Food Safety and Milk Banking

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Food Safety
Donor Screeners
Milk Techs
Fundraising
Board of Directors
EDs
Outreach & Marketing

Food Safety Modernization ACT (FSMA)

https://stopfoodborneillness.org

1985 Salmonella

• 15,000 sick (estimated 200,000 total cases)
• 12 confirmed deaths (12 additional suspected deaths)
• Valve used in unpasteurized and pasteurized lines
• Class action lawsuit - Jewel took too long to report & correct
• State public health director fired

1993 E. coli 0157:H7

• 600 sick
• 170 hospitalized
• 4 deaths
• $50 Million Settlements
• Federal government raised temperature from 140 to 155

Janis Sowerby, Mother of Scott Hinkley
Died age 3, E. coli 0157:H7

*Those of us who have fought so hard are tired. We have suffered so much. But we are dedicated to this cause and will continue to fight for as long as it takes to get new reforms to protect the American consumers. Why does the American Meat Institute continue to fight the necessary changes that must take place to protect us? How many more will be murdered? How dare you say that testing meat would only confuse the consumer and make them more lax on cooking it properly?*

https://www.citizen.org/article/5-reasons-not-co-sponsor-s-746-thompson-levin-regulatory-roadblock-bill
2009 Salmonella

- 700 sick (estimated 24,000)
- 9 deaths
- Most extensive recall in history: 3,900 products
- Affected budget brand peanut butter
- 71 criminal charges
  - CEO - 48 year prison sentence
  - Peanut Broker - 20 years
  - QA Manager - 5 years
  - Plant Manager - 3 years
  - Plant Manager - 3 years

Peanut Corporation of America

- Filthy conditions
  - Rats, mice, birds
  - Rust, holes in ceilings and walls
- Staff
  - Lack of training, low pay, used temp workers
  - High turnover
- FDA registration
  - Failure to register Texas plant
- Lab testing
  - Dispensed product before results were available
  - Dispensed product that tested POSITIVE for salmonella
  - Shipped without re-testing
  - Re-tested until negative results achieved
  - Created false COAs

"They [peanuts] need to be air hosed off because they're covered in dust and rat crap."

"Just ship it."

FDA Requirements

FSMA regulations mandate a shift from a reactive to preventative approach with a heavy emphasis on documentation

CFR Title 21

- CFR Title 21 - Food and Drug Administration Department of Health and Human Services – Subchapter B – Food for Human Consumption

FMSA

- FSMA - Food Safety Modernization Act: two parts of compliance to FSMA
  1. Compliance with Good Manufacturing Practices - detailed in Policies and Procedures or SOPs. Documentation of evidence that procedures are followed and staff is trained.
2. FOOD SAFETY PLAN
A set of written documents that is based on food safety principles. It is developed by a team of staff and is specific to the location. The team must include a PCQI.

Food Safety Plan

**Key Components**
- Assemble an FSP Team
  - PCQI
  - Executive Director
  - Operations Director
  - Lab Supervisor
  - "Person In Charge" of Donor Screening

Assemble an FSP Team

- Conduct a Risk-Based Hazard Analysis
- Establish Preventative Controls
- Oversight and Management
- Monitoring
  - Corrective actions
  - Identification
  - Documentation
- Monitoring
- Corrective actions
- Identification
- Documentation

Responsibilities of FSP Team

- Conduct Hazard Analysis and develop FSP
- Develop Documents
- Review and update FSP as needed
- Ensures implementation of preventative controls
- Ensures staff is knowledgeable of CCPs and the safeguards in place to reduce or prevent potential hazards
- Staff is trained to properly carry out and document preventative controls

Hazard Analysis

- Hazard—Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.
- Identify foreseeable hazards in your milk bank's operations.
- B = Biological hazards including bacteria, viruses, parasites, and environmental pathogens
- C = Chemical (including radiological) hazards, food allergens, substances such as pesticides and drug residues, natural toxins, decomposition, and unapproved food or color additives
- P = Physical hazards include potentially harmful extraneous matter that may cause choking, injury or other adverse health effects
- Completed by a PCQI – Certified milk bank staff member or qualified consultant.

