



# FSIS Foodborne Illness Investigations: Current Thinking

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# FSIS Investigations

- Multifaceted, multidisciplinary undertaking
- “Three-Legged Stool” of Investigations
  - Environmental Health
  - Epidemiology
  - Laboratory





# FSIS Investigation Objectives

- Determine whether human illnesses are associated with FSIS-regulated products
- Identify source of production, distribution
- Gather information to guide response
- Take appropriate action to prevent further exposure to consumers



# FSIS Investigation Objectives

- Initiate enforcement action as appropriate
- Identify contributing factors
- Report on results of investigation
- Recommend steps to prevent future occurrences



# Investigations are Unique

- Components outlined generally in presentation
- Phases of investigations may occur nearly simultaneously
- Flow of information and data is dynamic

# Epidemiology





# Applied Epidemiology Division

- Applied Epidemiology \*
  - Application and evaluation of epidemiologic methods
  - Epidemiologic practice aimed at protecting/improving health of a population
  
- Two Branches
  - Foodborne Disease Investigations Branch
  - Zoonoses and Food Hazards Surveillance Branch

\* Last, A Dictionary of Epidemiology, fourth edition



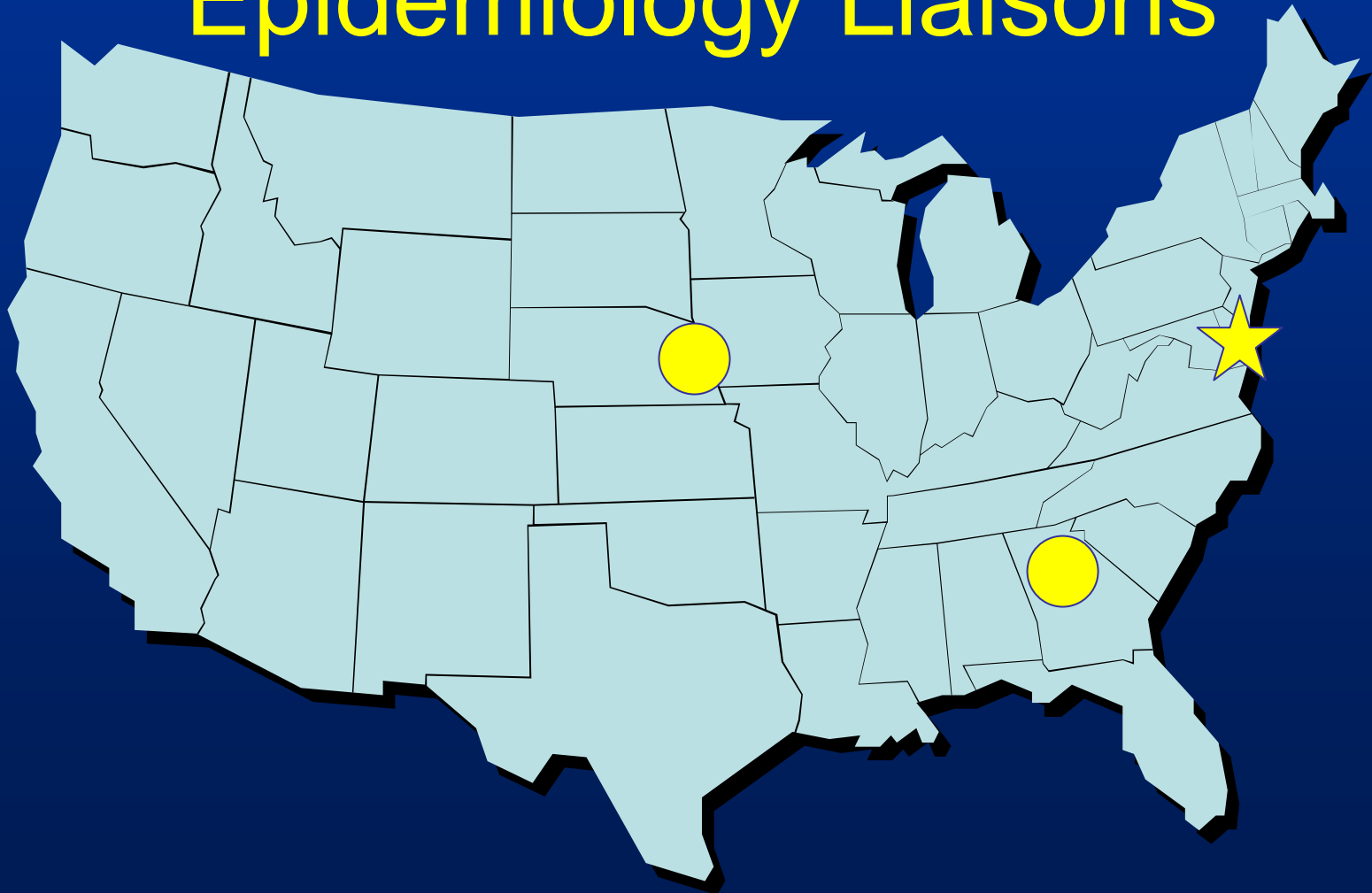
# Foodborne Disease Investigations Branch

