Food safety: General principles for edible horticultural crops

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Outline
- Foodborne illnesses and outbreaks (estimates)
- Food safety hazards
- Outbreaks
- Routes of contamination
  - Processing/handling considerations
- Food Safety Modernization Act (FSMA)

U.S. foodborne illness

- CDC ESTIMATES
  - Major foodborne pathogens (31 organisms)
  - 9.4 million cases/year
  - 56,000 hospitalizations
  - 1,200 deaths
  - Unspecified illness
  - 20 to 61 million cases/year
  - Combined about 1 in 6 ill every year - most very mild but many severe

Reported outbreaks linked to FDA-regulated foods, by agent 1996-2009 (532 outbreaks)

Reported illnesses linked to FDA-regulated foods, by vehicle 1996-2009 (29,750 illnesses)
Types of produce associated with outbreaks, 1996-2009 (87)

- Tomatoes: 17.2%
- Melons: 16.1%
- Leafy greens: 32.2%
- Others: 6.9%
- Green onions: 10.3%
- Herbs: 10.3%
- Berries: 3.4%

Costs of foodborne illness

- Estimates: 50 to 80 billion/year
- Affected person:
  - loss of earnings and productivity
  - cost of medical treatment
  - cost of death
- National costs:
  - cost of investigation
  - medical costs - insurance

Chemical hazards

- Chemicals
  - Pesticides
  - Sanitizers
- Allergens
  - Undeclared ingredients
  - Cross contaminants
- Unapproved additives
- Mycotoxins
  - E.g., patulin

Examples of major mycotoxins

- Aflatoxin (corn, peanuts, figs, tree nuts)
- Patulin (apple juice)
- Fumonisin (corn)
- Ochratoxin (corn, cereals, coffee beans)

A food safety hazard

- Is a biological, chemical or physical property
- that is reasonably likely to cause injury or illness in the absence of its control

Chemical Hazards - Mycotoxins

- Toxins produced by fungi
  - Primarily Aspergillus spp., Penicillium spp., and Fusarium spp.
- Long-term chronic toxicity of concern
  - Can be carcinogenic
  - Influence immune response

Examples of major mycotoxins

- Aflatoxin (corn, peanuts, figs, tree nuts)
  - Aspergillus flavus, Aspergillus parasiticus
- Patulin (apple juice)
  - Penicillium expansum
- Fumonisin (corn)
  - Fusarium moniliforme
- Ochratoxin (corn, cereals, coffee beans)
  - Penicillium verrucosus, Aspergillus ochraceus
Preventing aflatoxin formation

- Pre-harvest
  - Resistant varieties (if practicable)
  - Crop rotation, irrigation
  - Insect management
  - Minimize damage during harvesting

- Post-harvest
  - Dry to <15% moisture
  - Facility with temperature-moisture control
  - Insect and pest management

Physical hazards

- Foreign objects capable of injuring the consumer
  - Glass
  - Wood
  - Stones
  - Hard plastic
  - Metal

Metal detection is a (the) Critical Control Point. (Difficult to screen other types of physical hazards)

Food Allergy

- Key components of food allergies:
  - An immunologic response to a food protein
  - (food intolerances usually related to carbohydrates)
  - Extremely small amounts may cause a reaction
  - Reactions can be severe and even life-threatening

Allergens

- The “big eight” (90% of allergies in U.S.)
  - Cow’s milk, peanuts, tree nuts, shellfish, egg, soybean, crustacea, fish, wheat

- Less common
  - Cottonseed, sesame seed, poppy seed, sunflower seed, other legumes, mollusks

- Biggest reason for “Class I” recalls
  - Non-declared allergens

- Control
  - Allergen management, labeling

https://farrp.unl.edu/allergencontrolfi
### Biological hazards
- If not controlled will cause illness
  - Bacteria (e.g., *Salmonella*), *Or* their toxins (e.g., *Clostridium botulinum* toxin)
  - Viruses (e.g., hepatitis A)
  - Parasites (e.g., protozoa)
    - *Cryptosporidium parvum*

