John Marcy, Ph.D.
University of Arkansas Cooperative Extension

Stokely–Van Camp, Swift & Co, Jerome Foods and Denny’s (8y)
Virginia Tech and University of Arkansas (25y)
HACCP, sanitation, and microbiology for meat and poultry
Provided testimony twice in U.S. Senate hearings following 1993 Jack in the Box E. coli outbreak in Washington & Pacific NW
Served for 2 years on a National Academy of Sciences committee on food safety criteria
Conference for Food Protection since 1994
Research Chefs Association – Culinary Arts for Food Techs (9y)
Fellow – Institute of Food Technologists
Certified Food Scientist
National Advisory Committee for Meat and Poultry Inspection
Stephanie Smith, 22, was paralyzed after being stricken by E. coli in 2007. Officials traced the E. coli to hamburger her family had eaten.
Hazard Analysis and Critical Control Point Principles and Application Guidelines

Adopted August 14, 1997

NACMCF
National Advisory Committee on Microbiological Criteria for Foods
Control Measures – Any action or activity that can be used to prevent, eliminate or reduce a significant hazard.

Hazard – A biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of its control.
1997 HACCP Principles and Application Guidelines

- **Hazard Analysis** – The process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.
1997 HACCP Principles and Application Guidelines

- Prerequisite Programs –

Procedures including Good Manufacturing Practices, that address operational conditions providing a foundation for the HACCP system.
Verification –

Those activities other than monitoring, that determine the validity of the HACCP plan and that the system is operation according to the plan.
Validation –

That element of verification focused on collecting and evaluating scientific and technical information to determine if the HACCP plan, when properly implemented, will effectively control the hazards.
1997 HACCP Principles and Application Guidelines

- HACCP Principle 6: Establish verification procedures
- HACCP Principle 7: Establish record-keeping and documentation procedures
1997 HACCP Principles and Application Guidelines

- Principle 1 – Conduct a Hazard Analysis
  - Hazard Identification
    - Brainstorming session
  - Hazard Evaluation
    - Severity
    - Likelihood of occurrence
1997 HACCP Principles and Application Guidelines

- Principle 6 – Establish Verification Procedures
  - Figure 2 – Example of a Company Established HACCP Verification Schedule
  - Appendix G – Examples of Verification Activities
1997 HACCP Principles and Application Guidelines

- Prerequisite Programs – Appendix A
  - Facilities and Grounds
  - Supplier Control
  - Specifications
  - Production Equipment
  - Cleaning and Sanitizing
  - Personal Hygiene
  - Training
  - Chemical Control
  - Receiving and Storage
  - Traceability and Recall and
  - Pest Control
Food Safety and Quality Programs

Prerequisite Programs

- GMPs
- HACCP
- SSOPs
Where do the Requirements for GMP’s Come From?

Food Drug and Cosmetic Act, FDCA (1938)

- gave regulatory power to FDA for foods
- regulations are in part 110 of title 21 of the CFR
- section 402(a)(4) of FDCA contains the provisions for labeling foods as adulterated
An unsafe food is a food that has been contaminated with a harmful substance (like bacteria, bone) and is injurious to health when consumed (diarrhea, broken tooth).

Protecting the food supply or “reducing the risk” of these harmful substances is the focus of food safety.
What is food quality?

- The quality of a food is determined by visual and organoleptic features like taste, color and texture.
- The product shelf-life dictates how long product quality is acceptable.
- The quality of food can deteriorate due to chemical reactions in a food (oxidation) and from biological breakdown (bacterial spoilage).
Programs used to maintain food safety and quality

- GMPs – Good manufacturing Practices
- SOPs – Standard Operating Procedures
- SSOPs – Sanitation Standard Operating Procedures
- HACCP – Hazard Analysis Critical Control Point
Biological Hazards

bacteria, viruses, parasites
# CDC Estimates of Foodborne Illness in the US 2011

Table 1. Estimated annual number of domestically acquired, foodborne illnesses, hospitalizations, and deaths due to 31 pathogens and unspecified agents transmitted through food, United States

