Food Safety Considerations for Value Added Tropical Fruits

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Why are we discussing food safety?

- Recent foodborne outbreaks focused the attention of regulatory, public and media’s interest towards produce safety.
- Outbreaks involving produce, have resulted in increased scrutiny and legal actions.
- Media coverage has forced companies to take reactionary measures.
Foodborne Hazards

- **Biological**
  - Microorganisms (bacteria, viruses, parasites), plants, animals

- **Chemical**
  - Allergens
  - Sanitizers, additives, chemicals

- **Physical**
  - Rocks, wood, plastics, metal, glass
Microbiology

Study of organisms that are too small to be seen with the naked eye

- Parasites
- Fungi (molds, yeasts, mushrooms)
- Bacteria
- Viruses
- Prions
Microbiology

Study of organisms that are too small to be seen with the naked eye

Parasites - *Cryptosporidium, Cyclosporia, Giardia*

Bacteria - *Salmonella, E. coli O157:H7, Shigella, Campylobacter*

Viruses - Norovirus, Hepatitis A
Contaminants present an “invisible challenge” because you can’t see them, and they usually don’t change the appearance, taste or odor of the food.
Sources of microorganisms in foods

- Soil
- Water
- Air
- Food Handlers
- Insects
- Packaging
- Surfaces
- Raw Ingredients
- Animals
Foodborne Outbreak

- Two or more people experience a similar illness after eating a common food
- 16,000 to 20,000 outbreaks reported per year
- 40 to 60% cause/source of infection not identified
Foodborne illness

- There exists a continuing, but preventable, burden of foodborne illness within the US.
- Trends have seen some decreases, but currently remain static

United States
- 76,000,000 cases estimated
- 350,000 hospitalization
- Approximately 5,000 deaths
- Approximately only 1:40 to 1:100 cases are ever reported

Mead et. al, 1999
Cost of Foodborne Illness

- **Personal costs**
  - Human life
  - Medical costs
  - Lost productivity
  - Physical and mental

- **Industry costs**
  - Recalls
  - Ligation
  - Lost business

Estimated losses:

$6.5 - 35 billion annually in USA
Estimated frequency of bacterial foodborne illness in the U.S.

- *Escherichia coli* O157:H7: 73,480 cases
- *Salmonella* spp.: 1,412,498 cases
- *Campylobacter* spp.: 2,453,926 cases
- *Listeria monocytogenes*: 2,518 cases

- *Escherichia coli* O157:H7: 61 deaths
- *Salmonella* spp.: 582 deaths
- *Campylobacter* spp.: 124 deaths
- *Listeria monocytogenes*: 504 deaths

### 1996-2006 fresh produce outbreaks by commodity

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Outbreaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lettuce</td>
<td>14</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>13</td>
</tr>
<tr>
<td>Cantaloupe</td>
<td>7</td>
</tr>
<tr>
<td>Raspberries/berries</td>
<td>6</td>
</tr>
<tr>
<td>Romaine lettuce</td>
<td>4</td>
</tr>
<tr>
<td>Basil</td>
<td>4</td>
</tr>
<tr>
<td>Green onions</td>
<td>3</td>
</tr>
<tr>
<td>Unknown</td>
<td>2</td>
</tr>
<tr>
<td>Spinach</td>
<td>2</td>
</tr>
<tr>
<td>Basil or Mesclun</td>
<td>2</td>
</tr>
<tr>
<td>Parsley</td>
<td>2</td>
</tr>
<tr>
<td>Melons</td>
<td>2</td>
</tr>
<tr>
<td>Honeydew melon</td>
<td>2</td>
</tr>
<tr>
<td>Mango</td>
<td><strong>2</strong></td>
</tr>
<tr>
<td>Almonds</td>
<td>2</td>
</tr>
<tr>
<td>Mixed lettuce</td>
<td>1</td>
</tr>
<tr>
<td>Cabbage</td>
<td>1</td>
</tr>
<tr>
<td>Green grapes</td>
<td>1</td>
</tr>
<tr>
<td>Snow Peas</td>
<td>1</td>
</tr>
<tr>
<td>Squash</td>
<td>1</td>
</tr>
</tbody>
</table>

Total = 72 outbreaks

Guzewich, FDA, 2007
1998-2006 fresh produce outbreaks

5 commodity groups make up >75 percent of produce-related outbreaks

<table>
<thead>
<tr>
<th>Commodity</th>
<th>% produce outbreaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lettuce/leafy greens</td>
<td>30%</td>
</tr>
<tr>
<td>Tomatoes</td>
<td>17%</td>
</tr>
<tr>
<td>Melons</td>
<td>13%</td>
</tr>
<tr>
<td>Herbs (basil, parsley)</td>
<td>11%</td>
</tr>
<tr>
<td>Green onions</td>
<td>5%</td>
</tr>
<tr>
<td><strong>Total % of 5 top commodities</strong></td>
<td><strong>76%</strong></td>
</tr>
</tbody>
</table>

Guzewich, FDA, 2007
Outbreaks related to tropical fruits, world wide

- **Avocado**
  - 10 outbreaks in USA 1998 – 2006 linked to Guacamole
  - Norovirus, *Campylobacter*, *Shigella*, Hepatitis A, and *Salmonella*

- **Banana**
  - 7 outbreaks in the USA 2002-2006 linked to Pie, Pudding and Plantains
  - Norovirus, *Staphylococcus aureus*, and *Salmonella*

- **Coconut**
  - 7 outbreaks world wide 1953 – 1999 linked to Dried, Milk and desheled
  - *Salmonella*, *Shigella*, and *Vibrio cholerae*
Outbreaks related to tropical fruits, world wide

- **Mamey**
  - 1 outbreaks in USA 1998 – 1999 linked to Frozen Smoothie
  - *Salmonella*

- **Mango**
  - 4 outbreaks in the USA 1998-2003 linked to Raw Imported
  - *Salmonella*

- **Papaya**
  - 2 outbreaks world wide 1996 – 2009 linked to Fresh-cut
  - *Salmonella*

- **Pineapple**
  - 8 outbreaks world wide 1994 – 2006 linked to Fresh-cut
  - Norovirus, E. coli, Campylobacter and *Salmonella*
What do I need to do?

- Once you “add value” to your product, you become a **food processor**
- Following the 2002 bioterrorism act you must register with FDA, if you are not already registered
- www.fda.gov
FDA Industry Systems

To make submissions to FDA (e.g., Food Facility Registration, Prior Notice, etc.) you must first create an account. Select "Create New Account" below.

If you already have an account, enter your account ID and password.

NEW USERS

LOGIN

Existing account holders, enter your account ID and password.

Account ID: 

Password: 

Forgot your password?

See Instructions

See Tutorial

Help Desk

Under 18 U.S.C. 1001, anyone who makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

I understand
FDA Registration Requirements

- Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("The Bioterrorism Act")
  - Section 305: Registration of food facilities
  - Section 307: Prior notice of imported food shipments
  - Section 303: Administrative Detention
  - Section 306: Establishment and Maintenance of Records
Sec. 305:
Registration of Food Facilities

- Who Must Register?
  - Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold food (subject to FDA’s jurisdiction) for human or animal consumption in the U.S.

- Domestic facilities
  - interstate commerce
  - intrastate commerce
Failure to Register

- Failure to register, update, or cancel a registration as required is a prohibited act

- FDA can bring a civil or criminal action
What else should you do?

- As a grower:
  - Implement Good Agricultural Practices during production and harvesting
Good Agricultural Practice

- Commonly called GAP or GAPs
- Should be considered an “Insurance Policy”, not a burden
- Basic GAPs are a collection of common sense, easy to implement practices.
- Many are already being performed by prudent growers when performing daily tasks
Basic tenets of GAPs

1. Pesticides and their use
2. Employee Hygiene and Training
3. Field Sanitation and Harvesting Practices
4. Water
5. Soil, Manure & Biosolids
6. Vertebrate Pest control
7. Traceability/Records/Documentation
What else should you do?

- As a grower:
  - Implement Good Agricultural Practices during production and harvesting
- As a packer/while adding value
  - Implement Good Manufacturing Practices/Standard Sanitation Operating Procedures
Current Good Manufacturing Practice

- GMP in *Manufacturing, Packing, or Holding Human Food* (1968)
  - Title 21
  - Code of Federal Regulations (CFR)
  - Part 110
    - 21 CFR 110

- [http://www.access.gpo.gov/nara/cfr/waisidx_06/21cfr110_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/21cfr110_06.html)
Good Manufacturing Practice

- GMP in Manufacturing, Packing, or Holding Human Food (21 CFR Part 110)
  - General Provisions
    - Definitions
    - Personnel
Good Manufacturing Practice

- GMP in Manufacturing, Packing, or Holding Human Food (21 CFR Part 110)
  - General Provisions
  - Buildings and Facilities
    - Plant and Grounds
    - Sanitary Operations
    - Sanitary Facilities and Controls
Good Manufacturing Practice

- GMP in Manufacturing, Packing, or Holding Human Food (21 CFR Part 110)
  - General Provisions
  - Buildings and Facilities
  - Equipment and Utensils
Good Manufacturing Practice

- GMP in Manufacturing, Packing, or Holding Human Food (21 CFR Part 110)
  - General Provisions
  - Buildings and Facilities
  - Equipment and Utensils
  - Production and Process Controls
    - Raw Materials
    - Manufacturing Operations
    - Warehousing and Distribution
Good Manufacturing Practice

- GMP in Manufacturing, Packing, or Holding Human Food (21 CFR Part 110)
  - General Provisions
  - Buildings and Facilities
  - Equipment and Utensils
  - Production and Process Controls
  - Defect Action Levels
Newer Approaches

- Hazard Analysis Critical Control Point (HACCP)
  - Mandated for Meat and poultry, seafood, and juices
    - Requires pre-requisite programs
    - Requires written and documented SSOPs

- Example in recent FDA regulation
  - 21 CFR 120
Sanitation Standard Operating Procedures

- Sanitation controls - Each processor shall have and implement a sanitation standard operation procedure (SSOP) that addresses sanitation conditions and practices before, during, and after processing.
SSOP Requirements

- Mandatory sanitation monitoring of eight (8) key areas with record keeping
- Mandatory corrective actions with record keeping
Eight Key SSOPs

1. Safety of water
2. Condition and cleanliness of food-contact surfaces
3. Prevention of cross-contamination
4. Maintenance of hand-washing, hand-sanitizing and toilet facilities
5. Protection from adulterants
6. Labeling, storage and proper use of toxic compounds
7. Employee health conditions
8. Exclusion of pests
What does this mean for you?

- Food safety hazards have been associated with value-added tropical fruits, and some value-added tropical fruits allow *Salmonella* to grow
- You must register your facility with FDA
- Become familiar with GAPs during production
- Become familiar with GMPs/SSOPs during processing
Questions?