



Directive 8080.3 - Foodborne Illness Investigations

District Office Correlation

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Need for FSIS Directive 8080.3

- Collaborative relationship already developed and utilized
- Single set of procedures not formally adopted
- Standardization of procedures
- Public health necessity for prompt response and action



FSIS 8080.3 Contents

- I. Purpose**
- V. Background**
- VI. Terminology**
- VII. Determining the Need for a Foodborne Illness Investigation: Surveillance and Information Monitoring**
- VIII. Actions Once a Foodborne Illness Investigation is Initiated**
- IX. Product Sampling and Laboratory Analysis**
- X. Environmental Assessment: Product Traceback and Traceforward**



FSIS 8080.3 Contents

XI. Data Analysis and Assessment

XII. Agency Action

XIII. Close-Out and Final Assessment

XIV. Continuous Activities

**Attachment I: Roles and Responsibilities of FSIS
Personnel Throughout Foodborne Illness
Investigations**

**Attachment II: Surveillance for Human Foodborne
Illnesses**



FSIS Investigations

- Multifaceted, multidisciplinary undertaking
- Require substantial collaboration
- “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



Consumer Complaints vs. Illness Investigations

- Procedures for consumer complaints outlined in FSIS Directive 5610.1
- Consumer complaints reported from consumers
- Consumer complaints may involve FSIS interview of consumers
- CCMS manages consumer complaints



DISCLAIMER:

Investigations are Unique

- Phases of investigations may occur nearly simultaneously
- Steps outlined do not always occur in the specified order
- Flow of information and data is dynamic



Epidemiology





OPHS 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



Foodborne Disease Investigations Branch





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

- Alert to FSIS program areas for early notification
 - All alerts generate Non-Routine Incident Report (NRIR)
- Weekly FSIS investigations meeting

