United States Department of Agriculture
Food Safety and Inspection Service

Overview of Trim Sampling Compliance Guidelines and Discussion

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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 *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 *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)

>250,000#/day	>1/month
>50,000 but </=250,000#/day	At least monthly
>1,000 but </=50,000#/day	At least once every 2nd months
</=1,000	At least once every 3rd month

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