<table>
<thead>
<tr>
<th>Foodborne Agents</th>
<th>Estimated annual number of illnesses (90% credible interval)</th>
<th>%</th>
<th>Estimated annual number of hospitalizations (90% credible interval)</th>
<th>%</th>
<th>Estimated annual number of deaths (90% credible interval)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>31 known pathogens</td>
<td>9.4 million (6.6–12.7 million)</td>
<td>20</td>
<td>55,961 (39,534–75,741)</td>
<td>44</td>
<td>1,351 (712–2,268)</td>
<td>44</td>
</tr>
<tr>
<td>Unspecified agents</td>
<td>38.4 million (19.8–61.2 million)</td>
<td>80</td>
<td>71,878 (9,924–157,340)</td>
<td>56</td>
<td>1,686 (369–3,338)</td>
<td>56</td>
</tr>
<tr>
<td>Total</td>
<td>47.8 million (28.7–71.1 million)</td>
<td>100</td>
<td>127,839 (62,529–215,562)</td>
<td>100</td>
<td>3,037 (1,492–4,983)</td>
<td>100</td>
</tr>
</tbody>
</table>
# CDC Estimates of Foodborne Illness in the US 2011

## Table 2. Top five pathogens contributing to domestically acquired foodborne illnesses

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Estimated number of illnesses</th>
<th>90% Credible Interval</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Norovirus</strong></td>
<td>5,461,731</td>
<td>3,227,078–8,309,480</td>
<td>58</td>
</tr>
<tr>
<td><strong>Salmonella, nontyphoidal</strong></td>
<td>1,027,561</td>
<td>644,786–1,679,667</td>
<td>11</td>
</tr>
<tr>
<td><strong>Clostridium perfringens</strong></td>
<td>965,958</td>
<td>192,316–2,483,309</td>
<td>10</td>
</tr>
<tr>
<td><strong>Campylobacter spp.</strong></td>
<td>845,024</td>
<td>337,031–1,611,083</td>
<td>9</td>
</tr>
<tr>
<td><strong>Staphylococcus aureus</strong></td>
<td>241,148</td>
<td>72,341–529,417</td>
<td>3</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td></td>
<td>91</td>
</tr>
</tbody>
</table>
Norovirus is responsible for 58% of Foodborne Illness

Cruise Ship Norovirus Hits 3 Ships Over Weekend

Huff Post 3/9/12
Virus

- intracellular parasitic microorganism
- does not grow on foods
- causes infection
- usually transferred by human contact, can be inherent to water and some seafood
# CDC Estimates of Foodborne Illness in the US 2011

## Table 3. Top five pathogens contributing to domestically acquired foodborne illnesses resulting in hospitalization

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Estimated number of hospitalizations</th>
<th>90% Credible Interval</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Salmonella</em>, nontyphoidal</td>
<td>19,336</td>
<td>8,545–37,490</td>
<td>35</td>
</tr>
<tr>
<td>Norovirus</td>
<td>14,663</td>
<td>8,097–23,323</td>
<td>26</td>
</tr>
<tr>
<td><em>Campylobacter</em> spp.</td>
<td>8,463</td>
<td>4,300–15,227</td>
<td>15</td>
</tr>
<tr>
<td>Toxoplasma gondii</td>
<td>4,428</td>
<td>3,060–7,146</td>
<td>8</td>
</tr>
<tr>
<td><em>E.coli</em> (STEC) O157</td>
<td>2,138</td>
<td>549–4,614</td>
<td>4</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td></td>
<td>88</td>
</tr>
</tbody>
</table>

