



# **Food Safety Assessments for *Escherichia Coli* O157:H7**

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# CY 2007 FSIS Recall Data

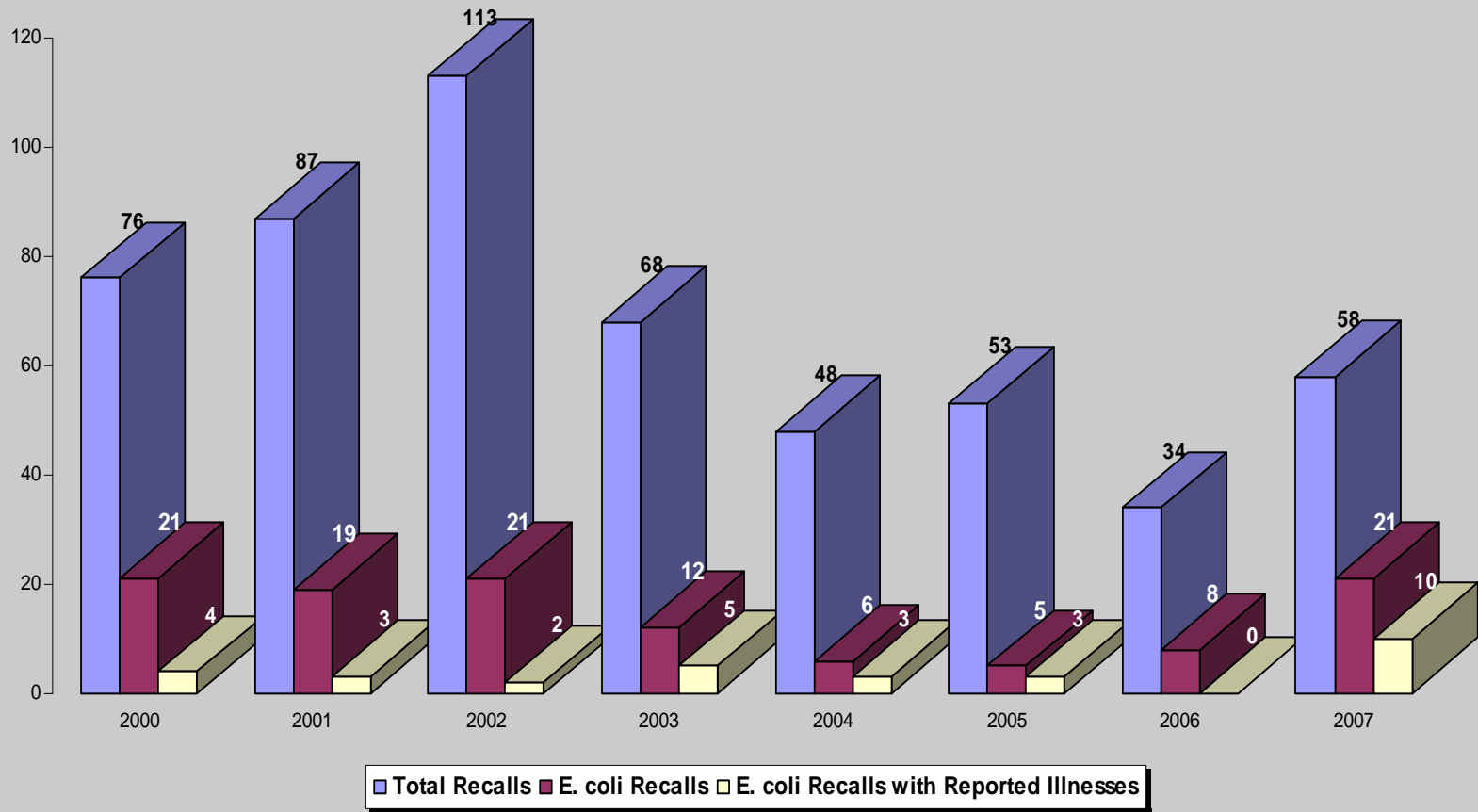
- 21 class I recalls due to *E. coli* O157:H7
- Total poundage for all 21 cases was approximately 33,358,521 lbs.
- Primarily involved ground beef, but other products were involved, e.g. pepperoni pizza and mechanically tenderized steaks.



