Subjects

- Pathogens
- FDA News
- HACCP/Preventive Measures
- Environmental Testing
- General Food Safety Issues
  - Wood Aging Boards
- Resources
Microbial foodborne diseases (2011)

- 47.8 million cases of gastrointestinal illnesses; 9.4 million due to known and 38.4 million due to unknown pathogens
- 127,000 serious illnesses resulting in hospitalizations; 56,000 due to known and 71,000 due to unknown pathogens
- 3,037 deaths (range: 1,492–4,983); 1,351 due to known and 1,686 due to unknown pathogens
### Top 5 Causes of Foodborne Illness

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Estimated annual number of illnesses</th>
<th>90% Credible Interval</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norovirus</td>
<td>5,461,731</td>
<td>3,227,078–8,309,480</td>
<td>58</td>
</tr>
<tr>
<td><em>Salmonella</em>, nontyphoidal</td>
<td>1,027,561</td>
<td>644,786–1,679,667</td>
<td>11</td>
</tr>
<tr>
<td><em>Clostridium perfringens</em></td>
<td>965,958</td>
<td>192,316–2,483,309</td>
<td>10</td>
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<tr>
<td><em>Campylobacter</em> spp.</td>
<td>845,024</td>
<td>337,031–1,611,083</td>
<td>9</td>
</tr>
<tr>
<td><em>Staphylococcus aureus</em></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>
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</tbody>
</table>

### Top 5 Requiring Hospitalization

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Estimated annual 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>
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<tr>
<td><em>Campylobacter</em> spp.</td>
<td>8,463</td>
<td>4,300–15,227</td>
<td>15</td>
</tr>
<tr>
<td><em>Toxoplasma gondii</em></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>
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<tr>
<td><strong>Subtotal</strong></td>
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<td></td>
<td>88</td>
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Top 5 Causing Death

<table>
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<tr>
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<th>Estimated annual number of deaths</th>
<th>90% Credible Interval</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salmonella, nontyphoidal</td>
<td>378</td>
<td>0–1,011</td>
<td>28</td>
</tr>
<tr>
<td>Toxoplasma gondii</td>
<td>327</td>
<td>200–482</td>
<td>24</td>
</tr>
<tr>
<td>Listeria monocytogenes</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>Campylobacter spp.</td>
<td>76</td>
<td>0–332</td>
<td>6</td>
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<tr>
<td><strong>Subtotal</strong></td>
<td></td>
<td><strong>88</strong></td>
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10 deadliest foodborne and waterborne outbreaks

1. **Typhoid fever, 1924-25** - Oysters from Long Island, NY, held in polluted waters, sickened more than 1,500 people in New York, Chicago, and Washington, D.C.; 150 died.
2. **Typhoid fever, 1903** - A public water source in Ithaca, NY, was polluted from a dam construction site, resulting in a typhoid outbreak involving 1,350 people; 82 died, including 29 Cornell University students.
3. **Streptococcus, 1911** - Raw milk delivered door-to-door in the Boston area was responsible for a strep outbreak; 45 people died.
4. **Listeria, 2011** - “Rocky Ford” cantaloupe from Colorado became contaminated, probably in the packing facility, sickening at least 146 people in 28 states; 33 deaths and one miscarriage. Ten additional deaths were possibly related to the outbreak.
5. **Listeria, 1985** – Mexican cheese made by a Los Angeles company sickened mostly Hispanic women, many who were pregnant; 28 died.
6. **Streptococcus, 1922** - Raw milk delivered door-to-door in Portland, OR, was contaminated; 22 died.
7. **Listeria, 1998** - Ball Park hot dogs and Sara Lee deli meats were recalled after Listeria was found in the Michigan processing plant; 21 died.
8. **Botulism, 1919** - Canned ripe olives from California sold to inland states were contaminated and caused outbreaks in three states; 19 died.
9. **Salmonella Typhimurium, 2008-09** - Peanut butter and paste contaminated with S. Typhimurium caused at least 714 illnesses in 46 states; 9 died.
10. **Listeria, 2002** - Sliced turkey meats from Pilgrim’s Pride were responsible for a multiple state outbreak; 8 died.
Norwalk like viruses