# CDC Estimates of Foodborne Illness in the US 2011

## Table 4. Top five pathogens contributing to domestically acquired foodborne illnesses resulting in death

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Estimated number of deaths</th>
<th>90% Credible Interval</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Salmonella, nontyphoidal</em></td>
<td>378</td>
<td>0–1,011</td>
<td>28</td>
</tr>
<tr>
<td><em>Toxoplasma gondii</em></td>
<td>327</td>
<td>200–482</td>
<td>24</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>255</td>
<td>0–733</td>
<td>19</td>
</tr>
<tr>
<td>Norovirus</td>
<td>149</td>
<td>84–237</td>
<td>11</td>
</tr>
<tr>
<td><em>Campylobacter spp.</em></td>
<td>76</td>
<td>0–332</td>
<td>6</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td></td>
<td>88</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Decrease</th>
<th>Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campylobacter</td>
<td></td>
<td>14% ↑</td>
</tr>
<tr>
<td>Listeria</td>
<td></td>
<td>6% ↓†</td>
</tr>
<tr>
<td>Salmonella</td>
<td></td>
<td>3% ↑†</td>
</tr>
<tr>
<td>Shigella</td>
<td></td>
<td>13% ↓†</td>
</tr>
<tr>
<td>STEC* O157</td>
<td></td>
<td>10% ↓†</td>
</tr>
<tr>
<td>Vibrio</td>
<td></td>
<td>43% ↑</td>
</tr>
<tr>
<td>Yersinia</td>
<td></td>
<td>6% ↓†</td>
</tr>
</tbody>
</table>

*Shiga toxin-producing *Escherichia coli*  
†Not statistically significant
Sporeforming Bacteria (Pathogens)

*Clostridium botulinum*
Proteolytic – Type I
Nonproteolytic – Type II

*Clostridium perfringens*

*Bacillus cereus*
Clostridium botulinum

- Ubiquitous in nature; present in soil and water
- In U.S., 145 cases per year – 15% foodborne, 65% infant and 20% are wound botulism
• An Ohio resident was hospitalized after 5 days of progressive dizziness, blurred vision, dysphagia, and difficulty breathing.

• The patient required mechanical ventilation and botulism antitoxin. He had tasted potato soup from a bulging plastic container, noted a bad taste, and discarded the remainder.

• The soup had been purchased from the refrigerated section of a local grocer, but it had been kept unrefrigerated for 42 days.

• He was hospitalized for 57 days and then to rehab.
**Clostridium perfringens**

- Sporeformer
- Anaerobic (without oxygen)
- Spores survive pasteurization
- Toxin mediated infection
- Causes abdominal pain, diarrhea, nausea
- Mild disease of short duration
- Incubation 6–24 hours
Bacillus cereus

- Sporeformer
- Facultative Anaerobic (with / without oxygen)
- Spores survive pasteurization
- Toxins produced or Toxin mediated infection
- Causes abdominal pain, diarrhea, nausea
- Mild disease of short duration
- Infection – incubation 6–15 hours
- Emetic toxin – symptoms in $\frac{1}{2}$ to 6 hours
- Often associated with grains / rice
Nonsporeforming Bacteria

*Brucella abortis, B suis*
*Campylobacter spp.*
Pathogenic *Escherichia coli* (e.g., *E. coli O157:H7*)
*Listeria monocytogenes*
*Salmonella* spp. (e.g., *S. typhimurium, S. enteriditis*)
*Shigella* spp. (e.g., *S. dysinteriae*)
*Staphylococcus aureus*
*Streptococcus pyogenes*
*Vibrio* spp. (e.g., *V. cholerae, V. vulnificus*)
*Yersinia enterocolitica*
Campylobacter

- Gram negative bacterium
- Microaerophilic
- **Grows between 32–45°C**
- **Isolated primarily from raw poultry products and raw milk.**
- Primary habitat is the intestinal tract of chickens. Widely distributed in nature.
- Infective dose: As low as 100 – 1000/g
The Westchester County Health Department says that many people became ill with Campylobacter infections after attending a food festival at the Kenisco Dam in Valhalla, New York in early June.

The Burger and Beer Bash was held outdoors on June 6, 2013. The outbreak is now over, according to public health officials.
No food was left from 30 food vendors so the cause was never known.

Since most Campylobacter infections are associated with poultry & cross contamination, an educational emphasis on safe off-site practices was the course of action.
Healthy People 2010 Campy Objective
Human Illness per 100K population

- 1997: 19.3
- 2010: 8.5
Shiga toxin producing *Escherichia coli* (STECs) or Enterohemorrhagic *E. coli* (EHEC)

- Severe cramping, nausea or vomiting, and diarrhea that initially is watery, but becomes grossly bloody. In some cases, the diarrhea may be extreme, appearing to consist entirely of blood and occurring every 15 to 30 minutes. Fever typically is low-grade or absent.
- O157 ~ 75% & rest are O111, O26, O121, O103, O145, and O45
- Infective dose of O157 may be as low as 10 – 100 cells
- If proceeds to HUS, mortality is 3 – 5%
Listeria monocytogenes

