

## **One Team, One Purpose**



# **Food Safety and Inspection Service**

Protecting Public Health and Preventing Foodborne Illness



2017 InFORM Open Session

# Outbreak Investigation from Detection to Action: The USDA-FSIS Perspective

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> Garden Grove, CA November 6, 2017

# Enhancing Collaboration and Information Sharing to Improve FSIS Foodborne Outbreak Response

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## Food Safety and Inspection Service: Icebreaker Question: Who has regulatory oversight of slaughter/processing of this food product?



## Food Safety and Inspection Service: Mission in Action



We are the public health agency in the USDA responsible for ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled.

### Our Authority

Through a series of Acts, Congress empowers FSIS to inspect all meat, poultry, and processed egg products in interstate commerce.

- Federal Meat Inspection Act (FMIA), 1906
- Agricultural Marketing Act (AMA), 1946
- Poultry Products Inspection Act (PPIA), 1957
- Humane Methods of Slaughter Act (HMSA), 1958
- Egg Products Inspection Act (EPIA), 1970

# Food Safety and Inspection Service: FSIS Organizational Structure



### Laboratories and AES



# Food Safety and Inspection Service: Illness Reporting to FSIS

- Speed and accuracy are essential in foodborne illness investigations
- Identification of suspect product quickly:
  - May prevent further illnesses
  - May prevent future outbreaks
  - Ensures the public's confidence in the food supply and public health system
  - Minimizes economic and public health costs



## Recently Revised Directive 8080.3

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

## **FSIS DIRECTIVE**

8080.3 Rev. 2

10/27/17

### FOODBORNE ILLNESS INVESTIGATIONS

#### I. PURPOSE

This directive provides personnel from the Office of Data Integration and Food Prote (ODIFP), Office of Field Operations (OFO), Office of Investigation, Enforcement and (OIEA), Office of Policy and Program Development (OPPD), Office of Public Affairs Consumer Education (OPACE), and Office of Public Health Science (OPHS) the protect they are to follow when investigating foodborne illnesses potentially associated with regulated meat, poultry, or processed egg products. It also identifies the factors tha FSIS foodborne illness investigation. This directive is being reissued in its entirety to changes in organization structures and corresponding changes in responsibilities du foodborne illness investigation.

#### **II. CANCELLATION**

FSIS Directive 8080.3, Rev. 1 Foodborne Illness Investigations, 9/4/13

### III. BACKGROUND

A. As a public health regulatory agency, FSIS investigates reports of foodborne illne potentially associated with FSIS-regulated products.

This Directive provides information on:

- Factors that determine the need for an investigation
- Product sampling considerations
- Procedures for traceback and traceforward activities
- Considerations for determining the epidemiological association between illness and product
- Agency actions based upon findings

# Food Safety and Inspection Service: FSIS Investigation Objectives

- 1. Determine whether human illnesses are associated with FSIS-regulated products
- 2. Identify the source of production and its distribution
- 3. Gather information to guide response
- 4. Take appropriate action to prevent further exposure to consumers
- 5. Identify contributing factors



Food Safety and Inspection Service: Outbreaks Investigated by FSIS



# Food Safety and Inspection Service: Initiating a Foodborne Illness Investigation

- AES investigator creates an incident report notifying FSIS program areas of foodborne illness investigation
- Email alert to program contacts
  - Information is considered confidential and to be shared with public health and agriculture colleagues on a "need-to-know" basis
- Update email alerts sent when new developments occur in investigation
- Emergency Management Committee (EMC) may be activated if outbreak is severe, widespread, or involves other circumstances requiring senior management decision-making

# Food Safety and Inspection Service: Product Sampling and Laboratory Analysis

- Determine whether to sample and test products potentially implicated in an FSIS foodborne illness investigation
- Non-intact (open package) product may be sampled if certain criteria met
- Affected establishment(s) should be notified of sampling
- Results from non-FSIS laboratories will be evaluated as per FSIS Directive 10,000.1

# Food Safety and Inspection Service: Important Considerations for Traceback

- Coordination among local, state, and territorial partners essential for successful outcomes of traceback investigations
- Traceback and traceforward goals
  - Personal identifiers remain confidential
  - Establishment identified where implicated product originated
  - Information available about establishment's suppliers
  - Distribution chain of implicated product identified
  - Product in commerce located and detained



Food Safety and Inspection Service: Importance of Records

- FSIS relies heavily on industry records, including retail, to traceback products during outbreaks involving foodborne illness
- Essential to quickly and effectively determine source product
- Uniform and standard records made available throughout distribution chain enable rapid identification and linkage of products with source



# Food Safety and Inspection Service: Agency Action

- Agency action is not limited to recall of meat and poultry products
- If human illness has been definitively linked to FSISregulated product, actions FSIS may take include:
  - Issuance of a public health alert
  - Increased frequency of microbial sampling
  - Enhanced inspection
  - Public Health Risk Evaluation (PHRE)
  - Comprehensive Food Safety Assessment (FSA)
  - Incident Investigation Team (IIT)
  - Notice of Intended Enforcement (NOIE)

