

# Outbreak Investigation for Food Safety Professionals

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*Your gateway to Federal food safety information.*

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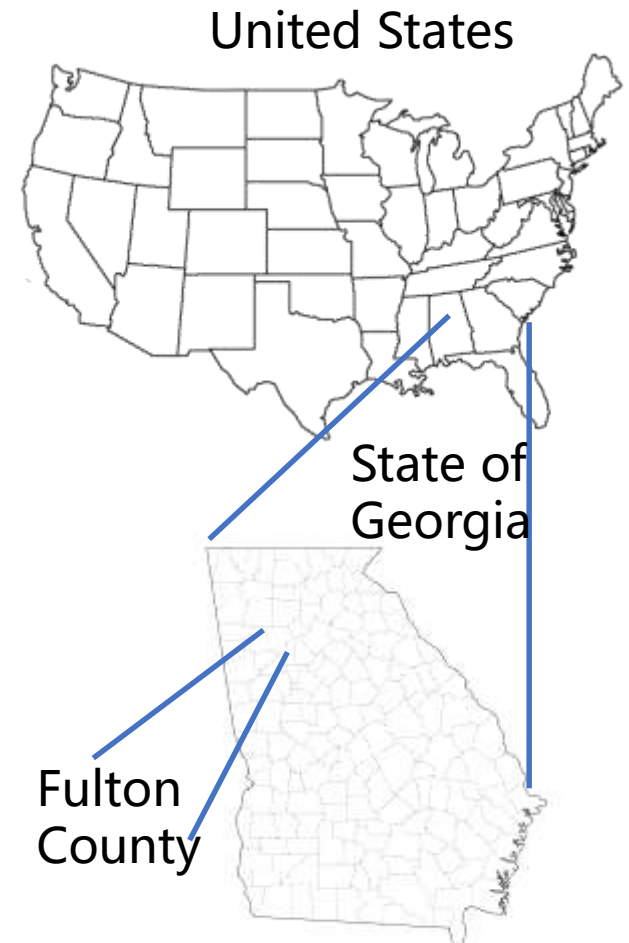
*Food Safety Summit*

*May 10, 2023*

# Public Health Infrastructure in the United States

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- Federal
  - National public health agency (CDC)
- State
  - 50 state + 1 district health departments
- Local
  - >2,500 local health departments



# Public Health Infrastructure in the United States: The Federal Agencies

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- Risk identification agency: Centers for Disease Control and Prevention (CDC) (non-regulatory)
- Risk management/regulatory agencies: Food and Drug Administration (FDA), U.S. Department of Agriculture Food Safety and Inspection Service (FSIS)

## CDC

- Disease surveillance
- Outbreak detection and investigation
- Education and training of public health staff
- Problem identification
- Source implication

## FDA & FSIS

- Food safety policies
- Inspection and enforcement
- Product recall and traceback
- Investigation of farm (FDA) and food production facilities
- Risk assessment and

# Our Mission

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The Food Safety and Inspection Service is responsible for ensuring that meat, poultry and egg products are safe, wholesome and properly labeled.

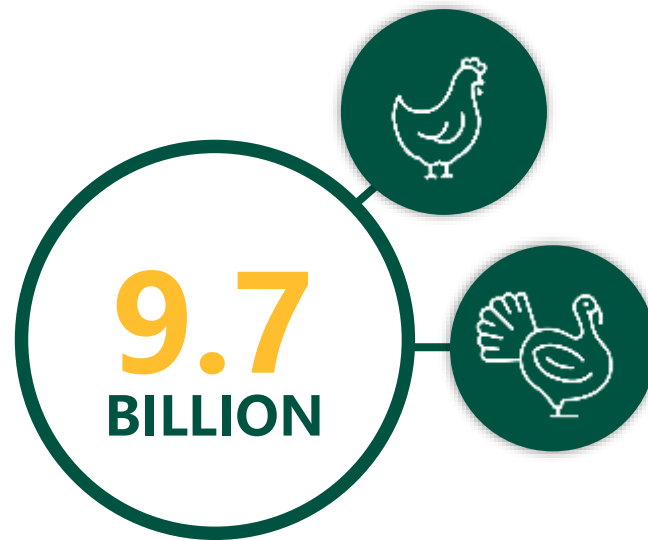


# Our Inspection by the Numbers

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HEAD OF  
LIVESTOCK  
INSPECTED



