Overview of Trim Sampling Compliance Guidelines and Discussion

Daniel Engeljohn, PhD
Office of Policy and Program Development
Outline of Today’s Presentation

• Overview of
  • Purpose of the guideline
  • Guideline content
  • Next steps regarding the guideline

• Opportunity to provide public comment
  • Clarification to issues raised will be provided, when possible
Purpose of the Guideline

- Adverse events related to *E. coli* O157:H7 in both CY2007 and CY2008 (through 10/7/08) identified that controls for this pathogen are not adequate to protect public health
  - Outbreak-associated recalls in both years
  - Increase in % positive test results in both trim and ground beef in both years
    - **Trim**: 0.42% (CY2007) vs 0.71% (CY2008)
    - **Ground beef**: 0.20% (CY2007) vs 0.40% (CY2008)
Purpose of the Guideline (continued)

- Provide information about the design of sampling and testing programs
  - Primary focus on trim manufacturers, especially those that slaughter the beef used as trim source materials
  - Assist in the development of programs to assess the adequacy of process controls
  - Design sampling and testing programs that lead to reductions of contaminated product
Guideline Content

• Identification of principles of SPC related to \textit{E. coli} O157:H7 control
  • Contamination during slaughter/dressing is reasonably likely to occur, even under GMP
  • Contamination should be minimized to the maximum extent practical
  • Decontamination treatments should remove \textit{E. coli} O157:H7, to the maximum extent practical, to a non-detectable level
    • Capability of the slaughter/dressing operation, through validation, should be known
    • Microbial indicators of process control should be established
Guideline Content
(Principles of SPC continued)

• Sampling and testing for *E. coli* O157:H7 should occur at a frequency sufficient to find evidence of contamination exiting the slaughter/dressing operation
  • Every production lot should be sampled and tested for *E. coli* O157:H7
  • Results of the testing should inform the HACCP system (i.e., provide feedback; cause an investigation of cause; where appropriate, cause an adjustment to controls)
    • Adequacy of the slaughter/dressing operation
    • Adequacy of the sampling/testing program
Guideline Content

(Principles of SPC continued)

• High prevalence months for *E. coli* O157:H7 are known and should be addressed
  • Controls should address the higher likelihood of this pathogen contaminating carcasses and be as protective as those during low prevalence months
    • Contamination may overwhelm the capability of the slaughter/dressing operation and the subsequent decontamination/antimicrobial treatments
  • Trim sampling and testing for *E. coli* O157:H7 provides an indication of the adequacy of the prior controls; programs should be designed to provide high confidence that contamination is minimized and at a low level

• Sporadic positive test results are expected and not evidence of process control failure
  • Multiple positive test results involving same source materials (“high event days”) could indicate systemic failure to adequately control for the presence of *E. coli* O157:H7 (out-of-control process)
    • Negative results are suspect (false negative)
    • Insanitary conditions may have occurred
Guideline Content
(Testing Results for Trim)

• FSIS nationwide baseline survey found 0.68% of trim available for use as raw ground beef contaminated with *E. coli* O157:H7

• Some, but not all, sampled production lots were pre-tested by the establishment

• Anecdotal information suggests that the average annual positive rate in pre-tested trim is 1-2%
  • FSIS selected 1.5% as a guidance value for purposes of deriving “high event day” criteria for identifying potential false negative results
Guideline Content

(Verification Testing)

• Testing should be for both *E. coli* O157:H7, as well as for microbial indicators of process control
  • Although HACCP systems should require little end-product testing, validated safeguards built in early in the slaughter/dressing process currently are not sufficient to ensure adequate control for *E. coli* O157:H7
    • Testing is an essential part of an effective HACCP system, especially on trim before distribution to grinding operations
    • Testing should occur at all opportunities where raw beef is handled prior to sale to consumer
  
• Each testing event provides added confidence that if *E. coli* O157:H7 was present, it is present at a low level sufficient to remain non-detectable
Guideline Content
(Small/Very Small Plant Frequency for Testing)

- Practical considerations for designing effective HACCP systems differ for these plants compared to large plants, particularly because source materials often are purchased.
  - Minimum frequencies for testing assumed that all production lots of source materials were subjected to testing.
  - Increase testing frequency during high prevalence months (e.g., factor of 2).

<table>
<thead>
<tr>
<th>Production Rate</th>
<th>Testing Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;250,000#/day</td>
<td>&gt;1/month</td>
</tr>
<tr>
<td>&gt;50,000 but &lt;=250,000#/day</td>
<td>At least monthly</td>
</tr>
<tr>
<td>&gt;1,000 but &lt;=50,000#/day</td>
<td>At least once every 2nd month</td>
</tr>
<tr>
<td>&lt;=1,000</td>
<td>At least once every 3rd month</td>
</tr>
</tbody>
</table>
Guideline Content
(Designing Trim Sampling Plans)

• Define the production lot (i.e., sampled lot)
  • If same source materials are present in other production lots, establishing microbiological independence is essential
    • Design a sample collection procedure to find point source contamination (at least N-60)
  • Production lot size is a critical consideration
    • The larger the lot size, the greater the vulnerability for not finding E. coli O157:H7
    • Best to collect the entire sample from each combo bin for a composited sample representing the lot; if boxed trim is available, best to collect one or more samples from each box for a composited sample representing the lot
Guideline Content
(Understand the Laboratory Testing Method Capability)

- FSIS analyzes a 325g composited sample
  - Ensure that the laboratory is analyzing a sample size at least equivalent to this
  - The laboratory may enrich individual production lot samples, select an aliquot from each enrichment, and then combine these aliquots for a “composite” analysis in order to ensure laboratory efficiency and reduce cost – this can be acceptable
  - If a positive is found in this “composite,” the laboratory may individually analyze an aliquot from the original enrichment in order to discern which production lot(s) contributed to the positive finding – this can be acceptable and is not considered “retesting”
Guideline Content
(Process Control)

• Proper interpretation of the sampling and testing results for a well designed program is critical for ensuring that false negative product is not released for use in raw ground beef

• Using the previously identified 0.68% and 1.5% criteria, an establishment can ascertain whether the % positive rate is greater than 1.5%, with 95% confidence

• If 55 production lots are produced in a given period of time (daily for large volume establishment; ~ 1 per weekday -- a quarter – for a very small establishment)
  • 3 positives could indicate a systemic failure for control of *E. coli* O157:H7 in the source materials
  • Establishments using screen methods capturing O157 and non-O157 STECs likely would have a higher positive rate than FSIS
Guideline Content
(Summary)

• Properly designed raw beef HACCP systems
  • Have feedback mechanisms to reduce the likelihood of systemic failure to control for *E. coli* O157:H7
    • Use sampling and testing for *E. coli* O157:H7 to discern when evidence of systemic failure is developing, and investigate each positive finding in order to correct and prevent future incidents
Next Steps

• Obtain public comment on the draft guideline
• Revise the guideline
• Issue a final guideline
  • Ensure that stakeholders are aware of the document
  • Provide instruction to FSIS personnel on how to interpret the guidance (it is not a regulatory document; it intended to provide a framework for FSIS personnel to consider when assessing the adequacy of HACCP systems during a Food Safety Assessment)
• Assess consistency and uniformity of sampling and testing trim
  • Update the guidance, as necessary
Thank you

• Public comments will now be received
  • Clarification to issues raised will be provided, when possible