United States Department of Agriculture
Food Safety and Inspection Service

Shiga Toxin-Producing *E. coli* O121 Outbreak of Infections Associated with Frozen Food Snack Items, 2012 - 2013

~ FSIS Perspective ~

November 19, 2013
InFORM 2013 Conference
San Antonio, Texas

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Food Safety and Inspection Service
Office of Investigation, Enforcement and Audit
Compliance and Investigations Division
Houston, Texas

Presentation Outline

- FSIS – key statutes, regulations, and directives that support outbreak response
- FSIS response to STEC O121 outbreak
  - Epidemiology
  - Laboratory
  - Trackback
  - Food Recall
  - Environmental Assessment
- Outcomes and perspective

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Food Safety and Inspection Service (FSIS)

The Food Safety and Inspection Service is the *public health agency* in the U.S. Department of Agriculture responsible for ensuring that the nation's commercial supply of *meat, poultry, and egg products* is safe, wholesome, and correctly labeled and packaged.

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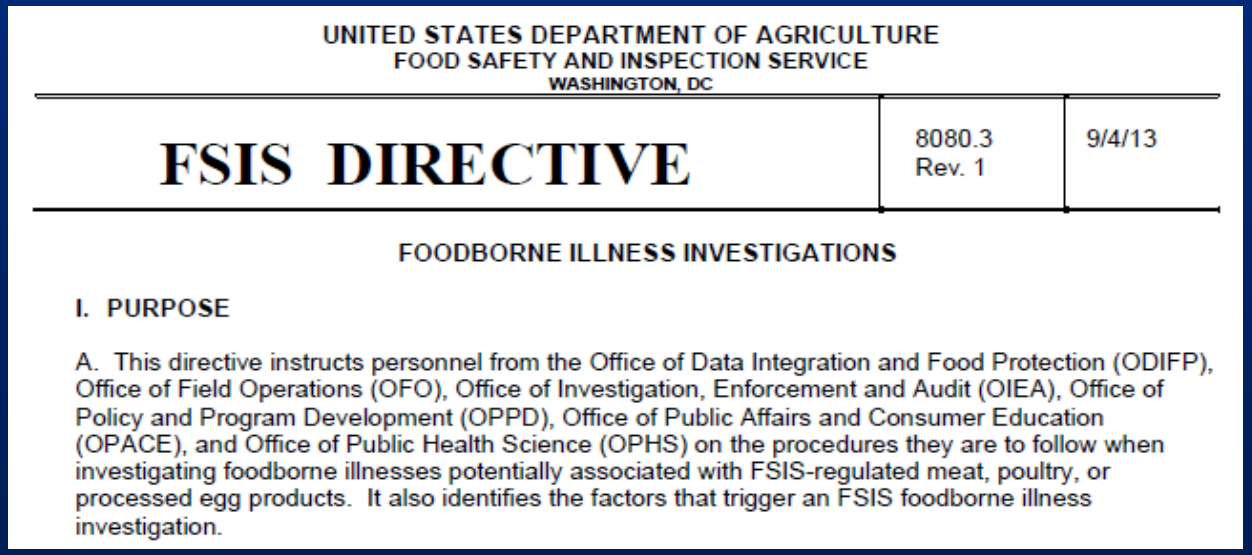
Key Statutes, Regulations, and Directives

- Federal Meat Inspection Act - 1906
- Poultry Products Inspection Act - 1957
- Egg Products Inspection Act - 1970
- Pathogen Reduction/HACCP Systems Final Rule - 1996
- FSIS Directive 8080.3 Foodborne Illness Investigations - 2013



UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE | 8080.3 Rev. 1 | 9/4/13

FOODBORNE ILLNESS INVESTIGATIONS

I. PURPOSE

A. This directive instructs personnel from the Office of Data Integration and Food Protection (ODIFP), Office of Field Operations (OFO), Office of Investigation, Enforcement and Audit (OIEA), Office of Policy and Program Development (OPPD), Office of Public Affairs and Consumer Education (OPACE), and Office of Public Health Science (OPHS) on the procedures they are to follow when investigating foodborne illnesses potentially associated with FSIS-regulated meat, poultry, or processed egg products. It also identifies the factors that trigger an FSIS foodborne illness investigation.