Food Safety and Inspection Service: Close-out and Final Assessment

- Analyze steps taken throughout outbreak investigation from identification of problem through actions taken
- Close-out call among stakeholders to discuss lessons learned and where improvements might be indicated
- Assess whether there are changes that the Agency could make in its inspection or enforcement procedures
- Determine whether the Agency can improve its policies and investigation procedures

# Food Safety and Inspection Service: Information Sharing with Partners

- FSIS Notice: Sharing Information with State or Local Agencies, Foreign Government Officials, and International Organizations (issued on 7/7/16)
  - Promote transparency and strengthen information sharing while ensuring that proprietary and pre-decisional information is not disclosed
  - Information that falls within one of the FOIA Exemptions will be redacted by FOIA staff prior to sharing
  - Examples of such information include confidential business information, pre-decisional information, and investigatory records

# Food Safety and Inspection Service: Collaborations

- Working with FDA and states to ensure FSIS is engaged with each state's Rapid Response Team
- APHIS-FSIS MOU: Continuing discussions to improve processes and procedures specific to pre-harvest investigations
- Co-lead a shopper/loyalty card and other purchase data resources workgroup with the North Carolina Department of Agriculture & Consumer Services
  - Participation from CDC, FDA, and various state/local health and agriculture departments

Food Safety and Inspection Service: Lessons Learned

- Good communication and trust among federal, state, and local public health partners essential
- Lessons learned during outbreak investigations have led to changes in FSIS programs and policy to improve the safety of meat and poultry products
- Sharing lessons learned and other information from investigations can help to prevent foodborne illness

# 2011 Ground Turkey/Salmonella Heidelberg Outbreak Investigation

Food Safety and Inspection Service: Investigation Background

- 7/7/10: Ground turkey sample collected from Est. P-963 positive for *Salmonella* Heidelberg
- 4/11/11: NARMS retail ground turkey sample from same establishment positive for *Salmonella* Heidelberg with same PFGE pattern
- 5/20/11: AES notified by the FSIS Eastern Laboratory of a cluster of 29 Salmonella Heidelberg infections from 18 states; PFGE indistinguishable from ground turkey isolates

## Salmonella Heidelberg Illnesses by State (n=136)



Source: https://www.cdc.gov/salmonella/2011/ground-turkey-11-10-2011.html

**Epidemiological and Antimicrobial Resistance Summary** 

- 136 case-patients from 34 states
  - Ages ranged from <1 to 90 years (median=23)</li>
  - Onset dates ranged from 2/27/11 to 10/17/11
  - 37/94 (39%) hospitalized
  - 1 death reported
  - 51/94 (54%) consumed ground turkey prior to illness onset
- Clinical and leftover ground turkey isolates tested for antimicrobial susceptibility by CDC NARMS with resistance to ampicillin, gentamicin, streptomycin, and tetracycline

# Food Safety and Inspection Service: Public Health Response

- 7/29/11: FSIS issued a public health alert due to concerns about illnesses caused by *Salmonella* Heidelberg that may be associated with ground turkey consumption
- 8/3/11: FSIS issued recall release; Est. P-963 recalled approximately 36 million pounds of ground turkey products with use or freeze by dates of 2/20/11 through 8/23/11
- 9/11/11: Est. P-963 recalled approximately 185,000 pounds of ground turkey products because of 2 positive ground turkey samples collected as part of the FSIS IIT investigation



# FSIS Traceback & Traceforward Investigations



## Mark W. Crowe

### Director

**Compliance and Investigations Division** Office of Investigation, Enforcement, and Audit

# Food Safety and Inspection Service: CID Structure and Employees

Headquarters		Field	
Director	1	Regional Directors	4
Deputy Director	1	Supv. Investigators	13
Sr. Compliance Specialist	1	Sr. Investigators	7
		Investigators	149
		Support Staff	9



Food Safety and Inspection Service: CID Responsibilities

- Surveillance
- Investigations
  - a) Alleged violations
  - b) Foodborne illness outbreaks
  - c) Recalls
- Product control
- Food Defense and Emergency Response
- Education
- Liaison

CID Role in Foodborne Illness Outbreak Investigations

- Collaborates with the OPHS Investigations Team
- Collaborates with State and local agencies
- Conducts traceforward / traceback activities
- Collects information / evidence that can be used to inform Agency decision making; enforcement action, product recall
- Product sampling
- "Boots on the ground"



Traceback: 2011 Ground Turkey/Salmonella Heidelberg Outbreak

On July 18, 2011, CID was notified by AES of a cluster of *Salmonella* Heidelberg illnesses in Ohio

Ohio Case Patient Line List Information		
The Knowns	The Unknowns	
Illness onset date	Establishment number	
Consumption date	Distribution information	
Purchase date & location	Specific lot numbers	
Limited product information		

