Hazards in Cheesemaking

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Why Should I Care?

The New York Times

62 DEATHS FROM CHEESE TRACED TO SINGLE SOURCE
By ROBERT LINDSEY, Special to the New York Times
Published: July 14, 1985

Dirty Wash. company blamed in cheese recall
Sally Jackson Cheese voluntarily recalled products over E. coli risk

Listeria illness, death tied to Wisconsin-made Crave Brothers cheese
Award-winning product pulled from shelves
Why Should I Care?

It's the Ethical Thing To Do

It's the Law!
"Despite the progress that has been made, occasional milkborne outbreaks still occur, emphasizing the need for continued vigilance at every stage of production, processing, pasteurization and distribution of milk and milk products. Problems associated with assuring the safety of milk and milk products have become extremely complex because of new products, new processes, new materials and new marketing patterns, which must be evaluated in terms of their public health significance."

Pasteurized Milk Ordinance, 2015 Revision
Today's Topics

**CHECKLIST**

- Intro to FSMA
- Dairy Hazards
- Hazards in Cheesemaking
- Conducting a Hazard Analysis
- Case studies
The Food Safety Modernization Act (FSMA)

- Comprehensive legislation designed to protect the American public by focusing on prevention of illness rather than response to outbreaks
- Puts the responsibility into the hands of the manufacturer to produce safe food
- Applies to ALL food manufacturers

- [http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm)
What Does FSMA Cover?

1. Prevention
2. Inspection and Compliance
3. Response
4. Imports
5. Enhanced Partnerships
What Does FSMA Cover?

1. Prevention
   Preventive Controls for Human Food Rule (9/17/15)

2. Inspection and Compliance

3. Response

4. Imports

5. Enhanced Partnerships
21 CFR 117
Current Good Manufacturing Practices, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

• Subpart A – General Provisions
• Subpart B – Current Good Manufacturing Practices
• Subpart C – Hazard Analysis and Risk-based Preventive Controls
• Subpart D – Modified Requirements
• Subpart E – Withdrawal of a Qualified Facility Exemption
• Subpart F – Requirements Applying to Records That Must Be Established and Maintained
• Subpart G – Supply-chain Program
What Do I Have To Do?

• Required Training

• GMPs

• Food Safety Plan
What Do I Have To Do?

- **Required Training**
  - GMPs
- **Food Safety Plan**

- **Qualified Individual** (anyone handling food)
  - food hygiene and food safety principles
  - job duties

- **Preventive Controls**
  - Qualified Individual (people developing the Food Safety Plan)
  - FDA-approved curriculum or adequate experience
What Do I Have To Do?

• Required Training
• GMPs
• Food Safety Plan

• Personnel
• Plants and grounds
• Sanitary operations
• Sanitary facilities
• Equipment & utensils
• Processes & controls
• Warehousing & distribution
• Defect action levels
What Do I Have To Do?

• Required Training

• GMPs

• Food Safety Plan

• Written Plan
  – hazard analysis
  – preventive controls
  – oversight & management of preventive controls
  – associated records
Facility Definitions

- **A Covered Facility** is one that manufactures or processes food, from one or more ingredients, using a wide variety of processes.

- **A Qualified Facility** is defined as
  - Business with average annual sales of < $500,000, during the previous 3-year period, and at least half the sales to consumers, local retailers or restaurants (within the same state or within 275 miles) OR
  - Very small business with sales averaging < $1,000,000, adjusted for inflation, during the previous 3-year period, for the sales of human food plus the market value of human food manufactured, processed, packed or held without sale.
Subpart D – Modified Requirements for Qualified Facilities

• Submit Attestations:

  1. That the facility meets the definition of a Qualified Facility (financial and distribution requirements)

  2. (i) You have identified the potential hazards associated with the food, are implementing preventive controls to address the hazards, and are monitoring the PCs to ensure effectiveness, OR

     (ii) The facility is in compliance with State, local, county or other applicable non-Federal food safety laws
What are my deadlines?