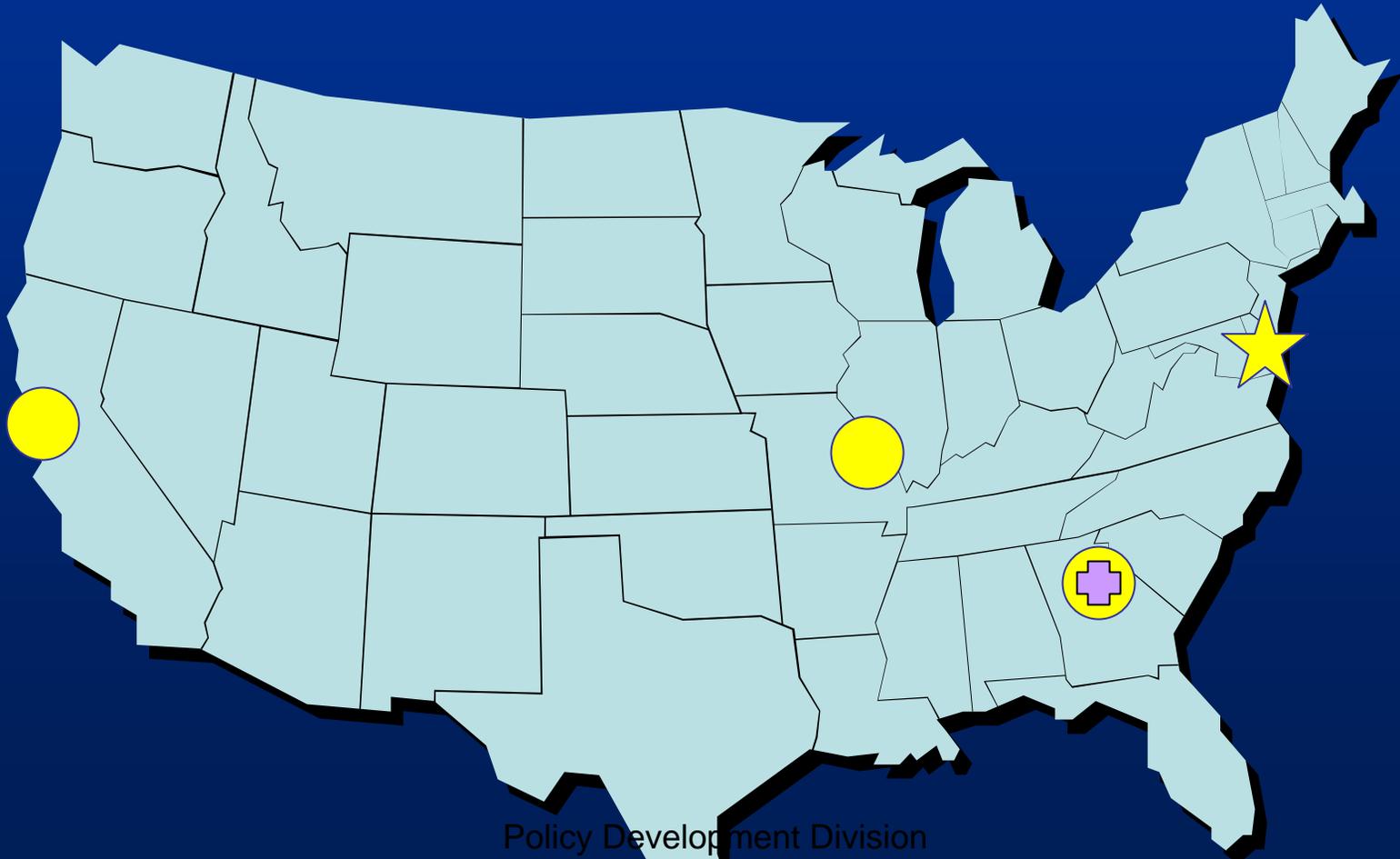


Laboratory





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?



OFO Roles in Product Sampling

8080.3, Section IX-B

- Collecting, preparing, and shipping samples
 - Procedures in FSIS Directive 8010.3
 - Focus on product distributed within establishments
- Notification of affected firm of collection
- Works closely with OPHS microbiologists to ensure chain of custody, secure and timely shipment to FSIS laboratories



Pulsed-Field Gel Electrophoresis (PFGE)