http://www.fsis.usda.gov/wps/wcm/connect/1bffb125-cd80-4b3a-ab45-1f4c0ad863d9/8080.3.pdf?MOD=AJPERES

FSIS Response to STEC O121 outbreak

- Epidemiology
- Laboratory
- Traceback
- Food Recall
- Environmental Assessment

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Epidemiology – background

Applied Epidemiology Staff

Director (acting) - Kis Robertson

Senior Public Health Advisor - Ken Dobson

Surveillance Team - Kristal Southern, Team Lead (acting)
- includes Consumer Complaint Monitoring System oversight

Annette Bush, Washington DC	Wu San Chen, Atlanta	Wanda Wilson, Washington DC

Investigations Team - Bonnie Kissler, Team Lead

Latasha Allen, Atlanta	Alice Green, Minneapolis

Prevention and Control Team - Neena Anandaraman, Team Lead

Tempora Fisher, Washington DC	Tim Ihry, Omaha	Patsy White, Omaha

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Epidemiology – STEC O121 Investigation

Surveillance Team - March 6 – 19, 2013

- Applied Epi Surveillance Team monitors hypothesis generation phase
- CDC and state epidemiologists note frozen food and pepperoni exposures
- CDC hosts multistate conference calls
- CDC offered to conduct open-ended interviews using single interviewer
- Combined interview data: 15/15 (100%) frozen food consumption; 10/12 (83%) pepperoni; 7/10 (70%) frozen pizza; 8/12 (67%) frozen bites/rolls, 7/11 (64%) Corp A products, 4/9 (44%) Corp B products; 5/9 (56%), Corp C products, 3/9 (33%), Corp D products; 12/15 (80%)

Investigations Team – starts March 20, 2013

- Investigations Team secures new case counts, food histories, and clarification of pepperoni exposure for 3 case-patients

March 25, 2013 - CDC informed OPHS/AES Investigations Team that NY PCR positive for *E. coli* O121 leftover product from a case-patient's home. AES Investigations Team alerted FSIS OPHS Science Staff microbiologists.

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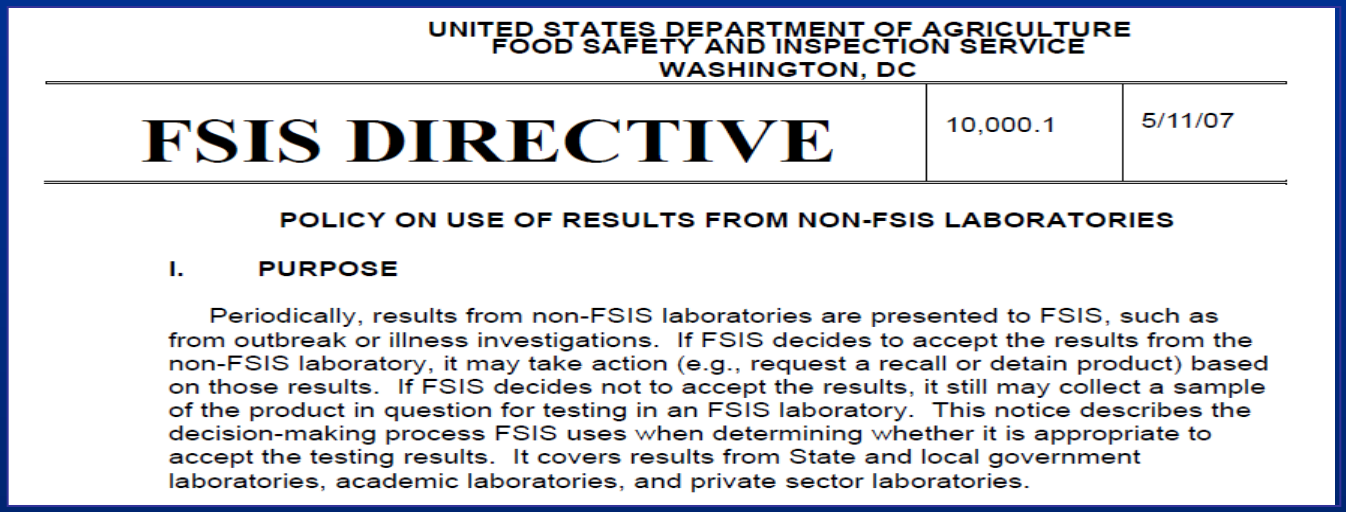
Laboratory - background



