



Foodborne Outbreaks 101: Introduction to CDC's Investigational Process for Multistate Foodborne Outbreaks

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Outbreak Investigation Process

Foodborne Diseases in the United States: A Changing Landscape

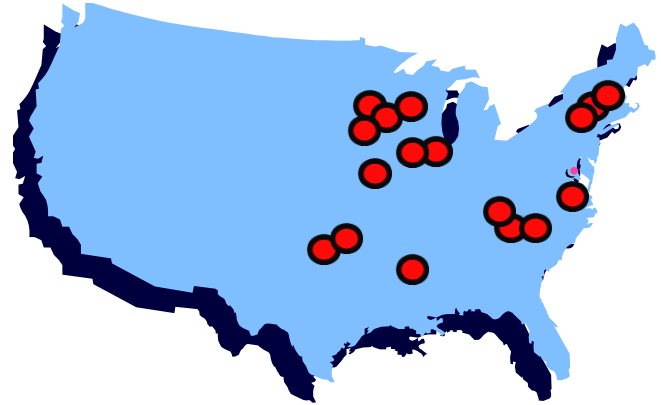
- Food production and distribution has changed substantially over the last several decades
- Fewer producers, with wider distribution
- More “ready-to-eat” and industrially produced foods
- Has caused a shift in the types of outbreaks that occur



Foodborne Diseases in the United States: A Changing Landscape



“Classic” Foodborne Outbreak



Disseminated Foodborne Outbreak

Detecting Outbreaks with PulseNet

- Subtyping enteric bacteria is essential to identifying highly disseminated outbreaks
- PulseNet laboratory network established in 1996
 - Over 80 participating laboratories in the US
 - 60,000+ isolates subtyped annually
- Bacteria collected from ill people undergo DNA “fingerprinting” using pulse-field gel electrophoresis (PFGE)

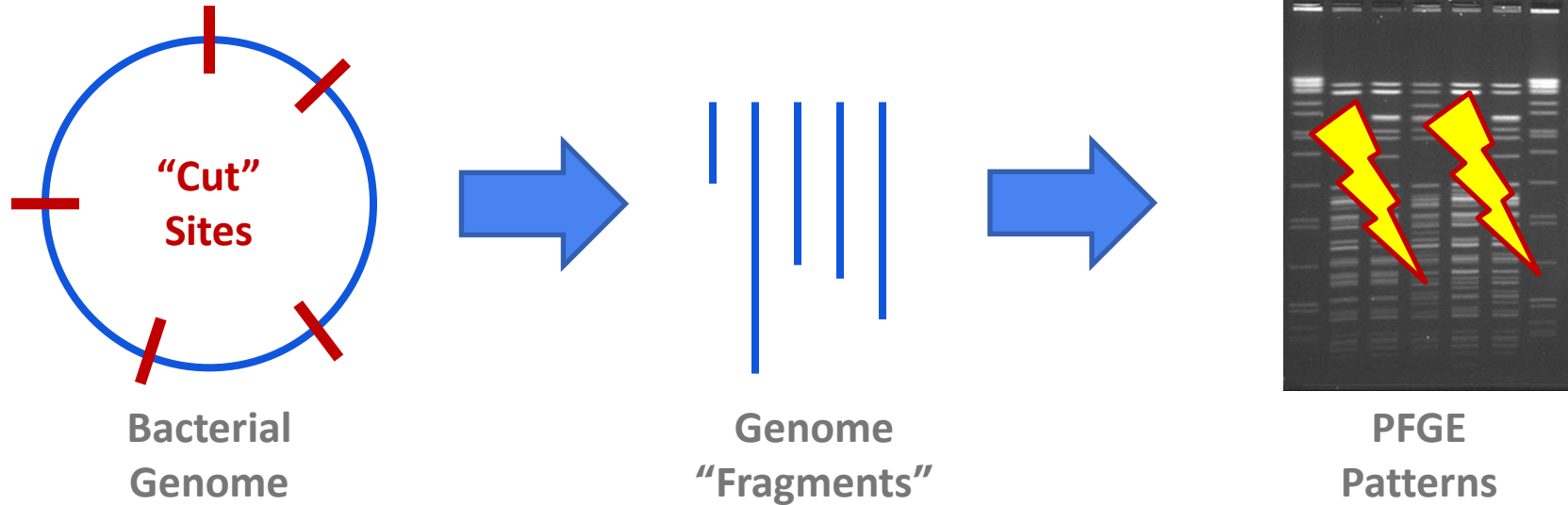


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Bacteria with the same “fingerprint” are *more likely* to come from a common source

Conceptual Framework for PFGE Subtyping

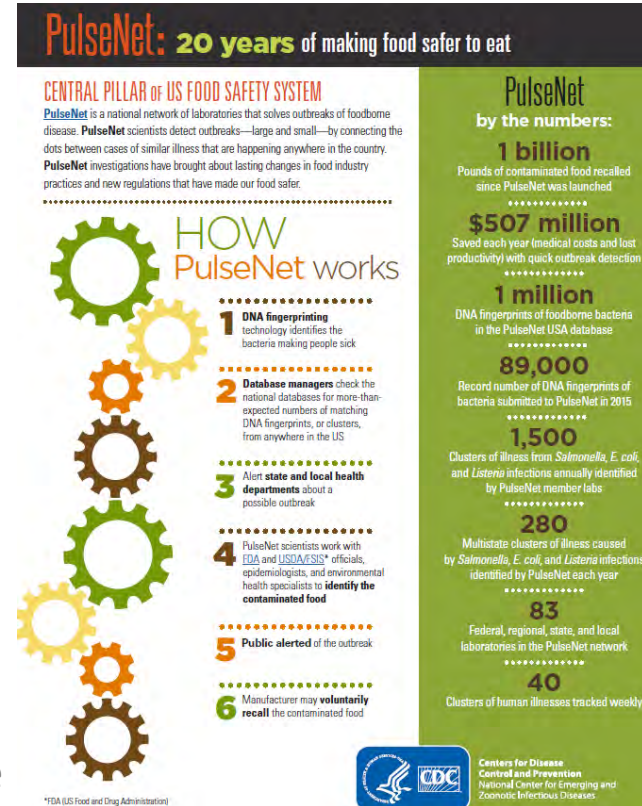


Comparing isolates is analogous to comparing two books based on the number of words in each chapter

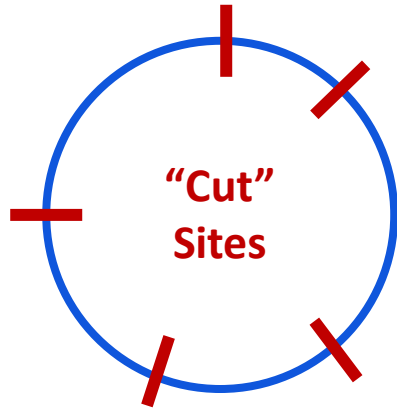
Other lab workflows needed for serotype, virulence factors, etc.