Food Safety and Inspection Service: Traceback: 2011 Ground Turkey/Salmonella Heidelberg Outbreak

Shopper card information provided to CID at time of notification listed:

- Product (HS GRND Turkey)
- Quantity (1.2 lb tray pack, case-ready)
- Date & time of purchase (June 4, 2011)
- Specific store number (Retail Store A)

# Food Safety and Inspection Service: Traceback: 2011 Ground Turkey/Salmonella Heidelberg Outbreak

# **Traceback activities conducted at Retail Store A:**

- HSW GRND = Honeysuckle White Ground Turkey, case ready
- 15 cases, 6/1.2 pounds of Honeysuckle White Ground Turkey, under Distributor B Invoice # 1111, dated May 31, 2011

# Food Safety and Inspection Service: Traceback: 2011 Ground Turkey/Salmonella Heidelberg Outbreak

# **Traceback activities conducted at Distributor B**

- Confirm shipment to Retail Store A
- Distributor B received 624 cases, 6/1.2 lb.
  Honeysuckle White Ground Turkey, from Cargill-Springdale, Est. P-963, under Bill of Lading # S2222, dated May 26, 2011

### Traceback: 2011 Ground Turkey/Salmonella Heidelberg Outbreak

### Cargill-Springdale, Est. P-963

• On or about May 26, 2011, processed and shipped to Distributor A: 624 cases of Honeysuckle White Ground Turkey 6/1.2 lbs., under Bill of Lading #S2222, dated 5/26/11

### Distributor B, Akron, OH

- On May 27, 2011, received from Cargill, Est. P-963, 624 cases Honeysuckle White Ground Turkey 6/1.2 lbs., under Bill of Lading #S2222
- On May 31, 2011, shipped to Retail Store A 15 cases of Honeysuckle White Ground Turkey 6/1.2 lbs., Invoice #1111

### Retail Store A, Akron, OH

- On May 31 2011, received from Distributor A 15 cases of Honeysuckle White Ground Turkey 6/1.2 lbs., Invoice #1111
- On June 4, 2011 sold one, 1.2 lb. tray pack of Honeysuckle White Ground Turkey to Ohio Case Patient

### **Ohio Case Patient**

- On June 4, 2011 purchased one, 1.2 lb. tray pack of Honeysuckle White Ground Turkey from Retail Store A
- On June 4, 2011 became ill after consuming Honeysuckle White Ground Turkey processed by Cargill-Springdale, Est. P-963. Shopper card information available.
# Food Safety and Inspection Service: Questions?



# FSIS Foodborne Outbreak In-Plant Investigation, Recalls and Food Safety Assessment

Chau Vu

Supervisory Enforcement, Investigations, and Analysis Officer Alameda District Office of Field Operations

# **Recall Investigation**

- Enforcement Investigations and Analysis Officers (EIAOs) visit the establishment to conduct in-plant investigation to determine affected lot(s) of product and determine scope of recall
- Product Information: Establishment number, Product type, Product brand, Product name, Lot Code #, Best By/Use By Date, Packaging Date, UPC Code, Product Label, Shipping Container Label, Case Code #
- Traceback Activities: Supplier information can be for meat and poultry and/or for non-meat ingredients such as vegetables and spices

# **Recall Investigation**

Determine the scope of affected lot(s) through interview and review of records for traceability of affected lot(s):

- Traceback Activities: Multiple suppliers vs. single supplier (for processing establishment) – review receiving records, sales invoices, production records, shipping records, etc.
- Carry-over of affected lot(s) to other days of production – review receiving records, production records, HACCP records, work-in-progress records, etc.
- 3) Use of affected lot(s) in other products

# **Recall Investigation**

Determine the scope of affected lot(s) through interview and review of records for traceability of affected lot(s):

- 4) Shelf-life of product (fresh or frozen) scope of recall
- 5) Sharing of equipment/production line(s) between affected lot(s) and other products: review SSOP records and other sanitation records to determine time of clean-up to clean-up to determine scope of affected lot(s)
- 6) HACCP process control: review of HACCP Critical Control Point (CCP) records for CCP deviations including corrective actions

# **Recall Investigation**

Determine the scope of affected lot(s) through interview and review of records for traceability of affected lot(s):

- 7) Trace-forward activities: Determine distribution information (i.e. primary consignees, poundage produced, poundage held at establishment, poundage distributed, if distribution is for Commodity/USDA Foods, Dept. of Defense, Internet/Catalog Sales)
- 8) Provide information gathered to Recall Management and Technical Analysis Staff (RMTAD) to determine if recall is warranted and classification of recall

# Directive 8080.1, Rev. 7, Recall of Meat and Poultry Products Recall Classification (Health Risk)

#### **Class I**

Reasonable probability that consumption of product will cause serious, adverse health consequences or death

