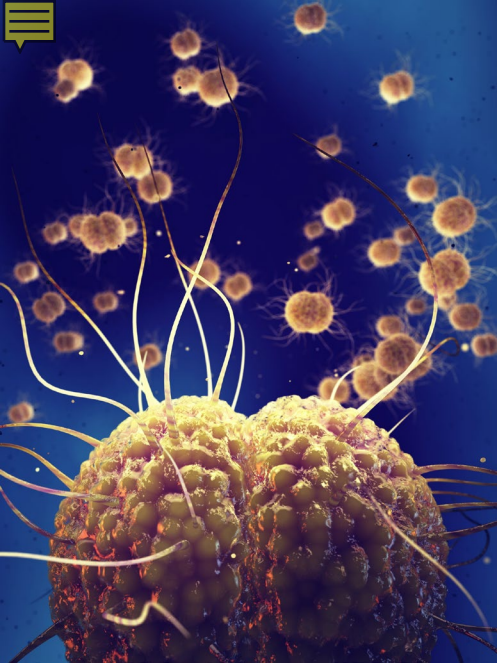




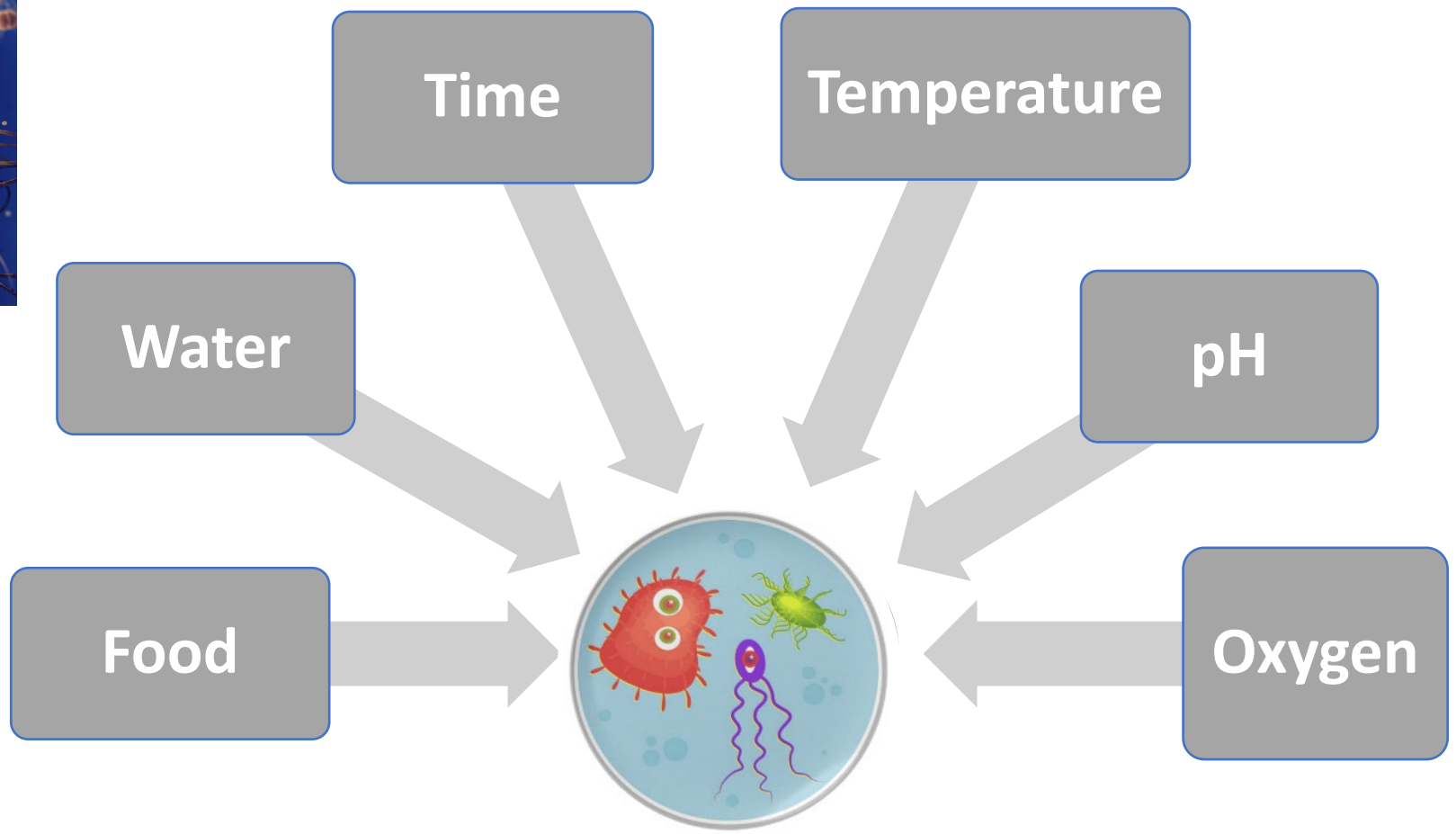
Bacteria

- 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**

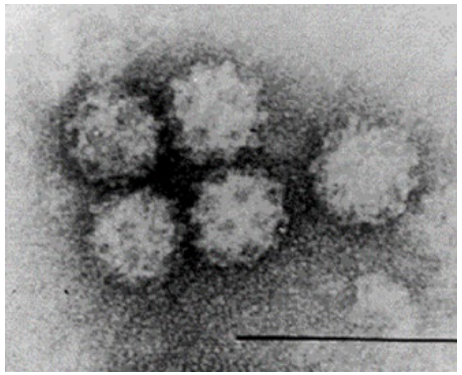
Time	# of Bacteria
20 min	2
40 min	4
1 hour	8
80 min	16
100 min	32
2 hours	64
4 hours	4096
6 hours	262,144
8 hours	16,777,216



Conditions for Bacterial Growth



Viruses



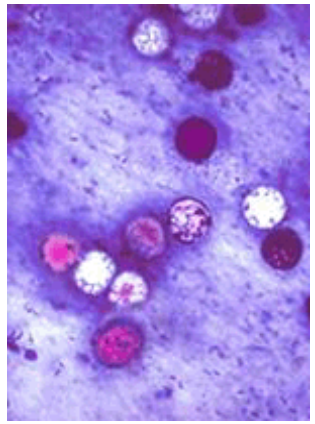
- **Viruses** are small particles that multiply **only in a host**, not in the environment or on produce
- Contamination most often linked to an **ill worker** handling fresh produce (**fecal-oral route**) or contaminated water
- **It only takes a few virus particles** to make someone ill
- Can be **very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

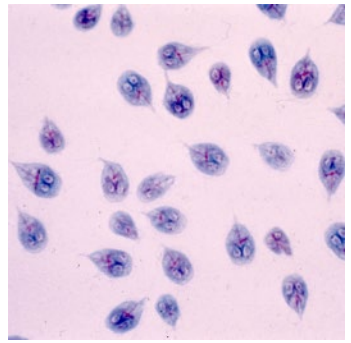
coxsackievirus

NoroCORE Food Virology
Collaborative for Outreach, Research & Education

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 (**very long incubation period**)
- Giardia, *Toxoplasma gondii* (often carried by cat): Pregnancy





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).