Strengths and Limitations of PFGE-Based Subtyping

- Successful over the last 20 years in detecting highly disseminated outbreaks
 - Would not have otherwise been detected
 - Would have been detected much later
- Limitations to PFGE-based subtyping
 - Some PFGE patterns are common, limiting utility
 - PFGE patterns are indirectly reflective of underlying bacterial genome
 - Genetically related bacteria can appear different by PFGE
 - Genetically unrelated bacteria can appear the same by PFGE



WGS Provides a Higher Resolution View of the Bacterial Genome



PFGE only gives information at a "cut" site via the banding pattern



WGS has the ability to give us information at nearly every position in the genome

Comparing isolates is analogous to comparing two books based on all the words in the book

Serotype, virulence, etc. can be identified in one workflow

Implementation of Whole Genome Sequencing (WGS)

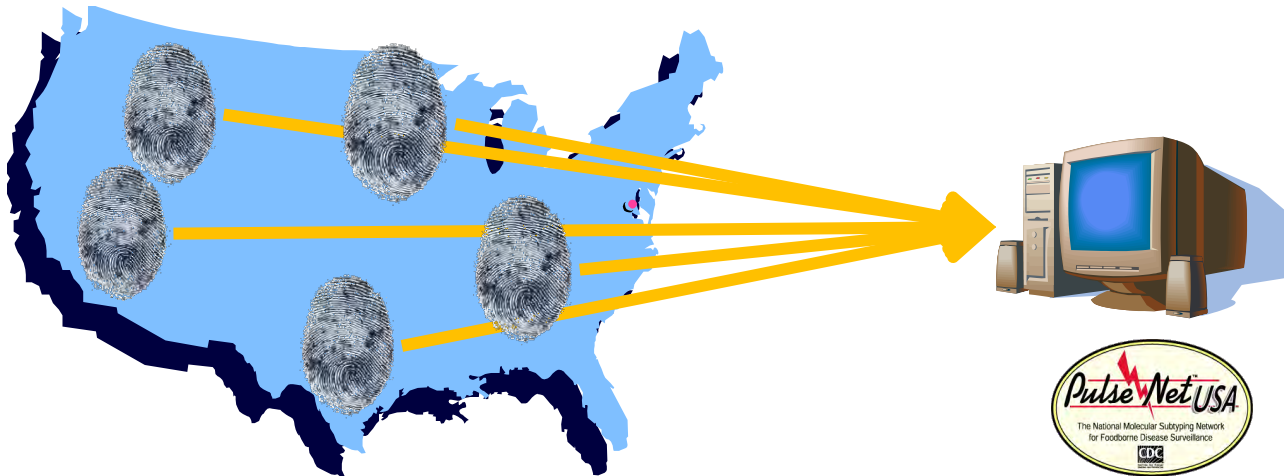
- *Listeria monocytogenes*
 - Transitioned to routine sequencing of all isolates in 2013
 - Outbreak detection is now largely based on WGS



- *Salmonella* and Shiga toxin-producing *E. coli* (STEC)
 - Outbreak detection still based on PFGE
 - WGS used for further subtyping to address specific investigation questions
 - Moving to routine sequencing of all *Salmonella* and STEC in the coming years

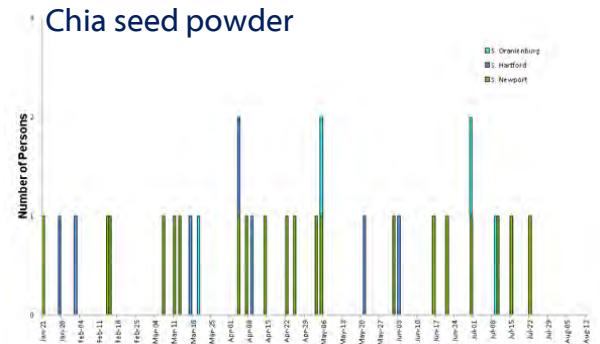
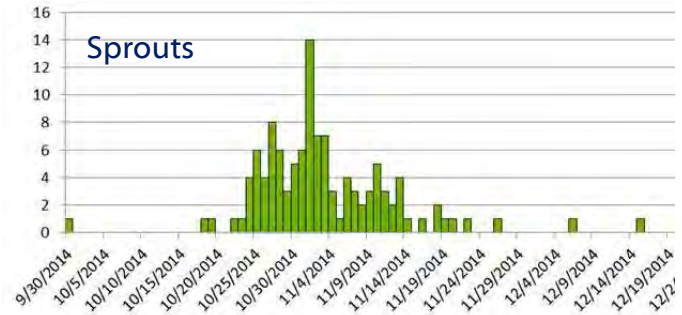
Detecting Outbreaks with PulseNet

- PFGE/WGS data from illness-causing bacteria are transmitted to CDC
- Monitored for temporal clusters
- When a cluster is identified, PulseNet notifies epidemiologists to investigate



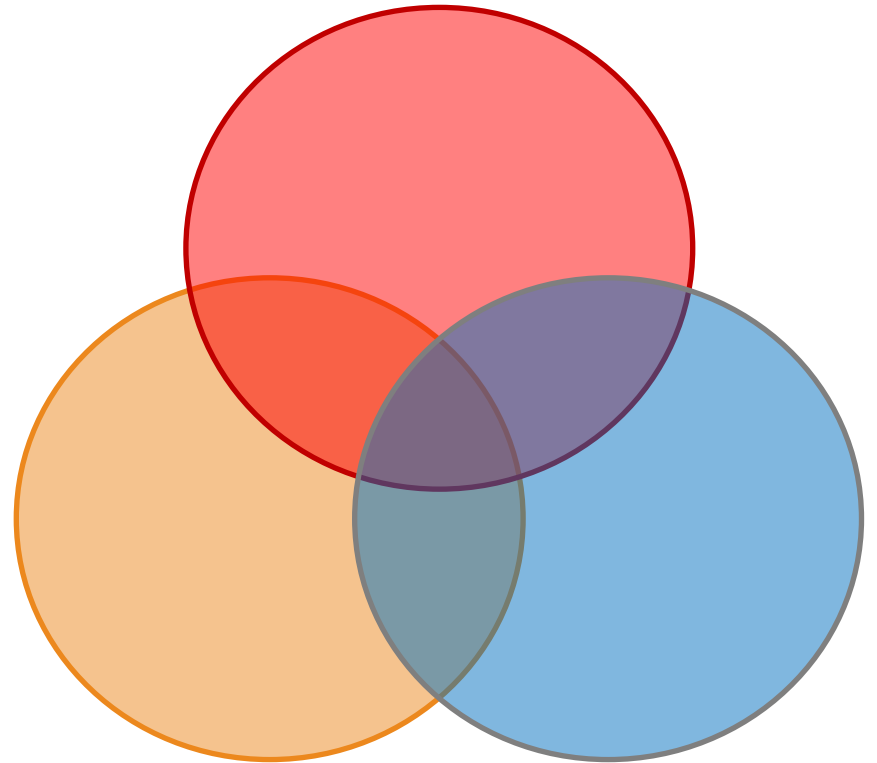
Generating Hypotheses About the Source

- Demographics of ill people in the outbreak (age, sex, race/ethnicity)
- Geographic distribution
- Shape of the epidemic curve
 - Rapid ascent and descent?
 - Slow ascent and prolonged?
- Pathogen type and history
- Food exposure frequencies from initial interviews



Testing Hypotheses: How Do We Determine a Food is the Cause of an Outbreak ?