#### **Class II**

Remote probability of adverse health consequences from use of the product

#### Class III

Use of product will not cause adverse health consequences

# Directive 8080.1, Rev. 7, Recall of Meat and Poultry Products Verification Process Determine the risk

Recall classification	FSIS verification activities begin as soon as possible within a period of:	FSIS verification activities should be substantially completed within:
Class I	3 days	10 days
Class II	5 days	12 days
Class III	10 days	17 days

# **Directive 8080.1, Rev. 7, Recall of Meat and Poultry Products**

#### **Verification Process**

#### **Determine the risk**

Class I recalls with illness, outbreak, or school lunch implications

Number of Consignees	Number of Effectiveness Checks to Make	Deviations for Recall to be Considered Ineffective
1 to 200	100 %	0
201 to 10, 000	200	0
10,001 to 500,000	800	1
Over 500,001	1250	2

#### Food Safety and Inspection Service: Public Health Risk Evaluation (PHRE)

# Directive 5100.4, Rev. 4, EIAO PHRE Methodology (5/22/15)

- EIAO conducts PHRE for public health risk triggers, when an establishment has produced an adulterated product, or has produced product associated with an outbreak.
- PHRE is conducted for each establishment scheduled for a Food Safety Assessment (FSA) and other For Cause.
- PHRE process has 2 parts, the PHRE Decision (EIAO recommendation) and the Assessment Plan (statutes/regulations, scope of FSA, and steps).

#### Food Safety and Inspection Service: Public Health Risk Evaluation (PHRE)

## EIAO to review:

- 1) FSAs completed at the establishment
- 2) Enforcement history (AssuranceNet) data
- 3) Noncompliance Records (NRs) issued by FSIS
- 4) Public Health Information System (PHIS) profile data
- 5) Weekly Meeting Notes by In-Plant Inspection Personnel
- 6) Memoranda of Interview by In-Plant Inspection Personnel
- 7) Recall history
- 8) Laboratory Information Management System (LIMS) data including Pulse Field Gel Electrophoresis (PFGE) results
- 9) Consumer Complaint Monitoring System (CCMS) data 10) In-Plant Inspection Personnel and Frontline Supervisor

## Directive 5100.1, Rev. 4, EIAO Food Safety Assessment (FSA) Methodology (5/29/15)

EIAO to conduct a Food Safety Assessment (FSA) to determine whether the food safety systems are scientifically sound and supported and if the establishment is meeting the regulatory requirements.

UNITED STATES DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE WASHINGTON, DO FSIS DIRECTIVE 5100.1 5/29/15 Rev 4 ENFORCEMENT, INVESTIGATIONS AND ANALYSIS OFFICER (EIAO) FOOD SAFETY ASSESSMENT (FSA) METHODOLOGY Implementation of new FSA procedures in PHIS will be 6-10-15. For FSAs scheduled prior to this date, the EIAO is to record his or her FSA reports using Word versions of the modified tools. Updated tools will be available on the EIAO SharePoint site on 6-1-15. CHAPTER I - GENERAL L PURPOSE The purpose of this directive is to provide instructions to EIAOs on how to conduct FSAs using a new work methodology, so an EIAO can complete the in-plant portion of most FSAs in 5 to 7 production days. This directive also provides instructions on how to document FSAs using the FSA tools that are a series of questionnaires that an EIAO is to use to gather information. The new work methodology is designed to focus the FSAs on public health risk and to increase consistency in how EIAOs conduct FSAs. For the purposes of this directive, the term "EIAO" also refers to EIAO-trained Public Health Veterinarians (PHVs) when they are conducting EIAO activities. The term 'District Office (DO)" includes the District Manager (DM); the Deputy District Manager (DDM); the Supervisory Enforcement, Investigations and Analysis Officer (SEIAO); and the District Case Specialist (DCS) II. CANCELLATION FSIS Directive 5100.1, Revision 3. Enforcement, Investigation and Analysis (EIAO) Comprehensive Food Safety Assessment Methodology, 8/23/11 III. SIGNIFICANT CHANGES 1. Establishment of a timeline for the completion of most FSAs from 2 to 4 weeks to 5 to 7 production days; 2. FSAs are to be performed after the EIAO derives results from a Public Health Risk Evaluation (PHRE): 3. The EIAO is to focus on certain processes during the FSA based on the PHRE; 4. Any Routine Listeria monocytogenes (RLm) sampling is to be conducted before the start of an FSA: and

The EIAO is to focus on assessing and analyzing the establishment's food safety system as a whole and is not to only verify whether individual regulatory requirements are in compliance.

DISTRIBUTION: Electronic

OPI: OPPD

EIAO to analyze the following:

- Hazard Analysis decisions: Identifying appropriate biological (i.e. pathogens of concern such as *Salmonella* and *Campylobacter* in poultry slaughter and processing), chemical, and/or physical hazards as Reasonably Likely to Occur (RLTO) or Not Reasonably Likely to Occur (NRLTO)
- 2) Hazard Analysis decisions supported by prerequisite programs, SSOPs, HACCP plans, scientific documentation, suppliers' documentation, validation studies, challenge studies, Certificates of Analyses (COAs), etc.