Covered Facilities, > 500 employees
- cGMP and HARPC 9/17/16
- Supply-chain program 9/17/17

Covered Facilities, 10 – 499 employees
- cGMP and HARPC 9/17/17
- Supply-chain program 9/17/17

Qualified Facilities
- Begin recording data for Attestation 1/1/16
- Submission of Attestation 12/17/18
- Applicable cGMP and PC requirements 12/17/18
ACS Safe Cheesemaking Track

Friday
10:00 - 11:30 am  Hazards in Cheesemaking
                  Kerry Kaylegian, Ph.D., Penn State
1:30 - 3:00 pm    PRP and Preventive Controls
                  Marianne Smukowski, WI Center for Dairy Research

Saturday
9:00 - 10:30 am  Developing a Sanitary Facility
                  Neville McNaughton, CheezSorce
12:15 - 1:45 pm  Pathogen Behavior in Cheese
                  Dennis D'Amico, Ph.D., Univ. of Connecticut
2:15 – 3:45 pm  Product Testing, Sampling, and Environmental Monitoring
                  Kim Bukowski, Cornell University
Dairy Hazards

- Biological
- Chemical
- Physical
Food Hazards

• Hazards **ARE:**
  – agents that cause illness or injury resulting from the ingestion of food

• Hazards **ARE NOT:**
  – agents responsible for spoilage
  – tolerable levels of contamination (insect parts, hair, filth)
  – violations of standards of identity
  – economic fraud
Biological Hazards

- Bacteria
- Fungi
- Viruses
- Parasites
Biological Hazards

Infections

• Consumption of live pathogens that grow in the body

• Dose varies by infecting agent & individual health status

• Enteric bacteria
  – *Salmonella*
  – *Campylobacter jejuni*
  – *E. coli* (pathogenic)
  – *Yersinia*
  – *Shigella*

• Environmental bacteria
  – *L. monocytogenes*

• Viruses
  – Norwalk
  – Hepatitis A

• Parasites (water)
  – *Cyclospora*
  – *Cryptosporidium*
  – *Giardia*
Biological Hazards
Intoxications

- Consumption of preformed toxins
- Usually large numbers of pathogens are need to produce sufficient toxin to cause illness
- Some toxins are very heat stable and may persist after the vegetative pathogens are destroyed

- *Bacillus cereus*
- *Clostridium perfringens*
- *Clostridium botulinum*
- *Staphylococcus aureus*
Microbial Hazards – Sequelae
(Secondary Illnesses)

- *Campylobacter*
  - reactive arthritis
  - hemolytic uremic syndrome
  - septicemia, infections of nearly any organ
  - Guillian-Barré syndrome

- *Salmonella*
  - septicemia
  - reactive arthritis, septic arthritis

- *E. coli*
  - hemolytic uremic syndrome
## Pathogens Commonly Associated with Dairy

<table>
<thead>
<tr>
<th>Organism</th>
<th>Source</th>
<th>Disease Characteristics</th>
<th>Onset/Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campylobacter jejuni</td>
<td>intestinal tract, feces</td>
<td>diarrhea, abdominal pain, fever</td>
<td>2 – 5 days, 5 – 10 days</td>
</tr>
<tr>
<td>Escherichia coli O157:H7, others</td>
<td>intestinal tract, feces</td>
<td>bloody diarrhea, abdominal pain, kidney failure (HUS)</td>
<td>2 – 3 days, 7 – 10 days, +hospitalization</td>
</tr>
<tr>
<td>Listeria monocytogenes</td>
<td>water, soil, environment</td>
<td>flu-like symptoms, miscarriage, fetal death</td>
<td>3 – 70 days</td>
</tr>
<tr>
<td>Salmonella ssp.</td>
<td>environment, feces</td>
<td>diarrhea, nausea, fever</td>
<td>12 – 72 hrs, 4 – 7 days</td>
</tr>
<tr>
<td>Yersinia enterocolitica</td>
<td>environment, water, infected animals</td>
<td>diarrhea, appendicitis</td>
<td>12 – 74 hrs</td>
</tr>
</tbody>
</table>
Pathogen Sources

• Raw milk
• Contaminated water
• Soil
• Personnel
• Processing plant
  – floors
  – drains
  – cooling systems
  – air handling systems
  – biofilms on equipment
Pathogens – Growth & Survival

- Nutrients
- Water
- Temperature range
- pH
- Salt
- Other inhibitors
  - bacteriocins

Pathogens that GROW at cold temperatures:
- *Listeria monocytogenes*
- *Bacillus cereus*
- *Yersinia enterocolitica*

*Listeria monocytogenes*
- GROWTH in 10% salt
- SURVIVAL in 20-30% salt
Controlling Biological Hazards