POULTRY  
CARCASSES  
INSPECTED



POUNDS OF  
LIQUID, FROZEN  
AND DRIED EGG  
PRODUCTS  
INSPECTED



FOOD SAFETY  
PROCEDURES

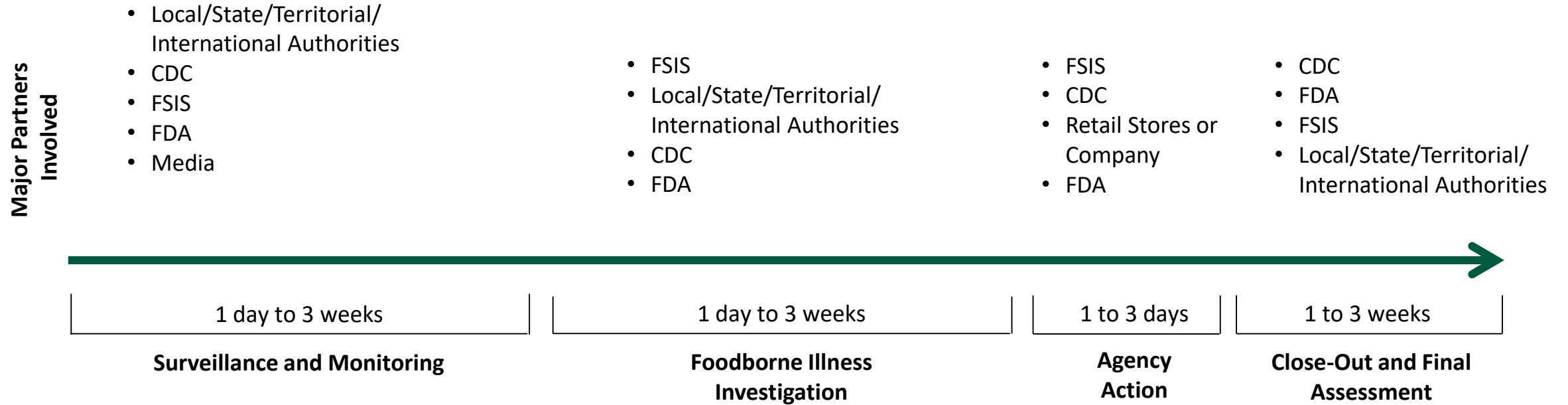
# What is FDA CORE?

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- Office of Coordinated Outbreak Response and Evaluation
- Manages surveillance, response, and analysis activities related to incidents of illness linked to FDA-regulated human food, cosmetics, and dietary supplements
- Designed to streamline and strengthen FDA's efforts to:
  - Detect
  - Investigate
  - Respond
  - Evaluate
  - Apply Lessons Learned

# Outbreak Investigation



*Timeframes are based on historical data. Several factors can influence an investigation's timeline.*

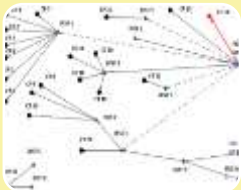
# Outbreak Investigation

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## EPIDEMIOLOGY

Who, What, When, Where, How



## TRACEBACK/TRACEFORWARD

Determine source or distribution; documentation is key



## LABORATORY

Food, clinical; whole genome sequencing (WGS)



## ENVIRONMENTAL HEALTH

Assessments and inspection





# PulseNet USA

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- CDC detects outbreaks mainly through our surveillance system called PulseNet
- PulseNet is a national laboratory network that connects foodborne illness cases to detect outbreaks
- PulseNet laboratory network established in 1996
  - Over 80 participating laboratories in the U.S.
  - 60,000+ isolates subtyped annually



# PulseNet

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- Subtyping enteric bacteria is essential to identifying highly disseminated outbreaks
- Bacteria collected from ill people undergo DNA “fingerprinting” using Whole Genome Sequencing (WGS)
- WGS examines (almost) the entire genome of a bacteria to assess relatedness between isolates
- Sequences from illness-causing bacteria are transmitted to CDC
- Monitored for closely related temporal clusters of isolates
- When a cluster is identified, PulseNet notifies epidemiologists to investigate