EIAO to analyze the following:

3) Salmonella Category of poultry slaughter suppliers

- Category 1: Consistent Process Control
- Category 2: Variable Process Control
- Category 3: Highly Variable Process Control



EIAO to analyze the following:

4) Product Lotting and Cross-Contamination:

- Source materials can be meat/poultry and can also include non-meat ingredients such as vegetables and spices;
- Carry-over of affected lot(s) to other days of production
- Product from different flock or supplier

EIAO to analyze the following:

5) Antimicrobial Interventions: review supporting documentation to determine any parameters of application (e.g. concentration, pH, dwell time, temperature, pressure, etc.)

EIAO to analyze the following:

- Microbiological Testing: review establishment's microbiological sampling plan to monitor process control and effectiveness of interventions
- 7) Process Control Procedures:
  - a) Adequate sanitary dressing practices to prevent contamination and to minimize cross-contamination
  - b) Decontamination of carcasses that become contaminated

EIAO to analyze the following:

- 8) Pre-harvest Interventions: whether establishments receive birds from growout farms, hatcheries, and breeder flocks that implement pre-harvest best practices
- 9) Implementation of other best practices incorporated into HACCP system, SSOP, prerequisite program, or HACCP plan throughout the slaughter and processing steps (Draft FSIS Compliance Guideline for Controlling *Salmonella* and *Campylobacter* in Raw Poultry, December 2015)

EIAO documents the FSA findings and analysis of the findings in the FSA tools and makes the recommendation to the District Office for one of the following outcomes for the FSA:

- 1) No Further Action
- 2) Issuance of Noncompliance Records
- 3) Issuance of Notice of Intended Enforcement
- 4) Issuance of Notice of Suspension

Food Safety and Inspection Service: Incident Investigation Team (IIT)

#### **Directive 5500.3 Incident Investigation Team Review (7/19/06)**

The FSIS Emergency Management Committee (EMC) may be activated to manage:

- 1) An illness or outbreak in which a meat, poultry, or egg product produced by the establishment has been implicated;
- 2) Significant or repetitive contamination or adulteration incidents; or
- 3) Repetitive microbiological sampling failures as a result of either the Agency or establishment testing (e.g., *Escherichia coli* O157:H7, *Listeria monocytogenes*, or *Salmonella*)

## Food Safety and Inspection Service: Notice of Intended Enforcement Action

The establishment or the actions of establishment personnel constitute a situation that justifies the action under **Title 9 CFR 500.4**, and that such conditions have resulted in adulterated product or create insanitary conditions that could cause product to be adulterated.

Timeline: 2011 Ground Turkey/Salmonella Heidelberg Outbreak

July 29, 2011 – FSIS issues a Public Health Alert about the illnesses, reminding the public to fully cook ground turkey.

August 3, 2011 – Establishment voluntarily recalled 36 million pounds of selected ground turkey products in response to outbreak investigation.

August 4, 2011 – FSIS issued a Notice of Suspension (NOS) for the raw ground process.

August 9, 2011 - the Emergency Management Committee(EMC) initiated the Incident Investigation Team (IIT), in accordance with Directive 5500.3.

Timeline: 2011 Ground Turkey/Salmonella Heidelberg Outbreak

August 10, 2011 – After establishment submitted action plan and revisions, FSIS placed suspension in abeyance.

August 22, 2011 – In response to information by CDC, the District Office issued letter of concern:

- 1) To ensure that live poultry potentially contaminated with the outbreak strain are not used in Not Ready To Eat (NRTE) comminuted turkey product.
- 2) To ensure live poultry potentially contaminated with the outbreak strain are diverted to a non-Cargill operated poultry slaughter establishment for use in NRTE comminuted turkey product.

August 22, 2011 – IIT began its investigation.

IIT Findings, Establishment Conclusions, and Recalls

- 1) Establishment added a Critical Control Point (CCP) to the Slaughter HACCP plan for the monitoring of the antimicrobial in the final bird chiller.
- 2) Establishment indicated that no market-age commercial birds were diverted to non-Cargill operated poultry establishments.
- 3) Establishment indicated to IIT that:
  - a) Individuals within a flock are not traceable to single breeder flocks as poults from hatcheries are mixed as they are delivered to farms.
  - b) The IIT determined that the breeder flock drag-swab study and the commercial flock cecal study do not support the control of all potential suspect commercial flock suppliers.

# Food Safety and Inspection Service: IIT Findings, Establishment Conclusions, and Recalls

- 4) The CCP 11B (whole-bird rinse study), the *Salmonella* Control Program (wing studies), the intensified sampling program, and the FSIS IIT sampling program document concerns with the establishment's control of *Salmonella* prevalence and *Salmonella* Heidelberg outbreak strains.
- 5) IIT supports the establishment's voluntary recall of products linked to human illness.
- 6) On September 7, 2011, as a result of IIT findings, the District Office issued Notice of Intended Enforcement (NOIE) to the establishment.