- Coordinate FSIS foodborne illness investigations
- Collaborate with public health partners to investigate illnesses potentially associated with FSIS-regulated product
- Serve as liaison between public health partners and FSIS specialty personnel





# Public Health and Epidemiology Liaisons





# FSIS Surveillance and Information Monitoring

- Local, state, territorial public health
- CDC via FSIS Liaison to CDC
- Other federal agencies (FDA, NPS, etc.)
- Internal foodborne illness and hazards surveillance
  - Consumer complaints, PFGE clusters
- Media reports



# Assessment of Preliminary Data

- Does available information suggest a link between product and illness?
- Are methods scientifically valid?
- Are preliminary findings plausible?
- Do preliminary epidemiologic, laboratory, and environmental findings correlate?
- Do literature and past experiences support preliminary findings?



# Initiating an FSIS Investigation

- Initial alert to FSIS program areas for early notification
- Weekly FSIS investigations meeting
- Assess criteria for non-routine incidents



# Deliberate Contamination

- Potential non-routine incidents immediately reported and supplemental protocols followed
- Managed by Emergency Management Committee (EMC)
  - Incident Commander from Office of Food Defense and Emergency Response

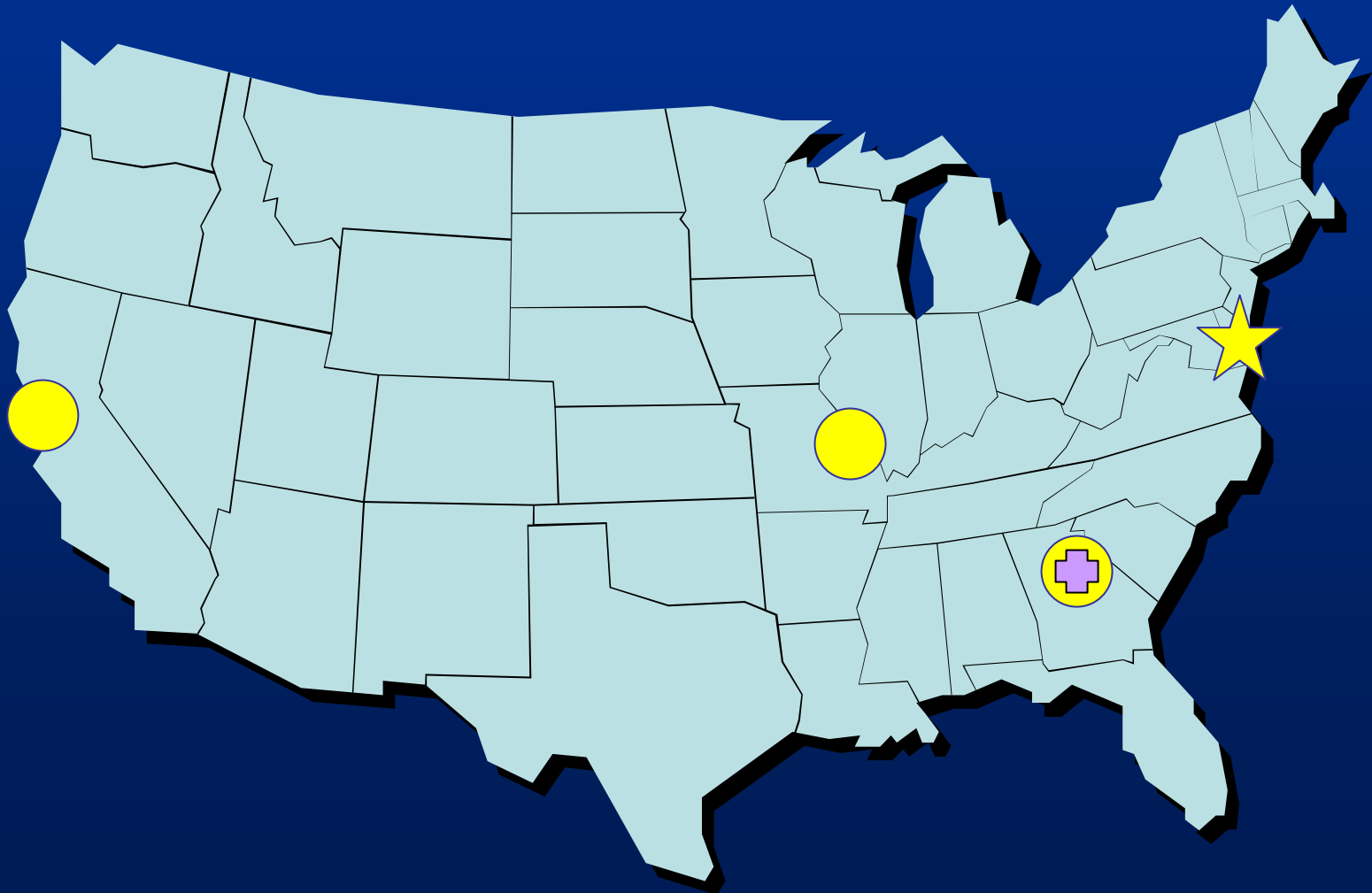


# Laboratory





# FSIS Laboratories





# Product Sampling Assessment

- Do available data support a link between product and illness?
- Is product available meeting FSIS criteria for product identity, chain of custody, product handling?
- Has a non-FSIS laboratory tested product?
- Can testing be performed by, or in association with, FSIS?





# Non-Intact Product

- Product with opened packaging or product removed from original packaging
- May be in commerce or consumer's home
- Useful when intact product is not available and when additional information is needed to determine whether a link exists
- Testing results can result in Agency action



# Non-Intact Product Sampling Assessment

- How was non-intact product handled by case-patient?
- Was non-intact product stored properly?
- Are packaging materials and product labels available? Can product identity be ascertained?