### Multinational outbreaks

<table>
<thead>
<tr>
<th>Year</th>
<th>Pathogen</th>
<th>Cases</th>
<th>Regions</th>
<th>Food</th>
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</thead>
<tbody>
<tr>
<td>2014</td>
<td><em>L. monocytogenes</em></td>
<td>35</td>
<td>North America</td>
<td>Caramel apples</td>
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<tr>
<td>2013</td>
<td>Hepatitis A</td>
<td>1,444</td>
<td>Europe</td>
<td>Mixed berries</td>
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<tr>
<td>2011</td>
<td><em>E. coli</em> O104:H4</td>
<td>4,321</td>
<td>Europe, North America</td>
<td>Fenugreek sprouts</td>
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<tr>
<td>2008</td>
<td><em>Salmonella</em></td>
<td>1442</td>
<td>North America</td>
<td>Fresh peppers</td>
</tr>
<tr>
<td>2007</td>
<td><em>Salmonella</em></td>
<td>51</td>
<td>Europe, North America</td>
<td>Fresh basil</td>
</tr>
<tr>
<td>2007</td>
<td><em>Shigella</em></td>
<td>175</td>
<td>Australia, Europe</td>
<td>Alfalfa sprouts</td>
</tr>
<tr>
<td>2006</td>
<td><em>E. coli</em> O157:H7</td>
<td>206</td>
<td>North America</td>
<td>Fresh spinach</td>
</tr>
</tbody>
</table>

### 2011 *E. coli* O104:H4
- Outbreak centered in Northern Germany
  - As of June 14, 2011
    - 4,321 cases, >800 HUS (estimated >100 will need kidney transplants), >50 deaths (including otherwise healthy adults)
      - HUS = hemolytic uremic syndrome
  - 14 European countries, U.S., Canada
  - Linked to organic sprouts (imported fenugreek seed)

### 2014 listeriosis - caramel apples
- Commercially produced, prepackaged caramel apples
- Linked to single California packing facility
- 35 illnesses/7 deaths; 12 states; Manitoba

- Hypothesis:
  - Increased water activity and pH under caramel layer
  - Growth in microenvironment at interface

- Limitations of growth for *L. monocytogenes*
  - pH 4.4
  - *a*<sub>w</sub> of 0.92
## Multistate outbreaks

<table>
<thead>
<tr>
<th>Year</th>
<th>Pathogen</th>
<th>Cases</th>
<th>States</th>
<th>Food</th>
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</thead>
<tbody>
<tr>
<td>2014</td>
<td>Salmonella</td>
<td>275</td>
<td>29 + DC</td>
<td>Cucumbers</td>
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<tr>
<td>2014</td>
<td><em>E. coli</em> O121</td>
<td>19</td>
<td>6</td>
<td>Clover sprouts</td>
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<tr>
<td>2014</td>
<td>Salmonella</td>
<td>115</td>
<td>12</td>
<td>Bean sprouts</td>
</tr>
<tr>
<td>2011</td>
<td><em>L. monocytogenes</em></td>
<td>147</td>
<td>28</td>
<td>Cantaloupes</td>
</tr>
<tr>
<td>2010</td>
<td><em>E. coli</em> O145</td>
<td>26 (+7)</td>
<td>5</td>
<td>Lettuce</td>
</tr>
</tbody>
</table>

### Listeriosis from cantaloupe 2011

- Cantaloupe - whole melon
- First outbreak with this vehicle
- 147 people - 99% hospitalized
- Ages <1 (3 newborns) to 96 years, most over 60, median 77 years
- 33 deaths + 1miscarriage
- Most deadly outbreak in the U.S. in 100 years