# CY 2007 FSIS Recall Data

- The reasons for the recall were:
  - 8 due to FSIS testing and the firm did not hold the sampled lot
  - 3 due to industry sampling
  - 10 due to illnesses

***E. coli*-Related Recalls in Relation to Total Recalls by Calendar Year  
for FSIS-Regulated Products**





# FSIS Notice 65-07

- In the October 12, 1997 Notice, FSIS directed its field personnel to:
  - Conduct an awareness meeting with management officials.
  - Ascertain whether and how the establishment reassessed.
  - Complete *E. coli* O157:H7 checklist.



# *E. Coli* O157:H7 Check List

- FSIS collected information on the control measures for *E. coli* O157:H7 to:
  - Identify operations that are not employing certain interrelated practices that directly contribute to the control of this pathogen.
  - Capture production control practices.
  - Help prioritize FSA.
  - Inform the design of Risk-based verification testing.



# HACCP Size: *E. coli* O157:H7 Checklist

## Establishments in the *E. coli* O157:H7 Checklist

HACCP Size	Number of Establishments Represented in E. Coli Checklist	Percentage of Establishments Represented in E. Coli Checklist
Large	61	3%
Small	907	39%
Very small	1,343	58%
Other / Unknown*	11	<1%
Total	2,322	100%

\* 6 establishments have a HACCP size of 'N' (Not applicable) and 5 were unable to be determined through PBIS



# Food Safety Assessments (FSA)

- In mid-November, 2007, OFO initiated FSA's at beef producing establishments to assess the outcome of the reassessments efforts.
- OFO established criteria for prioritizing the locations for conducting these FSA.





# Criteria for Prioritizing FSA At Beef Producing Establishments

1. Slaughter and/or processing with large volume production.
2. Small/very small slaughter with low volume.
3. Small/very small that grind or produce non-intact steaks, etc. with large volume.
4. Small/very small that grind or produce non-intact steaks, etc. with low volume.



# Criteria for Prioritizing FSA At Beef Producing Est. continued

Within each category, the priority was:

1. Plants that did not reassess
2. Plants that reassessed within the last 6 months
  - a. Made no changes
  - b. Made changes to HACCP plan, prerequisite programs or SSOP with inadequate support
  - c. No interventions or using measures that are inconsistent with the best practices



# EIAO Conducting FSA

- Enforcement Investigations and Analysis Officers (EIAO) conducted FSA's at beef producing establishments using the prioritization criteria outlined above.
- There were 224 FSA conducted from 11/14/07 to 3/17/2008



# FSA Outcomes

- **224** Food Safety Assessments were reported by all 15 FSIS districts .
- **34** of the **224** FSA resulted in no action and **190** resulted in the following FSIS action:
  - **9** resulted in issuing a re-assessment letter requesting additional information.
  - **122** resulted in an noncompliance record (NR).
  - **55** resulted in NOIE
  - **2** resulted in suspension



# FSA Resulting in Enforcement Per Plant Size

<b>Total 224 FSA</b> (11/14/07 – 3/17/08)	<b>22 Large Plants</b> ( <b>9.8%</b> )	<b>108 Small Plants</b> ( <b>48.2%</b> )	<b>94 Very Small Plants</b> ( <b>42%</b> )
<b>No. and % of NOIE</b>	6 NOIE (10.9%)	25 (45.5%)	24 (43.6%)
<b>No. and % of Suspension</b>	0	1 (50%)	1 (50%)



# Common Findings

- Failure to conduct hazard analysis or identify the hazards associated with key steps in the production process, e.g. mechanical tenderization step to produce non-intact cuts of beef.



# Common Findings

- Failure to provide supporting documentation for decisions on selection of CCPs and critical limits. For example why the proper concentration of lactic acid used is 2%?



# Common Findings

- Failure to carry out the monitoring and verification procedures per the prerequisite program, e.g. obtaining certificates of analysis for *E. coli* O157:H7 from suppliers and verifying their accuracy on an ongoing basis.





# Common Findings

- Failure to take appropriate corrective action as prescribed in the company's HACCP or prerequisite program. For example, failure to reject and control incoming beef trim with positive *E. coli* O157:H7.



# Common Findings

- Failure to maintain proper HACCP records to show that CCP monitoring, calibration frequencies, or corrective actions were taken appropriately according to their plans.



# Common Findings

- Failure to validate, and verify the ongoing effectiveness, of interventions designed to control E. coli O157:H7, including failure to describe procedures used in the application of the intervention.



# Common Findings

- Failure to consistently implement segregation and disposition measures to control product intended for grinding that is untested, or that tests presumptive positive or positive.



# Questions?