- Total: 23 million cases and 310 deaths
- Foodborne: 9.2 million cases and 120 deaths
- Up to 1 to 10 billion norovirus particles per g feces and 1 million infectious particles per ml of vomit
- Very low infectious dose (1/100,000 of 1/10,000 ml of vomit may contain enough virus to cause disease
Salmonella

- Increasingly recognized as a pathogen that can survive extremely well and for extremely long time in:
  - Dry food environments (cereal plants, powdered products)
  - Low water activity foods (peanut butter, cereal, flour, spices)
- Can cause disease even if no growth occurs in food
- Heat resistance is increased tremendously if Salmonella is present in a dry matrix
  - Temperatures that yield a >5 log reduction of Salmonella in milk may be virtually ineffective in reducing Salmonella present in low water activity food or ingredients
O157 EHEC

- Shiga toxin–producing *E coli* (STEC) is among the most common causes of foodborne diseases.
- GI illnesses, including nonbloody and bloody diarrhea.
- Patients with these diseases, especially children, may be affected by neurologic and renal complications, including Hemolytic Uremic Syndrome (HUS).
Non O157 EHEC

- Disease and transmission similar to O157:H7
- Approx. 112,700 human cases and 270 hospitalizations annually in US (2011 data)
- "Big Six" – O26, O45, O103, O111, O121, O145
- Declared an adulterant by USDA
- Tests for non O157 STEC/EHEC are now available
- Previous outbreaks have occurred in US, including one E. coli O157:NM outbreak linked to raw milk (2008)

E. coli O103 outbreak linked to raw milk cheese

- Three people became sick with E. coli O103 after consuming cheese made with unpasteurized cow’s milk.
- Raw milk cheese form implicated facility tested positive for Shiga-toxin E. coli (STEC)
  - Cheese had been aged 60 + days
**Campylobacter**

- Generally causes mild gastrointestinal human illness
  - Campylobacteriosis is one of the most common bacterial foodborne illnesses
- Linked to Guillain–Barré syndrome (acute neuromuscular paralysis)
- Linked to chicken and poultry, but also dairy and dairy products
- About 850,000 foodborne cases and 75 deaths/year in the US

**Listeria monocytogenes**

- Causes septicemia, abortion and encephalitis in humans and in animals
- Incubation period 7 - 60 days
- Human listeriosis occurs in both epidemic and sporadic cases
- Affects predominantly elderly and immuno-compromised people, pregnant women and newborns.
- Approx. 1,500 human cases/year in the U.S., resulting in approx. 250 deaths/year
- Responsible for majority of microbial food recalls
For the first time in 108 years, Blue Bell announces a product recall.

One of our machines produced a limited amount of frozen snacks with a potential listeria problem.

When this was detected all products produced by this machine were withdrawn. Our Blue Bell team members recovered all involved products in stores and storage.

This withdrawal in no way included our half gallons, quarts, pints, cups, three gallon ice cream or the majority of take-home frozen snacks.

For more information call 979-836-7977, Monday – Friday 8 a.m. – 5 p.m. CST or click here.
April 15, 2015

Blue Bell Creameries Expands Recall of Products Produced in Broken Arrow, Oklahoma Due to Possible Health Risk

Contact:
Consumer:
979-398-7077

Media:
Gene Grabowski
202-270-6000

FOR IMMEDIATE RELEASE — April 7, 2015 — Brenham, TX — Blue Bell Creameries is expanding its recall of products that were produced in the Broken Arrow, Okla., plant to include Banana Pudding Ice Cream pots which tested positive for Listeria monocytogenes, and additional products manufactured on the same line. These items have the potential to be young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, Listeria monocytogenes infection can cause miscarriages and stillbirths among pregnant women.

The products being recalled are distributed to retail outlets, including food service accounts, convenience stores and supermarkets in Alabama, Arizona, Arkansas, Colorado, Florida, Georgia, Illinois, Indiana, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Nevada, New Mexico, North Carolina, Ohio, Oklahoma, South Carolina, Tennessee, Texas, Virginia, and Wyoming.