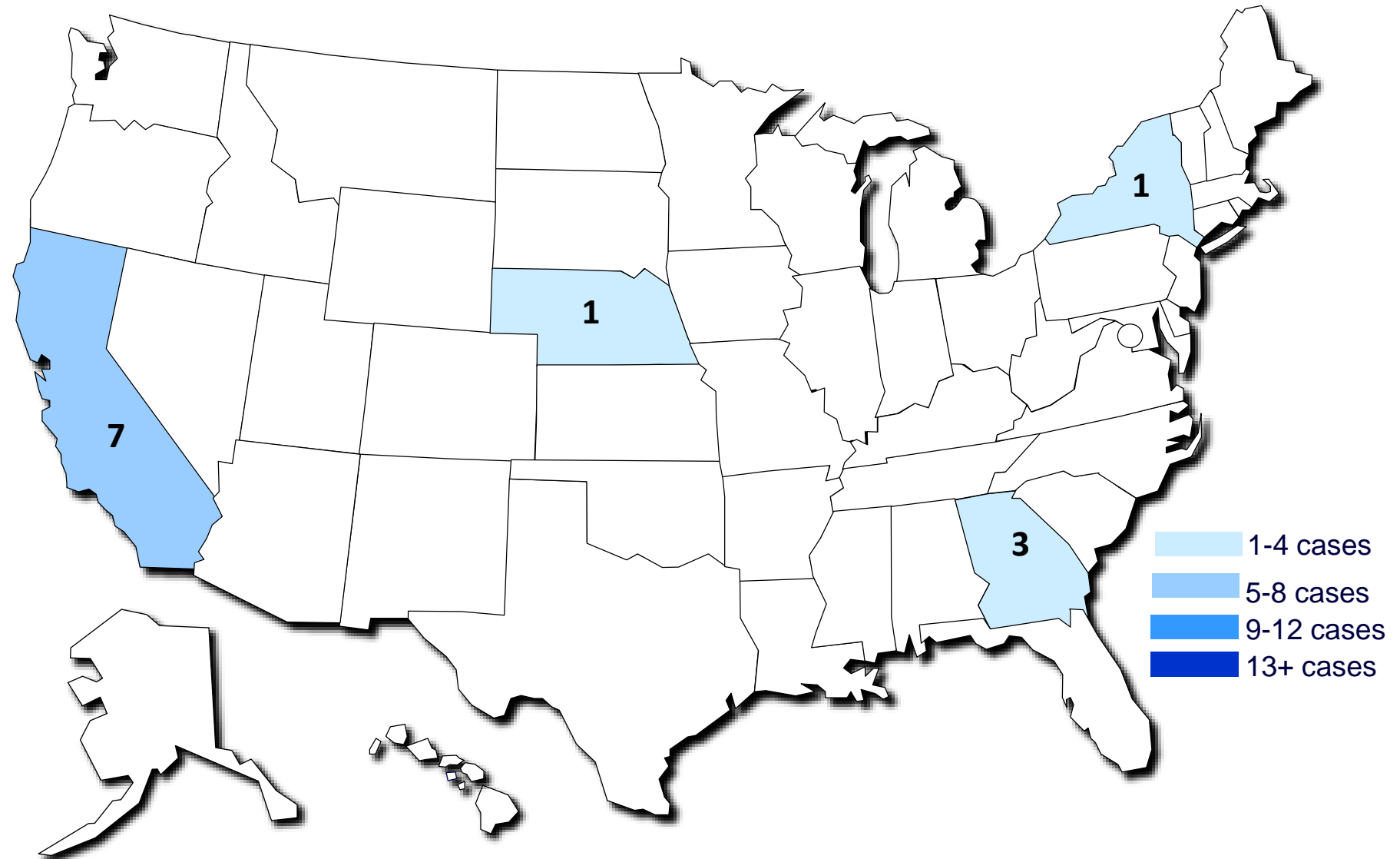
# Outbreak Scenario

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This outbreak scenario is fictitious and is loosely based on multiple outbreaks CDC, FDA, and FSIS have worked on in the past. All state, epidemiologic information, and responses are to be used as an example.

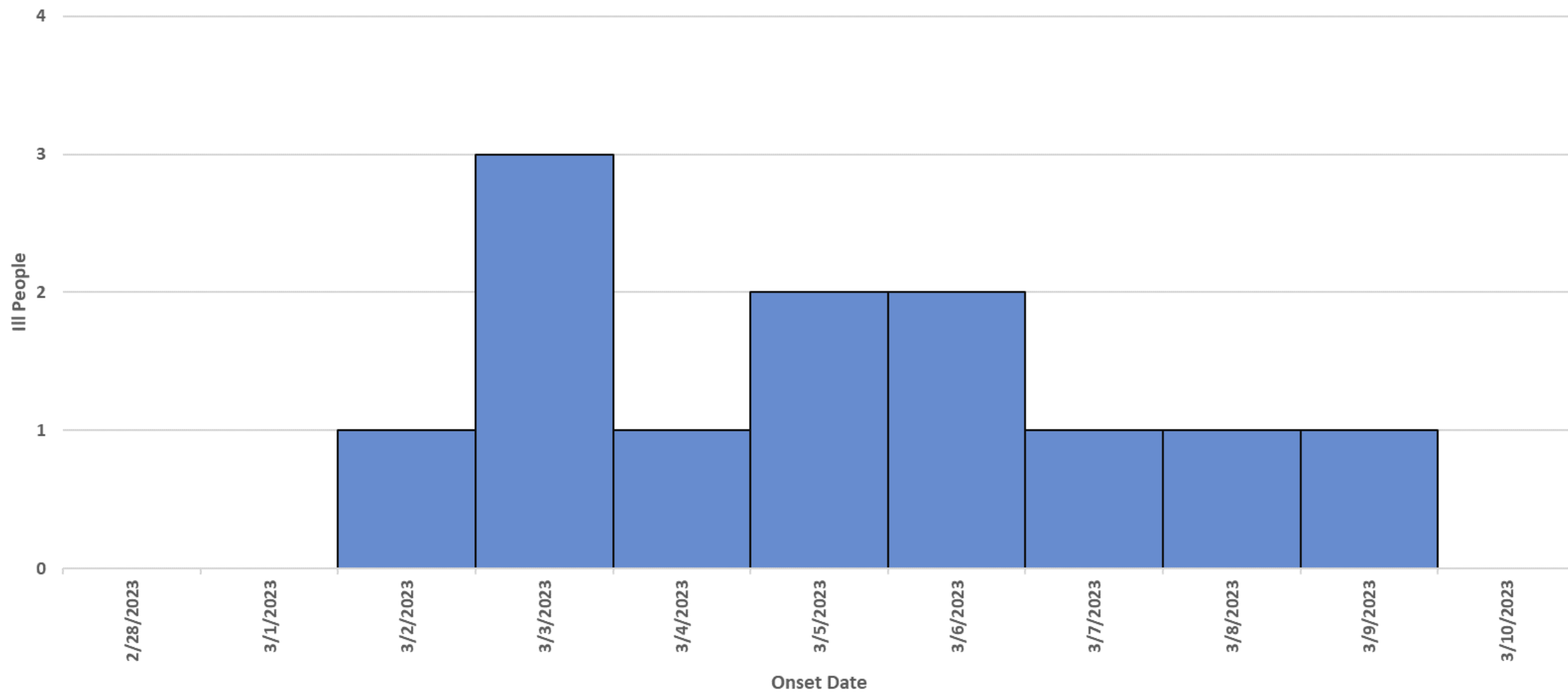
# Epidemiologic Information from PulseNet

