



FSIS Regulatory Update

8th Annual OutbreakNet Meeting

16th Annual PulseNet Update Meeting

Atlanta, GA, August 30, 2012

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Office of Public Health Science, FSIS



Agenda

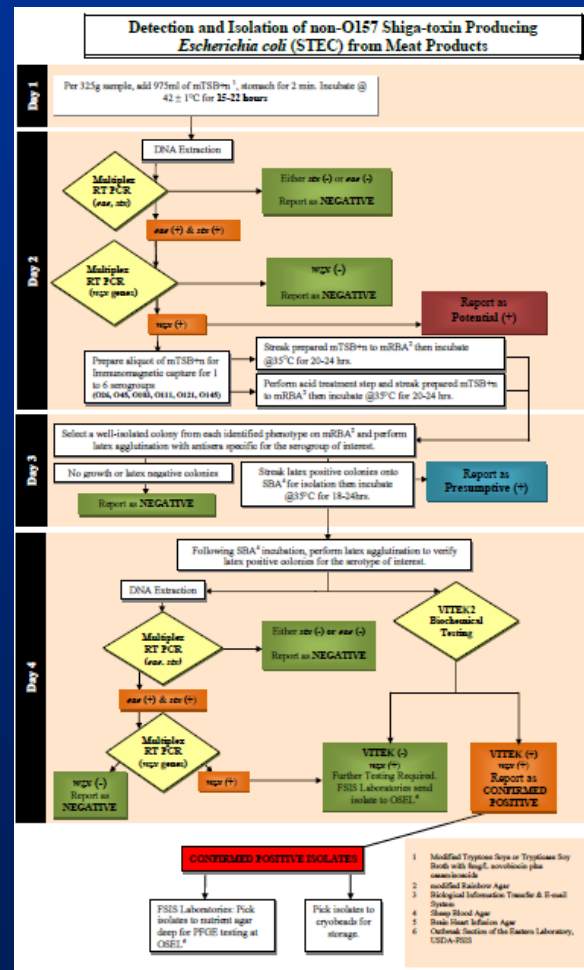
- Non O157 STEC Testing
- National Residue Testing
- Major Outbreaks



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)





Serogroup of non-O157 STEC isolates from humans sent to CDC

	Serogroup	1983-2002	2003-2006	Total	Cumulative n	Cumulative %
1	O26	209	309	518	518	26.3%
2	O111	152	188	340	858	43.6%
3	O103	117	224	341	1199	60.9%
4	O121	80	81	161	1360	69.1%
5	O45	63	99	162	1522	77.3%
6	O145	43	61	104	1626	82.6%
7	O165	14	15	29	1655	84.1%
8	O118	9	20	29	1684	85.6%
9	O91	8	15	23	1707	86.7%
10	O113	8	1	9	1716	87.2%
11	O153	7	4	11	1727	87.8%
12	O146	6	1	7	1734	88.1%
13	O174	6	8	14	1748	88.8%
	other typed	95	125	220	1968	100.0%
	total	817	1151	1968		



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

Target STEC	Federal Plants			Import
	Trim Verification Percent Positive (Number)	Follow-up to RGB Positive at Supplier Percent Positive (Number)	Follow-up to RGBC Positive Percent Positive (Number)	Verification/ Intensified Percent Positive (Number)
O157:H7	0.61% (7/1147)	1.03% (1/97)	2.14% (3/140)	0.95% (5/525)
Total non-O157 STEC³	1.07% (5/467)	0.00% (0/2)	24.29% (17/70)	0.00% (0/37)
O26	0.00% (0/467)	0.00% (0/2)	5.71% (4/70)	0.00% (0/37)
O45	0.21% (1/467)	0.00% (0/2)	4.29% (3/70)	0.00% (0/37)
O103	0.43% (2/467)	0.00% (0/2)	12.86% (9/70)	0.00% (0/37)
O111	0.21% (1/467)	0.00% (0/2)	0.00% (0/70)	0.00% (0/37)
O121	0.00% (0/467)	0.00% (0/2)	0.00% (0/70)	0.00% (0/37)
O145	0.21% (1/467)	0.00% (0/2)	1.43% (1/70)	0.00% (0/37)



Update: National Residue Program (NRP)