No illnesses have been confirmed to date.
Food Safety Modernization Act

Required Records

- Written food safety plan
- Records that document monitoring of the preventive controls
- Records that document corrective actions
- Records that document verification
- Records that document training for the qualified individual
Overview of Key FSMA Provisions

Provisions that were effective immediately:

- New FDA authority for mandatory recalls
- Expanded FDA authority to request records re: “food of concern”
- New whistle-blower employee protection provisions
- New mandatory facility inspection schedule for FDA
- New FDA authority to collect fees for facility re-inspections and recall activities by the FDA if mandatory recall request is not complied with

Helados La Tapatia, Inc. Recalls Products Because of Possible Health Risk

- FOR IMMEDIATE RELEASE - March 19, 2014 - Helados La Tapatia, Inc., of Fresno, California, is voluntarily recalling all ice cream products, popsicles, fruit bars/cups and bolis due to a possible health risk from Listeria monocytogenes. Helados La Tapatia, Inc., is coordinating closely with regulatory officials.
- Listeria monocytogenes is an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, Listeria infection can cause miscarriages and stillbirths among pregnant women.
- The products were distributed in Arizona, California, Nevada, Washington, Guam and Canada in retail stores. The products are sold under the brand names of Helados La Tapatia and Icesations.
- No illnesses have been reported to date. The recall was the result of a routine inspection program by the U.S. FDA which revealed the presence of the bacteria on certain food processing equipment.
- A separate UPC Inventory of the products and their UPC codes is provided.

Cornell University Department of Food Science
Facility Inspection Schedules for FDA

- FDA must conduct initial inspections of “high risk” facilities within 5 years and follow-up inspections every 3 years thereafter.
- FDA must conduct initial inspections of facilities that are not “high risk” within 7 years and follow-up inspections every 5 years thereafter.
- FDA will consider a variety of factors in the determination of whether a facility is “high risk.”
- FDA may rely on other Federal, State, or local agencies to conduct the inspections.
- FDA examining whether it should exempt on-farm activities by small and very small businesses.

FDA Suspends Registration for Sunland, Inc.’s Peanut Butter Facility

The U.S. Food and Drug Administration (FDA) has ordered Sunland Inc., the nation’s largest producer of organic peanut butter and other peanut products, to close its door in the aftermath of a scathing report on the company’s filthy standards and cleanliness at its Portales, New Mexico facility.

This inspection of the Sunland facility followed detection of 41 breaches in 28 states from the consumption of Sunland’s tainted peanut butter, mostly from Trader Joe’s groceries. Sunland also made over 340 other products that had to be recalled between September and November. The FDA’s tests of the facility found that the facility was highly contaminated with salmonella, and also uncovered Sunland’s history of shipping products to consumers in spite of positive salmonella test results.

In a statement released today, the FDA stated, “In the interest of protecting public health, the U.S. Food and Drug Administration suspended the food facility registration of Sunland Inc., a producer of nuts, and related seeds.” The notice also explained that “a facility’s registration is suspended, if facility is prohibited from introducing food into interstate or intrastate commerce.” The FDA said its decision was based on Sunland’s history of violations and the fact that the peanut butter it produced has been linked to an outbreak of Salmonella Bremera that has sickened 41 people in 23 states.”
FDA Shuts Roos Foods Plant Linked to Multistate Listeria Outbreak

CHICAGO – FDA has shut down the Roos Foods plant linked to a multistate Listeria outbreak.

Consumer Reports

The Roos Foods plant in Illinois was shut down by the FDA after it linked the plant to a multistate Listeria outbreak.

The FDA said that Roos Foods was not found to be in compliance with current good manufacturing practices.

The plant was shut down on April 15, 2015.

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The FDA said that Roos Foods was not found to be in compliance with current good manufacturing practices.