• Keep them out
• Keep them from growing
• Kill them
Chemical Hazards

- Allergens
- Drug residues
- Vitamins
- Mycotoxins
- Pesticides
- Cleaning chemicals & sanitizers
- Radiological hazards
Chemical Hazards - Allergens

• Reactions to food allergens
  – hives, skin rash, abdominal cramps, vomiting, diarrhea
  – difficulty breathing, swelling of the tongue, throat, face
  – drop blood pressure, unconsciousness, anaphylactic shock
  – death

• Most common allergens ("The Big 8")
  1. Peanuts
  2. Tree nuts
  3. Shellfish
  4. Eggs
  5. Milk
  6. Soy
  7. Fish
  8. Wheat (gluten)
Chemical Hazards – Allergens

• Sources
  – ingredients
  – rework
  – product changeover with inadequate cleaning
  – improper labelling of incoming ingredients and finished products
Chemical Hazards – Drug Residues

- Antibiotics in milk
- **ALL** milk is required to be tested before processing
  - tankers are tested before unloading
- PMO, Appendix N. Drug Residue Testing and Farm Surveillance
  - industry responsibilities
  - regulatory responsibilities
  - testing program
    - definitions
    - methods
Chemical Hazards - Vitamins

- Addition of Vitamin A & D for fortification
  - over addition to product
  - high levels of exposure for employees
- See PMO, Appendix O. Vitamin Fortification of Fluid Milk Products
  - methods for vitamin addition
  - metering pumps
  - GMPs for vitamin addition
  - testing methods
  - problems involved with fortification
Chemical Hazards - Pesticides

- Incoming ingredients
- Pest control in the plant
- Pest control around the plant grounds
Chemical Hazards - Mycotoxins

- Produced by some mold strains
- Can be a problem with dairy animal feeds
  - transfers into the milk
- Illness
  - gastroenteritis
  - liver disease
  - cancer
  - death
Chemical Hazards
Cleaning & Sanitizing Chemicals

• Chemical type & use
  – know the hazards associated with each chemical used in the facility
  – proper labeling
  – correct usage rate
  – proper method of mixing concentrates
  – personal protective equipment
  – first aid and spill response
  – employee training

• Chemical storage
  – store chemicals properly (acids, flammables, etc.)
  – restricted access areas
Radiological Hazards

• New hazard definition with FSMA

• Sources
  – milk produced in a radioactive area
  – uniforms washed with uniforms from hospitals with radiological testing?
  – areas high in radon?
Controlling Chemical Hazards

• Ingredient control
  – supplier auditing program
  – certificate of analysis (COA), required testing
  – testing at receiving (e.g., drug residues)
  – proper storage & labeling
  – formulation specifications & verification

• Process control
  – process order for allergen & non-allergen containing products
  – SSOPs for cleaning chemical use
  – proper storage of toxic compounds
  – protection of product packaging
Physical Hazards

- Glass
- Metal
- Plastic
- Wood chips
- Stones
Physical Hazards

• Glass
  – bottles, jars, light fixtures, gauge covers

• Metal
  – shavings, equipment parts, cheese molds, wires from cheese harps, screens

• Plastic
  – packaging material, pallets, equipment covers, cheese molds

• Wood
  – pallets, boxes, building structure, aging boards
Physical Hazards

• Solid materials that can cause choking or traumatic injury (cuts)

• Action levels
  – hard or sharp objects 7 to 25 mm (0.25 – 1.0 in) in length
  – less than 7 mm (.25 in) for high risk groups
Controlling Physical Hazards

- Ingredient control
- Sieves, screens, filters
- Metal detection
- X-ray systems
- Visual inspection
- Glass control program
Hazards in Cheesemaking
Hazards in Cheesemaking

- Raw milk & ingredients
- Cheese making & aging process
- Packaging
- Environment
- Personnel
Hazards in Cheesemaking

• Raw milk & ingredients
  – biological
    • pathogens
  – chemical
    • allergens
    • drug residues
    • mycotoxins
  – physical hazards
    • ingredient packaging
    • pallet splinters, etc.
Hazards in Cheesemaking

• Cheese making, brining & aging process
  – biological
    - • pathogen growth
    - • inadequate acidification
    - • improperly cleaned equipment
    - • biofilms on equipment
    - • contaminated water
    - • cheese mites
  – chemical
    - • cleaning chemicals
    - • allergens
    - • contaminated water
  – physical hazards
    • cheese harp & screen wires
    • aging board splinters
    • cheese cloth pieces
    • cheese mold pieces
    • metal from equipment
Hazards in Cheesemaking