NRP Mission Statement

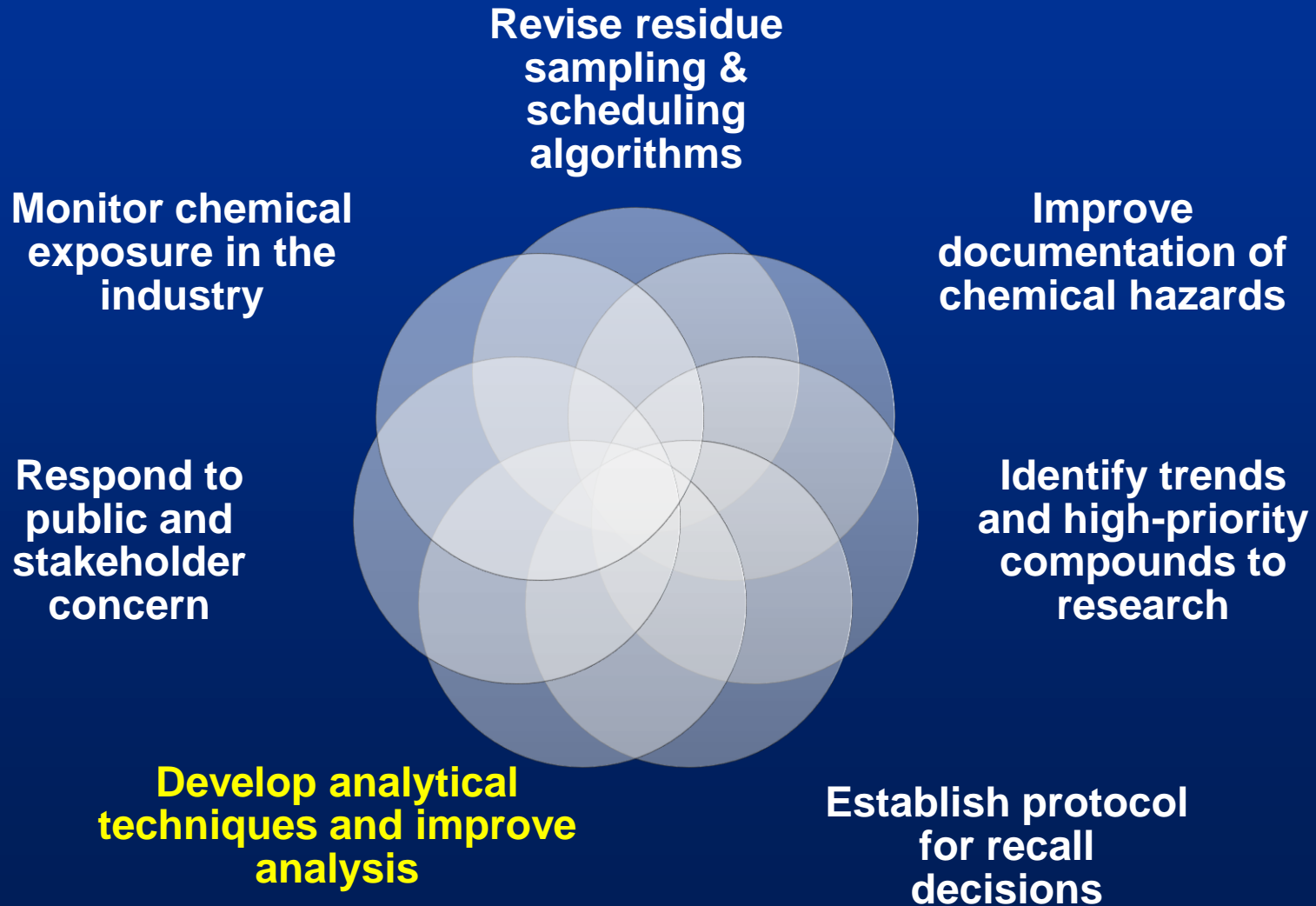
- To protect consumers from unsafe exposure to chemical residues in meat, poultry, and egg products