The plant was shut down on April 15, 2015.
New Requirements for Hazard Analyses and Preventive Controls

- Focus of the new requirements is on prevention
- All registered facilities are required to:
  - Conduct a hazard analysis
  - Develop and implement preventive controls to address identified hazards
  - Establish procedures for corrective action in the event preventive controls are not implemented or are ineffective
  - Conduct follow-up hazard analyses every 3 years or earlier if changes may result in new hazards or increased the risk of identified hazards
- Facilities must prepare a written plan documenting its hazard analysis, preventive controls, and corrective action procedures

Seven Steps in HACCP

1. Conduct a Hazard Analysis (HA)
2. Identify the Critical Control Points (CCP)
3. Establish critical limits or thresholds which must be met at each CCP
4. Establish procedures to monitor CCPs
5. Establish the corrective action taken when critical limits are exceeded.
6. Establish procedures to verify that the HACCP system is working
7. Establish effective record keeping that will document the HACCP
Good Manufacturing Practices

Requirements Under the Code of Federal Regulations CFR
Title 21 (Food & Drug - FDA) Part 110
Current Good Manufacturing Practices
in Manufacturing, Packaging
or Holding Human Food

110.3 Definitions
110.5 Current GMP
110.10 Personnel
110.19 Exclusions
110.20 Plant & Grounds
110.35 Sanitary operations

110.37 Sanitary facilities
110.40 Equipment & utensils
110.80 Process & controls
110.93 Warehousing/distribution
110.110 Natural or unavoidable defects in food

GMPs = General required guidelines that are the basis for more specific regulations and company policies


Sanitation Standard Operating Procedures

- **Sanitation Controls** - Each processor shall have and implement Sanitation Standard Operation Procedures (SSOP) or Prerequisite Programs that address sanitation conditions and practices **before**, **during**, & **after processing**.

- **Must be**:
  - *Designed to support the HACCP plan*
  - *In compliance with appropriate regulations*
  - *In writing, procedures with documentation*
Eight Key Sanitation Conditions and Practices

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

*There will some overlap between the different SSOPs*

*There will be some items that are not covered by the mandatory 8 SSOPs*
Product Description

**Product:** Normandy Camembert

**Issue Date:** October 6, 2014
**Supersedes:** Version 2

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<th>Most Current Version (X=yes)</th>
<th>Comments</th>
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</tbody>
</table>

**HACCP System Validation Documentation (Annually or when changes are made in raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product and consumer complaints):**

- X X

**HACCP System Verification Documentation (Including calibration of CCP monitoring equipment (i.e., past. equipment checks); review of CCP monitoring records, corrective action records and calibration records; and plant signatures and date on all of these records):**

- X X Updated 10/13/14 following deviation

**Other Applicable NCIMS Requirements - Appendix K (list each separately, add rows as needed):**

- X X

**Other Prerequisite Programs that are relied upon in the Hazard Analysis to reduce the likelihood of a potential hazard (List each separately, add rows as needed):**

- Prerequisite Program #1 - Safety of Water
- Prerequisite Program #2 - Condition and Cleanliness of Food Contact Surfaces
- Prerequisite Program #3 - Prevention of Cross-Contamination
- Prerequisite Program #4 - Maintenance of Hand Washing and Sanitizing and Toilet Facilities
- Prerequisite Program #5 - Protection of milk or milk product, packaging material, and product contact surfaces from adulteration
- Prerequisite Program #6 - Proper Labeling, Storage, and Use of Toxic Compounds
- Prerequisite Program #7 - Control of Employee Health Condition
- Prerequisite Program #8 - Exclusion of Pests from the milk plant

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<tr>
<td>Product Description(s)</td>
<td>X</td>
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**Required HACCP documents including forms are dated or identified with current version number. Each page is identified with a new date or version number whenever:**

- X X Updated 09/01/14
Environmental sampling plans – the need for written procedures and plans for corrections

- Written plans for corrections that need to be performed after positive samples are essential
  - Plans need to be plant specific
  - Each positive sample should be followed up with additional investigations
- All corrections need to be documented in writing
Building an Environmental Plan

- Symbols
- Drain 🚰
- Doors ❌

Assumptions
- All floors slope to drains
Build an Environmental Sampling Plan

Wooden Boards for Aging…..

Excerpt from FDA Policy Letter

The use of wooden shelves, rough or otherwise, for cheese ripening does not conform to cGMP requirements, which require that “all plant equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained.” 21 CFR 110.40(a). Wooden shelves or boards cannot be adequately cleaned and sanitized.
Undeclared Allergens Behind Half of FDA’s Fourth-Quarter Recalls

By [No author listed] [March 30, 2015]

Recalls in the final three months of 2014 totaled up to 150 events, up from the previous highest quarter of the year. The total included recalls overseen by both the U.S. Food and Drug Administration (FDA) and USDA’s Food Safety and Inspection Service (FSIS).