Contamination Sources

Humans

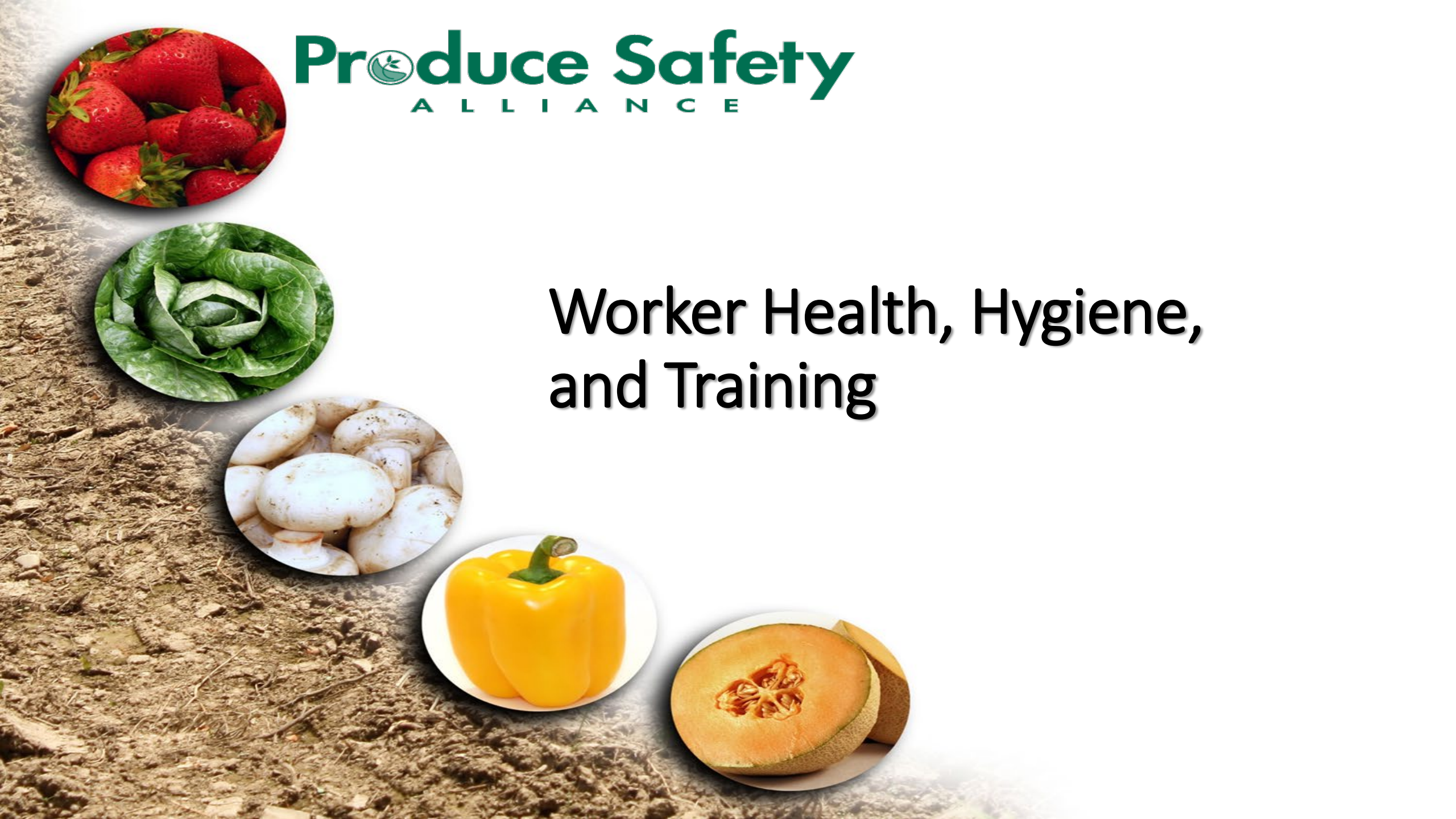
Soil

Produce

Animals

Buildings
Equipment
Tools

Water



Worker Health, Hygiene, and Training

Workers Are A Food Safety Concern Because They…

- **Can <u>carry</u> 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

Clothing

Hands

Footwear

Tools & Equipment

Illness & Injury

Importance of Training Workers

- Fresh **fruits and vegetables** often receive **no additional processing** (such as cooking), so **contamination with a pathogen can result in illness when the produce is consumed.**
- Workers need to use **food safety practices every day** to reduce produce safety risks
- Food safety practices are learned so **training is key to successful** implementation
- *PSR of FSMA, **mandates** workers safety, **GAP** was **recommendation** .*

Soil Amendments

What Is A Soil Amendment?

- **Soil amendments** are any **chemical, biological, or physical materials** intentionally added to the soil **to improve and support plant growth** and development
- May reduce **soil erosion** and **sediment runoff**
- Many different types of soil amendments are available
- **Soil amendments can present produce safety risks**
- Assessing risks and implementing GAPs can reduce risks

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

§

Assessing the 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 & Biosolids

- 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 (International travelers?)

§

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

§

Pathogens in Animal Manure

- All **manures can carry human pathogens**
- Some **animals tend to be reservoirs** for certain pathogens (*STEC in Cattle, Campylobacter is poultry*)
- Many things can affect animals shedding pathogens in their manure
  - Age
  - Husbandary practices
  - Diet
  - Season
  - Environmental conditions

Untreated Soil Amendments

- Untreated biological soil amendments of animal origin are **considered high risk** since they have not been treated to reduce or eliminate pathogens
- All of the **following soil amendments** would be considered **untreated**:
  - **Raw manure**
  - **'Aged' or 'stacked' manure**
  - **Untreated manure slurries**
  - **Untreated manure teas**
  - Agricultural teas with supplemental microbial nutrients
  - Any soil amendment mixed with raw manure

§

Reducing Soil Amendment Risks

- Selection
- Treatment
- Application Timing
- Application Methods
- Handling and Storage
- Recordkeeping

Composting as a Treatment

- Composting is a **controlled biological process** that decomposes organic matter and reduces pathogens
- Temperature is the primary method of pathogen reduction for **thermophilic composting**; however, chemical and biological factors also contribute
- Only a composting process that has been scientifically validated ensures pathogen reduction
- Process monitoring and recordkeeping are critical to ensuring the compost is adequately treated

§

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, controlled composting processes

Wildlife, Domesticated Animals, and 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

BIRD•B•GONE® Inc.

§

Co-Management: Striking a Balance

- Farmers must address **food safety requirements**, but should keep the c**onservation 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**

Agricultural Water

Two Sections on Water

- **Part I: Production Water**
  - Water used in contact with produce **during growth**
  - Irrigation, fertigation, foliar sprays, frost protection

- **Part II: Postharvest Water**
  - Water used during or after harvest

Probability of Contamination

Public Water Supply

Treated

Ground Water

Surface Water

Open to Environment

Requirements for Public Water Sources

Source	Testing Requirement
Public Water Supply	Copy of test results or current certificates of compliance

- With appropriate documentation, there is no requirement to test water that meets the requirements for public water supplies.