- Three types of evidence used:
 - **Epidemiologic**: association between illness and exposure
 - **Traceback**: suspected food item converges on a common source of contamination
 - **Microbiologic**: pathogen found in the food, farm or facility



Testing Hypotheses: Epidemiologic Evidence

- *“Are ill people eating any foods more often than we would expect?”*

EPIDEMIOLOGIC



Patterns in where and when people got sick, and past outbreaks caused by the same germ



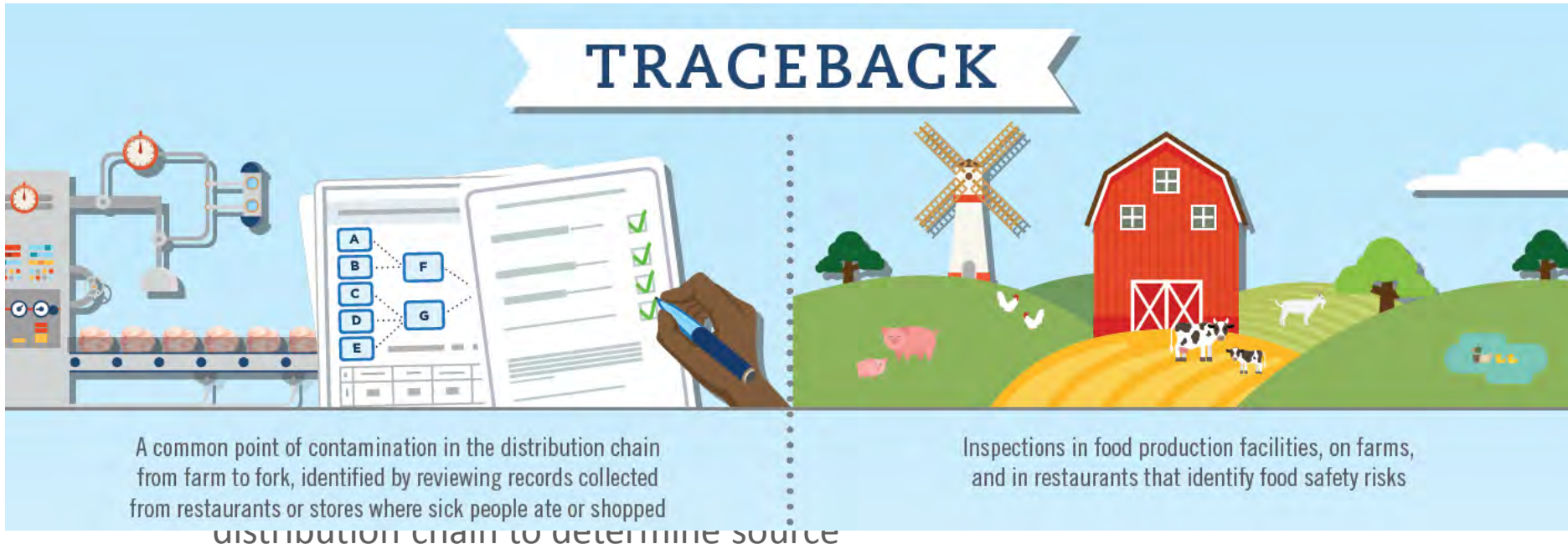
Interviews with sick people to look for foods or other exposures occurring more often than expected



Discovery of clusters of unrelated sick people who ate at the same restaurant, shopped at the same grocery store, or attended the same event

Testing Hypotheses: Traceback Evidence

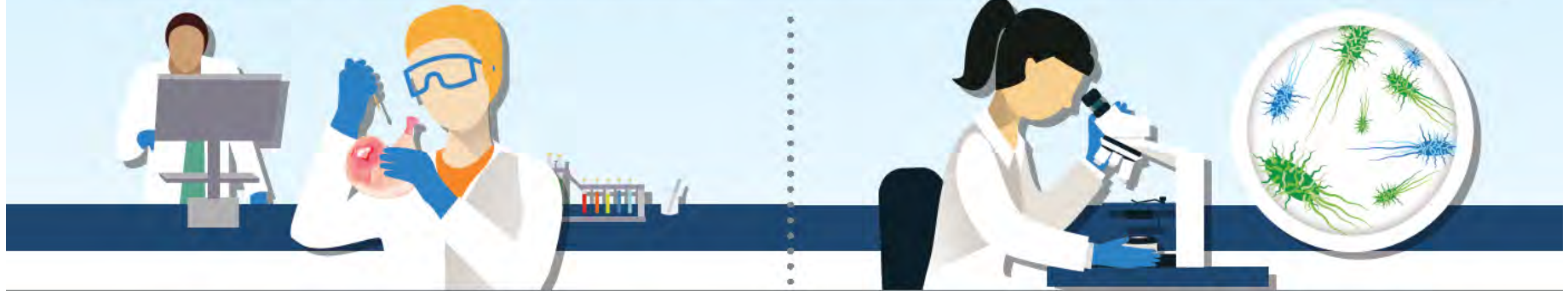
- *“Can most/all illnesses in the outbreak can be linked back to food coming from a common point of contamination?”*



Testing Hypotheses: Microbiologic Evidence

- *“Can the same bacteria that is making people sick be found in the food or production environment?”*

FOOD & ENVIRONMENTAL TESTING



The germ that caused illness is found in a food item collected from a sick person's home, a retail location, or in the food production environment

The same DNA fingerprint linking germs found in foods or production environments to germs found in sick people

Testing Hypotheses: Interpretation

- Making the link between a company or food item and an outbreak is not taken lightly
 - Implications for government credibility
 - Financial and brand impact on industry/companies
- All lines of evidence must be evaluated in concert to make a determination about the link
 - Want to be fast and right
 - Avoid errors, but balanced by the need to stop ongoing risk
 - All three legs are not needed, and in rare circumstances, may rely on a single strong line of evidence

Pinpointing the Cause

- Epidemiology, food testing, and traceback generally cannot address the “how” or “why” contamination occurred
- Work by the company and regulators to understand what went wrong
 - Environmental assessments
 - Evaluation of policies and procedures
 - Product testing
- CDC doesn't have a strong role in identifying “root causes” of an outbreak

Taking Actions to Prevent More Illnesses



■ CDC:

- Publicly communicating about the outbreak source
- Disseminating recall information
- Providing specific, actionable advice



■ Regulatory agencies:

- Consumer warnings
- Product recalls
- Recall effectiveness checks
- Facility closures



■ Industry:

- Issuing consumer warnings and product recalls
- Defining the scope of the contamination event
- Halting production and/or correcting processes

Confirming the Outbreak is Over

- 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
- Once the investigation is closed, it is reported to the CDC National Outbreak Reporting System (NORS)
 - Vehicle
 - Number of cases and hospitalizations

ACTIONS TO STOP THE OUTBREAK

Health officials evaluate all of these types of data to try to identify the source of the outbreak.