The count comes from government recalls managed and reported by Indianapolis-based Sosland Experion Solutions, which manages recalls.

Overall in 2014, food took a backseat to recalls in automotive, medical devices and pharmaceutical, which set records in both numbers and fines.

In the fourth quarter of 2014, FDA saw 147 recalls involving 5,189 establishments of 118 million recalled units. While the number of FDA food-related recalls was down, there was a 192 percent increase over the previous quarter in the number of units or volume involved.

Half the FDA recalls were for undeclared allergens and, for the second consecutive quarter, more than 8 percent of FDA food recalls were classified as Class II events, meaning there was no immediate threat to public health.

FDA monitors about 1 percent of the food manufactured for sale in the U.S., including both domestic and international food products.

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GAO: FDA Not Keeping Pace With FSMA Foreign Inspection Mandate

By [No author listed] [March 30, 2015]

The Food and Drug Administration (FDA) needs to do more to ensure that its foreign offices are keeping food imported to the U.S. safe, a new report released Friday by the Government Accountability Office (GAO).

In 2009, GAO studied FDA’s foreign offices and found that they engaged in a variety of activities relating to food safety but faced challenges due to an increasing workload and other factors.

In this follow-up to the 2009 report, GAO found that the agency is not keeping pace with the number of foreign inspections mandated by the Food Safety Modernization Act (FSMA).

Under the act, FDA was required to inspect 600 foreign food facilities in the first year following its enactment and, for each of the next 3 years, inspect at least twice the number of facilities inspected during the previous year.

By this estimate, the agency should have inspected 4,900 facilities in 2014, but it only conducted 3,193 inspections this past year.

"FDA officials told us that the agency has not met -- and is not planning to meet -- the FSMA mandates," GAO’s report states. "They questioned the usefulness of conducting the number of inspections mandated by FSMA.

For the same reasons, government officials also question whether the number of inspections is in the range of a justifiable risk.

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Cornell University Department of Food Science

April 15, 2015
The U.S. Food and Drug Administration (FDA) has issued a proposed rule to amend and improve its regulations on food facility registration.

Facilities that manufacture, process, pack, or hold food for consumption in the U.S. must register with FDA, but "retail food establishments," farms, restaurants and certain other entities are exempt from the requirement.

The proposed rule would amend the definition of a retail food establishment to expand the number of facilities that wouldn’t have to register. FDA estimates that there are about 71,000 farms that only sell food directly to consumers through roadside stands, farmers markets, and Community Supported Agriculture (CSA) programs, and these would fall under the expanded exemption.

The additional establishments would then also not be subject to the requirements of the Food Safety Modernization Act (FSMA) preventive controls rule, which applies to facilities that are required to register.

“One of the most concerning aspects of the FSMA rules for farmers has been the confusion surrounding when FDA will consider a farm to also be a food facility,” said Sophie Kranzweig, policy specialist with the National Sustainable Agriculture Coalition. “This clarification is critical to understanding and avoiding FSMA’s adverse impacts on farms that sell directly to consumers.”

Cornell University Dairy Foods Extension

In This Issue

Cornell Ice Cream and Big Red Cheddar: Featured at the Farm Bureau Taste of NY Reception

Recent Publications & Presentations

Please check for a list of links to recent dairy food publications through Cornell Food Science.

Relevant Cornell Dairy News

How People Around the World Eat Their Yogurt

Milk industry fights back against ‘antidairy’ talk
Coliform Study

- Raw milk AND pasteurized milk cheeses
- Are coliforms a good indicator of anything???
- If you’d be willing to participate, in confidentiality, please see me after the meeting today, or email me at rdr10@cornell.edu

- https://www.facebook.com/BigRedFoodScience
- www.twitter.com/BigRedFoodSci
- www.milkfacts.info
- http://dairyextension.foodscience.cornell.edu/
- rdr10@cornell.edu