# Food Safety and Inspection Service: IIT Findings, Establishment Conclusions, and Recalls

- 7) On September 10, 2011, as a result of IIT sampling findings, FSIS requested voluntary recall of all affected ground turkey products.
- 8) The establishment voluntarily suspended the production of raw ground turkey and raw ground turkey components for commerce and diverted all ground products and components to cooking establishments.
- 9) On September 11, 2011, the establishment voluntarily recalled 185,000 pounds of ground turkey products because of possible contamination with *Salmonella* Heidelberg.

# Food Safety and Inspection Service: Questions?



# **FSIS Investigative Sampling**

Stephanie Defibaugh-Chavez, Ph.D. Senior Microbiologist Science Staff Office of Public Health Science

#### Overview

- Initiation of a special sampling project
- Considerations for:
  - Sample design
  - Using results to inform regulatory response
  - Logistics
- Examples
  - Ground turkey outbreak
  - Roaster pig outbreak

#### Food Safety and Inspection Service: Initiation of a Special Sampling Project

- Requests to initiate investigative or special sampling projects typically come from FSIS senior management in response to an outbreak or other incident associated with one or more establishments
- The FSIS Emergency Management Council (EMC), if activated, can also recommend sampling in these situations
- OFO or OPPD requests assistance in verifying that an establishment has implemented appropriate corrective actions following an incident, outbreak, or other regulatory action

#### **Considerations for Investigative/Special Sampling**



#### Logistics for Special Sampling Planning



Example #1:2011 Ground Turkey/Salmonella Heidelberg Outbreak

- Establishment identified that a specific type of grinding process was used to produce the primary ground products associated with illnesses
- Evidence of increased *Salmonella* percent positive during period of outbreak for products produced in this type of grinding process based on establishment testing



Example #1 (Ground Turkey): Sampling Design

- Two primary purposes for sampling:
  - Was the outbreak strain (*Salmonella* Heidelberg) associated with the products/environment at the establishment?
    - Establishment chose to cull flocks that they suspected were carriers of the outbreak strain; this process was ongoing during the initial investigative sampling
  - Was the establishment's sanitation sufficient to prevent crosscontamination?
- Target analyte: Salmonella

Example #1 (Ground Turkey): Sampling Design (cont.)

- Types of samples
  - Pre-chill and post-chill re-hang samples (paired carcass sponges)
    - 28 pairs of carcass sponges collected from carcasses before the chiller and at the approximate time they would be leaving the chiller
  - Turkey skin
    - 39 total
  - Mechanically separated turkey (MST)
    - 38 total
  - Ground turkey (produced from "bone-in" parts)
    - 14 total
  - Ground turkey (produced from deboned parts)
    - 23 total
  - Environmental samples collected from live-haul trailer, picker, chiller, and two different grinders
    - Pre-operational samples (10 total)
    - Operational samples (10 total)

Example #1 (Ground Turkey): Initial Investigative Sampling Results




## Example #1 (Ground Turkey): Sampling Results

#### Presence of outbreak strains

- 2 pre-chill samples were positive for Salmonella Heidelberg outbreak strain
  - Pre-chill samples are representative of carcass prior to all interventions, and similar evidence not seen at post-chill (after all interventions)
- Only one outbreak strain found in "bone-in" ground sample
  - At the time, these products were being diverted to cooking (all products received lethality at FSIS-regulated establishment)
- 6/33 positive isolates from MST were *Salmonella* Heidelberg outbreak strain
  - These products are typically incorporated into other products that are cooked at other FSIS-regulated establishments
- No outbreak strains identified in turkey skin samples

#### • Evidence of cross-contamination

- 10 pre-operational samples were collected; 2 samples were positive for Salmonella
  - Collected from trailer and picker; no outbreak strains
- 10 samples were collected during operations; 1 sample was positive for Salmonella
  - Collected from grinder during operations; not an outbreak strain

Example #1 (Ground Turkey): Outcomes of Investigation

- After an initial sampling period of two weeks with a team of FSIS personnel onsite, the sampling continued at the establishment for an additional 8 months to assess corrective actions implemented in the establishment
- Shortly after the second phase of testing began, an outbreak strain was detected in ground turkey products that were released into commerce
  - The company voluntarily conducted a second Class 1 recall based on the finding of the outbreak strain in FSIS investigative sampling
- This outbreak and a separate outbreak earlier the same year also associated with ground turkey prompted additional exploratory testing in ground and other comminuted poultry (chicken and turkey) products, which ultimately led to updated performance standards for comminuted poultry products

Example #2: Investigative Sampling at Establishment Linked to Pork-Related Illnesses

- A *Salmonella* outbreak was linked roaster pigs that were served at luau-type events
- FSIS traceback identified Est. 1628, Kapowsin Meats as the source of whole hogs for pig roasts
  - At least two possible farms were identified as source of the roaster pigs
- EMC was convened and recommended investigative sampling at a single implicated establishment to support possible regulatory action

Example #2 (Roaster Pigs): Sampling Design

- Two primary purposes for sampling:
  - Was the outbreak strain (Salmonella 4,[5],12:i:- or Salmonella Infantis) associated with the products/environment at the establishment?
  - Was the establishment's sanitation sufficient to prevent crosscontamination?
- Target analyte: Salmonella

Example #2 (Roaster Pigs): Sampling Design (Cont.)