### Listeria monocytogenes

- Matching isolates from
  - Melons, packing line, cold storage area
- Introduction of organism
  - Field, cull trucks
- Spread of organism
  - Facility had pooled water, floors difficult to clean, equipment difficult to clean, equipment previously used for another raw commodity
- Growth of organism
  - Wet melons placed into cold storage

### Listeriosis associated with stone fruit 2014

### Listeria is not a new issue for packinghouses

### Guidelines for Controlling *Listeria monocytogenes* in Small- to Medium-Scale Packing and Fresh-Cut Operations

[Guidelines link](http://anrcatalog.ucdavis.edu/pdf/8015.pdf)
Recurring pathogen and commodity combinations
- *Salmonella* Poona and *Salmonella Anatum*
- Cantaloupes
- *E. coli* O157:H7 (other EHECs?)
- Lettuce and leafy greens, sprouts
- *Salmonella*
- Mangoes, tomatoes, tree nuts, sprouts
- Hepatitis A
- Green onions
- *Shigella sonnei*
- Parsley, cilantro, and culantro

Enteric (fecal) pathogens (partial list)

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Enteric Source</th>
<th>Infectious Dose</th>
<th>Sequela</th>
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</thead>
<tbody>
<tr>
<td>BACTERIA</td>
<td>human animals</td>
<td>10 - 100,000</td>
<td>Reactive arthritis</td>
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<tr>
<td><em>Salmonella</em> spp.</td>
<td>YES</td>
<td></td>
<td></td>
</tr>
<tr>
<td><em>E. coli</em> O157:H7 (EHEC)</td>
<td>YES</td>
<td>human animals</td>
<td>10 - 1,000</td>
</tr>
<tr>
<td>Shigella</td>
<td>YES</td>
<td>Human</td>
<td>10 - 100</td>
</tr>
<tr>
<td>PROTOZOA</td>
<td>Cryptosporidium</td>
<td>human animals</td>
<td>&lt;20</td>
</tr>
<tr>
<td>VIRUS</td>
<td>Hepatitis A</td>
<td>human</td>
<td>10 - 100</td>
</tr>
</tbody>
</table>

What are the sources of contamination?

Routes of contamination

Commercial produce processing

Handling errors → contamination

- Have occurred at:
  - Production
  - Packing
  - Processing
  - Final preparation
- Contamination MOST important factor
- Temperature abuse SOMETIMES contributes
- Most critical in low-acid fruits and vegetables
  - Pathogens can multiply when fruit or vegetable cut
  - Only critical with bacteria
Transient vs resident microbial contamination

- Transient pathogen
  - Pathogen-contaminated fruit
  - Food Contact Surface

- Resident pathogen
  - Pathogen-contaminated surface
  - Food Contact Surface

Survival/growth of pathogens in produce

- Intact fruit/vegetable
  - Survival variable, growth rare

- Cut/wounded fruit/vegetable
  - Survival increases and growth possible

- Temperature
  - Growth slowed at lower temperatures
  - SURVIVAL sometimes increases at lower temperatures

- Humidity
  - Growth and survival enhanced with higher humidity

Growth of pathogens in (cut) produce

- High pH/low acid products:
  - Growth can be rapid at room temperature
  - Examples: sprouts, cut melons, chopped parsley, chopped lettuce

- Low pH/high acid products
  - Tomatoes: under some conditions, chopped tomatoes will support the growth of Salmonella
  - Apples: wound will support the growth of E. coli O157:H7

Innovative packaging

- Modified atmosphere packaging
- Vacuum packaging
- Shrink-wrap packaging
- Customized films
- Controlled atmosphere storage

- Changes in atmosphere/humidity may influence survival, growth of pathogens

Washing does NOT eliminate pathogens

- At best 1-3 log reductions can be expected under commercial conditions regardless of antimicrobial used

- Issues
  - Complexity
  - Stem scar area
  - Apples
    - Bacteria can enter core through blossom end
    - Stem end difficult access
  - Presume knife can transfer to edible flesh
  - Demonstrated for melons and tomatoes
Infiltration can occur in some products:

- Fruit pulp must be < 9°F warmer than water temperature to prevent infiltration.