Actions to protect the public are taken when there is clear and convincing information linking illness to a contaminated food.



Health officials warn the public



Companies recall contaminated products



Temporary closure of restaurants
or food production facilities

CDC Communications Process

For Multistate Foodborne Outbreaks

Gaining and Maintaining the Public's Trust

- Trust is essential for risk communication
 - Many risks are invisible (bacteria)
 - The information we have is often uncertain or incomplete
 - Much of the public cannot understand the information themselves
- Handle uncertainty with caution and clarity
 - Be clear about:
 - What we know
 - What we don't know
 - What we're doing to find out

Trust = Credibility

Why CDC Communicates about Foodborne Outbreaks

#1 REASON:

Specific source identified & public can take action

Other reasons CDC may communicate include:

- State health department(s) communicate
- High risk group involved
- Deaths, high hospitalization rate
- Intense media interest
- Misinformation being circulated

CDC's Role in Public Communication

- As a non-regulatory agency, CDC's role in taking actions to stop an outbreak is usually limited to posting outbreak notices
 - Since 2006, CDC has posted over 100 multistate foodborne outbreak notices on its website
- As the nation's public health agency, CDC serves as the unofficial "spokesperson" for multistate outbreaks, similar to coordinating the epidemiologic investigation

Timing for Public Communication

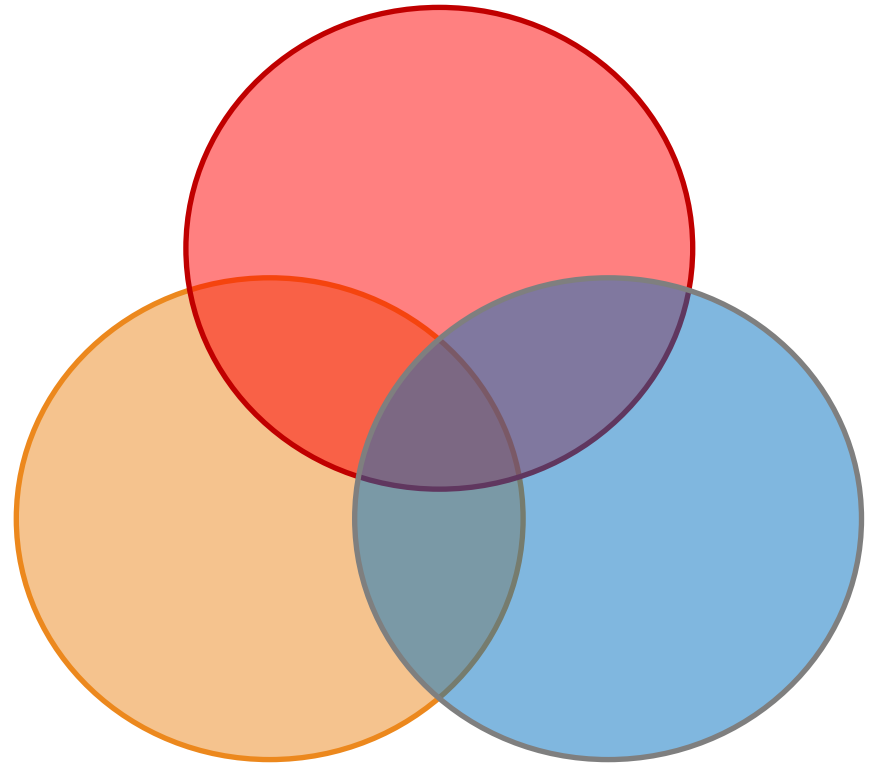
- **Communication to the public may be needed at any point, or it may never be needed**
 - In 2016, CDC investigated over 220 multistate clusters; 17 outbreaks were communicated about publicly
- **The decision about “when” typically occurs quickly**
 - New information can trigger communication at any point in an investigation

Timing for Public Communication

- **Posting a notice on the CDC website involves balancing many priorities:**
 - Being “fast and right”
 - Input from partners
 - Science and plain language
- **Often, CDC is not the first agency to “break the news”**
 - We may wait to communicate until a company issues a recall so we can link to it and give specific advice about what not to eat
 - A state or local health department may issue press first

Testing Hypotheses: How Do We Determine a Food is the Cause of an Outbreak ?

- Three types of evidence used:
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5 Common Communication Scenarios

- **A working document was developed to assist federal agencies during multistate outbreak investigations**
 - Describes 5 common scenarios encountered during investigations
 - Outlines reasons why or why not communication is needed
 - Acts as a guide when discussing the need for public communication between federal agencies

5 Common Communication Scenarios

Examples

Scenario 1

- Cluster of illnesses with no specific source identified

20 people infected with one strain of *E. coli*

Scenario 2

- Generic food type identified as likely vehicle

Epi signal for ground beef

Scenario 3

- Specific food product, brand identified as likely vehicle

Brand X ground beef is likely vehicle

Scenario 4

- Local outbreak, locals and/or state release press

Outbreak of *E. coli* infections in Ohio

Scenario 5

- Pathogen identified in food independent of any human illness

Ground beef recalled for *E. coli* contamination

Questions to Consider

- Is the outbreak ongoing?
- Is there a clear action step for people to take?
- Does the food item have a long shelf life?
- Is the food item widely distributed/available for purchase?
- Is a vulnerable group at higher risk?
- Is there sufficient evidence linking illness to the food item?
- Is the pathogen causing the outbreak causing severe illness?

Crafting the CDC Message

- Because our goal is to prevent additional illnesses, CDC's most important message is crafting the advice for consumers
- In order for our advice to lead to action, it needs to be:
 - Specific
 - Clear
 - Complete
- Identifying the company and its product(s) linked to an outbreak helps people take action

Ensuring Message Accuracy & Consistency

- **Confirmation from state public health partners about the number of cases to include and investigation details**
 - Content for web posting shared in advance before posting
- **Content cleared with regulatory agency involved**
- **Discussion of our plans with the implicated firm before posting**
 - Final content shared as FYI

Sharing content in advance helps ensure message accuracy and consistency to the public and media.

Disseminating the CDC Message

■ CDC Website

Multistate Outbreak of Shiga toxin-producing *Escherichia coli* O157:H7 Infections Linked to I.M.