§

Microbial Water Quality Profile: Survey of Ground Water Sources

Source	Initial and Annual Testing Requirement
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

§

Microbial Water Quality Profile: Survey of Surface Water Sources

Source	Initial and Annual Testing Requirement
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

§

Evaluating Water Quality: Use of Microbial Water Quality Profiles

- **Testing** is the only way to quantitatively evaluate the **microbial quality** of the water
- The **water quality profile** can help you:
  - 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

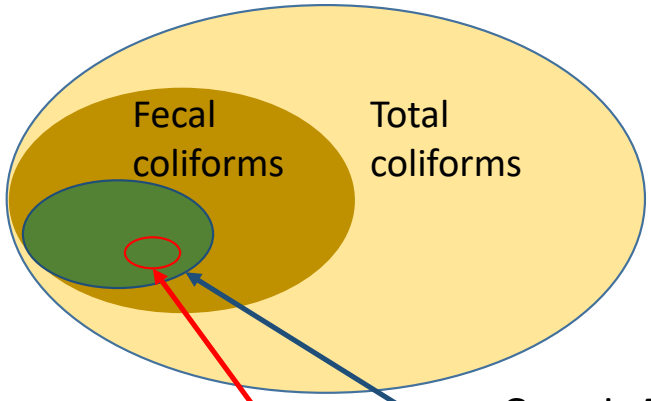
§

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

The Coliform Group of Bacteria

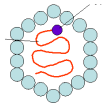
Other pathogens that may be present when feces is present



Pathogenic *E. coli*
Found in some feces

Generic *E. coli*
Bacteria found mostly in feces

Salmonella
A different bacteria



Hepatitis A
A virus

Cryptosporidium
A protozoan

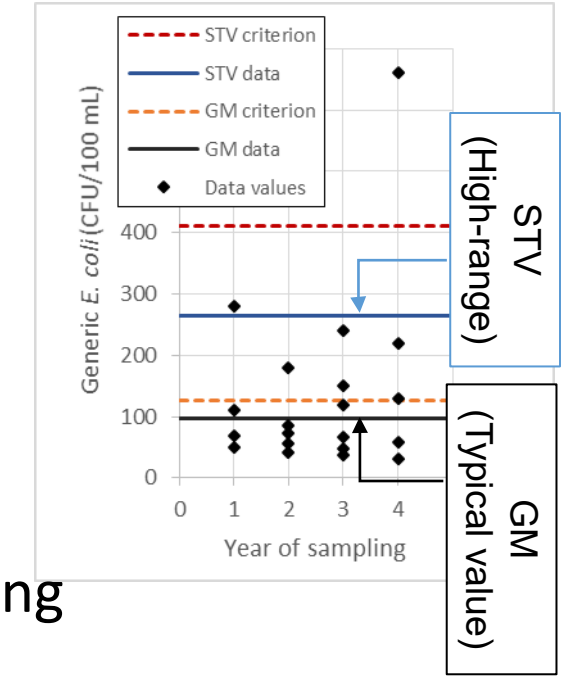
***Coliform*, a laboratory term for typically the these genera:**

- *Citrobacter*
- *Enterobacter*
- *Klebsiella*
- *Escherichia*

§

Geometric Means and Statistical Threshold Values

- Test results must be used to calculate **Geometric Means** and **Statistical Threshold Values** to compare to water quality criteria in the FSMA Produce Safety Rule
  - The **geometric mean (GM)** is a log-scale average, the "typical" value
  - The **statistical threshold value** (STV) is a measure of variability, the estimated "high range" value (approximated 90th percentile)
  - In the image to the right, both the GM and the STV values for the data meet criteria
- Tools will be available to assist in calculating these values



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Corrective Measures

- **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

§

Microbial Water Quality Profile:
Surface Water

START:
Establish initial water quality profile
At least 20 samples over 2-4 years

ANNUALLY AFTER START:
Collect at least 5 samples for analysis
Insert annual data into rolling data set

IF YOUR WATER CHANGES:
If the water quality profile no longer represents the quality of the water source, establish a new profile

IF YOUR PROFILE DOES NOT MEET GM OR STV CRITERIA:
As soon as practicable and no later than the following year, discontinue use of the water unless an allowed corrective measure is applied

ALLOWED CORRECTIVE MEASURES:
1. Apply a time interval to allow die-off (before harvest or end of storage) or removal
2. Re-inspect the water system, identify problems, and make necessary changes
3. Treat the water

§

Microbial Water Quality Profile:
Ground Water

START:
Establish initial water quality profile
At least **4 samples over 1 year**

ANNUALLY AFTER START:
Collect at least **1 sample** for analysis
Insert annual data into rolling data set

IF YOUR WATER CHANGES:
If the water quality profile no longer represents the quality of the water source, establish a new profile

IF YOUR PROFILE DOES NOT MEET GM OR STV CRITERIA:
As soon as practicable and no later than the following year, discontinue use of the water unless an allowed corrective measure is applied

ALLOWED CORRECTIVE MEASURES:
1. Apply a time interval to allow die-off (before harvest or end of storage) or removal
2. Re-inspect the water system, identify problems, and make necessary changes
3. Treat the water

§

Postharvest Water

Cornell University

Background on Infiltration Risk for Susceptible Produce

- **Infiltration (internalization)** can increase with deeper submersion and longer contact time
- **Wounded or bruised fruit** can have a greater risk of infiltration
- Infiltration risks can be higher when the **produce is warmer** than the tank water

Photo shows colored dye from water moving into produce pulp due to infiltration.