- 12 *E. coli* O157:H7 cases
- 4 states
- 5/12 (42%) female
- 3 hospitalizations
- 1 hemolytic uremic syndrome (HUS) case
- Onset date: March 2, 2023- March 9, 2023
- 0-1 alleles by WGS
- No epi information
- Not clustering in one area of U.S.



*Fictitious outbreak for educational purposes only*

## People Infected with the outbreak strain of *E. coli* O157:H7 by date of illness onset\* as of March 10, 2023



*Fictitious outbreak for educational purposes only*

# What would you do next?



**Use the Food Safety Summit app to answer**

- A. Monitor and wait for more illnesses to be reported
- B. Coordinate a call with states that have cases
- C. Collect and test foods from ill people's homes

# Multistate Conference Call

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- States interview cases to obtain food, water, and animal exposure information
- States enter food history data from initial interviews into web-based data sharing platform, SEDRIC
- CDC schedules a call to discuss outbreak including state partners with cases, FDA, and FSIS



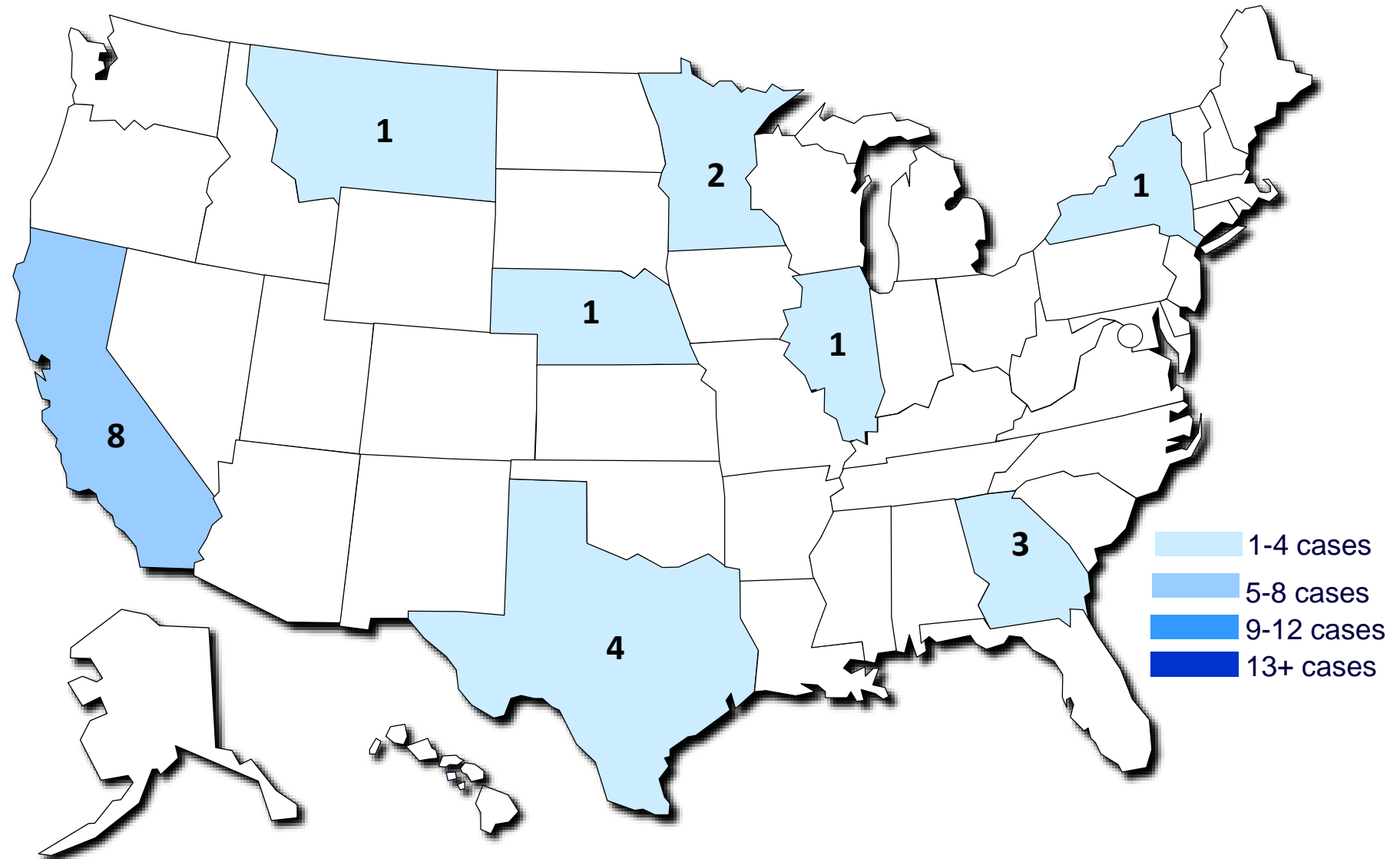
## Initial Interview Data

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- No obvious common food, water, or environmental exposure
- Obtain store shopper/loyalty card details for cases

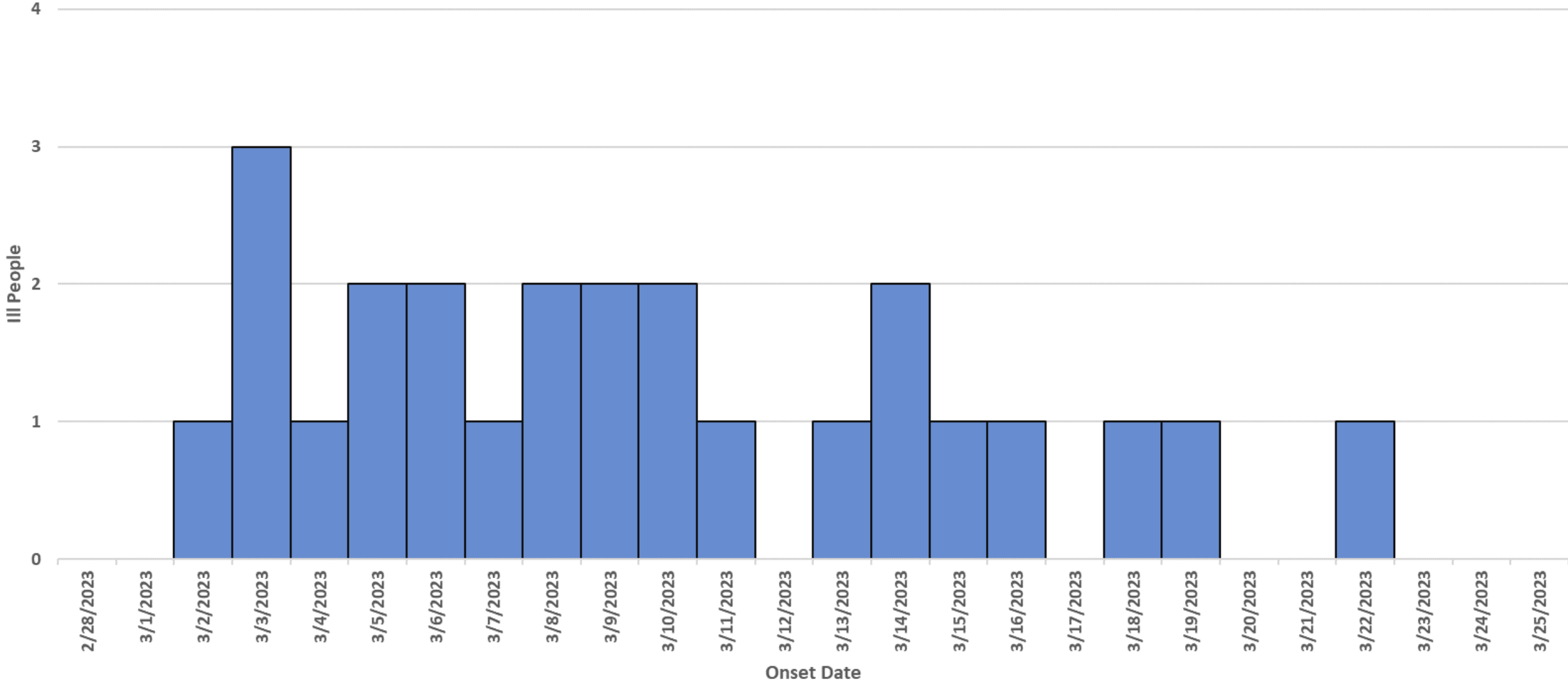
# Epidemiologic Information from PulseNet

- **25** cases
- **8** states