Types of sampling

#### **Cecal samples:**

Assess presence of outbreak strain in incoming animals/farms

#### **Carcass Swabs :**

Swab half a side of the carcass after the production line (assess HACCP plan and presence of outbreak strain in finished product)

#### **Environment:**

Pre-operational (assess sanitation) and during operations (assess presence of outbreak strain)







Example #2 (Roaster Pigs): Sampling Results

## Cecal samples

- Salmonella 4,[5],12:i:- outbreak strain isolated from all 8 samples
  - Pigs originated from two different farms

## Carcass swabs

- 14/14 carcass swabs were Salmonella positive
  - 3 samples were positive for Salmonella 4,[5],12:i:- outbreak strain and 2 samples were positive for Salmonella Infantis outbreak strain

## Environmental samples

- 8 pre-operational samples were collected and 2 samples tested positive for *Salmonella*, including one *Salmonella* 4,[5],12:i:- outbreak strain
- 8 samples were collected during operations; 6 were positive for Salmonella and 5 of those were outbreak strains

Example #2 (Roaster Pigs): Outcomes of the Investigation

- Collaboration between CDC, Washington, FSIS (OPHS, OIEA, and OFO) to gather epidemiological, traceback, and microbiological sampling data led to a recall
  - Notice of Intended Enforcement issuance on 8/11/15
  - FSIS Recall 110-2015: 116,262 pounds of whole hogs (8/13/15)
- FSIS sampling results revealed insanitary conditions at Est. 1628, leading to a recall expansion
  - FSIS Recall 110-2015 Expansion: 523,380 pounds of pork products (8/27/15)

## Thank You! Questions?



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# Completing the Loop: from Outbreak Investigations to FSIS Policy Changes

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- Policy outcomes for:
  - Ground turkey outbreak
  - Ground beef outbreaks
  - Stuffed chicken outbreaks

- FSIS recall release on 8/3/2011
- Federal Register Notice HACCP Plan Reassessment for Not-Ready-To-Eat Comminuted Poultry Products and Related Agency Verification Procedures Published December 6, 2012
  - Reassess Hazard Analysis and Critical Control Points (HACCP) plans
  - FSIS expanded its Salmonella Verification Sampling Program for Raw Meat and Poultry products to include all forms of nonbreaded, non-battered, comminuted NRTE poultry product

- FSIS also announced in the December 2012 Federal Register notice its intent to conduct a survey of its inspection program personnel (IPP) in chicken and turkey slaughter and further processing establishments, including establishments that produce comminuted poultry.
- The poultry checklist gathered information on establishment:
  - pathogen control programs,
  - chemical interventions,
  - sampling programs, and
  - changes to their HACCP plans.

- Federal Register HACCP Plan Reassessment for Not-Ready-To-Eat Comminuted Poultry Products and Related Agency Verification Procedures Published April 21, 2014
  - On May 8, 2013, FSIS issued instructions to its inspectors to begin verifying whether establishments had reassessed their HACCP plans (FSIS Notice 33-13).
  - FSIS began the new Agency sampling and testing of raw comminuted chicken and turkey products on June 1, 2013 (FSIS Notice 35-13).
  - Announced the Agency would prioritize Food Safety Assessments (FSAs) in establishments producing NRTE comminuted chicken and turkey products.

- FSIS utilized the results from the poultry checklist to prioritize the comminuted poultry FSAs.
- Issued Notice 26-14, EIAO Responsibilities Related to Food Safety Assessments in Establishments Producing Comminuted Chicken or Turkey Products, June 2014.

- Federal Register Notice Changes to the Salmonella and Campylobacter Verification Testing Program: Proposed Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Related Agency Verification Procedures and Other Changes to Agency Sampling published January 26, 2015.
  - FSIS announced and requested comment on new pathogen reduction performance standards for *Salmonella* and *Campylobacter* in raw chicken parts and not-ready-to-eat (NRTE) comminuted chicken and turkey products.
  - FSIS announced plans to begin sampling raw chicken parts to gain additional information on the prevalence and the microbiological characteristics of *Salmonella* and *Campylobacter* in those products.
  - FSIS announced the moving window approach for verification sampling.

- Federal Register New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcement of Implementation Schedule published February 11, 2016.
- FSIS began assessing whether establishments meet the new pathogen reduction performance standards for chicken parts and comminuted chicken and turkey products on May 11, 2016.