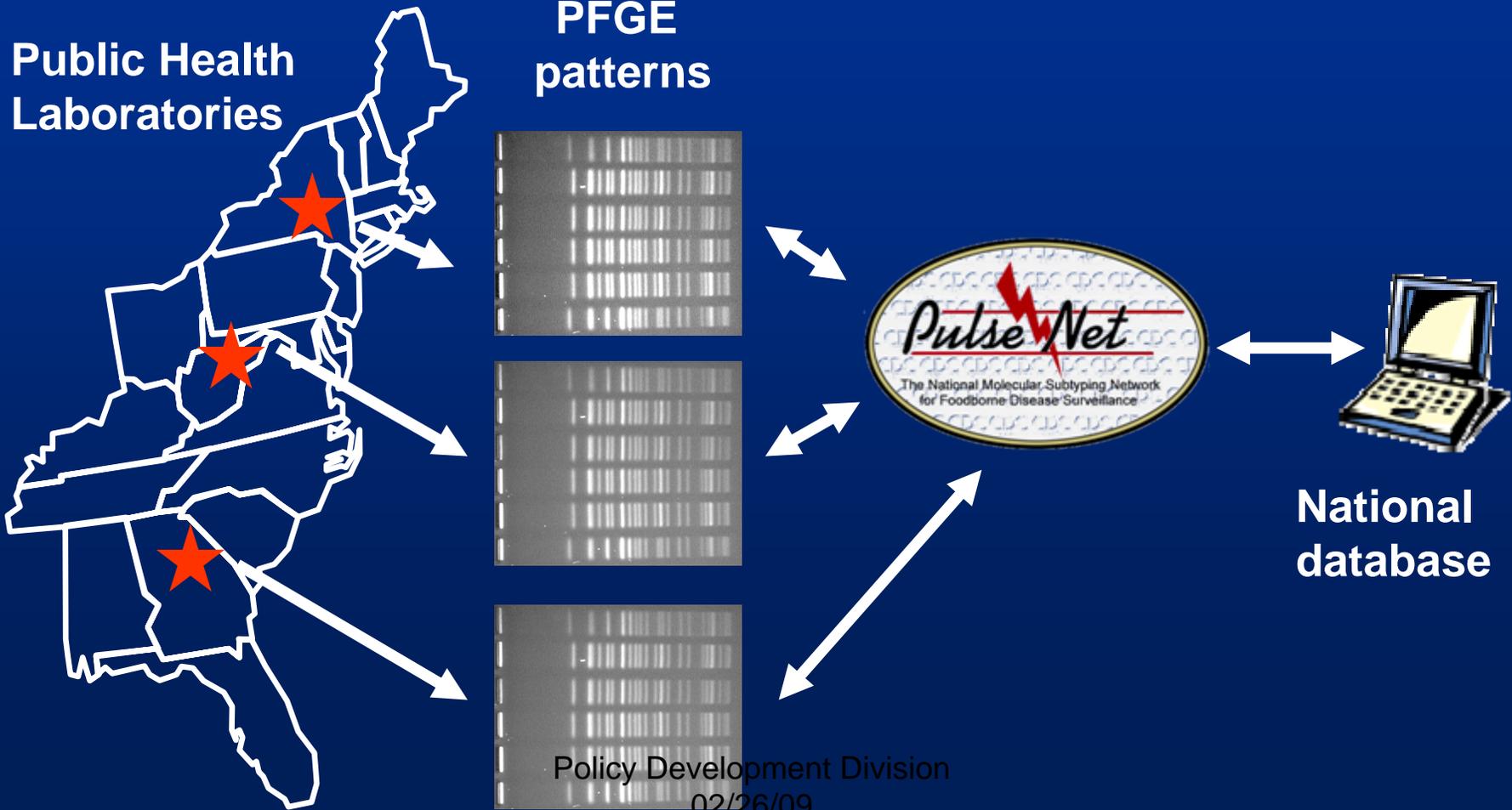
- Analytical tool used to create a “DNA fingerprint” (i.e. pattern) of a microbial isolate
- Reproducible and specific subtyping method for bacteria
- Bacteria with same PFGE pattern may share a common ancestor and source



FSIS Use of PFGE Data

- Regulatory decisions supported by, but not based solely upon, PFGE
- Supports information collected through:
 - Observations made at an establishment
 - Epidemiologic investigations
- With additional information, can:
 - Identify possible outbreaks and distinguish from concurrent sporadic cases
 - Determine sites of potential harborage or patterns of contamination in an establishment