Water Safety Study

microorganisms

MDPI

Article

Fate and Biofilm Formation of Wild-Type and Pressure-Stressed Pathogens of Public Health Concern in Surface Water and on Abiotic Surfaces

Md Niamul Kabir [1], Sadiye Aras [1], Sabrina Wadood [1], Shahid Chowdhury [1] and Aliyar Cyrus Fouladkhah [1,2,*]

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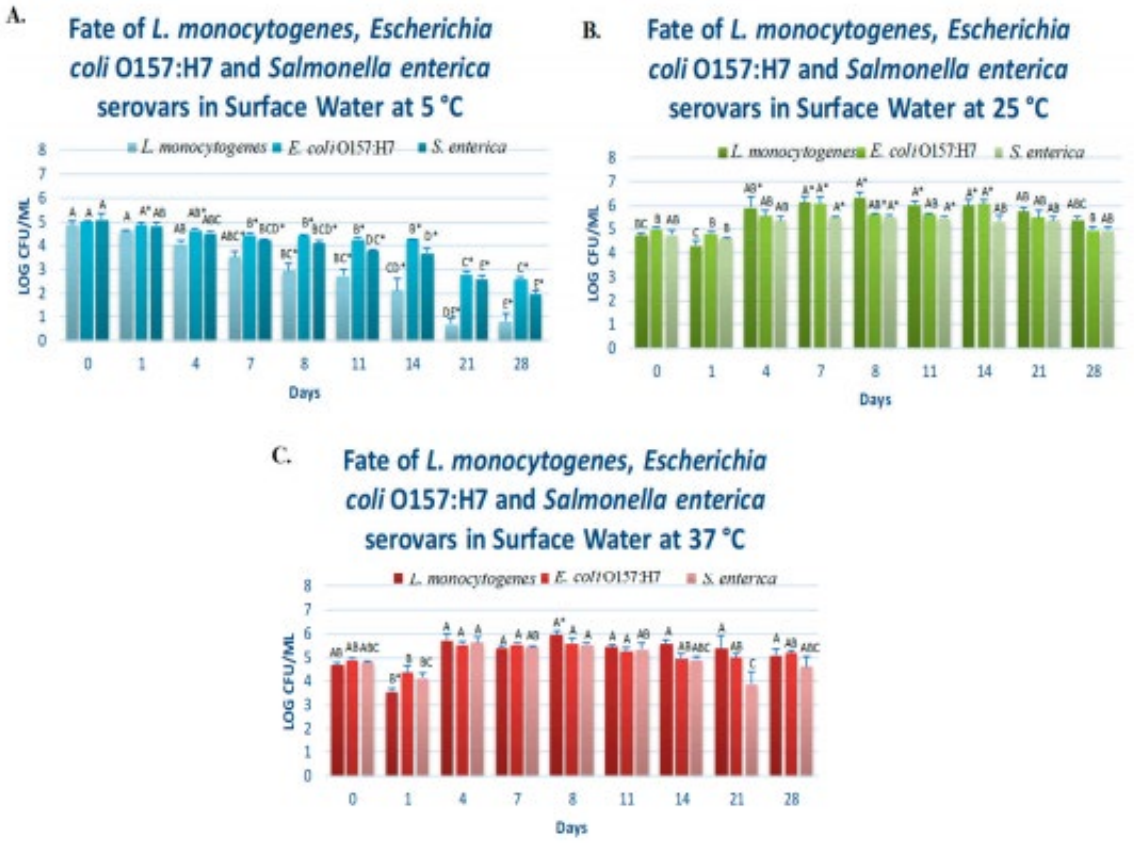
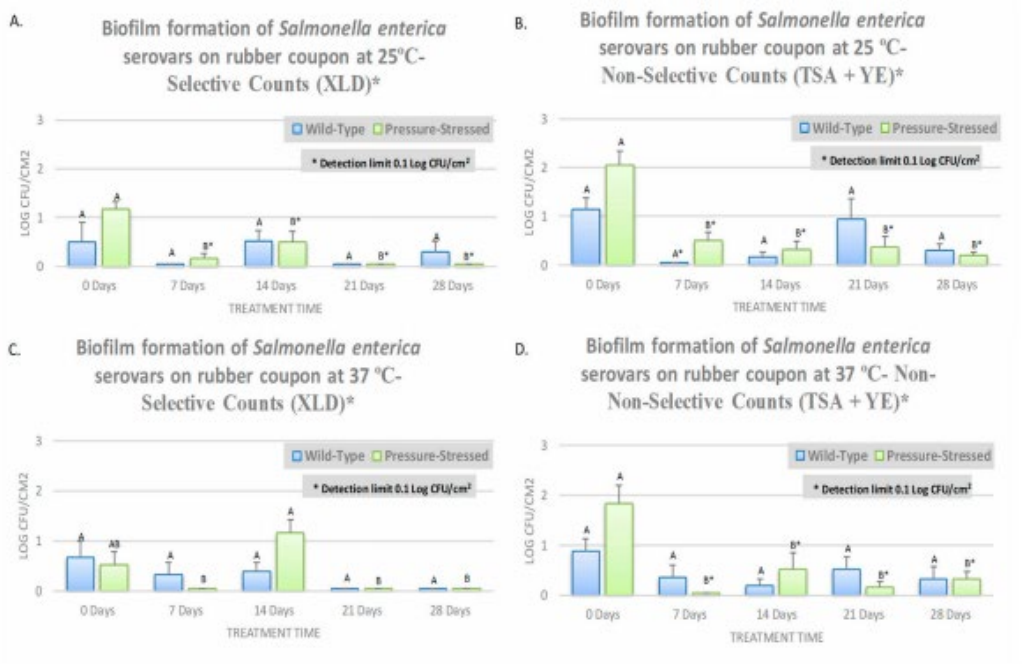
Public Health Burden of Waterborne Disease