<http://www.culinate.com/hunk/29180>



NRP Goals

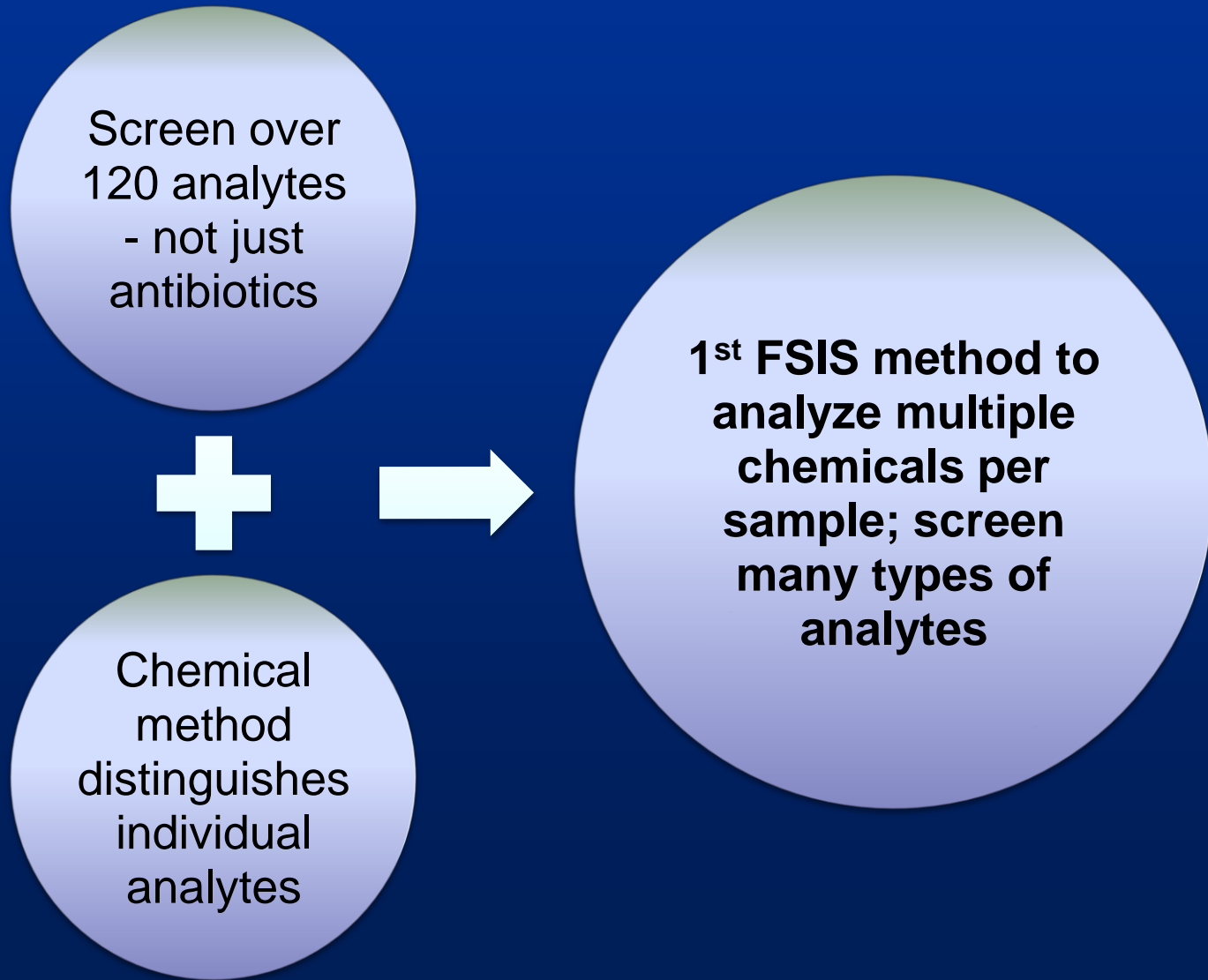




Multi-Residue Method (MRM)

