United States Department of Agriculture
Food Safety and Inspection Service

FSIS Regulatory Update

8th Annual OutbreakNet Meeting
16th Annual PulseNet Update Meeting
Atlanta, GA, August 30, 2012

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United States Department of Agriculture
Food Safety and Inspection Service

Agenda

• Non O157 STEC Testing
• National Residue Testing
• Major Outbreaks
Risk Management of Non-O157 STEC in FSIS-Regulated Foods
June 4, 2012 STEC Verification Activities

- FSIS will initiate testing of raw beef manufacturing trimmings derived only from cattle slaughtered on or after June 4, 2012

- Eligible samples would be tested for *E. coli* O157:H7 and the top 6 sero-groups of non-O157 STEC (O26, O45, O103, O111, O121, and O145)

FSIS method MLG 5B.01
## Serogroup of non-O157 STEC isolates from humans sent to CDC

<table>
<thead>
<tr>
<th>Serogroup</th>
<th>1983-2002</th>
<th>2003-2006</th>
<th>Total</th>
<th>Cumulative n</th>
<th>Cumulative %</th>
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<tr>
<td>1</td>
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<td>209</td>
<td>309</td>
<td>518</td>
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<tr>
<td>2</td>
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<td>152</td>
<td>188</td>
<td>340</td>
<td>858</td>
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<td>161</td>
<td>1360</td>
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<td>99</td>
<td>162</td>
<td>1522</td>
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<tr>
<td>6</td>
<td>O145</td>
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<td>61</td>
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<td>1655</td>
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<td>8</td>
<td>O118</td>
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<td>20</td>
<td>29</td>
<td>1684</td>
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<tr>
<td>9</td>
<td>O91</td>
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<td>15</td>
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<td>1707</td>
</tr>
<tr>
<td>10</td>
<td>O113</td>
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<td>1</td>
<td>9</td>
<td>1716</td>
</tr>
<tr>
<td>11</td>
<td>O153</td>
<td>7</td>
<td>4</td>
<td>11</td>
<td>1727</td>
</tr>
<tr>
<td>12</td>
<td>O146</td>
<td>6</td>
<td>1</td>
<td>7</td>
<td>1734</td>
</tr>
<tr>
<td>13</td>
<td>O174</td>
<td>6</td>
<td>8</td>
<td>14</td>
<td>1748</td>
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<tr>
<td>other typed</td>
<td></td>
<td>95</td>
<td>125</td>
<td>220</td>
<td>1968</td>
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<tr>
<td>total</td>
<td></td>
<td>817</td>
<td>1151</td>
<td>1968</td>
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</table>
Non-O157 STEC causes permanent, life-threatening damage to major organ systems

• Similar range of outcomes relative to *E. coli* O157:H7
  – Bloody diarrhea
  – Hospitalization
  – Hemolytic uremic syndrome
  – Death

• *E. coli* O157:H7 infection is often more severe
  – US: FoodNet, Hedican, Scallan
  – Studies from Hungary, Germany, Austria, Argentina, and Australia

• However, in some studies non-O157 infection is equivalent or more severe
  – Studies from Australia, Germany, Denmark, Switzerland
E. coli O26 Associated with Ground Beef, 2010

- August 5, 2010: FSIS notified by Maine Department of Agriculture of illness cluster
- 3 case-patients reported in 2 states, Maine and New York
  - *E. coli* O26 with a rare, indistinguishable PFGE pattern
  - No hospitalizations, deaths, or HUS reported
- Ground beef implicated as source
E. coli O26 Associated with Ground Beef, 2010

- August 28, 2010: Establishment A recalled 8,500 lbs of ground beef
- First ground beef recall associated with non-O157 in the United States
## Non-O157 STEC by Serogroup and *E. coli* O157:H7, Raw Ground Beef Components as of 8/19/2012

<table>
<thead>
<tr>
<th>Target STEC</th>
<th>Federal Plants</th>
<th>Import</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Trim Verification Percent Positive (Number)</td>
<td>Follow-up to RGB Positive at Supplier Percent Positive (Number)</td>
</tr>
<tr>
<td>O157:H7</td>
<td>0.61% (7/1147)</td>
<td>1.03% (1/97)</td>
</tr>
<tr>
<td>Total non-O157 STEC³</td>
<td>1.07% (5/467)</td>
<td>0.00% (0/2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Federal Plants</th>
<th>Import</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>O26</td>
<td>0.00% (0/467)</td>
<td>0.00% (0/2)</td>
</tr>
<tr>
<td>O45</td>
<td>0.21% (1/467)</td>
<td>0.00% (0/2)</td>
</tr>
<tr>
<td>O103</td>
<td>0.43% (2/467)</td>
<td>0.00% (0/2)</td>
</tr>
<tr>
<td>O111</td>
<td>0.21% (1/467)</td>
<td>0.00% (0/2)</td>
</tr>
<tr>
<td>O121</td>
<td>0.00% (0/467)</td>
<td>0.00% (0/2)</td>
</tr>
<tr>
<td>O145</td>
<td>0.21% (1/467)</td>
<td>0.00% (0/2)</td>
</tr>
</tbody>
</table>
Update: National Residue Program (NRP)
NRP Mission Statement

• To protect consumers from unsafe exposure to chemical residues in meat, poultry, and egg products

http://www.culinate.com/hunk/29180
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Food Safety and Inspection Service

**NRP Goals**

- Revise residue sampling & scheduling algorithms
- Improve documentation of chemical hazards
- Identify trends and high-priority compounds to research
- Establish protocol for recall decisions
- Develop analytical techniques and improve analysis
- Monitor chemical exposure in the industry
- Respond to public and stakeholder concern
Multi-Residue Method (MRM)