Soy nut butter recalled as 6 people are hospitalized with E. coli

By Debra Goldschmidt, CNN

🕒 Updated 3:54 PM ET, Fri March 3, 2017



Source: CNN



update on March

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(DA) are
hia coli O157:H7

57:H7 have been

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At A Glance

- Case Count: 29
- States: 12
- Deaths: 0
- Hospitalizations: 12
- Recall: Yes

More Information

- Recall and Advice to Consumers and Institutions
- Signs & Symptoms
- Key Resources
- Shiga Toxin-Producing *E. coli* and Food Safety
- Diaper-Changing Steps for Childcare Settings



Outbreak Example

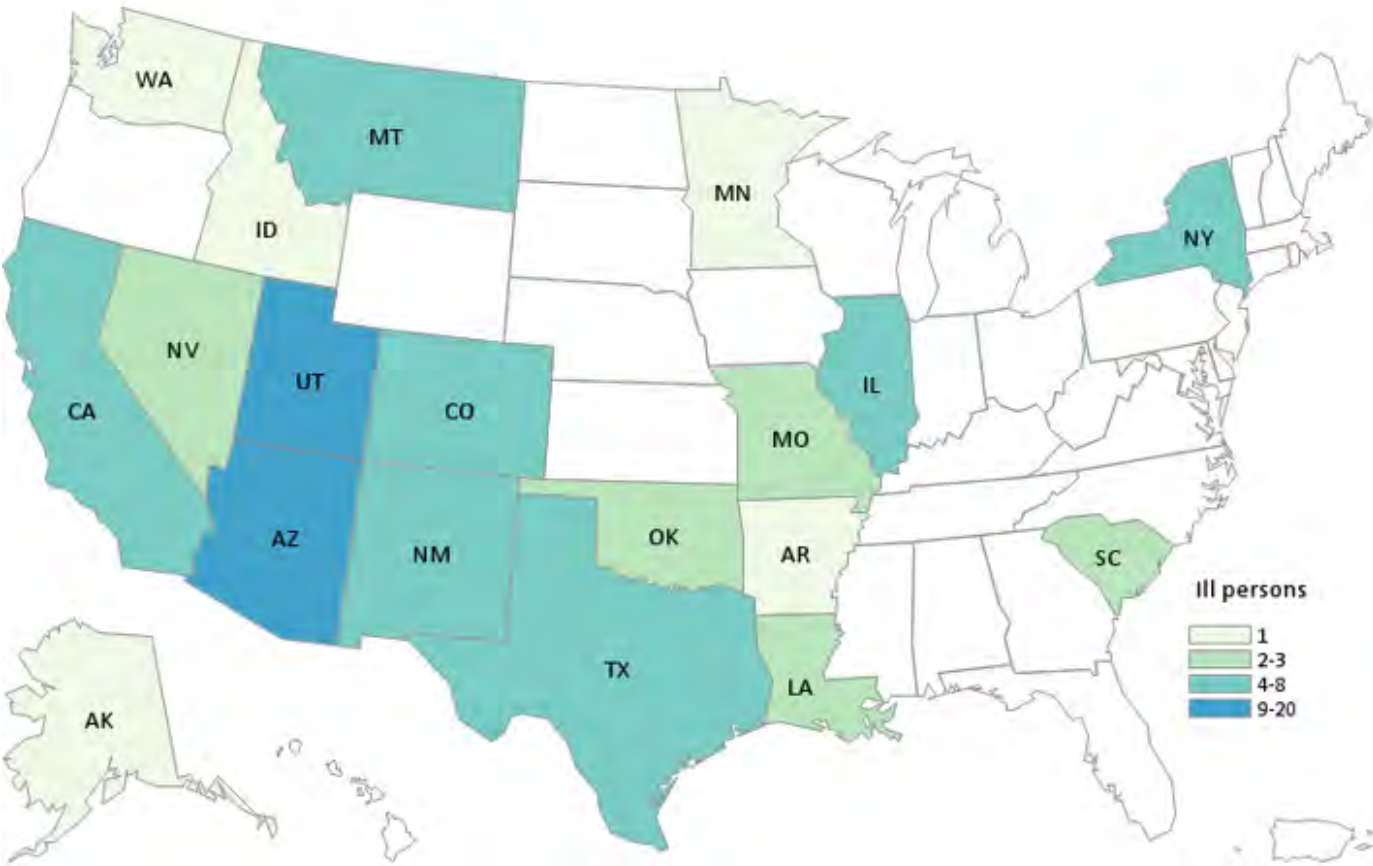
Salmonella Poona and Imported Cucumbers

An Outbreak Detected

- **August 18, 2015**
 - 32 ill people from 13 states with *Salmonella* Poona with an indistinguishable rare PFGE pattern
 - Past Poona outbreaks linked to cantaloupes, other melons, and turtles



People infected with the outbreak strains of *Salmonella* Poona, by state of residence, as of August 21, 2015 (n=86)



August 24, 2015

- **How many illnesses and where?**
 - 113 people in 20 states
- **Outbreak ongoing?**
 - Yes
- **What evidence do we have pointing to a vehicle?**
 - Epi: Several produce items of interest, nothing significant
 - Traceback: None
 - Lab testing: None

What scenario are we in?

Scenario 1

Epi Signal Emerges

- Interview data indicates ill people are eating cucumbers significantly more when compared to a survey of healthy people
- **11 sub-clusters identified in 8 states**
 - Grocery stores, childcare centers, military base, restaurants
 - Cucumbers were the common food item among all sub-clusters



August 28, 2015

What scenario are we in?

Scenario 2

- **How many illnesses and where?**
 - 173 people in 22 states
- **Outbreak ongoing?**
 - Yes
- **What evidence do we have pointing to a vehicle?**
 - Epi: Cucumbers significant, sub-clusters identified
 - Traceback: None
 - Lab testing: None

Traceback Investigation

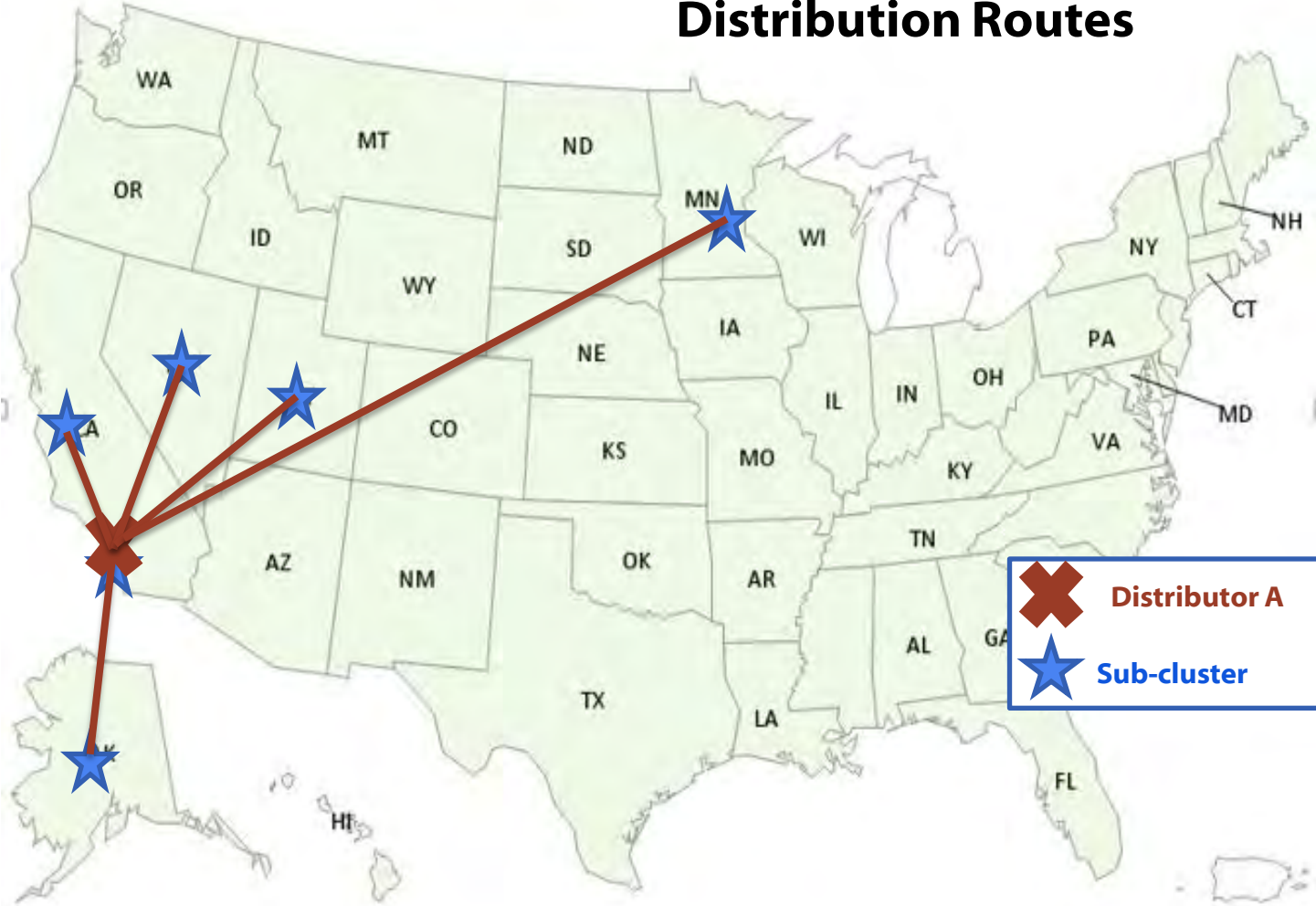
- Using purchase and shipment information
- Identifying a common source of contamination
- Typically performed by state and federal regulatory agencies