- **7/20 (35%)** female
- **4** hospitalizations
- 1 HUS
- Onset dates:  
March 2, 2023-  
March **22**, 2023
- 0-1 alleles by WGS



*Fictitious outbreak for educational purposes only*

# People Infected with the outbreak strain of *E. coli* O157:H7 by date of illness onset\* as of March 25, 2023



*Fictitious outbreak for educational purposes only*

# National Hypothesis Generating Questionnaire (NHGQ)

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- Standard set of >300 questions about food and other exposures
- CDC works with state partners to use the NHGQ to collect the same information across many states
- Can help identify one or more leading hypotheses

## Interesting NHGQ Results

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- 18/21 (86%) Pizza
- 16/21 (76%) Watermelon
- 12/21 (57%) Burgers
- 12/21 (57%) Leafy greens

# Shopper History Records

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- 4 shopper histories from 3 retailers
- All 4 (100%) shopper histories had frozen pizza purchases
  - Pizza Types: Cheese, Meat lovers, and Vegetarian
- FSIS investigators take these shopper histories and traceback pizza
  - 3 brands (Tasty Pizza, Meaty Pizza, and Little Rhody Pizza) produced by 2 companies
- FSIS shares traceback information with FDA

# What would you do next?



**Use the Food Safety Summit app to answer**

Now that pizza is the leading hypothesis, who regulates pizza?