# Use of Pulsed-Field Gel Electrophoresis (PFGE)

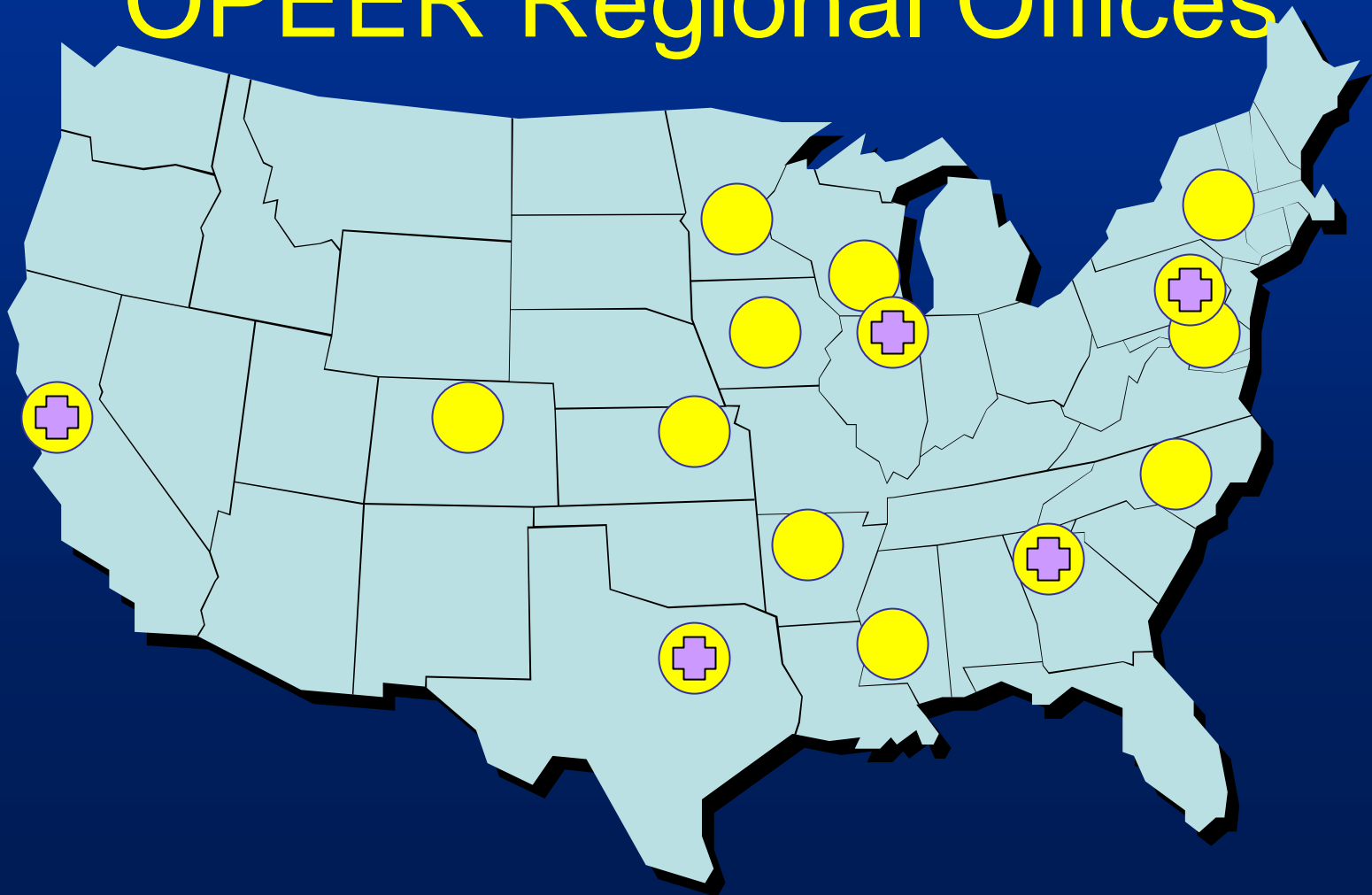
- All PFGE patterns derived from FSIS foodborne illness investigations and recall isolates uploaded to PulseNet
  - Recall watch to ensure adequate scope
- PFGE from FSIS *E. coli* O157, *Listeria* RTE, and *Salmonella* RTE product testing uploaded to PulseNet
- PFGE from FSIS *Salmonella* raw product testing accessible through VetNet

# Environmental Health





# OFO District Offices and OPEER Regional Offices





# Product in Commerce

- Office of Program Evaluation, Enforcement and Review
  - Traceback or traceforward of product
  - Locate or detain product
  - Collect product samples for testing
  - Environmental assessment of facilities
- Coordination with Office of Field Operations and public health partners



# Product in Establishment

- Office of Field Operations
  - Traceback or traceforward of product
  - Locate or detain product
  - Collect product samples for testing
  - Gather information about production practices
  - Perform assessments
- Coordination with Office of Program Evaluation, Enforcement and Review

# “Three-Legged Stool” (putting it all together)







# Data Analysis and Assessment

- Data collection and analysis, assessment of findings are ongoing throughout investigation
- Strength of association is measured using established epidemiologic principles
- Framework based on “Procedures to Investigate Foodborne Illness”



# Framework for Assessment

- Descriptive Information
- Time sequence
- Plausibility
- Dose-response
- Consistency
- Disease confirmation, laboratory analyses
- Analytical studies



Is there credible evidence  
to support an association  
between human illness and an  
FSIS-regulated product?



## Agency Action

- Recall committee convened to discuss findings of the investigation
- Agency action is not just voluntary recalls, other examples include:
  - Increased/enhanced inspection
  - Increased frequency of microbial sampling
  - Issuance of a public health alert



# Agency Action

- Congressional and Public Affairs Office leads public communications efforts
- Communication to affected local, state, territorial public health officials
- Investigation ongoing to ensure actions are sufficient in scope



# After-Action Activities

- Analyze what occurred and corrective and preventive actions taken by establishment
- Assess changes Agency may take to reduce possibility of repetition of circumstances leading to Agency action
- Address data gaps
- Coordinate FSIS close-out call



# Summary and Lessons Learned

- FSIS foodborne illness investigations are multidisciplinary and involve numerous program areas
- Substantial coordination and collaboration are essential between local, state, and federal public health partners