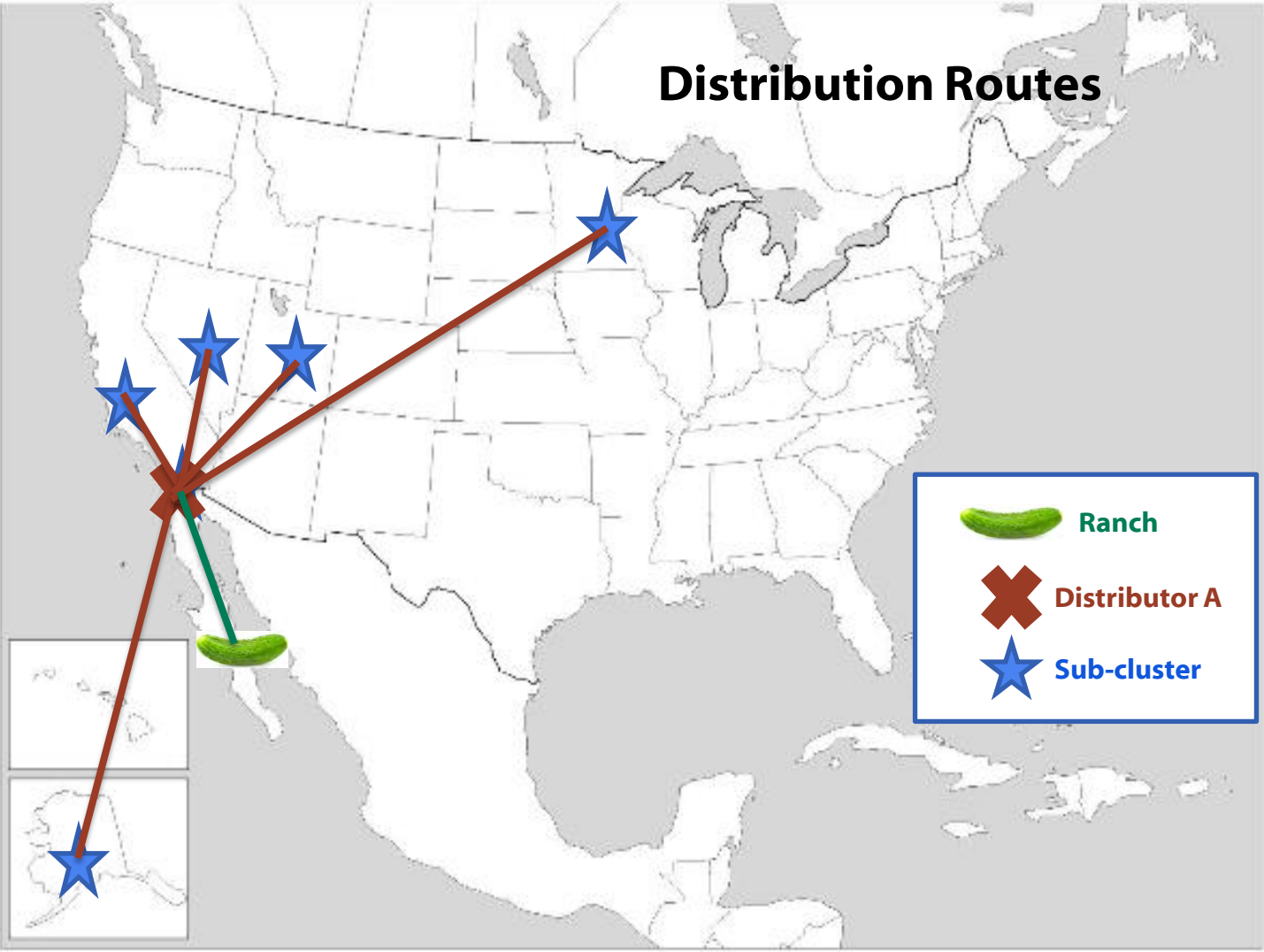
Illness Sub-clusters Investigated



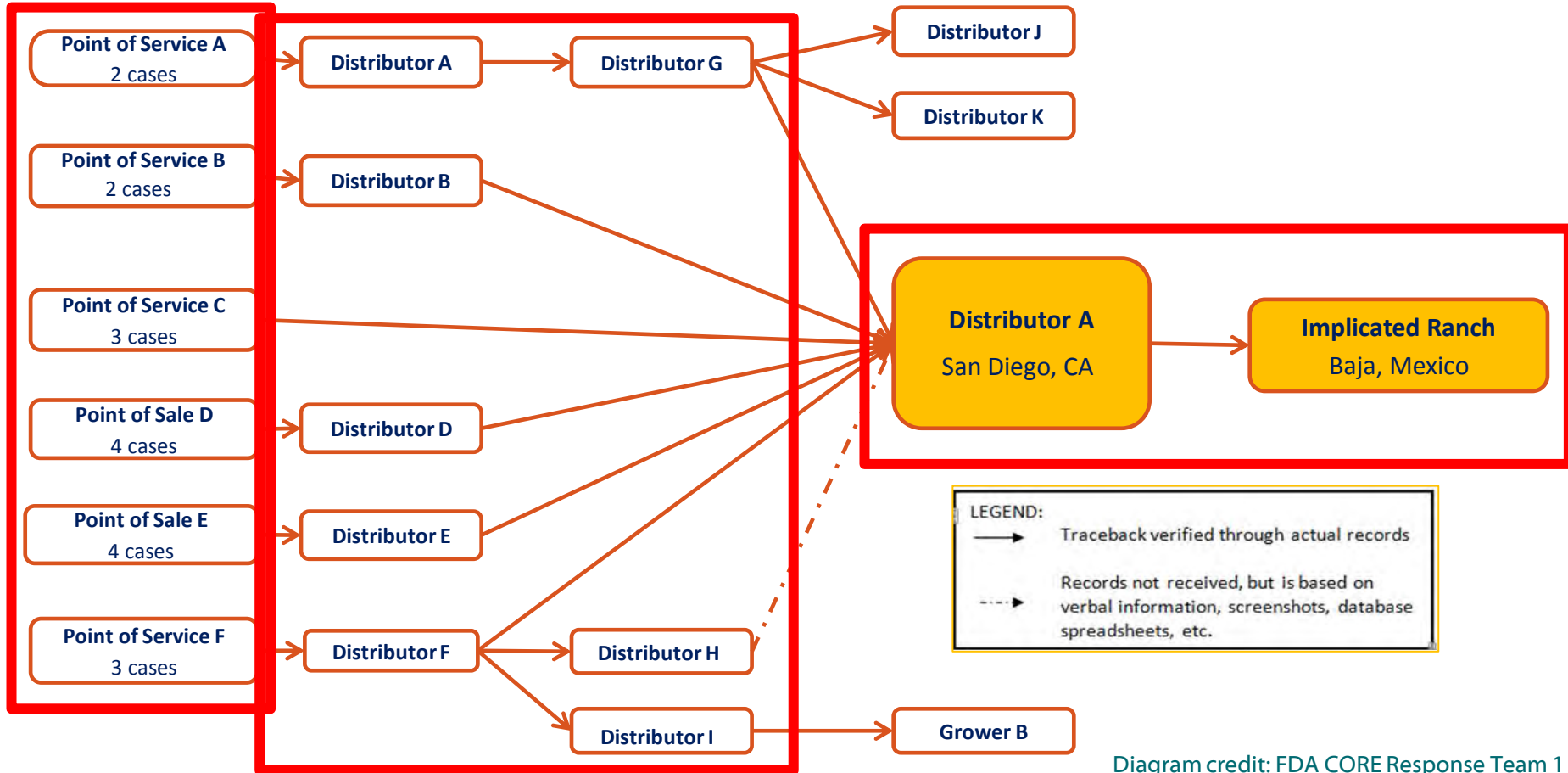
Distribution Routes



Distribution Routes

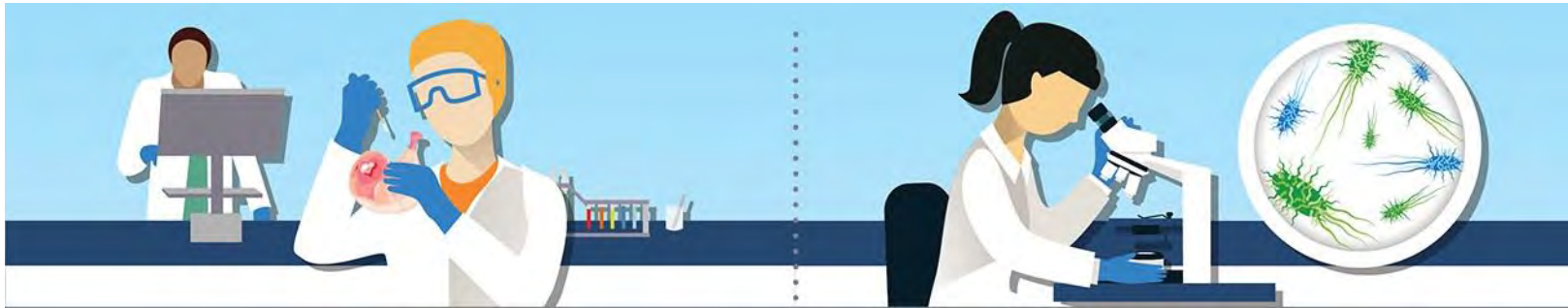


Traceback Investigation



Distributor A Product Testing

- **August 28, 2015**
 - Increased testing of imported cucumbers at United States-Mexico border initiated
 - Cucumbers collected for microbiological testing from Distributor A



September 1, 2015

- **How many illnesses?**
 - 200+ people & 1 death
- **Outbreak ongoing?**
 - Yes
- **What evidence do we have pointing to a vehicle?**
 - Epi: Cucumbers significant
 - Traceback: Likely imported from Mexico; ongoing
 - Lab testing: Pending

What scenario are we in?

Scenario 2-3

September 3, 2015: Planning to Go Public

- **What we know:**
 - 285 ill people in 27 states; 1 death
 - Going into Labor Day weekend
 - Several states drafting press releases
- **CDC & FDA held a call to discuss:**
 - When should we release something and what would our message be?
- **Options on September 3:**
 - “Investigation is ongoing, but no source has been identified.”
 - “Investigation is ongoing, but consumers should not eat cucumbers from Baja California, Mexico until we know more.”

Cucumber Source Identified

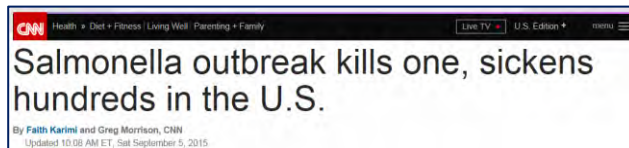
- FDA's traceback identified Distributor A as the sole distributor of cucumbers
 - Cucumbers imported from a single farm in Baja California, Mexico
- Call held with firm to update them on the investigation findings
- Specific source identified – public can take action (*Scenario 3*)

Crafting the CDC Message

- **Several challenges to clear communication:**
 - How do people identify the recalled cucumbers?
 - Is the list of states that received cucumbers complete?
 - How do we explain why we waited to issue press?
 - Will washing cucumbers prevent illness?
 - Are US-grown cucumbers affected/safe?