• Packaging
  – biological
    • pathogens
    • cross-contamination
  – chemical
    • cleaning chemicals
  – physical hazards
    • packaging materials
    • pallet splinters

★ Cheese is exposed to the air when packaging
★ Need good environmental monitoring to ensure pathogen free environment
Hazards in Cheesemaking

- Environment
  - biological
    - pathogens

- Personnel
  - biological
    - pathogens

Managed as GMPs and Pre-Requisite Programs (PRPs)
Preventive Food Safety Systems

GMPs and Other Prerequisite Programs

- Process Controls
- Supply Chain Program
- Allergen Control Program
- Sanitation Controls

Safe and sanitary conditions for food manufacturing, processing, packing, and holding
Preventive Food Safety Systems

GMPs and Other Prerequisite Programs

Food Safety Plan

Hazard Analysis

Safe and sanitary conditions for food manufacturing, processing, packing, and holding
Preventive Food Safety Systems

GMPs and Other Prerequisite Programs

Food Safety Plan
- Hazard Analysis
- Process Controls
- Supply Chain Program
- Allergen Control Program
- Sanitation Controls
- Recall Plan

Safe and sanitary conditions for food manufacturing, processing, packing, and holding
Conducting a Hazard Analysis

• This is a 2-Step Process
  1. Hazard Identification
  2. Hazard Evaluation

• Really, it's a 3-Step Process
  3. Fill out the paperwork!
Hazard Analysis – Preliminary Steps

• Develop a flowchart or narrative of your entire process, including:
  – all inputs & outputs
  – all processing & handling steps
  – aging & storage
  – packaging
  – storage
  – distribution

• Walk the flowchart or narrative through your facility to make sure it is correct & complete
ACS Best Practices Guide

Peter Dixon HACCP Guide
Step 1 – Hazard Identification

- Identify the B, C & P hazards at each step in your flow chart
- Identify if a hazard can be:
  - INTRODUCED
  - ENHANCED
  - CONTROLLED
- Hazards may occur naturally, be unintentionally introduced, or intentionally introduced.
Step 2 – Hazard Evaluation

- For each hazard, determine:
  - Likelihood of occurrence
  - Severity of the hazard
  - Preventive control measures
Step 3 – The Paperwork

For each step:
- identify the type of hazard (B, C, P)
- identify the agent involved
- identify if and what control measures are needed at this step
- scientifically justify your decision

<table>
<thead>
<tr>
<th>(1)</th>
<th>(2)</th>
<th>(3)</th>
<th>(4)</th>
<th>(5)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Per Product Flow Diagram, list each Ingredient/Processing Step</td>
<td>Identify potential food safety hazards that are Introduced (I), Enhanced (E) or Controlled (C) at this step</td>
<td>Are listed hazards in this step severe &amp; reasonably likely to occur? (YES/NO)</td>
<td>Justify the decision in column (2) and:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>➢ If “NO” - identify the documented PP or SSOPs that will manage or reduce the likelihood of the hazard. Consider if a PP/SSOP can be modified or newly established to control the hazard?</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>➢ If “YES” - identify the control measure/step required to eliminate the hazard.</td>
<td></td>
</tr>
<tr>
<td>Raw Milk Receiving</td>
<td>BIOLOGICAL: Vegetative pathogens (Salmonella, campylobacter, Listeria, E. coli)</td>
<td>Yes</td>
<td>Pathogens have been associated with raw milk. Control point is the 60 day aging period before distribution.</td>
<td>No Controlled by acid production and 60 day aging at later steps</td>
</tr>
<tr>
<td></td>
<td>CHEMICAL: Beta-lactum drugs</td>
<td>No</td>
<td>We follow Appendix N and do appropriate testing. PP #13. Receiving, Storage and Handling of Raw Milk.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>PHYSICAL: Foreign material</td>
<td>No</td>
<td>Visual inspection and hand strainers.</td>
<td></td>
</tr>
<tr>
<td>Raw Milk Storage</td>
<td>BIOLOGICAL: Vegetative pathogens (Salmonella, campylobacter, Listeria, E. coli)</td>
<td>Yes</td>
<td>Pathogens have been associated with raw milk. Growth is controlled by PP #9 Temperature Control.</td>
<td>No Controlled by acid production and 60 day aging at later steps</td>
</tr>
</tbody>
</table>
Tips for Hazard Evaluations