- Microbes in water

- Maintaining water sanitation critical

Some surfaces may attract bacteria:

- Lettuce
  - *E. coli* O157:H7 found in cut edges and stomata (Seo and Frank, 1999)
  - *L. monocytogenes* and *Salmonella* attach to cut edges (Takeuchi et al., 2000)

- Honeydew melon surface

- Cantaloupe surface

Not all surfaces are equal:

- Smooth surfaces
  - Honeydew melon, tomato, oranges, apples

- Complex surfaces - hard
  - Netted rind difficult to “clean”
  - Scrubbing with clean brush significant improvement

- Complex surfaces - soft
  - Strawberries, broccoli, lettuce, parsley, sprouts

Guiding principles of food safety for fresh produce:

- Once contaminated, removing or killing pathogens is VERY difficult

  THEREFORE

- Prevention of contamination is favored: layered risk reduction strategies

Approach for risk reduction in fresh produce - proactive:

- Integrated farm-to-fork risk reduction
  - Good Agricultural Practices - production
    - FDA/USDA Document 1998
  - Good Packinghouse Practices - harvest/packing
    - Application of sanitation and hygiene GMPs
  - Good Manufacturing Practices - processing
    - CFR 21 110
  - Generating appropriate data

Food Safety Modernization Act (FSMA)
FSMA mandates and authorities

Most sweeping food regulation in over 75 years

- Hazard Analysis & Risk Preventive Controls
- Standards for Produce Safety
- Facility Inspections
- Mandatory Recall Authority
- Facility Registrations
- Record Inspection & Maintenance
- Import/Foreign Industry Provisions

FSMA January 4, 2011 - Food Safety Modernization Act

- Divided into 4 titles
  - 1. Prevention of Food Safety Hazards
    - Preventive controls
    - Produce safety rule
  - 2. Detection and Response to Food Safety Problems
  - 3. Improving the Safety of Imported Foods
  - 4. Misc. provisions

Compliance dates by business size

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<td>Produce Safety</td>
<td>Dec 15</td>
<td></td>
<td>Aug 18</td>
<td>Oct 31</td>
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<td>Preventive Controls</td>
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<td>Final</td>
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<td></td>
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<td></td>
<td></td>
<td></td>
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<td>Human</td>
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<td>Animal</td>
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<td>FSVP</td>
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</tbody>
</table>

New authority for initiating mandatory recall

- Reasonable probability the food is adulterated or misbranded by failing to disclose major food allergens
- Reasonable probability the food will cause serious adverse health consequences or death

Foreign Supplier Verification Program

- Every importer must establish a plan that verifies:
  - The foreign supplier complies with HARPC or Standards for Produce Safety
  - That the food is not adulterated or misbranded by failing to disclose major food allergens
- Importer must maintain records for no less than 2 years
- Noncompliance is grounds for refusal of an imported article
  - Automatic Detention Without Physical Examination

Voluntary Qualified Importer Program

- FDA must establish voluntary program in order to expedite importation of safe and secure food.
- Eligibility is determined by overall safety of food offered for import by the specific importer.
- Importers must obtain certification by third-party auditors (designated by FDA).
  - Developing a 3rd party accreditation program
- FDA to review eligibility of importers no less than once every three years.
Why Are These Proposed Rules Important?

- About 15 percent of the U.S. food supply is imported – including nearly 50 percent of fresh fruit and 20 percent of fresh vegetables.
- Consumers expect that food imported into the U.S. should meet the same level of public health protection as food produced domestically.