PFGE and CDC PulseNet



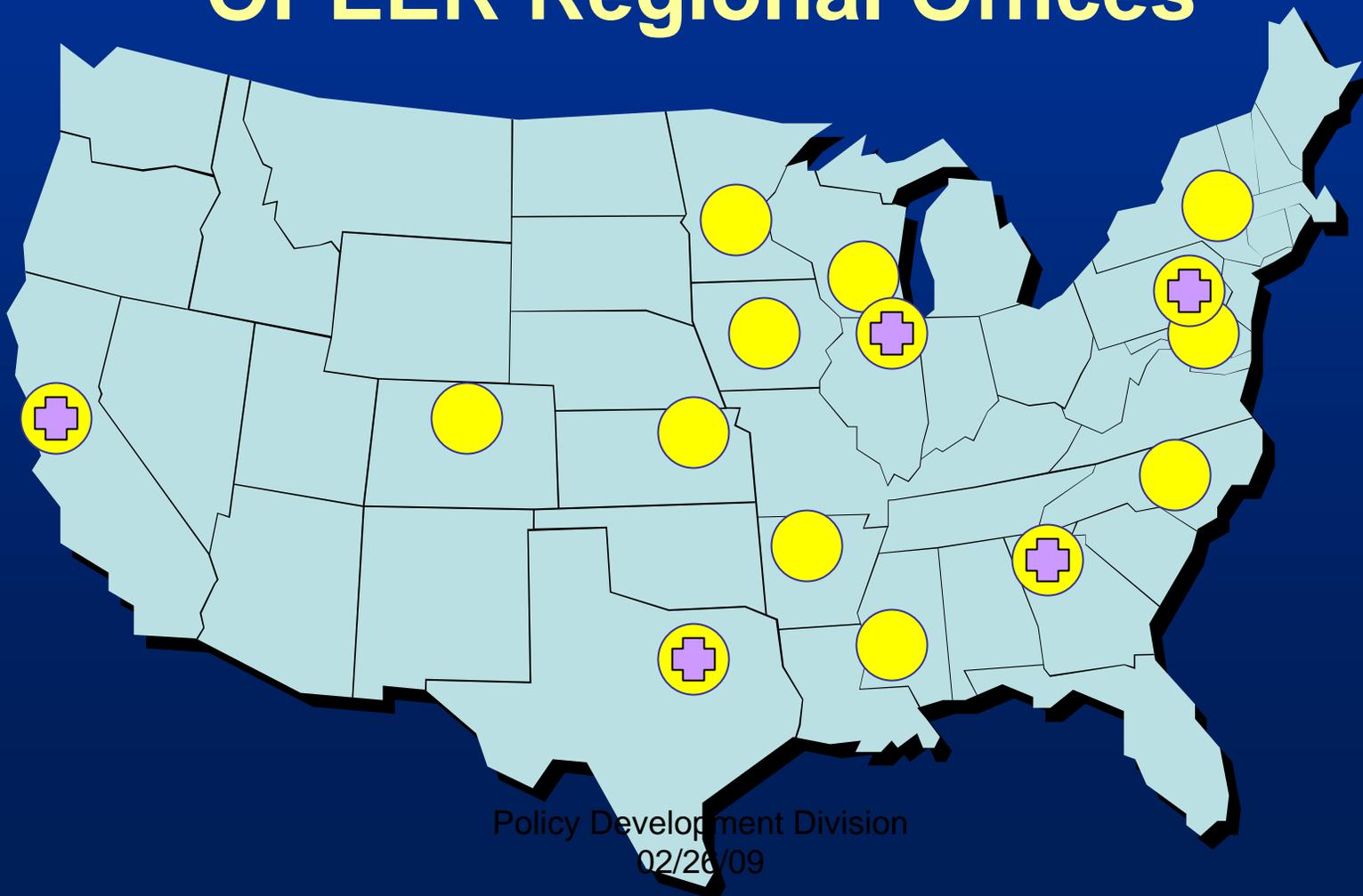


Environmental Health





OFO District Offices and OPEER Regional Offices





Product in Commerce

8080.3, Section X-A,B

- 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



OPEER Investigation Assistance

- OPHS works through OPEER Regional Manager
- Written requests from AED/FDIB
- Expectation is that OPHS and OPEER investigators work closely together
- Procedures outlined in 8010.1-8010.5



Product in Establishment

8080.3, Section X-A,C

- 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



OFO Investigation Assistance

- OPHS works through OFO Office of the Assistant Administrator
- Written requests from AED/FDIB
- Requests referred to District Manager
- Expectation is that OPHS and OFO investigators work closely together
- Documentation procedures outlined in 5100.3



Coordination with Local Public Health Partners

- Traceback/traceforward investigations often involve coordination locally
- Frequent communication is critical
- Discussion with FDIB about local public health partners' preferences beneficial

“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” (IAFP)



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:
 - Criminal, civil, administrative action
 - 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
- FSIS close-out call



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