PCQI – Preventative Controls Qualified Individual

**Definition:** A qualified individual who has successfully completed training in the development and application of risk-based preventative controls, at least equivalent to that received under standardized curriculum recognized as adequate by FDA, or is otherwise qualified through job experience to develop and apply a food safety system.

- Preventative Controls Qualified Individual (PCQI)
- Precautionary measures to prevent contamination or other hazards.
**Hazard Analysis**

**First Step**
Develop a flow chart of operations and identify critical control points (CCPs).

**CCP** - A point, step or procedure in processing at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard risk to an acceptable limit.

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**Hazard Analysis**

Examine each step of the process to determine if this step is a CCP.

<table>
<thead>
<tr>
<th>Processing</th>
<th>Hazard Analysis</th>
<th>CCP</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving</td>
<td>HIV, hepatitis B, hepatitis C, syphilis, and HTLV may be transmitted via human milk.</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serological screening is performed on each donor at a certified laboratory for:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>HIV 1/2, HTLV 1/2, Hepatitis B, Hepatitis C and Syphilis.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Preventive Controls**

- Process controls: During operations
  1. Donor screening
  2. Pasteurization

- Food allergen controls: N/A
  - HMBANA milk banks do not offer dairy free milk
  - Milk banks may offer dairy restricted milk that may contain dairy
  - All donor milk products may contain dairy, including dairy restricted
  - There is currently no test to assure that milk does not contain dairy allergen
  - “Dairy free” label introduces significant risk (regulatory, legal, financial)

Process Preventative Controls

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Preventative Controls</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holder Pasteurization</td>
<td>Prevents heat-sensitive bacteria and viruses.</td>
</tr>
</tbody>
</table>

### Hazard
- Bacteria are present in human milk.
- Viruses may be present in human milk.

### Preventative Steps
- Holder pasteurization kills heat-sensitive bacteria and viruses.

### Critical Limits
- **Temperature:** 62.0°C
- **Time:** 30 minutes

**Critical Limit is a Preventive Control**
- Parameters and limits associated with the control of a hazard.

**CRITICAL LIMIT (CL)**
- Is the criterion that specifies safe product from unsafe product.
- Is the maximum or minimum value that must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of the identified hazard.

**OPERATING LIMIT (OL)**
- A criterion that is more strict than the critical limits.
- Operators use operating limits to reduce the possibility of a deviation.

**Examples of Parameters that May Be Critical Limits**
- **Temperature**
- **Moisture level**
- **pH level**
- **Time**
- **Viscosity**
- **Holding activity**
- **Salt concentration**
- **Physical dimensions**
- **Weight**

**CASE ONE:** Automatic pasteurizer record review
- **SOP/FSP:**
  - Achieve initial temp of 62.5°C
  - Critical limit 62.0°C for 30 minutes
  - Brief fluctuation to 61.5°C acceptable if critical limit achieved

**CASE TWO:** Automatic pasteurizer record review
- **SOP/FSP:**
  - Achieve initial temp of 62.5°C
  - Critical limit 62.0°C for 30 minutes
  - Brief fluctuation to 61.5°C acceptable if critical limit achieved

**CORRECTIVE ACTION**
1. Discard batch and record date of disposition.
2. Re-work (re-pasteurization) and record date of SOP/FSP.
3. Re-categorize as research and record segregation.

**CORRECTIVE ACTION**
1. Discard batch and record date of disposition.
2. Re-categorize as research and record segregation.
Remains constant @ 62.0° C
Per food safety plan and SOP
Temperature set by tech may change to maintain control
62.0°

**CASE THREE:**
Automatic pasteurizer record review

**CORRECTIVE ACTION**
1. Discard batch and record date of disposition
2. Re-categorize as research and record segregation

**Operating Limit**
Temperature drops to 62.5 once during 30 minute run
Critical Limit
Temperature drops to 62.5 once during 30 minute run for one minute