- Gram positive bacterium
- Non-sporeformer
- Killed by pasteurization
- **High mortality rate – up to 20%**
- **Able to grow at refrigeration temp 31F (psychrotrophic).**
- Widely distributed in nature – soil, animal feces, sewage, water & silage
Salmonella

- Isolated from meat, poultry, dairy and egg products
- Primary habitat is the intestinal tract of animals. Widely distributed in nature.
- Infective dose: $10^7 - 10^9/g$
Killed by pasteurization

**Heat stable toxin**

Can be resistant to up to 15% salt (NaCl)

Referred to as “staph”

Commonly isolated from human skin.
**Staphylococcus aureus**

New York Firm Recalls Bologna Products Due To a Processing Deviation and Possible Contamination with *Staphylococcus aureus* Enterotoxin

Recall Release  
FSIS-RC-018-2011

**CLASS I RECALL**  
HEALTH RISK: HIGH

Congressional and Public Affairs  
(202) 720-9113  
Catherine Cochran

**WASHINGTON, March 9, 2011** - Zweigle's Inc., a Rochester, N.Y., establishment, is recalling approximately 2,997 pounds of bologna products that may be contaminated with *Staphylococcus aureus* enterotoxin, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced today.
*Staphylococcus aureus*

After discovering a malfunction with its smokehouse, the plant recooked the bologna products and shipped them to the distribution center. During routine inspection activities, FSIS discovered that the time delay in recooking the product created an environment allowing potential production of *Staphylococcus aureus* enterotoxin. FSIS has received no reports of illnesses associated with consumption of these products. Individuals concerned about an illness should contact a physician.
Streptococcus pyrogenes

- Killed by pasteurization
- Does not grow at refrigeration temperatures
- Red, sore throat (with or without white patches), painful swallowing, high fever, nausea, vomiting, headache, discomfort, and runny nose for about 4 days.
- Some people develop scarlet fever 2 or 3 weeks afterwards, which includes a rash, or rheumatic fever, which can harm the heart and other parts of the body, or *Streptococcus* could spread to other organs and cause serious illness or death.
**Vibrio vulnificus**

- Estuarine environments and is associated with plankton, shellfish, crustaceans, and finfish. Found throughout coastal waters of the continental US.

- Death occurs in an average of 35% of septicemia cases (and 20% of wound–infection cases).

- Incubation – 12 hours to 21 days (avg. 4 days).

- Fever, diarrhea, abdominal cramps, nausea, and vomiting.

- Septicemia is characterized by fever and chills, occasionally accompanied by vomiting, diarrhea, abdominal pain, and/or pain in the extremities.
Yersinia enterocolitica

- Killed by pasteurization, has been associated with pork, raw milk and oysters.
- **Does grow at refrigeration temperatures**
- Incubation – 1 to 11 days
- Symptoms – nonspecific, self-limiting diarrhea, but may cause a variety of autoimmune complications. *Yersinia* infections can mimic appendicitis.
Parasites are organisms that need a host to survive.

Thousands of kinds exist worldwide, but only about 100 types are known to infect people through food contamination.

Two types of concern from food or water:
- Parasitic worms [e.g., roundworms (nematodes), tapeworms (cestodes), flukes (trematodes)]
- Protozoa – Cyclospora and Cryptosporidium

Role of fecal material in transmission of parasites.
Parasitic Protozoa and Worms

- Cryptosporidium parvum
- Cyclospora cayetanensis
- Diphyllobothrium latum
- Entamoeba histolytica
- Giardia lamblia
- Anisakis simplex, Pseudoterranovia dicepiens
- Taenia solium, T. saginata
- Trichinella spiralis
Toxoplasma gondii

- Second leading cause of death from a foodborne organism
- Serious or deadly for babies infected in the womb or persons with compromised immunity.
- Pregnant women and immunosuppressed people should avoid consuming raw or undercooked meat, unpasteurized goat’s milk, and untreated water.
Chemical Hazards

Chemicals, toxins, allergens and radionuclides
Types of Naturally Occurring Chemical Hazards