• Can be based on experience, product history
• Justifications are science-based
• Consider product composition, expected use and expected consumers (think: at risk populations)
• Pay attention to outbreaks on products similar to yours

http://www.fda.gov/Safety/Recalls/
http://www.cdc.gov/foodborneoutbreaks/
http://www.outbreakdatabase.com/ (Marler Clark)
APPENDIX C

Examples of Questions to be Considered When Conducting a Hazard Analysis

The hazard analysis consists of asking a series of questions which are appropriate to the process under consideration. The purpose of the questions is to assist in identifying potential hazards.

A. Ingredients

1. Does the food contain any sensitive ingredients that may present microbiological hazards (e.g., Salmonella, Staphylococcus aureus); chemical hazards (e.g., aflatoxin, antibiotic or pesticide residues); or physical hazards (stones, glass, metal)?

2. Are potable water, ice and steam used in formulating or in handling the food?

3. What are the sources (e.g., geographical region, specific supplier)

B. Intrinsic Factors – Physical characteristics and composition (e.g., pH, type of acidulants, fermentable carbohydrate, water activity, preservatives) of the food during and after processing.

1. What hazards may result if the food composition is not controlled?
Hazard Analysis Review

• FSMA says review of Food Safety Plan every 3 years or when needed
  – when you change ingredients, chemicals, other suppliers
  – when you change your process or bring in new equipment
  – when there is an outbreak similar to a product you make
  – when new science indicates a review
Developing A Food Safety Plan

- Comply with GMPs
- Comply with Pre-Requisite Programs
- Conduct Hazard Analysis
- Determine, implement, monitor and document Preventive Controls
- Get trained to be a PCQI or work with someone who is a PCQI to develop your plan
Food Safety Resources

• ACS Best Practices Guide

• FDA
  [http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm](http://www.fda.gov/Food/GuidanceRegulation/FSMA/default.htm)

• Universities, trade organizations, consultants
Food Safety Resources

• Penn State
  – [http://extension.psu.edu/food/dairy](http://extension.psu.edu/food/dairy)
  – research project on developing tools to assist raw milk cheesemakers conduct hazard analysis begin 9/16
  – Preventive Controls for Human Food – Dairy Food Processing (PCQI certification)
    October 11-13, 2016 & February 21-23, 2017
    [http://extension.psu.edu/dairy-pc](http://extension.psu.edu/dairy-pc)
Case Study 1985

• Company: Jalisco, soft Hispanic cheese

• Vector: *Listeria monocytogenes*

• Illness count:
  – 142 cases
  – 93 were pregnant
  – 28 (58/68) deaths (10 newborns)
  – 20 miscarriages

• Source/problem: Used raw milk, pasteurizer problems

• Outcome: Company closed
  – the damages were estimated at $100 million, they only had $10 million in insurance

Case Study 2010

- **Company**: Sally Jackson Cheese, various cheeses
- **Vector**: *E. coli* O157:H7
- **Illness count**: 8 ill
- **Source/problem**: "Processed under conditions that create a significant risk of contamination"
  - numerous problems cited with condition of facilities (cracked floors, unsanitary conditions, wood slivers on floor, water not tested, dairy farm not licensed to produce milk)
- **Outcome**: Company closed

Data from Washington Department of Agriculture Reports
Case Study 2013

- Company: Crave Brothers, Les Frères, Petit Frère cheese
- Vector: *Listeria monocytogenes*
- Illness count: 6 ill, 1 death
- Source/problem: numerous citations
- Outcome: Temporarily closed, never identified root cause, developed a Corrective Action Plan, back in production
- Corrective actions included sanitizing and disinfecting the entire firm, replacing faulty and difficult-to-clean equipment, changing sanitary practices and traffic patterns during production, and establishing a product and environmental Listeria monitoring program.

http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm359588.htm
Case Study  2016

- Company:  Maytag, Blue Cheese
- Vector:  *Listeria monocytogenes*
- Illness count:  None, product tested positive, voluntary recall
- Source/problem:  Unknown
- Outcome:  Temporary closure of plant
Be Safe!

Make Great Cheese!
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