**Operating Limit**
Temperature set by tech may change to maintain control
63.0°

**CASE FOUR:**
Automatic pasteurizer record review

**CORRECTIVE ACTION**
1. Discard batch and record date of disposition
2. Re-categorize as research and record segregation

**Operating Limit**
Temperature drops to 62.3 once during 30 minute run
Critical Limit
Temperature drops to 62.3 once during 30 minute run for one minute

Operative and Management of Process Preventative Controls

Operative and management is critical to assuring preventative controls are appropriately applied:

- Monitoring
- Corrective Action
- Verification
- Records and Documentation

- definition:
  - How to monitor
  - Frequency of monitoring
  - Continuous monitoring - datalogger
  - Non-continuous monitoring - monitoring by exception
  - Who will monitor

- Verification:
  - Review of processes to ensure they are being properly carried out
  - Regular review of food safety plan
  - Review of records and documentation
  - Visual inspections
  - Environmental monitoring
  - Validation: Proof of accuracy using scientific principles
  - Thermometer and equipment validation
  - Microbial testing
Oversight and Management of Process Preventative Controls

Corrective Action
- Action that must take place if there is a deviation from a critical limit.
- EXAMPLE: time and temperature requirements of pasteurization were not met.
- Corrective action plan should be written (SOPs).
- Develop corrective action form and document any corrective actions taken.
  - Date and time of incident
  - Evaluation of incident
  - Action taken

Records
- Establish record keeping for each CCP
- Document everything!
  - Monitoring records
  - Verification and validation records
  - Corrective actions

Oversight and Management of Process Preventative Controls

Preventative Steps
- Holder pasteurization kills heat-sensitive bacteria and viruses.

Critical Limits
- Temperature: 62.5°C with brief fluctuations between 62°C and 64.5°C
- Time: 30 minutes

Monitoring
- What: control bottle is monitored with a calibrated thermometer. Milk is pasteurized for 30 minutes. Pasteurization begins when milk reaches 62.5°C. Control bottle must maintain temperatures between 62.0°C and 64.5°C for 30 minutes.
- How: Each batch is pasteurized.
- Who:

Sanitation Preventative Controls

These are steps taken to prevent cross-contamination from staff and environment.
- Cleaning and sanitization procedures
- Zoning
- Pest management

You must have written procedures that are followed and documented.

Cleaning and Sanitation Procedures

- Detailed procedure for each activity (example: handwashing), item (example: flasks, trays, freezers or pasteurizer) or area (example: lab floor).
- Includes a monitoring plan and documentation.

Zoning
- A zoning (segregation) plan is implemented when areas are identified for potential cross-contamination.
- Determined during Hazard Analysis
- Optimally, the facility is designed and constructed to separate areas where milk could be contaminated.
- Physically identified zones.
Zoning Considerations

- Cross contamination of raw milk across batches.
- Contamination of clean supplies with milk.
- Segregating clean and dirty utensils.
- Avoid contamination of packaging materials and outside of bottles.

Pest Management

REMEMBER: FSMA regulations mandate a shift from a reactive to preventative approach with a heavy emphasis on documentation.

- A pest management program should mirror this preventative nature of FSMA.
- Must be a targeted plan to not only deal with pests, but to prevent them and minimize their impact before they become a problem.
- The Preventative Controls for Human Food Regulation within FSMA requires that food plants have a written preventative pest management plan that includes monitoring.

Staff Training

Person in Charge - Chapter 2 of FDA Food Code 2017.
- A Person in Charge is present during all hours of operation.
- Certified Food Safety Manager – Needs to be an accredited program by the Conference for Food Protection.
- Oversees that employees are performing in compliance with HMBANA guidelines and cGMPs.
- Responsible for oversight and management of FSP.
- Determines exclusions for symptomatic food employees.