- 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



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

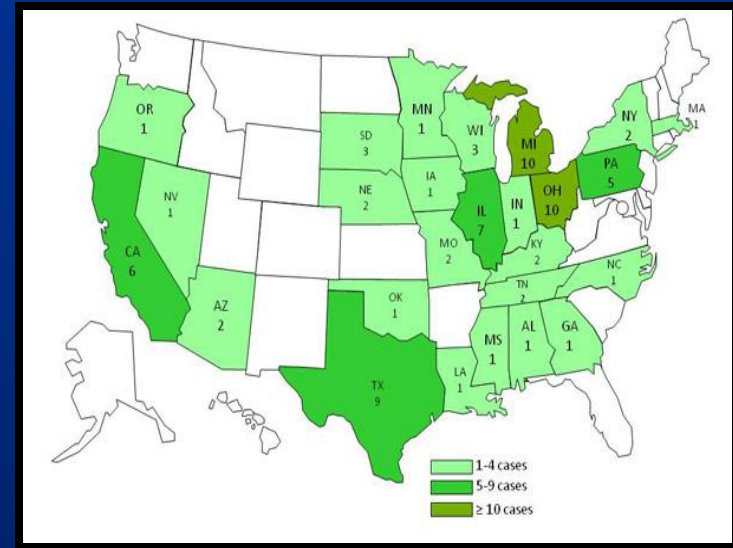


***Salmonella enterica* serotype Heidelberg: Ground Turkey**

- 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%

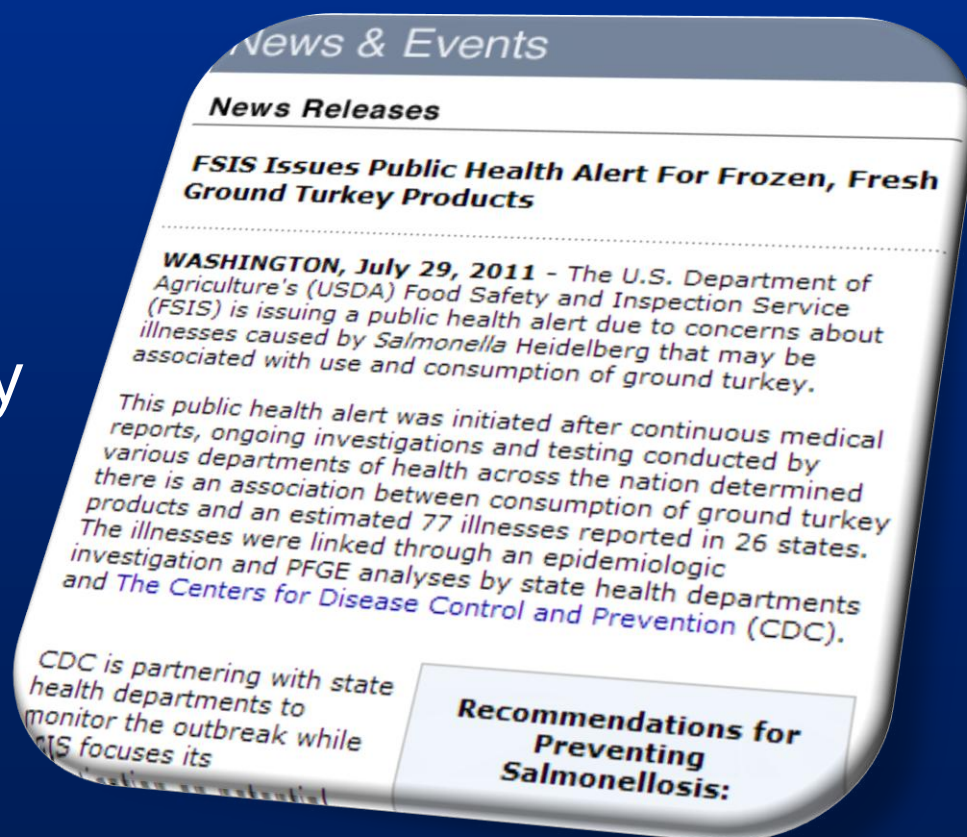


Case-patients by state as of Aug 1, 2011 (n =77)