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WASHINGTON, DC

FSIS DIRECTIVE | 10,000.1 | 5/11/07

POLICY ON USE OF RESULTS FROM NON-FSIS LABORATORIES

I. PURPOSE

Periodically, results from non-FSIS laboratories are presented to FSIS, such as from outbreak or illness investigations. If FSIS decides to accept the results from the non-FSIS laboratory, it may take action (e.g., request a recall or detain product) based on those results. If FSIS decides not to accept the results, it still may collect a sample of the product in question for testing in an FSIS laboratory. This notice describes the decision-making process FSIS uses when determining whether it is appropriate to accept the testing results. It covers results from State and local government laboratories, academic laboratories, and private sector laboratories.

FSIS, Office of Public Health Science, Science Staff microbiologists are guided by FSIS Directive 10,000.1 when contacting State agency or other laboratories that are testing FSIS-regulated foods.

FSIS Directive 10,000.1 - policy on use of results from non-FSIS laboratories

FSIS Science Staff microbiologist will ask the following questions:

1. Was the sample handled and stored properly prior to collection?
2. Did the party responsible for the sample collection maintain the sample's identity and integrity properly (e.g., through handling and storage) before submitting for testing? Did the party responsible for the sample properly ship it to the laboratory?

   FSIS will determine whether and how those responsible for maintaining the identity and integrity of the sample did so (e.g., there was an appropriate chain of custody, the sample was not subject to temperature abuse).
3. Did the non-FSIS laboratory use a methodology appropriate for the analysis in question?
4. Did the non-FSIS laboratory ensure that the results of its analysis are reliable and accurate?

Laboratory – STEC O121 investigation

After hearing from FSIS Applied Epi Investigations Team, an OPHS Science Staff microbiologist called the New York Department of Health Wadsworth Center Laboratories

- Case-patient's leftover mini chicken and cheese quesadillas
- PCR positive for *E. coli* O121 and *stx*2, PFGE is pending
- March 27, 2013 – *E. coli* O121 confirmed
- "Yes" to Directive 10,000.1 questions
- NY provided pictures of the package

Laboratory – Background

- FSIS Outbreaks Section of the Eastern Laboratory (OSEL) – Athens, GA
- Broad testing capability and capacity
- Food samples and swabs from illness investigations and special studies
- PFGE, MLVA, molecular serotyping, antimicrobial susceptibility testing

Richard Russell Research Center
Athens, GA

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Shipping Foodborne Illness Investigation Samples to FSIS OSEL

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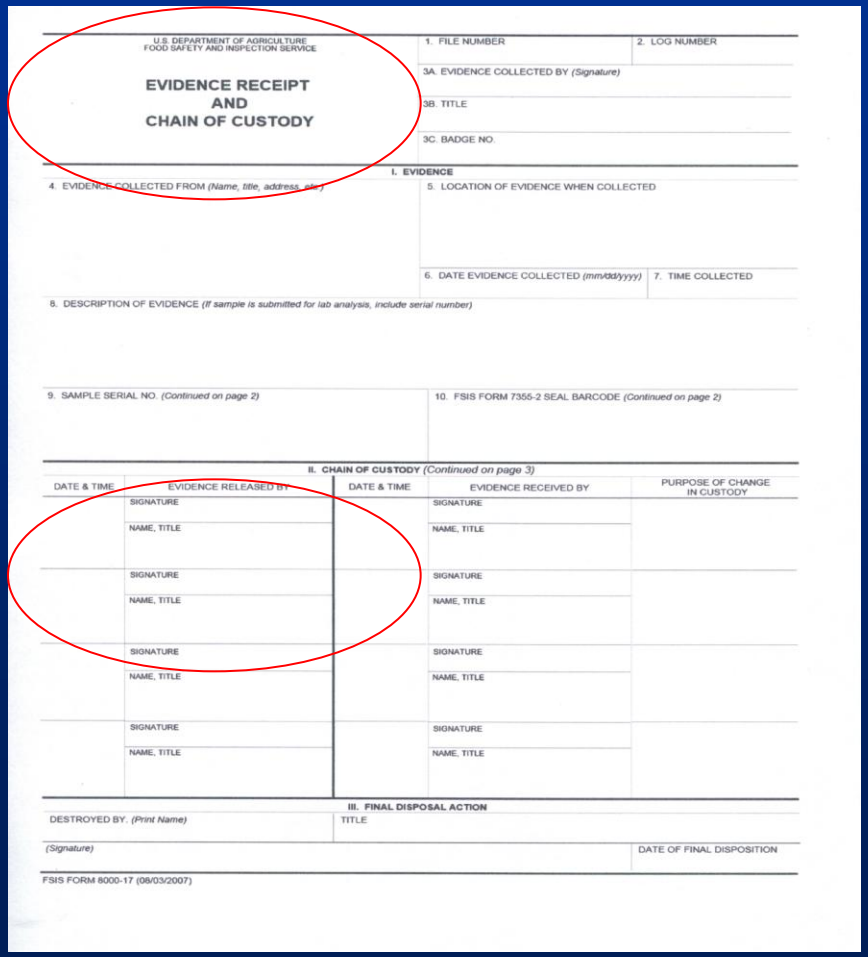
Forms and Seals to Ship Samples