Preparing for the Produce Safety Rule

- Good Agricultural Practices
  - Including harvest and post-harvest activities
  - If you have plans in place
    - Review and update
  - Work with growers and suppliers to ensure they have plans in place
    - Verify they are following them

Preventive Controls

- Require facilities that make or handle food for people and animals to put measures in place to help prevent foodborne illness

Examples of compliance with prevention standards

- Sanitation
- Training for supervisors and employees
- Environmental controls and monitoring
- Food allergen controls
- Recall contingency plan
- Good Manufacturing Practices (21CFR110)
- Supplier verification activities

- ALL written and/or documented

Produce Safety Alliance

- FDA, USDA, Cornell University
- Aim is to help produce growers and packers access food safety educational materials
- http://producesafetyalliance.cornell.edu/pssa.html
Preventive Control Alliance

http://www.iit.edu/ifsh/alliance/

- Established at the Illinois Institute of Technology’s Institute for Food Safety and Health (grant from FDA)

FSMA - the reality

- FSMA does not make food safer
- FDA makes rules that it intends to enforce for domestic and imports to keep produce safe
- Extension and outreach are pivotal to provide training
- Extension and outreach are pivotal to reach consumers to restore or support confidence in safety of food supply

Summary

- Fresh fruits and vegetables have been associated with significant foodborne illness
  - Illness to Total Servings per Year ratio is exceptionally small
- Pathogens associated with fruits and vegetables are associated with human or animal feces
- Prevention of contamination **throughout the supply chain** is preferred
  - Washing and temperature control important
  - Do not stand alone

Routes of contamination

- **ANIMALS, BIRDS**
- **PRODUCE**
- **HUMANS**
- **Plants**
- **Silage, feed**
- **Meat, milk, eggs**
- **Cross contamination**
- **Soil**
- **Harvesting, handling, processing environments**
- **Insects**
- **Sewage**

Damaged tissue can support growth

- Higher isolation rates in damaged or decayed produce
- **Peppers**
  - *E. coli* O157:H7 attaches preferentially to damaged tissue
  - Cells may migrate or flow from sound tissue to damaged tissue during drying of inocula
  (Han et al., 2000)

Toxin production by *Clostridium botulinum*

<table>
<thead>
<tr>
<th>Product</th>
<th>Temp.</th>
<th>Days to Toxin</th>
<th>Product Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Romaine</td>
<td>21</td>
<td>14 to 21</td>
<td>Inedible</td>
</tr>
<tr>
<td>Shredded cabbage</td>
<td>21</td>
<td>7</td>
<td>Inedible</td>
</tr>
<tr>
<td>Sliced potatoes</td>
<td>22</td>
<td>4 to 6</td>
<td>Acceptable</td>
</tr>
<tr>
<td>Sulfitated potatoes</td>
<td>22</td>
<td>4</td>
<td>Acceptable</td>
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Log scale

<table>
<thead>
<tr>
<th>Log reduction</th>
<th>% reduction</th>
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<tbody>
<tr>
<td>1</td>
<td>90%</td>
</tr>
<tr>
<td>2</td>
<td>99%</td>
</tr>
<tr>
<td>3</td>
<td>99.9%</td>
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<table>
<thead>
<tr>
<th>Log reduction</th>
<th>Bacterial cells/g</th>
<th>Log value</th>
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<tbody>
<tr>
<td>0 (initial)</td>
<td>100,000</td>
<td>5</td>
</tr>
<tr>
<td>1</td>
<td>10,000</td>
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<td>2</td>
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<tr>
<td>4</td>
<td>10</td>
<td>1</td>
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Why didn’t FDA choose to propose regulations based solely on commodity risk?

Why didn’t FDA choose to propose regulations based solely on commodity risk?

New authorities for increased facility inspections

- Domestic Food Facilities
  - High Risk Facilities: Once by January 2016 (then every three years)
  - Non-High Risk Facilities: Once by January 2018 (then every five years)

- Foreign Food Facilities
  - 600 inspections by January 4, 2012
  - 19,200 inspections by January 4, 2017
  - FDA can consider requiring records be submitted for review instead of an inspection