- A. FDA
- B. FSIS
- C. EPA
- D. Both FDA and FSIS

## Dual Jurisdiction Establishments

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- Product regulated by FSIS:
  - Raw with >3% meat/poultry
  - Cooked with 2% or more meat/poultry
- Frozen pizza production:
  - Whole pizza is heat treated (but not fully cooked, not shelf-stable)
  - Uncooked dough
  - Ready-to-Eat cheese, meat, vegetables
- Voluntary recalls initiated by companies could involve products regulated by both FDA and FSIS (e.g. multiple pizza types)



# San Diego County, California Neighborhood BBQ Event

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- Approximately 50 people attended neighborhood BBQ
- Food items
  - Pulled pork
  - Burgers
  - Ribs
  - Pasta salad
  - Grilled vegetables
  - Watermelon
  - Other foods but are not remembered
- Leftover food samples collected and tested; no *E. coli* detected
- No food vehicle identified



# What would you do next?



**Use the Food Safety Summit app to answer**

- A. Deploy a focused questionnaire to ask specific questions about pizza
- B. Wait for more illnesses to be reported
- C. Post a CDC Food Safety Alert
- D. Ask retailers to issue a recall

# Deploy a Focused Questionnaire

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- Focus questions on frozen pizza types and brands:
  - Cheese
  - Pepperoni
  - Meat lovers
  - Vegetarian
  - Others
- Where was pizza consumed? In or out of the home?
- Add questions about burgers and watermelon from sub-cluster

## Deploy a Focused Questionnaire

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- 13/25 completed focused questionnaire
- 12/13 reported eating frozen pizza
- Brands reported: Tasty Pizza, Meaty Pizza, and Little Rhody Pizza
- 3/13 reported eating burgers
- Upon re-interview, one case reported Little Rhody frozen pizza was served at the BBQ sub-cluster
- Collected shopper purchase histories from 7 cases