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EVIDENCE RECEIPT AND CHAIN OF CUSTODY

1. FILE NUMBER | 2. LOG NUMBER

3A. EVIDENCE COLLECTED BY *(Signature)*

3B. TITLE

3C. BADGE NO.

I. EVIDENCE

4. EVIDENCE COLLECTED FROM *(Name, title, address, city)*

5. LOCATION OF EVIDENCE WHEN COLLECTED

6. DATE EVIDENCE COLLECTED *(mm/dd/yyyy)* | 7. TIME COLLECTED

8. DESCRIPTION OF EVIDENCE *(If sample is submitted for lab analysis, include serial number)*

9. SAMPLE SERIAL NO. *(Continued on page 2)*

10. FSIS FORM 7355-2 SEAL BARCODE *(Continued on page 2)*

II. CHAIN OF CUSTODY *(Continued on page 3)*

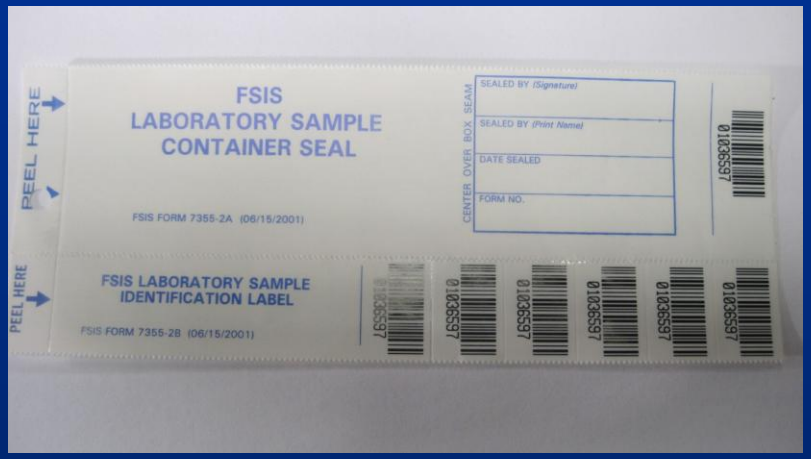
DATE & TIME	EVIDENCE RELEASED BY	DATE & TIME	EVIDENCE RECEIVED BY	PURPOSE OF CHANGE IN CUSTODY
	SIGNATURE NAME, TITLE		SIGNATURE NAME, TITLE	
	SIGNATURE NAME, TITLE		SIGNATURE NAME, TITLE	
	SIGNATURE NAME, TITLE		SIGNATURE NAME, TITLE	
	SIGNATURE NAME, TITLE		SIGNATURE NAME, TITLE	