Summary of Requirements for Symptomatic Food Employees

Hepatitis A

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Cause of Foodborne Outbreaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fatigue</td>
<td>Hepatitis A infection, caused by Hepatitis A virus (HAV), is</td>
</tr>
<tr>
<td>Sudden nausea and vomiting</td>
<td>the leading cause of human and hepatitis throughout the</td>
</tr>
<tr>
<td>Abdominal pain or discomfort</td>
<td>world and is mainly propagated via the fecal-oral route.</td>
</tr>
<tr>
<td>Clay-colored bowel movements</td>
<td>Outbreaks</td>
</tr>
<tr>
<td>Loss of appetite</td>
<td>The virus is transmitted from infected individuals to</td>
</tr>
<tr>
<td>Low-grade fever</td>
<td>healthy individuals via fecal particles or ingestion of</td>
</tr>
<tr>
<td>Dark urine</td>
<td>contaminated food or water.</td>
</tr>
<tr>
<td>Joint pain</td>
<td>The virus can also be transmitted through contact with</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Outbreaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norovirus</td>
</tr>
<tr>
<td>Shingella spp.</td>
</tr>
<tr>
<td>STEC</td>
</tr>
<tr>
<td>HAV</td>
</tr>
<tr>
<td>Typhoid fever</td>
</tr>
</tbody>
</table>

No, if not diagnosed.

Hepatitis A

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Cause of Foodborne Outbreaks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jaundice</td>
<td>Hepatitis A infection, caused by Hepatitis A virus (HAV), is</td>
</tr>
<tr>
<td>Symptoms</td>
<td>the leading cause of human and hepatitis throughout the</td>
</tr>
<tr>
<td>Excluded</td>
<td>world and is mainly propagated via the fecal-oral route.</td>
</tr>
<tr>
<td>onset within the last seven days</td>
<td>Outbreaks</td>
</tr>
<tr>
<td>When approval is obtained from a regulatory</td>
<td>HEP A cases are down in the U.S., but there is still an</td>
</tr>
<tr>
<td>authority</td>
<td>occasional outbreak.</td>
</tr>
<tr>
<td>Food employee has been jaundiced for more than 7 calendar days.</td>
<td>Multistate frozen strawberry outbreak 2016</td>
</tr>
</tbody>
</table>
| Food employee provides medical documentation. | No, if not diagnosed.

Sore Throat with Fever

Exclude When food employee provides written medical documentation.

Infected Wound or Pustular Boil

Restrict When the infected wound or boil is properly covered.

Jaundice

Exclude if the symptom occurred within the last seven days. When approval is obtained from a regulatory authority.

Symptoms

- Jaundice
- Fever
- Nausea
- Vomiting
- Abdominal pain or discomfort
- Clay-colored bowel movements
- Loss of appetite
- Low-grade fever
- Dark urine
- Joint pain

Diagnosis

- Hepatitis A is typically diagnosed by a doctor.
- Symptoms usually appear within 2 weeks of exposure.
- An antibody test can confirm the diagnosis.

Prevention

- Avoid close contact with infected individuals.
- Wash hands frequently with soap and water.
- Wear gloves when handling food.
- Cook food to proper temperatures.
- Use separate equipment and utensils for raw and cooked foods.

Hepatitis A Vaccine

- Recommended for people at high risk of exposure, such as healthcare workers and travellers to areas with high Hepatitis A prevalence.
- Available as a single-dose vaccine.
- Recommended for those over the age of 2 years who may have been exposed to Hepatitis A.

Outbreak Response

- Notify local health department.
- Discontinue the use of the affected product.
- Clean and sanitize the affected area.
- Educate staff on proper hygiene practices.
- Implement additional sanitation measures.

Infection Control

- Isolate infected individuals.
- Use personal protective equipment.
- Implement strict hand hygiene.
- Clean and sanitize all affected areas.

Summary

- Hepatitis A is a serious liver infection caused by the Hepatitis A virus.
- Symptoms typically appear within 2 weeks of exposure.
- Diagnosis is typically made through a blood test.
- Prevention involves avoiding close contact with infected individuals and practicing good hygiene.
- A vaccine is available for people at high risk.
- Outbreak response includes notifying health authorities, isolating infected individuals, and implementing infection control measures.
Noroviruses

- Highly Contagious
- Leading cause of acute gastroenteritis in the U.S.
- Bacillus

Symptoms
- Vomiting
- Diarrhea
- Nausea
- Stomach Pain

How to Prevent Norovirus
- Wash hands often
- Stay home when sick and for two days after symptoms stop
- Avoid preparing food for others when sick and for two days after symptoms stop

Highly Contagious
- Leading cause of acute gastroenteritis in the U.S.