# Should CDC post a Food Safety Alert?

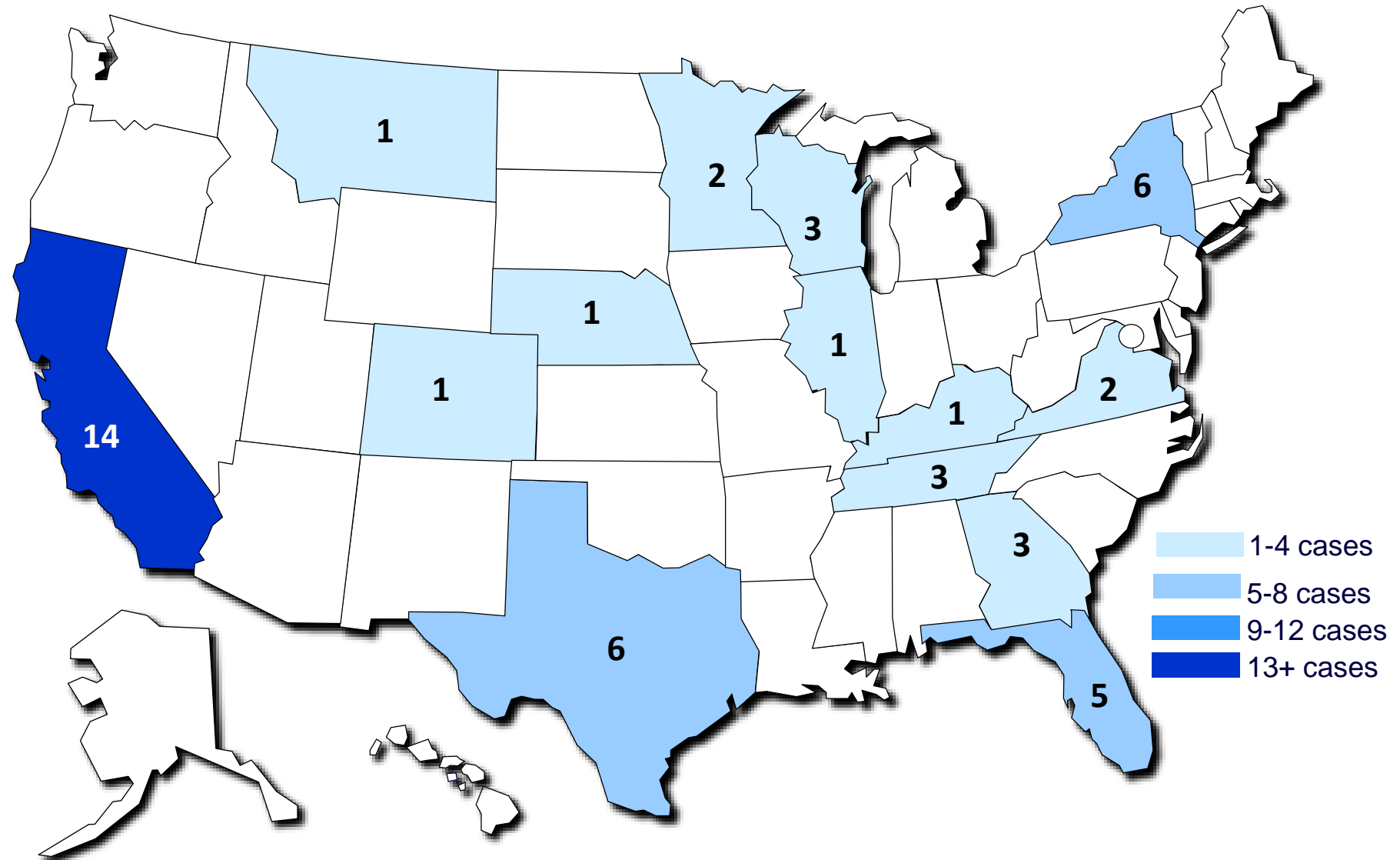


**Use the Food Safety Summit app to answer**

- A. Yes, advise the public to avoid eating any frozen pizza
- B. Yes, advise the public to avoid eating any Tasty Pizza, Meaty Pizza, or Little Rhody Pizza
- C. Yes, advise the public that are at high risk of serious *E. coli* infections to avoid eating any frozen pizza
- D. No. Do not post an alert until we have more specific product information

# Epidemiologic Information from PulseNet

- **49** cases
- **14** states
- **23/48 (48%)** female
- **10** hospitalizations
- 1 HUS
- Onset dates:  
March 2, 2023-  
March **24**, 2023
- 0-**2** alleles by WGS



*Fictitious outbreak for educational purposes only*

# Establishments

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## Establishment A

- FSIS regulated only
- Meat pizzas
- All heat treated

## Establishment B

- FDA and FSIS regulated, dual jurisdiction establishment
- Vegetarian pizzas
- Cheese pizzas
- Meat pizzas
- All-heat treated

- FSIS and FDA will be collecting additional information at the establishment level.

# Schedule Company Calls, Friday

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- Organize call Friday with 2 companies:
  - Company 1 produces Tasty Pizza and Meaty Pizza (at Establishment A)
  - Company 2 produces Little Rhody Pizza (at Establishment B)
- Share outbreak information
- Share information of purchases traced to their establishments
- Request information on consumer complaints and any sample positives
- Follow up with questions and fact finding



# Additional Purchase History Records

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- **15** shopper purchase histories from **6** grocery stores
- Pizza Types
  - Cheese
  - Meat lovers
  - Vegetarian
- FSIS investigators take these shopper purchase histories and traceback pizza
  - **3** brands from 2 companies (Produced at Establishment A and B)

# What would you do next?



**Use the Food Safety Summit app to answer**

- A. Sample finished products and ingredients
- B. Ask Company 1 and Company 2 for a recall
- C. Post a CDC Food Safety Alert
- D. Conduct investigations at Establishments A and B
- E. Both A and D

# Regulatory Agencies Conduct Fact Finding

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- FDA and FSIS identify fact finding questions
- Ingredients:
  - Raw
  - Ready-to-eat
- Establishment flow
- Product distribution
- Sampling results