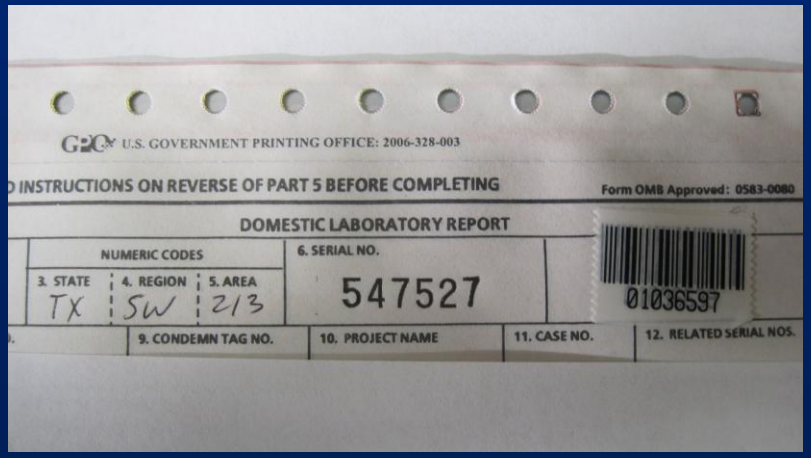
III. FINAL DISPOSAL ACTION

DESTROYED BY. *(Print Name)* | TITLE

(Signature) | DATE OF FINAL DISPOSITION

FSIS FORM 8000-17 (08/03/2007)





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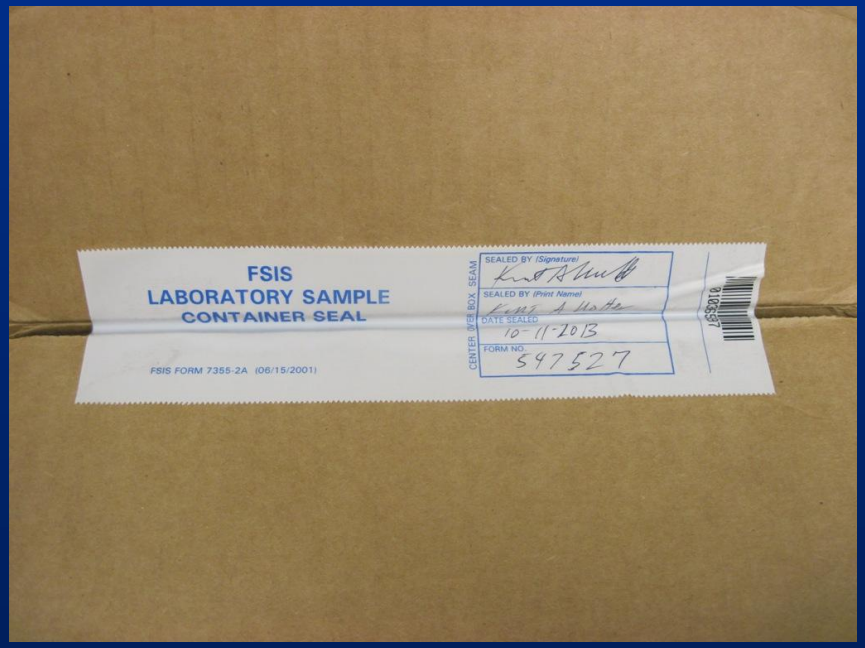
Forms and Seals to Ship Samples



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FSIS OSEL received food samples and chain of custody forms from Harris County Public Health and Environmental Services (HNPHES) laboratory in Houston, Texas

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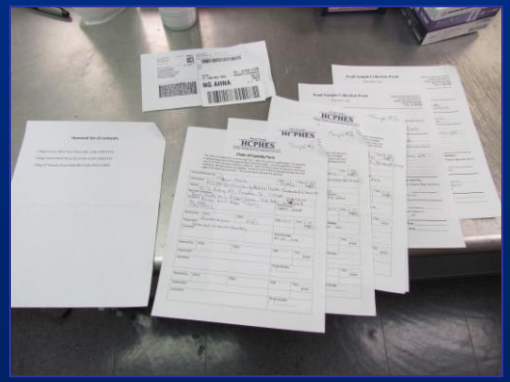
FSIS OSEL

- March 29, 2013 - Received the food samples and chain of custody forms from HCPHES
- Started analyses per FSIS Microbiological Laboratory Guideline - Chapter 5B.03

Two opened bags of Corp A's mini pizza slices
- one bag STEC O121 positive
- outbreak strain by PFGE



HCPHES Chain of Custody Forms

One opened bag of Corp B's pizza rolls
- STEC O121 negative

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Traceback - Background

- Traceback - actions taken to identify and document flow of product back to the originating official establishment from other official establishments, retail stores, warehouses, distributors, restaurants, or other firms in commerce
- The Compliance and Investigations Division of the FSIS Office of Investigation, Enforcement and Audit performs tracebacks and collaborates with states and local agencies on traceback investigations.