- Mycotoxins (e.g., aflatoxin)
- Scombrotoxin
- Ciguatoxin
- Shellfish toxins
  - Paralytic shellfish poisoning (PSP)
  - Diarrhetic shellfish poisoning (DSP)
  - Neurotoxic shellfish poisoning (NSP)
  - Amnesic shellfish poisoning (ASP)/Domoic Acid
- Pyrrolizidine alkaloids
- Phytohemagglutinin
Scombroid Fish Poisoning

- Named for the family Scomberidae (tunas and mackerels)
- Can involve any fish containing high levels of free histidine, mahi mahi, tuna, bluefish, sardines, mackerel
- Bacteria break down free histidine into histamine
Histamine Formation

Histidin $\xrightarrow{\text{Decarboxylase}}$ Histamine

$\text{H}_2\text{N} - \text{CH} - \text{CO}_2\text{H}$  $\xrightarrow{}$  $\text{H}_2\text{N} - \text{CH}_2$

$\text{H}_2\text{N} - \text{CH} - \text{CO}_2\text{H}$  $\xrightarrow{\text{Decarboxylase}}$  $\text{H}_2\text{N} - \text{CH}_2 + \text{CO}_2$
Scombroid Fish Poisoning

- **Onset**: immediate to 30 minutes
- **Initial symptoms**: tingling or burning sensation in the mouth, rash on the upper body, drop in blood pressure, headache, itching of the skin
- **Later symptoms**: nausea, vomiting, and diarrhea
- **Duration**: 3 hours to several days
- **Treatment**: antihistamines
- **Control**: proper chilling and temperature control
- **FDA guideline**: 50 ppm
Ciguatera Fish Poisoning

- **Four toxins**: structure not determined, heat stable
- **Source**: Groupers, barracudas, snappers, jacks, mackerel, and triggerfish feeding on several algae species including *Gambierdiscus*
- **Range**:
  - Tropical and subtropical waters worldwide
  - U.S.: East coast, Puerto Rico, Hawaii, Virgin Islands
- **Onset**: <6 hours
- **Symptoms**:
  - **Gastrointestinal**: nausea, vomiting, diarrhea
  - **Neurological**: numbness and tingling around mouth, joint pain, muscle ache, headache, temperature sensory reversal
  - **Cardiovascular**: arrhythmia, bradycardia, tachycardia, reduced blood pressure
Amnesic Shellfish Poisoning

- **Source:** Molluscan shellfish (mussels) feeding on algae (*Pseudo-nitzschia* spp.), viscera of Dungeness crab and anchovies
- **Range:** Northeast and northwest North America

![Domoic Acid 8 Isomers](image-url)
Amnesic Shellfish Poisoning

- **Onset:**
  - Gastrointestinal symptoms within 24 hours
  - Neurological symptoms within 48 hours

- **Symptoms:**
  - Gastrointestinal: vomiting, diarrhea, vomiting
  - Neurological: confusion, memory loss, disorientation, seizure coma

- **FDA guideline:**
  - 20 ppm domoic acid in all fish
  - 30 ppm domoic acid in viscera of Dungeness crab
Diarrheic Shellfish Poisoning
Okadaic acid and its derivatives

- **Source:** molluscan shellfish feeding on algae (*Dinophysis* and *Prorocentrum* spp.)
- **Range:** Japan, southeast Asia, Scandinavia, western Europe, Chile, New Zealand, eastern Canada
- **Toxins:** heat stable
- **Onset:** 30 minutes to 3 hours
- **Symptoms:** mild diarrhea, nausea, vomiting, abdominal pain, chills, headache, fever
- **Duration:** 2–3 days with or without treatment
- **FDA guideline:** 0.2 ppm okadaic acid plus 35–methyl okadaic acid (DXT 1) in all fish
Neurotoxic Shellfish Poisoning
Polyether brevetoxins (6 toxins + 2 phosphorus containing toxins)

- **Source:** molluscan shellfish feeding on algae (*Gymnodinium breve*)
- **Range:** gulf of Mexico and southern Atlantic coast in U.S.; New Zealand
- **Toxins:** heat stable
- **Onset:** a few minutes to a few hours
- **Symptoms:** tingling and numbness of the lips, tongue, and throat, muscular aches, dizziness, cold hot sensation reversal, diarrhea, vomiting
- **Duration:** a few hours to several days
- **FDA guideline:** 0.8 ppm brevetoxin–2 equivalent (20 mouse units/100g) in clams, mussels and oysters
Paralytic Shellfish Poisoning
Saxitoxins (12–20 analogs)