Product	Maximum acce	eptable percent	Performance	
	pos	itive	standard *	
	Salmonella	Campylobacter	Salmonella	Campylobacter
Comminuted Chicken (325 g sample)	25.0	1.9	13 of 52	1 of 52
Comminuted Turkey (325 g sample)	13.5	1.9	7 of 52	1 of 52

2011 Ground Turkey/Salmonella Heidelberg Outbreak

## Comminuted Turkey Establishment Aggregate Categories for Sample Collection Period July 3, 2016 to September 30, 2017

		All Establishments		Large Establishments		Small Establishments		Very Small Establishments	
		Number	Percent	Number	Percent	Number	Percent	Number	Percent
Salmonella	Category 1	14	35.9	4	21.05	9	47.37	1	100
	Category 2	10	25.64	5	26.32	5	26.32	0	0
	Category 3	15	38.46	10	52.63	5	26.32	0	0
	TOTAL	39	100	19	100	19	100	1	100
Campylobacter	Pass	1	50	1	50	0	0	0	0
	Fail	1	50	1	50	0	0	0	0
	TOTAL	2	100	2	100	0	0	0	0

## Food Safety and Inspection Service: Ground Beef Outbreaks

- FSIS investigators and other public health officials use records kept at all levels of the food distribution chain, including the retail level, to identify the sources of outbreaks.
- FSIS has often been impeded in these efforts when an outbreak involves ground beef because of a lack of documentation identifying all source materials used in its preparation.
- In some situations, official establishments and retail stores have not kept adequate records that would allow effective traceback and traceforward activities.

Food Safety and Inspection Service: Ground Beef Outbreaks

- On December 14, 2015, FSIS published the final rule, "Records to be Kept by Official Establishment and Retail Stores That Grind Raw Beef Products."
- The Rule became effective on June 20, 2016, and full enforcement started April 1, 2017.
- This rule is necessary to improve FSIS's ability to accurately trace the source of foodborne illness outbreaks involving ground beef and to identify the source materials that may be attributable to these outbreaks.

## Food Safety and Inspection Service: Ground Beef Outbreaks

- The cleaning and sanitizing of equipment used to grind raw beef is important because it prevents the transfer of *E. coli* 0157:H7 and other bacteria from one lot of product to another.
- When records are available and complete, FSIS is often able to identify specific production in an official establishment.

Status of retail grinding record	Number of	Number	
	investigations	resulting in	
		recalled product	
Available and complete	11	6	
Not available	11	1	
Available, but incomplete	6	1	

**Ground Beef Outbreaks** 

- § 320.1 Records to be kept.
- (b) \* \* \*
- Added (4)(i) In the case of raw ground beef products, official establishments and retail stores are required to keep records that fully disclose:
  - (A) The establishment numbers of the establishments supplying the materials used to prepare each lot of raw ground beef product,
  - (B) All supplier lot numbers and production dates,
  - (C) The names of the supplied materials, including beef components and any materials carried over from one production lot to the next,
  - (D) The date and time each lot of raw ground beef product is produced, and
  - (E) The date and time when grinding equipment and other related foodcontact surfaces are cleaned and sanitized.

- From 1998 to 2015, public health officials have investigated nine outbreaks attributed to consumption of not ready-to-eat (NRTE) stuffed chicken products that appeared ready-to-eat (RTE).
- Following a recall release on March 10, 2006, FSIS initiated various policy initiatives to modify the labelling of NRTE stuffed chicken products that appear RTE.

- Letter to Industry (March 20, 2006)
- FSIS Notice 75-06 Verification Instructions For Changes In Label Requirements For Uncooked And Raw, Frozen, Breaded, Boneless Poultry Products (November 13, 2006)
- Labeling Policy Guide (January 17, 2007)
  - Prominent statement on the principal display panel designating the product as raw, uncooked, or notready-to-eat
  - Clearly stated recommendation of endpoint internal temperature (165 F) measured by the use of a food thermometer
  - Validated cooking instructions

- In 2015, two separate outbreaks occurred resulting in a public health alert issued on July 1, 2015, followed by two separate recalls.
- In response to these recent outbreaks FSIS issued Notice 15-16 Profile Update In Establishments That Produce Not-Ready-To-Eat Stuffed Chicken Products That Appear Ready-To-Eat.
- Properly identifying these products within PHIS will aid the Agency in identifying establishments to include in an upcoming exploratory sampling program.

- FSIS expects to design a sampling program to verify industry's level of process control for these products.
- FSIS is considering sampling multiple locations including:
  - poultry source materials (to assess incoming contamination),
  - finished product (to assess whether a reduction of incoming contamination occurred during product formulation and processing), and
  - post par-frying food contact surface contamination (to assess whether recontamination occurred before packaging).

## Food Safety and Inspection Service: Questions?

## **Contact Information**

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