- Modern approach to residue testing
- Collaboration with Agricultural Research Service
- FSIS labs received new methods in 2011
- The MRM methods be implemented as part of overall improvements to NRP
MRM: a Significant Improvement

- Screen over 120 analytes - not just antibiotics
- Chemical method distinguishes individual analytes

1st FSIS method to analyze multiple chemicals per sample; screen many types of analytes
The NRP initiatives will result in:

- Identification of emerging contaminants
- Prevention of adulterated meat, poultry, and egg products from entering the marketplace
- Discouragement of improper behavior by producers, processors, and importers
- Closure of regulatory gaps between Agencies
Update: Outbreaks
FSIS Investigations: Facts and Figures

• Directive 8080.3 describes FSIS “investigations”
• Investigate 20-30 illness clusters per year
• Average size of investigated outbreaks is about 25 case-patients; can be substantially smaller depending on the pathogen (e.g., Lm)
• About 1/3 of all investigations are linked to a product recall
• FSIS attention on Salmonella has increased in recent years, in association with major outbreaks
FY11 Investigations

- 7 illness clusters investigated
  - 4 *Salmonella*
  - 2 *E. coli* O157:H7
  - 1 Lm

- 4 out of 7 (57%) associated with a product recall

- 2 multi-state outbreaks associated with > 100 case-patients, both involving *Salmonella enterica Serotype* Heidelberg
  - Ground turkey
  - Chicken livers
Salmonella enterica serotype Heidelberg: Ground Turkey

- May 20, 2011: PulseNet Database Team identified cluster; FSIS Outbreaks Section (OSEL) shared with Applied Epidemiology Division

- 29 case-patients in 18 states with indistinguishable PFGE pattern

- No clear exposure pattern initially identified

- Three NARMS retail ground turkey samples matched the cluster by PFGE
  - Resistant to ampicillin, streptomycin, tetracycline, and gentamycin
FSIS Investigates Outbreak

- June 24, 2011: FSIS initiated an investigation
- Ground turkey consumption associated with high proportion of case-patients
  - 32% respondents indicated recent ground turkey consumption compared to 11%
FSIS Response

- July 29, 2011: FSIS issued a public health alert
- The alert noted 77 illnesses in 26 states
- Proper cooking and handling of raw poultry advised
Ground Turkey Recall

- August 3, 2011: Establishment B recalled 36 million lbs of ground turkey products
- 182 case-patients from 38 states linked to outbreak*
- Largest recall of ground turkey to date
  - Approximately 2 million lbs recovered from commerce

* As of June 2012
Salmonella enterica Serotype Heidelberg: Chicken Livers

- September 2, 2011: CDC notified FSIS of illness cluster
  - 221 case-patients in 34 states
  - Case definition was refined; initial count reduced to 170
    - Common PFGE pattern; increase in northeastern states directed focus to those states
- Identified exposures: chicken and eggs
- Kosher community appeared disproportionately affected
FSIS Investigation

• September 7, 2011: began an FSIS investigation
  – FDA engaged due to possible involvement of FDA-regulated products
  – Kosher milk soon identified as additional possible exposure of concern

• November 2, 2011: New York State Agriculture and Marketing Service reported leftover chicken livers positive for outbreak strain

• FSIS found labeling issue: Product appeared to be ready-to-eat (described as ‘broiled’”) but was in fact only partially cooked
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Chicken Liver Recall

• November 8, 2011: Establishment C recalled broiled chicken liver products.
Outbreak Investigations: FY 11 Lessons Learned

• Strong relationships with federal, state, and local public health partners continue to be vital

• Epidemiological evidence used in combination with laboratory findings is key to well-informed assessments

• Early detection and actionable traceback information help ensure effective response
Thank you!
Back-Up Slides

Background on STEC/nSTEC similarities
nSTEC lab methods
Early Detection Consumer Complaints
**STEC and ECOH behave similarly!**

- **No discernible differences in translocation between STEC and non-O157 STEC following blade or chemical tenderization of beef subprimal:**
  - Majority of cells to top-most 1 cm (25% to 82%)
  - STEC and non-O157 STEC were recovered from all six segments

- **No discernible differences in thermal resistance between STEC and non-O157 STEC following cooking of blade tenderized or chemically-injected steaks:**
  - Higher temperatures generated greater lethality (1.5 to 4.5 log reduction)
  - No difference in lethality based on steak thickness (1.0 or 1.5 in.)

- **No discernible differences in viability (survival of STEC and non-O157 STEC, but not growth) in blade tenderized beef or chemically injected steaks during storage at 4°C for 15 days**

- Greater risk for consumption of blade and chemical tenderized steaks compared to otherwise similar, but intact, steaks
  - 2-fold blade tenderized steaks
  - 4-fold chemically-injected steaks
MLG 5B.02 nSTEC Method Overview

Day 1
• Sample prep and primary enrichment

Day 2
• PCR screen for \textit{stx} and \textit{eae} genes
• PCR screen for O group specific genes
• Immunomagnetic separation, Modified Rainbow Agar (mRBA) Plating

Day 3
• Latex agglutination of colonies on mRBA
• Streak latex (+) colonies onto Sheep Blood Agar (SBA) plates

Day 4
• Individual colonies on SBA
  • Latex positive
  • PCR positive (\textit{stx}, \textit{eae}, O group)
  • Biochemically identified as \textit{E. coli}
Early Detection: Consumer Complaints

- In summer 2012, FSIS plans to deploy an electronic Consumer Complaint Form (eCCF) on its Web site
- Intended to provide a mechanism for consumers to report problems with FSIS-regulated food
- Goal is to improve FSIS’s ability to detect and respond to foodborne hazards
- May potentially augment pre-hospital event surveillance
Thank You