# Multistate Call

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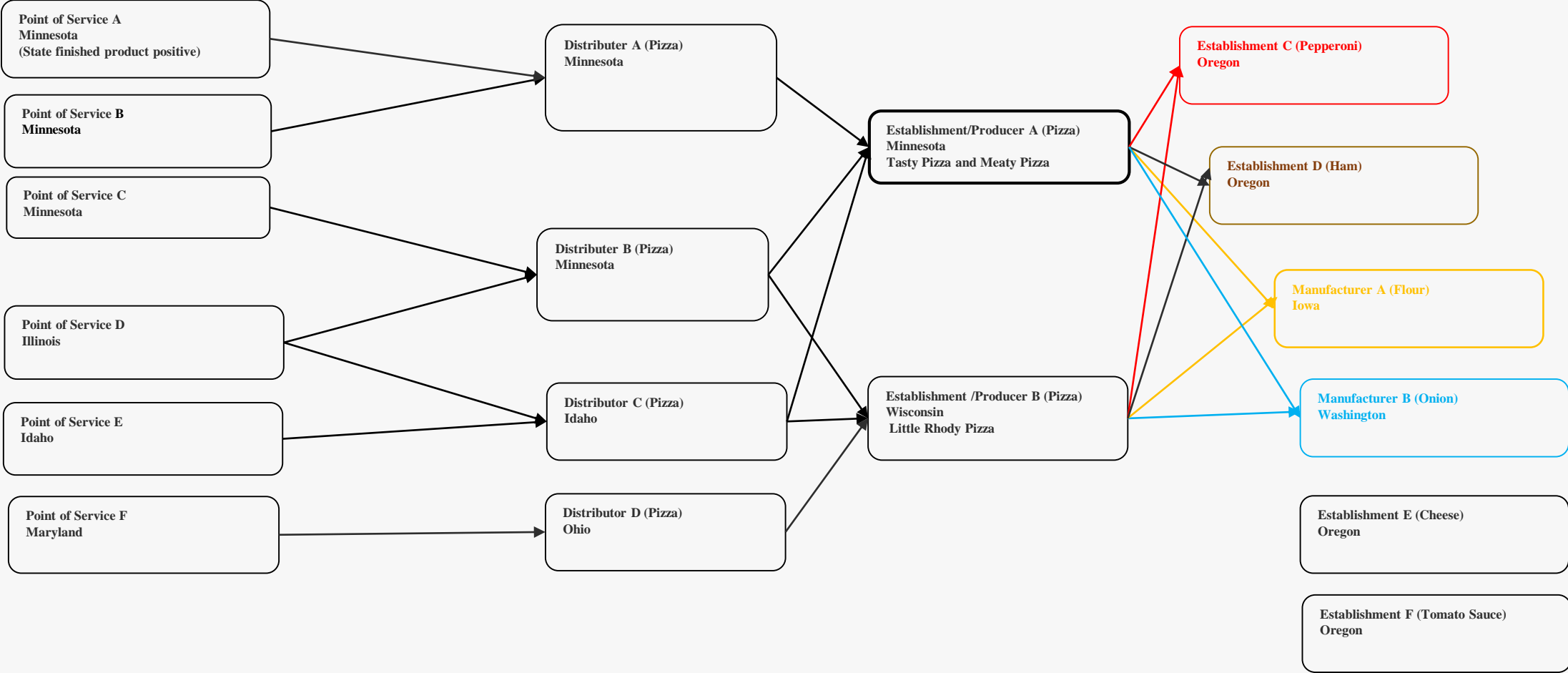
- States provide updated case count, health outcomes, pending cases, and food exposures
- CA, MN, and IL collect frozen pizzas from retail – results pending
- Federal updates

# Regulatory Agencies In-Plant Findings Discussion

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- Identify common ingredient suppliers to both establishments:
  - Ready-to-eat pepperoni (Establishment C)
  - Ready-to-eat ham (Establishment D)
  - Raw flour (Producer E)
  - Onions (Producer F)
- Discussion of testing pepperoni, ham, flour, and onions

# Traceback Diagram



# Product Sample Results

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- CA, MN, and IL samples:
  - CA and IL samples, *E. coli* not detected
  - MN Tasty Pizza brand supreme pizza sample, *E. coli* detected, serotype unknown
- FSIS collected ready-to-eat ingredients for testing, results pending
- FDA collected raw ingredients for testing, results pending

# Public Communications

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- Officials in MN are releasing public communications about positive result and plan to name Tasty Pizza
- CDC, MN, FDA, and FSIS schedule call with establishment that produced Tasty Pizza brand to notify them of results and planned MN public communications
- Tasty Pizza conducts voluntary Class I recall of pizzas from same production lot as the pizza tested by MN



# Regulatory Agencies Sampling Results

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- FSIS
  - Pepperoni and ham samples, *E. coli* not detected
- FDA
  - Flour, *E. coli* detected serotype pending

## Expanded Recall

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- *E. coli* O157:H7, positive for outbreak strain in flour
- All pizzas (both FDA and FSIS regulated) containing the contaminated lot of flour recalled
- Further information collected regarding flour distribution; potential for additional recalls

# What would you do next?



**Use the Food Safety Summit app to answer**

- A. Monitor for additional illnesses
- B. Regulatory effectiveness checks
- C. Update CDC Food Safety Alert with new recall information
- D. Both A and C
- E. All of the above

# Recall and Outbreak Closing Activities

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- Providing information to the public and food establishments
- Updating agency websites to include information about the recall
  - [www.fsis.usda.gov/recalls](http://www.fsis.usda.gov/recalls)
  - [www.fda.gov/safety/recalls-market-withdrawals-safety-alerts](http://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts)
- Regulatory agencies conducting recall effectiveness checks

## Confirming the Outbreak is Over

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- CDC will continue to monitor for additional illnesses
- CDC will close an investigation after reports of illness either stop or return to “expected levels”
- Other information is considered
  - Reporting delays for the pathogen and other factors that affect reporting (e.g., holidays)
  - Whether the source of contamination was known/mitigated
- Scheduling after action review calls

## Final Thoughts

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- Multistate foodborne outbreak investigations can be complex
  - Require swift, coordinated action
- Numerous agencies play unique and critical roles
  - CDC, state, and local public health officials
  - State and federal regulatory agencies
  - Industry
- Need to evaluate all the evidence (epi, lab, traceback) to get the right answer

# Thank you

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