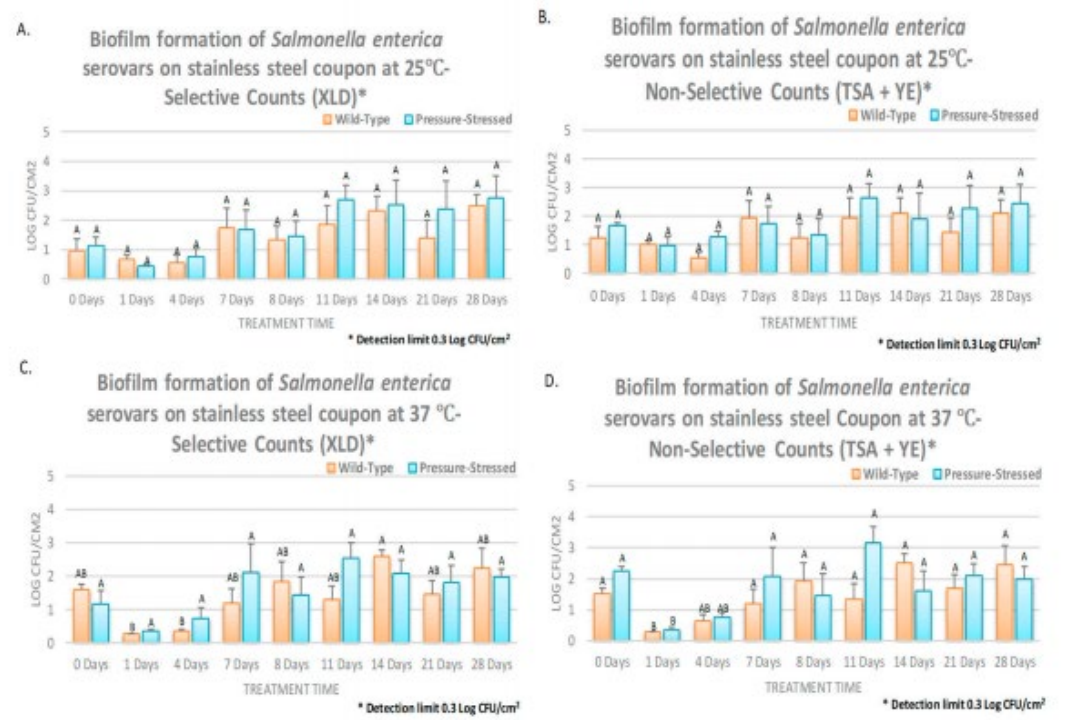
17 waterborne pathogens cause estimated: (Collier et al., 2021)

601,000 **illness**; 118,000 **hospitalization**; 6,630 **deaths**, and cost the economy up to $ 8.77 **billions.**



Water Safety Study-
Biofilm Formation on Abiotic Surfaces





Key Water Quality Variables

- **Quality at start of use**
  - No detectable generic *E.coli* in 100 mL of sample
- **pH**
  - Can impact the effectiveness of antimicrobial treatments
- **Temperature**
  - Must be monitored to minimize potential for infiltration
- **Turbidity**
  - Can be used to manage water change schedule

