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United States Department of Agriculture

Food Safety and Inspection Service



# **The Role of USDA's Food Safety and Inspection Service to Ensure Foodborne Disease Control and Prevention**

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## Presentation Overview

- How FSIS collaborates with public health partners during outbreak investigations
- Case Study #1: *E. coli* O157:H7 in Ground Bison
- Case Study #2: *S. Heidelberg* in Chicken livers
- Summary of Lessons Learned



## Objectives of an FSIS Investigation

Epidemiological  
and Microbiological  
Analysis



1. Determine whether human illnesses are associated with FSIS-regulated products

Traceback and  
Traceforward



2. Identify source of production and distribution

3. Gather product information to guide response

Agency Response



4. Take appropriate action to prevent further exposure to consumers (e.g. recalls)

In-plant Assessments



5. Identify contributing factors to prevent future problems



# Directive 8080.3

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 Field Operations (OFO), Office of Investigation, Enforcement and Audit Policy and Program Development (OPPD), Office of Public Affairs and Consumer Policy (OPACE), and Office of Public Health Science (OPHS) on the procedures they investigating foodborne illnesses potentially associated with FSIS-regulated meat and processed egg products. It also identifies the factors that trigger an FSIS food investigation.

B. This directive supplements, but does not conflict with or supersede, instructions for the Consumer Complaint Monitoring System (CCMS) as specified in [FSIS Directive 8080.1 Implement the Consumer Complaint Monitoring System](#).

### This Directive Provides Information On:

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



## FSIS Notification—Outbreak 1

- FSIS's Applied Epidemiology Staff was contacted by Colorado (CO) Department of Public Health & Environment (CDPHE) on 6/18/10
  - CDPHE reported 4 cases of *E. coli* O157:H7 with the same 2-enzyme PFGE pattern
    - Three of four consumed or had Brand A ground bison in their home prior to illness onset
  - Six additional cases from CO (1), CT (2), IL (1), MD (1) and NY (1) were later identified
    - All 6 reported ground bison consumption



## Bison Regulations

- Bison is under FDA authority as a non-amenable species, with inspection authority often delegated to state agriculture departments
- FSIS has a voluntary, fee-for-service inspection program which uses definitions and standards of the Federal Meat Inspection Act (FMIA)
  - CO Department of Agriculture requires firms producing bison products to join USDA program



## **Collaboration Between FDA and FSIS**

- Producer in question was under USDA FSIS's voluntary inspection program and FSIS officials were familiar with the plant operations
  - Thus, FSIS conducted the environmental investigation and assisted CDPHE with traceback efforts
- FDA and FSIS worked closely together to ensure formal actions taken were coordinated





## FSIS Traceback Investigation

- FSIS and Colorado State Collaboration
  - Shopper card information collected from 4 CO case-patients
  - FSIS reviewed records at Supermarket Chain A stores
    - All purchases implicated Brand A ground bison product
  - FSIS determined product came from Establishment A in Denver, CO



## FSIS Food Safety Assessment

- FSIS reviewed production practices and sampling records at Establishment (Est.) A
  - Est. A did not slaughter or grind beef and did not process elk or other wild game products
  - On 5/21/10, Est. A bison trim sampling identified O157 positive lots
  - Despite relatively high number of positive O157 samples, negative lots of trim from same production date were used to fabricate implicated ground bison



## FSIS Recall and Regulatory Actions

- Based on food histories of cases, traceback data, and findings during the in-plant investigation, FSIS requested a recall on 7/2/10
- Product recall totaled 66,000 pounds of ground and tenderized steak bison products
- FSIS conducted recall effectiveness checks
- FSIS's Office of Field Operations conducted verification activities at Est. A following issuance of the recall
- Ongoing surveillance showed recall effectively removed contaminated product from commerce



## **FSIS Notification—Outbreak #2**

- On 9/2/11, FSIS was notified by CDC of a cluster associated with whole cut chicken and/or eggs, leading to a collaborative investigation involving CDC-FSIS-FDA and States
- 190 case-patients with *S. Heidelberg* infections from 6 states (with New York having 109 cases)
- On 10/18/11, CDC notified FSIS that chicken liver was a suspect vehicle, as identified by New York City interviews



## FSIS-Regulated Product Testing

- On 11/2/11, New York State (NYS) Agriculture & Markets confirmed 2 positive food samples
- Non-intact broiled chicken livers and chopped chicken liver retail products
  - On 11/3/11, NYS Agricultural & Markets identified source establishment
  - On 11/4/11, CDC confirmed the product PFGE pattern was indistinguishable from the outbreak pattern



## **FSIS Recall and Regulatory Actions**

- On 11/8/11, based on the epidemiologic, laboratory and traceback findings, FSIS requested a product recall
- The establishment recalled an undetermined amount of 'kosher broiled chicken liver' products
- FSIS recall effectiveness checks were conducted to verify proper retrieval and disposition of recalled product



## FSIS Follow-up Actions

- FSIS conducted a Food Safety Assessment and intensified testing for *Salmonella* at the recalling establishment
  - All 36 samples were negative
  - Food safety program design and execution issues were identified at the establishment that showed failure to maintain sanitary conditions
  - Corrective actions were taken to ensure the establishment was compliant with appropriate regulations



## Food Safety Issues to Consider

- Consideration of label changes/safe handling instructions
  - Many consumers assumed the partially cooked Kosher par-broiled chicken liver products were fully cooked and ready-to-eat (RTE)
- Processing changes
  - The establishment decided to stop producing 'par-broiled' chicken liver products





