FSIS Regulations To Control *Listeria monocytogenes* in Meat and Poultry Products

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Listeria monocytogenes

- Gram-positive rod shaped bacterium

Environment

Processing Plants

Refrigerated and Ready-to-Eat foods
- deli meats
- ready-to-eat products
**Listeria monocytogenes Epidemiology**

- Estimated 2,493 cases/year\(^1\)
  - 2,298 (92%) Hospitalized
  - 499 (20%) Fatalities

- Foodborne listeriosis rare, but high mortality (~20%)

- Highest risk: neonates, elderly, immunocompromised

- Healthy People 2010 (cases per 100,000):

<table>
<thead>
<tr>
<th>1997 Baseline</th>
<th>2010 Target</th>
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<tbody>
<tr>
<td>0.5</td>
<td>0.25</td>
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\(^1\) Mead et al. (1999)
Listeria monocytogenes Infection

*Infected Individuals

- **Non-pregnant Women, Men, Children**
  - Septicemia
  - Meningoencephalitis

- **Pregnant Women**
  - Infants
    - Stillbirth
    - Fever
    - Spontaneous Abortion

- **Infants**
  - Convulsions
  - Death
  - Septicemia
  - Vomiting

*Mild flu-like symptoms*
Food Safety and Inspection Service (FSIS)

- FSIS is the public health agency within the USDA
  - Regulates meat, poultry and egg products to ensure these are not adulterated
  - Authority from FMIA, PPIA, EPIA
    FSIS can hold, detain or request recall on suspect products including raw, processed and ready-to-eat
  - Key Organization Units
    - Policy and Programs: policies, regulations, directives, notices
    - Public Health Science: microbiology, risk assessment, epidemiology, testing
    - Field Operations: inspection, compliance, recall
History of *Listeria*

- 1929: Human pathogen; *Listerella monocytogenes*
- 1940: Named *Listeria monocytogenes*; *Listerella* had been used for a mold in honor of brother Arthur and father Joseph Lister
- 1979: Recognized as emerging foodborne pathogen
- 1987: FSIS regulatory testing of ready-to-eat meat and poultry products initiated
  - Led to ‘zero tolerance’ policy
    - No detectable amount of *Listeria monocytogenes* on a 25 gram sample
FSIS Regulatory Testing for LM in RTE Products by Calendar Year 1990 - 2006

Percent Positive

Calendar Year


4.61% 4.03% 3.61% 3.44% 3.90% 3.02% 2.91% 2.25% 2.54% 1.91% 1.45% 1.32% 1.03% 0.76% 0.55% 0.64% 0.61%
Outbreaks of *Listeria monocytogenes* in Meat and Poultry Products

Ice cream or Salami:
- 36 illnesses
- 16 deaths
- Lm not isolated

**1998**

**1986**

Hot Dogs and Deli Meats:
- 101 illnesses
- 15 deaths
- 6 stillbirths/miscarriages
1998-1999

- FSIS Directive 10,240.1
  “Listeria monocytogenes: Testing Procedures and Sanitation Information”

- Federal Register Notice
  “Listeria Contamination of RTE Products: Compliance with the HACCP Systems Regulations”
  Reassess HACCP plan for Lm hazard

- FSIS Notice
  “Instructions for Verifying the Listeria monocytogenes Reassessment”
## Outbreaks of *Listeria monocytogenes* in Meat and Poultry Products

<table>
<thead>
<tr>
<th>Year</th>
<th>Ice cream or Salami</th>
<th>Turkey Deli Meat</th>
<th>Hot Dogs and Deli Meats</th>
</tr>
</thead>
</table>
| 1986 | • 36 illnesses  
      | • 16 deaths        
      | • *Lm* not isolated| 1998                    |
| 1998 | • 29 illnesses  
      | • 4 deaths         
      | • 3 miscarriages/stillbirths| 2000                  |
| 2000 | • 101 illnesses   
      | • 15 deaths        
      | • 6 stillbirths/miscarriages|                      |
**2000-2001**

- *Listeria* Action Plan Released
  - Healthy People 2010 Goal: 0.25/100,000 revised to 2005
- Direct Rule “Food Additives for Use in Meat and Poultry Products: Sodium Diacetate, Sodium Acetate, Sodium Lactate and Potassium Lactate”
- Proposed Rule: Performance Standards for the Production of Processed Meat and Poultry Products
- FDA and FSIS Published: Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods.
Outbreaks of *Listeria monocytogenes* in Meat and Poultry Products

- **Hot Dogs and Deli Meats:**
  - 101 illnesses
  - 15 deaths
  - 6 stillbirths/miscarriages

- **Turkey Deli Meat:**
  - 29 illnesses
  - 4 deaths
  - 3 miscarriages/stillbirths

- **Ice cream or Salami:**
  - 36 illnesses
  - 16 deaths
  - Lm not isolated

- **1986**
  - Hot Dogs and Deli Meats:
    - 101 illnesses
    - 15 deaths
    - 6 stillbirths/miscarriages

- **1998**
  - Turkey Deli Meat:
    - 29 illnesses
    - 4 deaths
    - 3 miscarriages/stillbirths

- **2000**
  - Turkey Deli Meat:
    - 46 illnesses
    - 7 deaths
    - 3 miscarriages/stillbirths

- **2002**
  - No specific outbreak mentioned
2002

- FSIS Directive 10, 240.2
  “Microbial Sampling of RTE Products for FSIS Verification Testing Program”

- December 9: Directive 10,240.3, "Microbial Sampling of RTE Products for the FSIS Verification Testing Program"
  - Include sampling of product, food contact surfaces, and of other surfaces in the RTE operation
  - Sampling based on high, medium or low risk products
Release of FSIS Risk Assessment for *L. monocytogenes* in Deli Meats
- Risk of listeriosis due to RTE products mitigated through post lethality processes

*Listeria* Interim Final Rule: Effective October 6
Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products

Establishments must use any of the 3 Alternative controls for Lm in the post-lethality environment:

- Alternative 1: Use of post-lethality treatment AND antimicrobial agent/process
- Alternative 2: Use of post-lethality treatment OR antimicrobial agent/process
- Alternative 3: Use of sanitation procedures
2004-2005

- Updated Compliance Guidelines and Questions and Answers for the Lm rule
- FSIS Assessment of *Listeria* Interim Rule
- Updated 2003 Risk Assessment model using actual volume data
- FSIS Notice
  RTE001 Sampling Program for the Lm Risk-Based Verification Program
  - Lm Risk-based Verification Program
FSIS Directives 10, 240.4 and 10, 240.5

- Products, environmental and food contact surface samples are collected based on a risk-ranking model
- Enforcement, Investigations, and Analysis Officer (EIAO) conduct testing
Human Impact

- Rates of human illnesses...
  - 1989-1993, Listeriosis Study Group reported a 44% decrease
  - 2005, CDC-led active surveillance, FoodNet project reported a 32% decrease from 1996-1998
  - 2005, Lm incidence close to HP 2005 goal (0.3 cases/100,000)
- Interim Final Rule estimated to save 118 lives
- Deli meat sliced at retail are 2.5 times more likely to contribute to a case of listeriosis than if sliced in a federally inspected establishment
- Most of the deaths for which we have data occur in the elderly and thus the most impact can be seen there
Conclusions

- Continued reduction in Lm positive sampling results

- FSIS regulations have led to more stringent control measures

- Additional studies are needed to determine the proportion of illnesses attributable to RTE FSIS-regulated products and impact of FSIS on listeriosis

- Continued efforts are needed to ensure the reduction of *Listeria monocytogenes* in the US
Acknowledgements

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