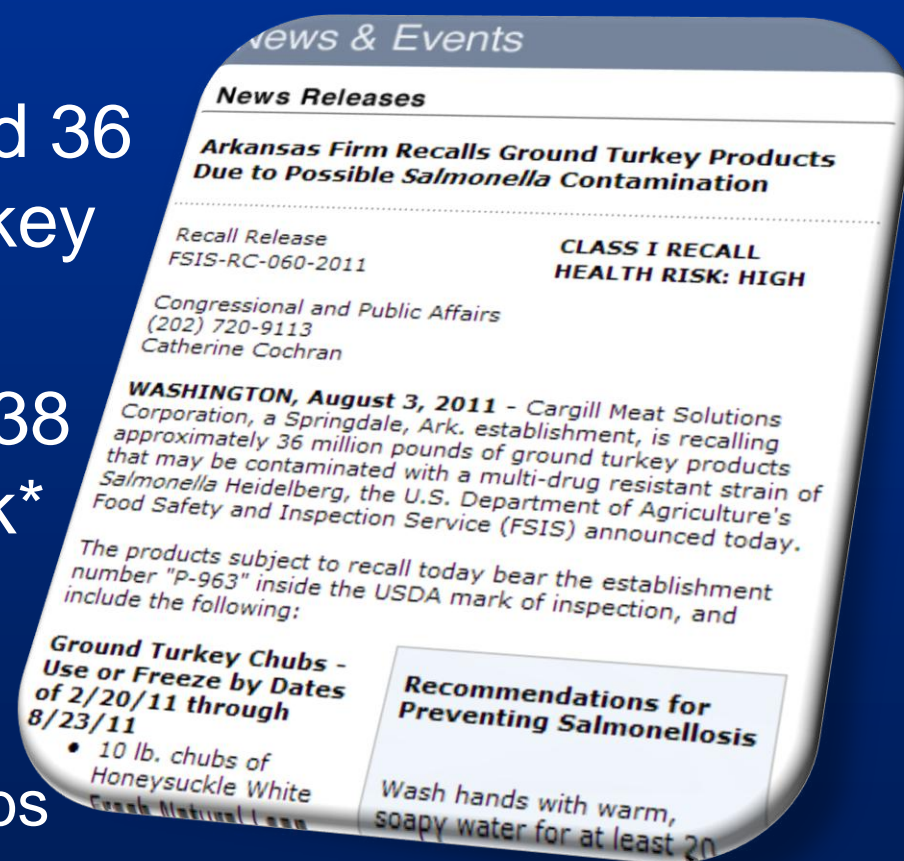
FSIS Response

- 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

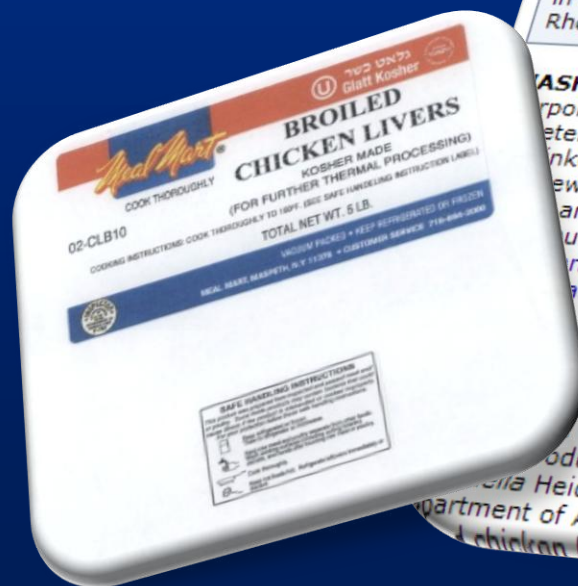


FSIS Investigation

- 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

Chicken Liver Recall

- November 8, 2011:
Establishment C
recalled broiled
chicken liver products



News Releases

New York Firm Recalls Broiled Chicken Liver Products Linked to Salmonellosis Illnesses

Recall Release **CLASS I RECALL**
FSIS-RC-090-2011 **HEALTH RISK: HIGH**

Congressional and Public Affairs
(202) 720-9113
Bill Bagley

Editor's Note: (Nov 9, 2011) In addition to the states listed below, products subject to this recall were distributed in retail stores and to institutional users in Florida, Ohio and Rhode Island.

WASHINGTON, November 8, 2011 - Schreiber Processing Corporation, a Maspeth, N.Y. establishment, is recalling an estimated amount of broiled chicken liver products that are linked to a cluster of *Salmonellosis* illnesses in New Jersey and New York, the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) announced today. FSIS is working with states, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) during this ongoing investigation.

The illnesses are linked to the consumption of broiled chicken livers that appear to be ready-to-eat, but are in fact raw and need to be fully cooked before consumption. Illnesses are also linked to chopped liver made from the product at retail stores. The outbreak strain of *Salmonella* Heidelberg was isolated by the New York State Department of Agriculture and Markets from samples of broiled chicken livers from the establishment, and chopped



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

United States Department of Agriculture
Food Safety and Inspection Service



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 subprimals**
 - 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

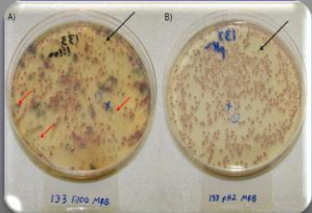
- Sample prep and primary enrichment



Day 2

- PCR screen for *stx* and *eae* genes
- PCR screen for O group specific genes
- Immunomagnetic separation, Modified Rainbow Agar (mRBA) Plating

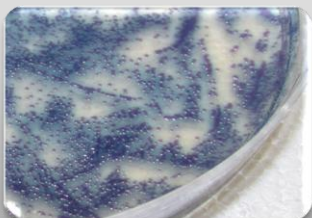
Potential
Positive



Day 3

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

Presumptive
Positive



Day 4

- Individual colonies on SBA
 - Latex positive
 - PCR positive (*stx*, *eae*, O group)
 - Biochemically identified as *E. coli*

Confirmed
Positive



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

United States Department of Agriculture
Food Safety and Inspection Service



Thank You