- **Source:** contaminated molluscan shellfish feeding on algae (*Alexandrium, Pyrodinium, Gymnodinium* spp.)
- **Range:** tropical to temperate waters worldwide
- **Onset:** ½ to 2 hours
- **Symptoms:** tingling, burning, numbness, drowsiness, incoherent speech, respiratory paralysis
- **Duration:** respiratory support within 12 hours of exposure results in complete recovery
- **FDA guideline:** 0.8 ppm saxitoxin equivalent (80μg/100g) in all fish
Intentionally Added Chemicals – Food Additives

- Direct (allowable limits under GMPs)
  - Preservatives (e.g., nitrite and sulfiting agents)
  - Nutritional additives (e.g., niacin)
  - Color additives
Unintentionally or Incidentally Added Chemicals

- Agricultural chemicals (e.g., pesticides, fungicides, herbicides, fertilizers, antibiotics and growth hormones)
- Prohibited substances (21 CFR, Part 21.189)
- Toxic elements and compounds (e.g., lead, zinc, arsenic, mercury, cyanide)
- Secondary direct and indirect
  - Plant chemicals (e.g., lubricants, cleaning compounds, sanitizers, paint)
Allergen Control

- Peanuts
- Tree Nuts
- Eggs
- Milk
- Soybeans
- Wheat
- Fish
- Shellfish
Food defense
  ◦ Intentional adulteration included in Sec 103 FSMA

Fukushima
  ◦ 2011 – Following damage to the nuclear power plant during an earthquake and tsunami in Japan
  ◦ Largest nuclear incident since Chernobyl disaster in 1986
  ◦ Radioactive water among biggest concerns
    • Radioactivity was subsequently detected in foods, particularly milk, vegetables, and seafood produced in areas neighboring the plant.
Radionuclides in Food

- As per FSMA: Radium (Ra) – $^{226}$Ra, $^{228}$Ra; Uranium (U) – $^{235}$U, $^{238}$U; Plutonium (Pu) – $^{239}$Pu; Strontium (St) – $^{90}$St; Iodine (I) – $^{131}$I, and Cesium (Cs) – $^{137}$Cs

- In certain locations in the United States, high concentrations of $^{226}$Ra, $^{228}$Ra and Uranium have been detected in private wells.

- EPA tests pasteurized milk for gamma analysis also analyzes for the detection of $^{90}$St.

- FDA tests 13 radionuclides as part of “Total Diet Study”
Considerations

- Use of contaminated water
  - Agricultural products
  - Animal byproducts
    - Milk (quarterly sampling by EPA)

  EPA's nationwide RadNet system monitors the air, precipitation, drinking water and milk for radiation [www.epa.gov/radnet/](http://www.epa.gov/radnet/)

- Proximity to nuclear reactor

- Use of ingredients that could be contaminated
Physical Hazards

Bone, plastic, metal, wood, glass, rocks, jewelry and body parts
Physical Hazard

- Any potentially harmful extraneous matter not normally found in food
Sources of Physical Hazards

- Contaminated raw materials
- Poorly designed or maintained facilities and equipment
- Faulty procedures during production
- Improper employee practices
Raw Material Receipt

- Material specifications
- Letters of guarantee
- Vendor inspection and certification
Equipment to Detect/Remove Foreign Materials

- Magnets/metal detector
- Screens/sifters
- Aspirators
- Riffle board
Facility

GMPs insure that the facility is not a source of physical hazards
Processes/Procedures

Identify hazardous practices (potential sources of metal, glass, etc.)
Employee Practices

- Adhere to GMPs
- Employee education
- Control maintenance work
<table>
<thead>
<tr>
<th><strong>Hazard</strong></th>
<th><strong>Control</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Glass from light fixture</td>
<td>Shatter-proof bulb shields</td>
</tr>
<tr>
<td>Metal fragments from equipment</td>
<td>PM; Magnets; metal detector</td>
</tr>
<tr>
<td>Wood from equipment</td>
<td>Eliminate</td>
</tr>
</tbody>
</table>