# FSIS Potential Actions Following Outbreak Investigations

- Product recalls
- Public health alerts
- Food safety assessments (FSAs)
- Incident investigation team (IIT) reviews
  - If problems are discovered by FSA or IIT, FSIS may:
    - Issue a Suspension or Notice of Intended Enforcement (NOIE)
    - Increase product sampling



## Lessons Learned From Outbreak Investigations

- Strong relationships with federal, state, and local public health partners are essential
- Epidemiological evidence in combination with laboratory findings is key to ensure well-informed assessments
- Early detection and actionable traceback information essential to ensure effective response

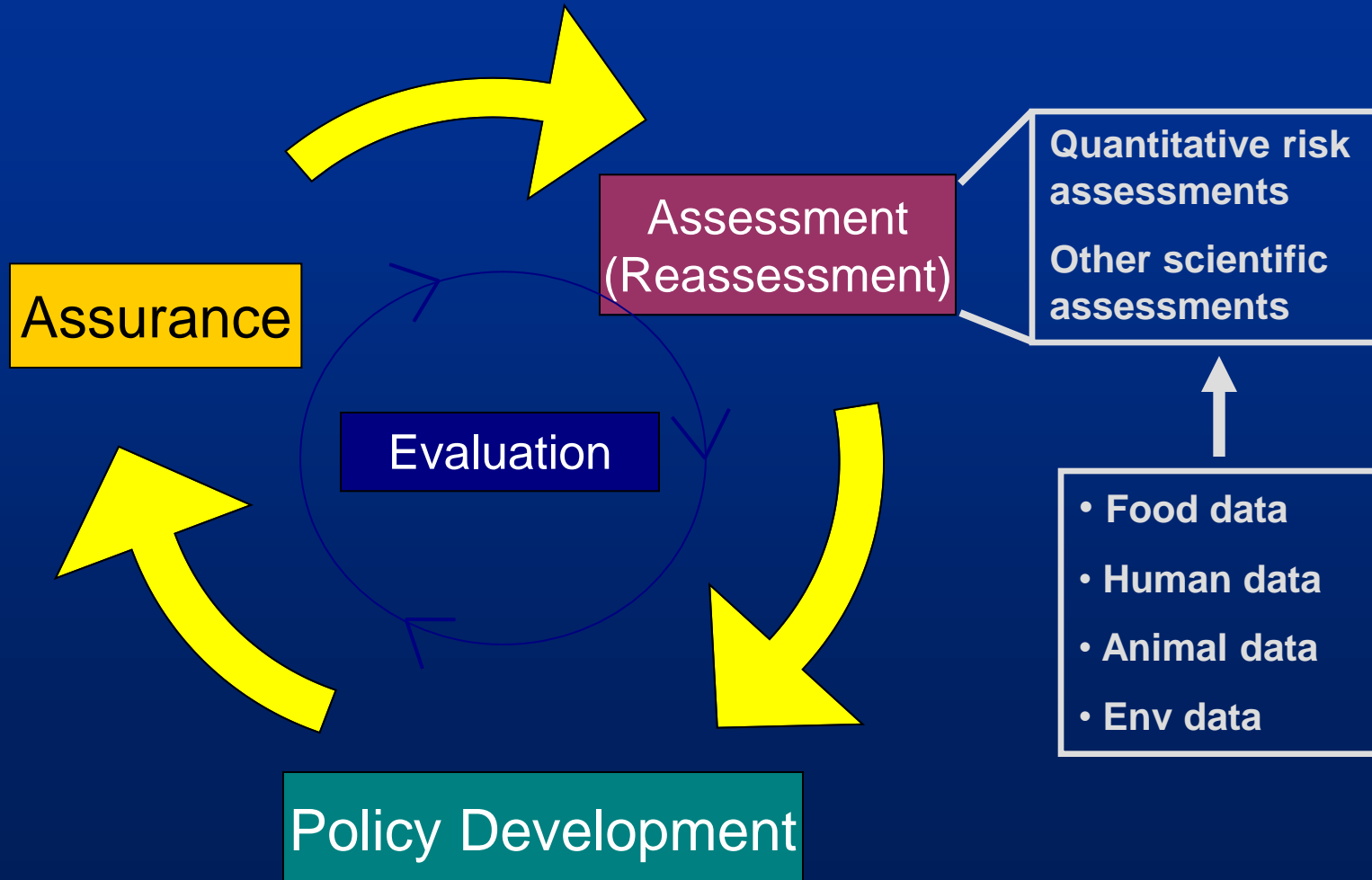


## Communication Between Public Health Partners, Industry and Consumers

- FSIS is now emphasizing early industry notification when investigative evidence potentially implicates an establishment
- Intent is to promote information sharing and responsiveness to food-borne public health threats among stakeholders



# FSIS Application of Public Health Model





## Turning Lessons Learned into Action

- FSIS continues to develop and implement strategic plans to improve its ability to control and prevent outbreaks, for example:
  - *Salmonella* Action Plan
    - Enhance *Salmonella* sampling and testing programs for early detection and targeted interventions
    - Training inspectors and providing tools to enhance the ability to detect and respond to food safety hazards
    - New approaches for providing *Salmonella*-related food safety messages to the public



# Turning Lessons Learned into Action

- STEC Sampling Program
  - On June 4, 2012 FSIS began verification testing for 6 non-O157 STECS (O26, O45, O103, O111, O121, O145) in domestic and imported beef manufacturing trimmings
  - In 2014 FSIS will conduct a Nationwide Beef and Veal Carcass Baseline Survey
- FDA/FSIS Risk Assessment on *Listeria (Lm)* in Deli Settings
  - A scientific evaluation of the risk of *Lm* associated with food items prepared in retail delis and an examination of interventions for *Lm* control



**Thank You!**

**Food Safety and Inspection Service  
United States Department of Agriculture**

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