Staff Training

Employees
- Food handler’s licenses – Lab techs
- cGMP onsite training by certified individual
- Health and hygiene training

Frequency
- Onboarding
- Annual HMBANA technical training check list
- Food Safety and Recall
- Ongoing – Should be a part of the culture. We should continuously be looking at quality and improving operations.
- Emails
- Employee Meetings
- Presentations
- DOCUMENT ALL TRAINING

Calibrations and Maintenance

HMBANA Guidelines Equipment Maintenance Frequency
- Storage and processing equipment – every 6 months
- Refrigerators
- Freezers
- Ice Machines
- Pasteurizers
- Dishwashers
Calibrations and Maintenance

- **Calibration** – is the act of comparing a device under test (DUT) of an unknown value with a reference standard of a known value. A person typically performs a calibration to determine the error or verify the accuracy of the DUT’s unknown value.
- Only refers to measuring devices.

Source: [https://us.flukecal.com/literature/about-calibration](https://us.flukecal.com/literature/about-calibration)

Calibrations and Maintenance

- **HMBANA Guidelines Equipment Calibration Frequency**
- Temperature measuring devices (thermometers) – NIST certified or similar agency, or calibrated quarterly by the milk bank using an NIST certified reference thermometer. Thermometers are also calibrated when dropped, damaged, or anytime accuracy is in question.
- Minimum Standards:
  - Validated and calibrated as needed.
  - Thermometers
  - Scales
  - Dispensers
  - Must keep records of calibrations.

Calibrations and Maintenance

- **Thermometers Used in Pasteurization and Milk Cooling Process**
- Minimum of two calibrated thermometers.
- One-point calibration
- **Cold-Point Calibration** – -20°C
  1. Place reference thermometer in freezer with DUT.
  2. Allow it to stabilize.
  3. Compare reading of the DUT to reference thermometer reading.

Calibrations and Maintenance

- **Accuracy Requirements – Pasteurization**
  - Food temperature measuring devices dually scaled in Celsius and Fahrenheit shall be accurate to ±1°C in the intended range of use.
  - Food temperature measuring devices scaled in Fahrenheit shall be accurate to ±2°F in the intended range of use.
- FDA Food Code 2017 4-203.11

Calibrations and Maintenance

- **Thermometers Used in Freezers and Refrigerators**
- Minimum of two calibrated thermometers.
- One-point calibration
- Cold-Point Calibration:
  1. Submerge DUT and reference thermometer in a container of ice water at 0°C.
  2. Allow it to stabilize.
  3. Compare reading of the DUT to reference thermometer reading.
  4. Adjust thermometer to reference thermometer reading according to manufacturer’s instructions and/or service, or replace thermometers that cannot be calibrated.
  5. Document calibration results.

Calibrations and Maintenance

- **Accuracy Requirements – Freezers and Refrigerators**
  - Thermometers that are dually scaled in Celsius and Fahrenheit shall be accurate to ±1.5°C in the intended range of use.
  - Devices that are scaled only in Fahrenheit shall be accurate to ±3°C in the intended range of use.
- FDA Food Code 2017 4-203.11
Calibrations and Maintenance

<table>
<thead>
<tr>
<th>Thermometer</th>
<th>Thermometer ID</th>
<th>Thermometer Reading</th>
<th>Reference Thermometer Reading</th>
<th>Corrective Action</th>
<th>Date</th>
<th>Staff Member</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thermometer A</td>
<td>64.7°C</td>
<td>65.0°C</td>
<td>N/A</td>
<td></td>
<td>3/18/2019</td>
<td>Shaina Starks</td>
</tr>
<tr>
<td>Thermometer B</td>
<td>63.8°C</td>
<td>65.0°C</td>
<td>Sent thermometer back to manufacturer for calibration</td>
<td>3/18/2019</td>
<td>Shaina Starks</td>
<td></td>
</tr>
</tbody>
</table>

Example Calibration Log

*Create a calibration/maintenance calendar

Main Equipment Components

- **Compressor**: Turns low pressure gas into high pressure gas.
- **Condenser**: Condenses gas into a liquid state.