Receipts

Shopper or Loyalty Cards

Labels and Packaging

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Recall of FSIS and FDA-Regulated Foods March 28, 2013

- Epi: CDC-States reported 24/24 (100%) ate multiple frozen food products; 13/19 (68%) ate Brand A frozen foods. Food histories helped shape the recall scope.
- Laboratory - NY lab positive food sample. Recall before PFGE results available.
- Traceback – full labeling

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Recall Release

CLASS I RECALL
HEALTH RISK: HIGH

Congressional and Public Affairs
Richard J. McIntire (202)720-9113
FSIS-RC025-2013

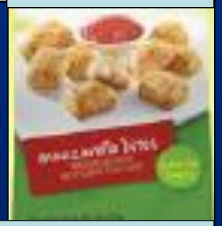
For FDA inquiries, contact:
Patricia El-Hinnawy (301) 796-4763

NEW YORK FIRM RECALLS FROZEN MINI QUESADILLA, PIZZA, CHEESE STEAK AND OTHER SNACK PRODUCTS DUE TO POSSIBLE *E. COLI* O121 CONTAMINATION

WASHINGTON, Ma… …on, a Buffalo, NY… approximately 196,222 poun… …ious other heat tre… frozen mini meals and snack… …ed with *E. coli* O1… of Agriculture's Food Safety… …ed today.

Brand A

Brand A



Nov. 12 - 19, 2012 production >196,000 pounds.

- Regulatory support - FSIS has determined that the products may be adulterated within the meaning of 21 U.S.C. 601(m)(1) or 453(g)(1), in that they may bear or contain a poisonous or deleterious substance that may render them injurious to health.

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Food Recall – April 4, 2013 Expansion

- The expanded recall covered products produced at the Corp. A's Georgia facility between July 1, 2011 and March 29, 2013 (current sell-by date).
- The recall was driven by concerns that the specific source of contamination, such as a dry ingredient, could not be identified and additional products may have been contaminated with STEC O121.

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Recall Release

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> 10.5 million pounds of product recalled

Environmental Assessment - Manufacturing Facility

The FSIS Office of Field Operations Atlanta District personnel conducted a comprehensive “for cause” food safety assessment (FSA) at the manufacturing facility in Georgia.

Key findings:

- Modern and automated facility; management cooperative.
- Fully cooked meat & poultry ingredients; dry ingredients concern.
- The establishment was found to be in regulatory non-compliance because their HACCP plan did not consider STECs as a hazard reasonably likely to occur in dry ingredients and because they failed to prevent shipment of adulterated product to commerce.

Outcomes and Perspective

- CDC centrally coordinated this multistate outbreak
- CDC open-ended interviews conducted by the same person provided useful information on food exposures.
- Success of non-O157 STEC testing in state and FSIS labs.
- Chain of custody of samples collected by NY and TX were established and maintained.
- Recall Committee convened – the food histories were of great value to FSIS and the company and helped guide the in-plant focus on production lots and ingredients.
- Food recalls announced by FSIS and FDA.
- Good communication and coordination with CDC and FDA.

Outcomes and Perspective

- Assessment of facility by both FSIS and FDA .
- The establishment is currently not producing any products for commerce and has requested a voluntary suspension of inspection until proposed HACCP plan and sanitation corrections are accepted, implemented, and validated by FSIS. ***A key focus is on cooking instructions on the package labels.***
- Challenge in identifying the contaminated ingredient.
- Short-term controls through food recall and actions taken at the manufacturing plant protected public health.
- On-going challenge associated with frozen convenience microwavable foods that need to be full cooked to assure food safety.

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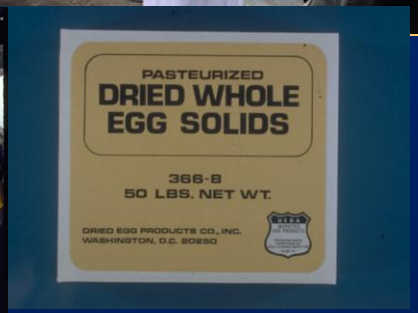
Thank you!

Meat

Poultry

FSIS



Egg Products