§

Choosing an Antimicrobial Product, Including Sanitizers

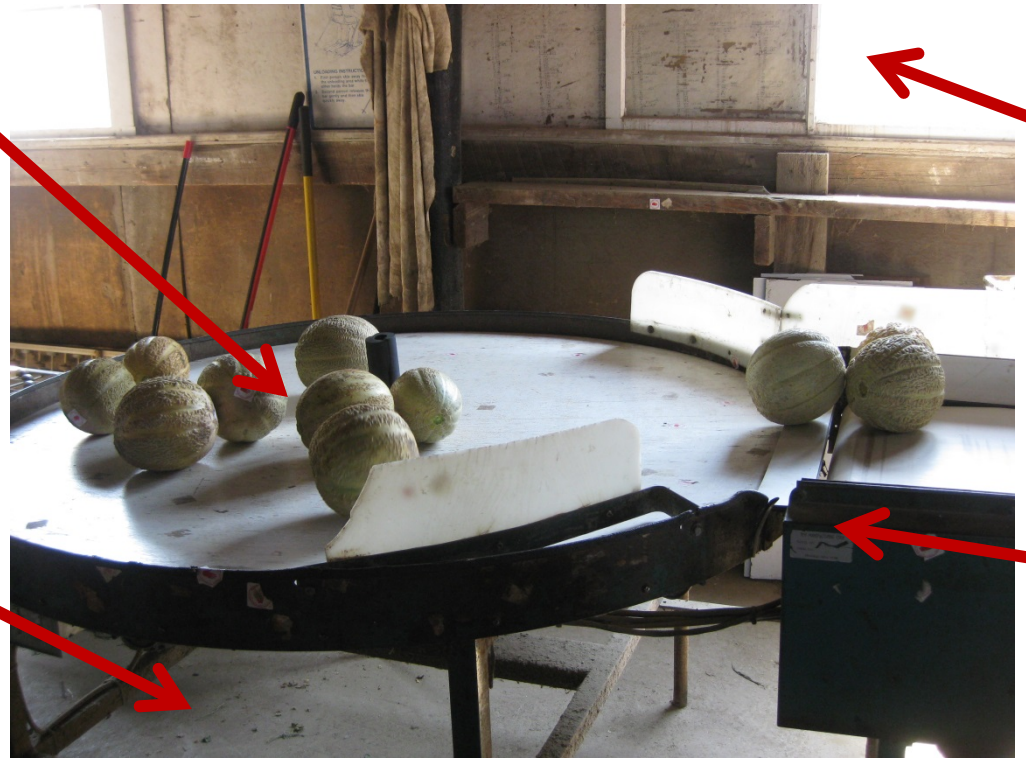
- **Chlorine sanitizers** are commonly used
  - Affordable and available
  - Corrosive, highly reactive
- **Many non-chlorine chemical** options
  - Ozone, peroxyacetic acid, hydrogen peroxide, etc.
- **Organic formulations** are available
  - Tsunami, Spectrum, Sanidate, VigorOx 15 F&V, etc.
  - Check with organic certifier
- **Must be labeled for use on produce**

Produce Safety
ALLIANCE

Postharvest Handling & Sanitation

Zones in the Packinghouse

Help prioritize cleaning and sanitation efforts by designating areas or ‘zones’ within the packing area.



Zone 1
(direct food contact surface)

Zone 4
(outside)

Zone 3
(floor)

Zone 2
(outside surface of washer)

Are Microbial Risks the Only Ones?

- Most of the contamination of fresh produce is caused by **microorganisms**
  - e.g., *E. coli* O157:H7, *Salmonella*, *Listeria monocytogenes*
- BUT, there are two other types of contamination issues to consider
  - **Chemical risks**
  - **Physical risks**

Chemical Food Safety Risks

- **Chemical hazards** include **pesticides, detergents, sanitizers**, and other chemicals used on the farm
- To reduce chemical food safety risks:
  - Keep **chemicals locked and stored** in an area away from produce packing and storage areas
  - **Train workers** and develop detailed SOPs for them to follow
  - **Keep SDS** on site in case of an emergency
  - Use only food grade lubricants, oils, and chemicals **according to their labeled** use
  - Use **non-reactive materials** that will not leach into produce

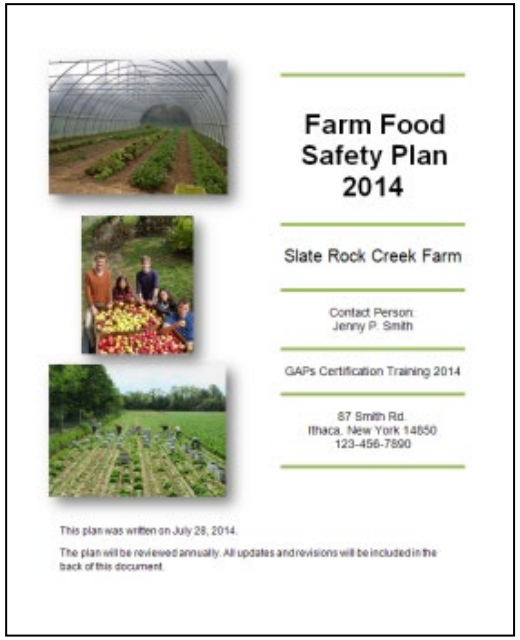
Produce Safety
ALLIANCE

How to Develop A Farm Food Safety Plan

Reasons for a Farm Food Safety Plan

The FSMA Produce Safety Rule does NOT require a written Farm Food Safety Plan. However,…

1. **Gets you organized and focused on food safety**
   - **Describes risks** you have identified and actions to address those risks
   - **Defines your practices, policies, and SOPs**
   - Efficient and effective use of your time and resources by prioritizing most important risk reduction steps
2. **Best way to be prepared!**
   - **Buyer questions/requirements**
   - *Third party audits*
   - *Food safety regulations*



Step 1: Assessing Risks

- **Review all farm operations** to identify practices that contribute to or increase produce safety risks
- Review the **farm environment** and adjacent land
- Focus on microbial, chemical, and physical risks
- Identify **risks that are most likely to occur**, noting the ones that could happen often
  - Because time and money are limited, prioritize which risks to address first