Equipment Maintenance

- Basic Freezer Components
- General Freezer Maintenance
- Detecting Common Issues

Equipment Maintenance

- It’s important to record freezer temperatures daily.
- Brush the aluminum condenser fins with a brush and vacuum remaining dust.
- Clean compressor with cloth to ensure it’s not leaking Freon
- Check door gaskets for any excessive wear and tear.

Condenser Fins

- It’s important to notice any significant changes in the temperature logs.
- Major increases or decreases in temperature are signs that the equipment is struggling. Make sure staff isn’t recording temperature during preset defrost cycles.
- Other major signs to look for are frozen coils, moisture build up around the door, and water build up in drain pan over days.
Frozen Coils

Calibration vs Maintenance

- Calibration refers to calibrating devices that measure. Devices that measure temperature, volume, time, etc.
- Examples of measuring devices are: thermometers, data logger, scale, and milk dispenser.
- Maintenance on equipment is upkeep cleaning / inspection to ensure the equipment is not under-performing.
- Maintenance on equipment should be every 6 months with record keeping of maintenance performed. If there is not any record of maintenance performed then it did not happen.

Recall

- Action taken by an establishment to remove an adulterated, misbranded, or violative product from the market.
- Recall Plan is REQUIRED for any food that has a hazard requiring preventative control.
- Must:
  - Be written
  - Be tested
  - Detail communication
  - Define roles and responsibilities
- Source: https://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129337.htm

Recall

- Class I recall: reasonable probability that the use of or exposure will cause serious adverse health consequences or death.
- Class II recall: a situation in which use of or exposure to a violative product may cause temporary or medically-reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- Class III recall: not likely to cause adverse health consequences.

Recall

- Market Withdrawal: occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.
- Stock Recovery: Self removal of a product that has not left the control of the milk bank.
Recall

A RECALL is required for any product in which a hazard requiring preventative controls has been identified.

**HMBANA Requirements**
- A system for tracking donor milk to donor is in place.
- Individual milk banks are responsible for ensuring they are compliant with state, federal, and provincial requirements for operation.
- Perform mock recall—Must be carried out the first year of operation and every two years after that in under 6 hours.
- Report recall verbally and in writing to chairperson of the Guidelines Committee and president of HMBANA.

**FDA Requirements**
- Visit FDA website for requirements and guidance documents.
- Know your District Recall Coordinator contact.

**Recall Plan**

**Suggested Components of a Recall Plan**
- Form a recall team including necessary milk bank staff, medical advisory board members, and any other applicable individuals.
- Develop recall SOP with step by step instructions on how to carry out a recall at your facility. Should include notification of recipients, notification of the public, disposing of product.
- Complete a root cause analysis.
- Develop documents and templates used to carry out recall.
- Inform and train staff on how to handle a product recall.
- Develop media management plan and messaging.

**Prepare for FDA inspection & HMBANA accreditation**
- Print copy of FDA registration or renewal and identify due date for next registration.
- Identify PCQI and research PCQI training options (if PCQI hasn’t received formal training).
- Identify Food Safety Manager and research training courses for state certification.
- Assemble food safety plan team.
- Print current FSP and place in binder that is available to staff.
- Update FSP as needed.
- Specific to your milk bank.
- Update processing flow chart.
- Create hazard analysis.
- Identify preventive controls, critical limits, corrective actions.
- Update and sign annually.

**Recall Plan Diagram**

- Critical Limits
  - Temperature: 62.0
  - Time: 30 min
  - Brief fluctuations to 61.5 acceptable if critical limits achieved

**FDA Resources**
- Guidance for Industry: Product Recalls, Including Removals and Corrections
- FDA District Recall Coordinators
  A current list of FDA recall coordinators can be found on FDA’s website at: