Requirements for a **food hub** that is **fully covered** under the Preventive Controls Rule

**USDA NIFA Food Safety Outreach Program : Jan 2019**
USDA NIFA Food Safety Outreach Program team

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Who is covered?
By the Preventive Controls Rule for Human Food

• Facilities that manufacture, process, pack, or hold human food
• Fully covered:
  • Not food hubs on farms (meeting the primary or secondary farm definition) or retail food establishments
  • Have >$1,000,000 in annual sales
What if my food hub is fully covered under the Preventive Controls for Human Food Rule?

- Subject to full requirements under 21 CFR Part 117
- Implement cGMPs and other prerequisite programs (SSOPs)
- Conduct a Hazard Analysis
- Develop a Food Safety Plan
  - See specific requirements for the FSP
- FSP development and certain other activities must be conducted by Preventive Controls Qualified Individual (PCQI)
- Register with FDA
- FDA inspection
Types of Foodborne Illness

- Chemical
  - Allergens
- Physical
- Biological
  - Bacteria
  - Viruses
  - Parasites

Foodborne Illness Acquired in the United States—Major Pathogens

Elaine Scallan,1 Robert M. Hoekstra, Frederick J. Angulo, Robert V. Tauxe, Marc-Alain Widdowson, Sharon L. Roy, Jeffery L. Jones, and Patricia M. Griffin

January 2011, CDC, Emerging Infectious Diseases

31 major pathogens

9.4 million episodes/year

Photo credits: www.foodsafety.gov
Potential sources of hazards

People

Ingredients

Environment
Don’t Let This Happen to You!

Examples of Outbreaks and Recalls

<table>
<thead>
<tr>
<th>Outbreak and/or Recall</th>
<th>Preventive Controls Lacking</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Salmonella</em> in peanut products for commercial use 2008-09 U.S.</td>
<td><em>Primary Processor</em> –</td>
</tr>
<tr>
<td>• ~3900 products recalled by 200+ companies</td>
<td>Process – Roaster validation</td>
</tr>
<tr>
<td>• 714 ill, 9 dead in 46 states</td>
<td>Sanitation – cross-contamination prevention and environmental</td>
</tr>
<tr>
<td></td>
<td>pathogen control</td>
</tr>
<tr>
<td></td>
<td><em>Customers</em> – Supply-chain program</td>
</tr>
<tr>
<td>Botulism from hazelnut yogurt 1989 England</td>
<td><em>Primary Processor</em> –</td>
</tr>
<tr>
<td>• 27 cases, 1 death</td>
<td>Process – validation or refrigeration of hazelnut conserve</td>
</tr>
<tr>
<td></td>
<td><em>Customers</em> – Supply-chain program</td>
</tr>
<tr>
<td>Allergen recalls</td>
<td>Allergen controls – accurate labeling and prevention of allergen</td>
</tr>
<tr>
<td>• Undeclared allergens account for over 1/3 of FDA food recalls</td>
<td>cross-contact</td>
</tr>
<tr>
<td>• Most common root cause – wrong package or label</td>
<td></td>
</tr>
</tbody>
</table>
### Selected multistate outbreaks in fresh produce reported by the U.S. Centers for Disease Control and Prevention, 2006-2018

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Pathogen</th>
<th>Year</th>
<th>Case Count/Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Romaine lettuce</td>
<td><em>Escherichia coli</em> O157:H7</td>
<td>2018</td>
<td>210/5</td>
</tr>
<tr>
<td>Leafy greens</td>
<td><em>Escherichia coli</em> O157:H7</td>
<td>2017</td>
<td>25/1</td>
</tr>
<tr>
<td>Alfalfa Sprouts</td>
<td><em>Escherichia coli</em> O157</td>
<td>2016</td>
<td>11/0</td>
</tr>
<tr>
<td>Clover Sprouts</td>
<td><em>Escherichia coli</em> O121</td>
<td>2014</td>
<td>19/0</td>
</tr>
<tr>
<td>Ready to eat Salads</td>
<td><em>Escherichia coli</em> O157:H7</td>
<td>2013</td>
<td>33/0</td>
</tr>
<tr>
<td>Organic spinach and spring mix</td>
<td><em>Escherichia coli</em> O157:H7</td>
<td>2012</td>
<td>33/0</td>
</tr>
<tr>
<td>Clover sprouts</td>
<td><em>Escherichia coli</em> O122</td>
<td>2012</td>
<td>29/0</td>
</tr>
<tr>
<td>Romaine lettuce</td>
<td><em>Escherichia coli</em> O157:H7</td>
<td>2011</td>
<td>58/0</td>
</tr>
<tr>
<td>Shredded Romaine lettuce</td>
<td><em>Escherichia coli</em> O145</td>
<td>2010</td>
<td>26/0</td>
</tr>
<tr>
<td>Spinach</td>
<td><em>Escherichia coli</em> O157:H7</td>
<td>2006</td>
<td>199/3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Pathogen</th>
<th>Year</th>
<th>Case Count/Deaths</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packaged salad</td>
<td><em>Listeria monocytogenes</em></td>
<td>2016</td>
<td>19/1</td>
</tr>
<tr>
<td>Caramel apples</td>
<td><em>Listeria monocytogenes</em></td>
<td>2015</td>
<td>35/7</td>
</tr>
<tr>
<td>Bean sprouts</td>
<td><em>Listeria monocytogenes</em></td>
<td>2014</td>
<td>5/2</td>
</tr>
<tr>
<td>Cantaloupes</td>
<td><em>Listeria monocytogenes</em></td>
<td>2011</td>
<td>147/33</td>
</tr>
<tr>
<td>Commodity</td>
<td>Pathogen</td>
<td>Year</td>
<td>Case Count/Deaths</td>
</tr>
<tr>
<td>--------------------</td>
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<td>-------------------</td>
</tr>
<tr>
<td>Pre-cut melon</td>
<td><em>Salmonella</em> Adelaide</td>
<td>2018</td>
<td>77/0</td>
</tr>
<tr>
<td>Sprouts</td>
<td><em>Salmonella</em> Montevideo</td>
<td>2018</td>
<td>10/0</td>
</tr>
<tr>
<td>Maradol papayas</td>
<td><em>Salmonella</em> (multiple)</td>
<td>2017</td>
<td>220/1</td>
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<tr>
<td>Alfalfa sprouts</td>
<td><em>Salmonella</em> Reading, <em>Salmonella</em> Albony</td>
<td>2016</td>
<td>36/0</td>
</tr>
<tr>
<td>Alfalfa sprouts</td>
<td><em>Salmonella</em> Muenchen, <em>Salmonella</em> Kentucky</td>
<td>2016</td>
<td>26/0</td>
</tr>
<tr>
<td>Cucumbers</td>
<td><em>Salmonella</em> Poona</td>
<td>2015</td>
<td>907/6</td>
</tr>
<tr>
<td>Cucumbers</td>
<td><em>Salmonella</em> Newport</td>
<td>2014</td>
<td>275/1</td>
</tr>
<tr>
<td>Bean sprouts</td>
<td><em>Salmonella</em> Enteritidis</td>
<td>2014</td>
<td>115/0</td>
</tr>
<tr>
<td>Cucumbers</td>
<td><em>Salmonella</em> Saintpaul</td>
<td>2013</td>
<td>84/0</td>
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<tr>
<td>Mangoes</td>
<td><em>Salmonella</em> Braenderup</td>
<td>2012</td>
<td>127/0</td>
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<tr>
<td>Cantaloupe</td>
<td><em>Salmonella</em> Typhimurium, <em>Salmonella</em> Newport</td>
<td>2012</td>
<td>261/3</td>
</tr>
<tr>
<td>Papayas</td>
<td><em>Salmonella</em> Agona</td>
<td>2011</td>
<td>106/0</td>
</tr>
<tr>
<td>Cantaloupe</td>
<td><em>Salmonella</em> Panama</td>
<td>2011</td>
<td>20/0</td>
</tr>
<tr>
<td>Alfalfa sprouts</td>
<td><em>Salmonella</em> 14</td>
<td>2011</td>
<td>140/0</td>
</tr>
<tr>
<td>Alfalfa sprouts</td>
<td><em>Salmonella</em> Newport</td>
<td>2010</td>
<td>44/0</td>
</tr>
<tr>
<td>Alfalfa sprouts</td>
<td><em>Salmonella</em> Saintpaul</td>
<td>2009</td>
<td>234/0</td>
</tr>
<tr>
<td>Raw produce</td>
<td><em>Salmonella</em> Saintpaul</td>
<td>2008</td>
<td>1414/2</td>
</tr>
<tr>
<td>Cantaloupes</td>
<td><em>Salmonella</em> Litchfield</td>
<td>2008</td>
<td>51/0</td>
</tr>
<tr>
<td>Tomatoes</td>
<td><em>Salmonella</em> Typhimurium</td>
<td>2006</td>
<td>183/0</td>
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<tr>
<td>Salad mix</td>
<td><em>Cyclospora cayetanensis</em></td>
<td>2018</td>
<td>511/0</td>
</tr>
<tr>
<td>Vegetable tray</td>
<td><em>Cyclospora cayetanensis</em></td>
<td>2018</td>
<td>250/0</td>
</tr>
<tr>
<td>Cilantro</td>
<td><em>Cyclospora cayetanensis</em></td>
<td>2014</td>
<td>117/0</td>
</tr>
<tr>
<td>Fresh produce</td>
<td><em>Cyclospora cayetanensis</em></td>
<td>2013</td>
<td>631/0</td>
</tr>
<tr>
<td>Frozen strawberries</td>
<td><em>Hepatitis A virus</em></td>
<td>2016</td>
<td>143/0</td>
</tr>
<tr>
<td>Pomegranate seeds</td>
<td><em>Hepatitis A virus</em></td>
<td>2013</td>
<td>165/0</td>
</tr>
</tbody>
</table>
Risk-based Preventive Controls

• Focus on what matters most for food safety
• Preventive, not reactive
• Work in conjunction with and supported by other programs like Good Manufacturing Practices
• Designed to minimize the risk of food safety hazards
Preventive food safety systems

Food Safety Plan
Including procedures for monitoring, corrective action and verification, as appropriate

Hazard Analysis

Recall Plan

Process Control

Sanitation Control

Allergen Control

Supply-chain Program

GMPs and Other Prerequisite Programs
Determining Preventive Controls is systematic

- Hazard Analysis
- Preventive Controls
- Parameters & Values
- Monitor
- Corrections / Corrective Action
- Verification & Record-keeping
Contents of a food safety plan

**Required**
- Hazard analysis
- Preventive controls*
  - Process, food allergen, sanitation, supply-chain and other
  - Recall plan*
- Procedures for monitoring, corrective action and verification*

**Useful**
- Facility overview and Food Safety Team
- Product description
- Flow diagram
- Process description

* Required when a hazard requiring a preventive control is identified
Scope of the food safety plan

• Specific to a facility
  • Preventive controls specific to a product and process

• Products may be grouped if hazards and controls are managed generally the same

• Define and address:
  • Specific product(s) and process(es)
  • Part of the food chain to be studied
  • Biological, chemical, and physical hazards
Food safety plan format is flexible
Main organizational sections

1. Background information - optional
2. Hazard analysis
3. Preventive controls
4. Recall plan
5. Implementation procedures
Background information

- Useful information to organize the plan:
  - Facility overview and Food Safety Team
  - Product description
  - Flow diagram
  - Process description
Hazard Analysis – Required

• Drives decision making for the controls that must be included in the Food Safety Plan
Preventive and Other Controls May Include:

Process preventive controls
- Critical control points (CCPs)

Food allergen preventive controls
- Accurate labeling
- Cross-contact prevention

Sanitation preventive controls
- Environmental pathogens
- Cross-contamination, cross-contact

Supply-chain preventive controls
Recall Plan

- Required when a hazard requiring a preventive control is identified
- What to do when something goes wrong
Implementation Procedures

• Examples that may be required include:
  • Validation studies
  • Procedures for monitoring, verification and corrective action
Who can prepare the Food Safety Plan?

• Prepared or preparation overseen by *Preventive Controls Qualified Individual*

• Someone who knows your operation well

• Preventive Controls Qualified Individual:

  An individual who has successfully completed training in the development and application of risk-based preventative controls at least equivalent to that received under the standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.
Activities that must be performed by a Preventive Controls Qualified Individual

1. Preparation of the Food Safety Plan
2. Validation of the preventive control
3. Records review
4. Reanalysis of the Food Safety Plan
FDA registration

• Fully covered facilities must register with FDA
• Facilities can register online on FDA’s website
  • http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006832.htm
• Registration renewal required biennially (every even year)
Information need for FDA facility registration

- Type of Registration
- Facility Name / Address Information
- Optional: Preferred Mailing Address Information
- Parent Company Name / Address Information
- Facility Emergency Contact Information
- Trade Names
- United States Agent
- Seasonal Facility Dates of Operation

- General Product Categories – human/Animal/Both
- General Product Categories – Food for Human Consumption; and Type of Activity Conducted at the Facility
- General Product Categories – Food for Animal Consumption; and Type of Activity Conducted at the Facility
- Owner, Operator, or Agent in Charge Information
- Inspection Statement
- Certification Statement
Frequency of inspection

• FSMA directs FDA to inspect domestic facilities at a rate determined by the risk its products pose to public health

• High-risk facilities are to be inspected every three years, while low-risk facilities are to be inspected every five years
Commonly occurring inspection violations

• **Lack of effective pest exclusion / screening** – FDA cites a facility for not taking effective preventative measures against pest presence in food processing areas or not implementing controls to protect food from contamination due to pests.

• **Sanitation monitoring** – FDA cites a facility for failing to effectively monitor sanitation practices and conditions consistently.

• **Floors, walls, and ceilings** – FDA cites a facility for being constructed in a way that inhibits proper sanitation and repair of the floors, walls, and ceilings.

• **Importer Verification** – FDA cites a seafood importer for failing to document verification of a supplier’s compliance with Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations.

• **Food Safety Plan Implementation** – FDA cites a facility for failing to implement procedures established in its written Food Safety Plan.
FDA inspection

• When a food facility registers with FDA, it grants FDA permission to inspect the facility at any given time

• Initial FDA food facility inspections are of no cost to the facility
  • Occur due to routine reasons, a facility’s level of potential risk to public health, or as a response to a problem or complaint

• If FDA discovers certain food safety violations during an initial inspection, the Agency may decide it needs to return at a later date to evaluate whether the facility implemented appropriate corrective actions.

• The second evaluation is considered a reinspection (also sometimes referred to as a “compliance follow-up inspection”)

• Cost of reinspection for 2018 is $248/hour