Step 2: Develop Practices to Reduce Risks

- **Develop practices that will reduce identified risks**
  - Use resources and ask for help if you are not sure!
- **Determined what resources are needed**
  - **Human resources (time and/or people)**
  - **Equipment or infrastructure** (may require changes/upgrades)
  - **Disposables** (hand soap, paper towels, etc.)
- **Create a list of tasks**/steps that need to be done
- **Designate a person**(s) to be in charge of each task

Step 3: Document and Revise

- **Write a plan to guide implementation** of practices
- **SOPs and policies will outline what needs to be done** for those who are responsible for completing the task
- **Build recordkeeping** into the logical flow of activities
- **Revise your plan** if it is not working or when practices change
- **Review and update your plan** at least annually, or whenever practices, personnel, or equipment changes

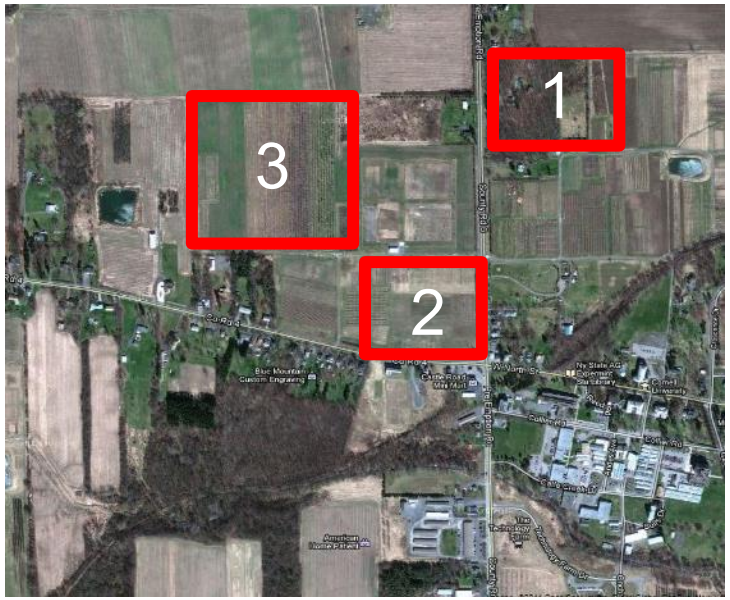
Final Steps

You have written your plan, your practices are in place, records are being kept, and delicious, high quality, safe produce is being grown and packed.

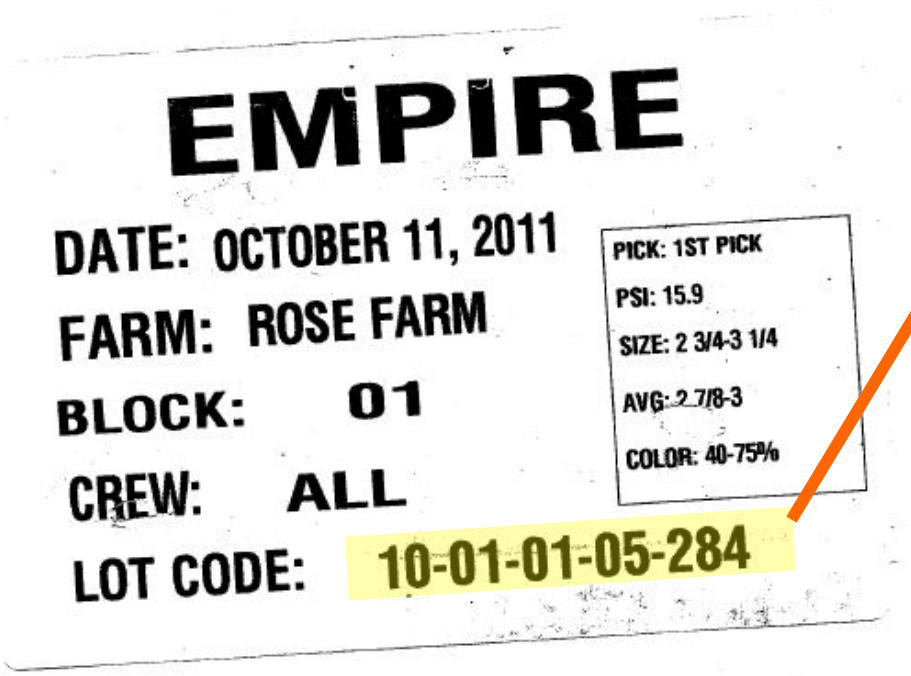
TRACEABILITY

Steps to Developing a Lot Code

- **To begin developing a lot code, growers should identify:**
  - **Field locations**
  - **Commodities and varieties grown**
  - A method for indicating **harvest and/or pack date**
  - **Harvest/packing crews**



Traceability Example



Farm Location: 10 (Rose Farm)
Block: 01
Fruit Type: 01 (Apples)
Variety: 05 (Empire)
Harvest Date: 284 (Julian date)

Exercise 4

- *In one paragraph, please explain why Produce Safety Rule of Food Safety Modernization Act is important.*
- *In your opinion, what component of the rule is most important and why?*
- *In your opinion, what component of the rule is most difficult to implement and why?*

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