Public Health Actions: Communications

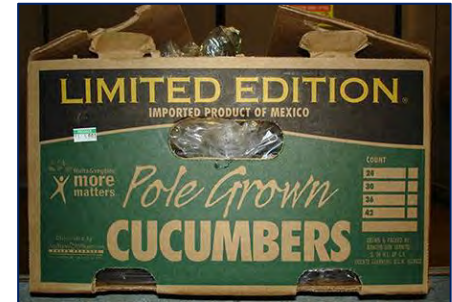
- On September 4, Distributor A issued a recall of all garden cucumbers sold from August 1-September 3
- CDC issues warning to not eat, sell, or serve imported cucumbers from Distributor A
- Extensive media coverage, public interest



Public Health Actions: Laboratory and Regulatory

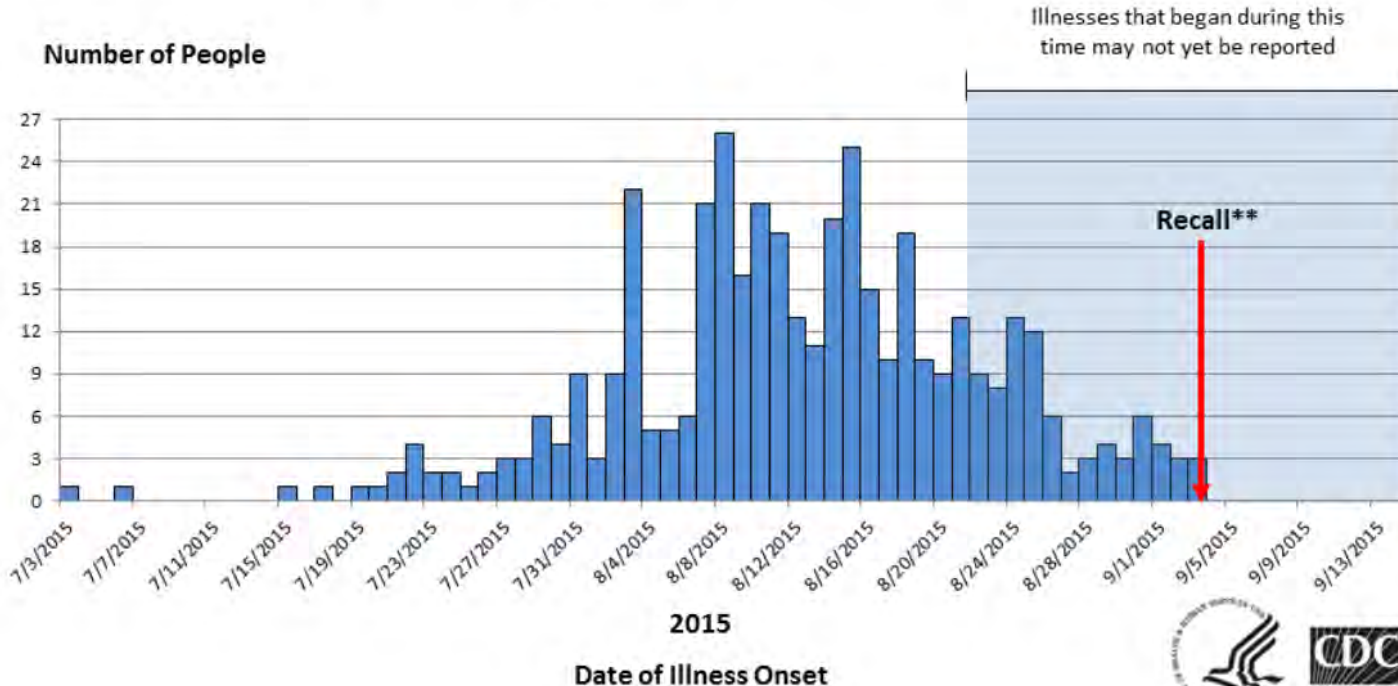
- **September 10, 2015**
 - Outbreak strain isolated from imported cucumbers from Mexico sold by Distributor A

- **September 14, 2015**
 - FDA actions stopped importation from Mexican ranch (FDA Import Alert)



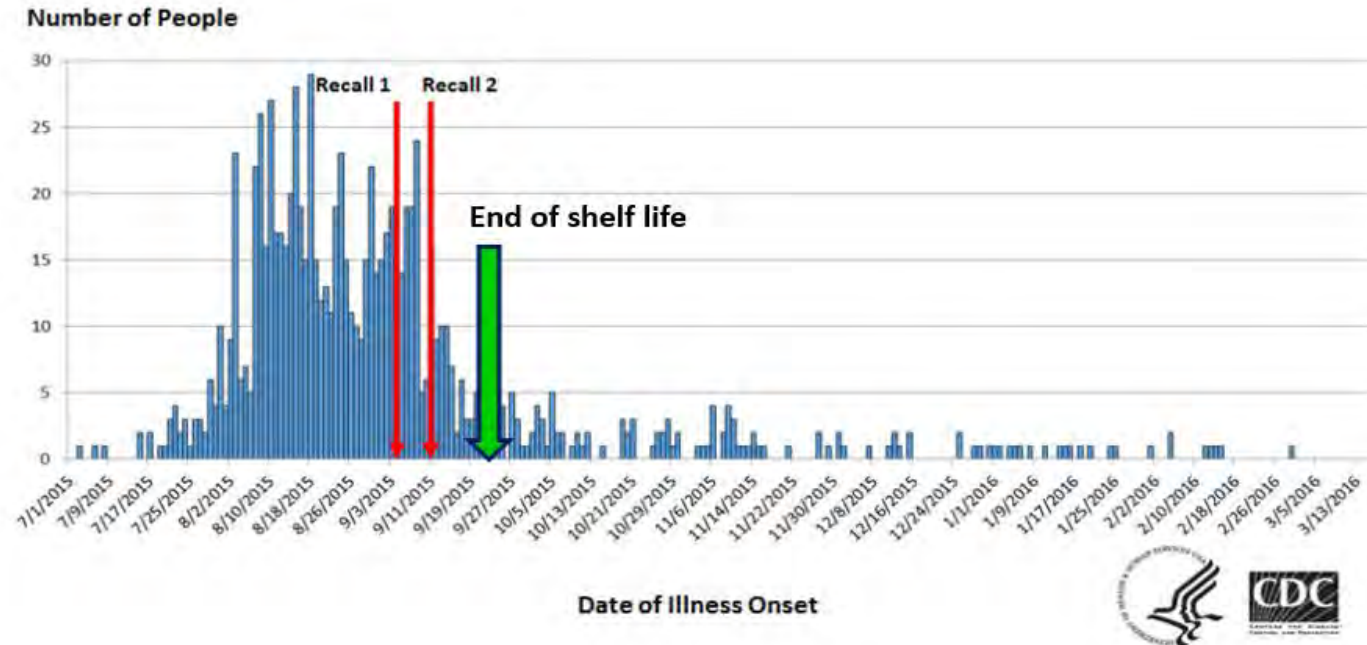
End of the Outbreak?

People infected with the outbreak strains of *Salmonella* Poona, by date of illness onset*



Illnesses Continue to be Reported

People Infected with the Outbreak Strains of *Salmonella* Poona, July 3, 2015–March 15, 2016 (n=907)



Theories for the Continued Illnesses

- **Cross-contamination**
 - Display bins
 - Reusable plastic containers
 - Grocery bags
- **Other foods**
 - Pickles?
 - Other produce from same farm or region?
- **Other theories investigated**
 - Packing houses
 - Unknown secondary distributors




Preventing Further Illnesses

- Possible ongoing cross-contamination
- CDC updates the advice to consumers and retailers

Advice to Consumers, Restaurants, and Retailers

Consumers who have purchased any recalled fruits and vegetables should do the following:

- Throw the recalled product away, even if some of it has been eaten and no one has gotten sick.
- Wash and sanitize drawers or shelves in refrigerators where recalled products were stored.
- Wash [reusable grocery](#)  bags often. Cloth bags should be washed in a washing machine, and plastic-lined bags should be scrubbed using hot water and soap.

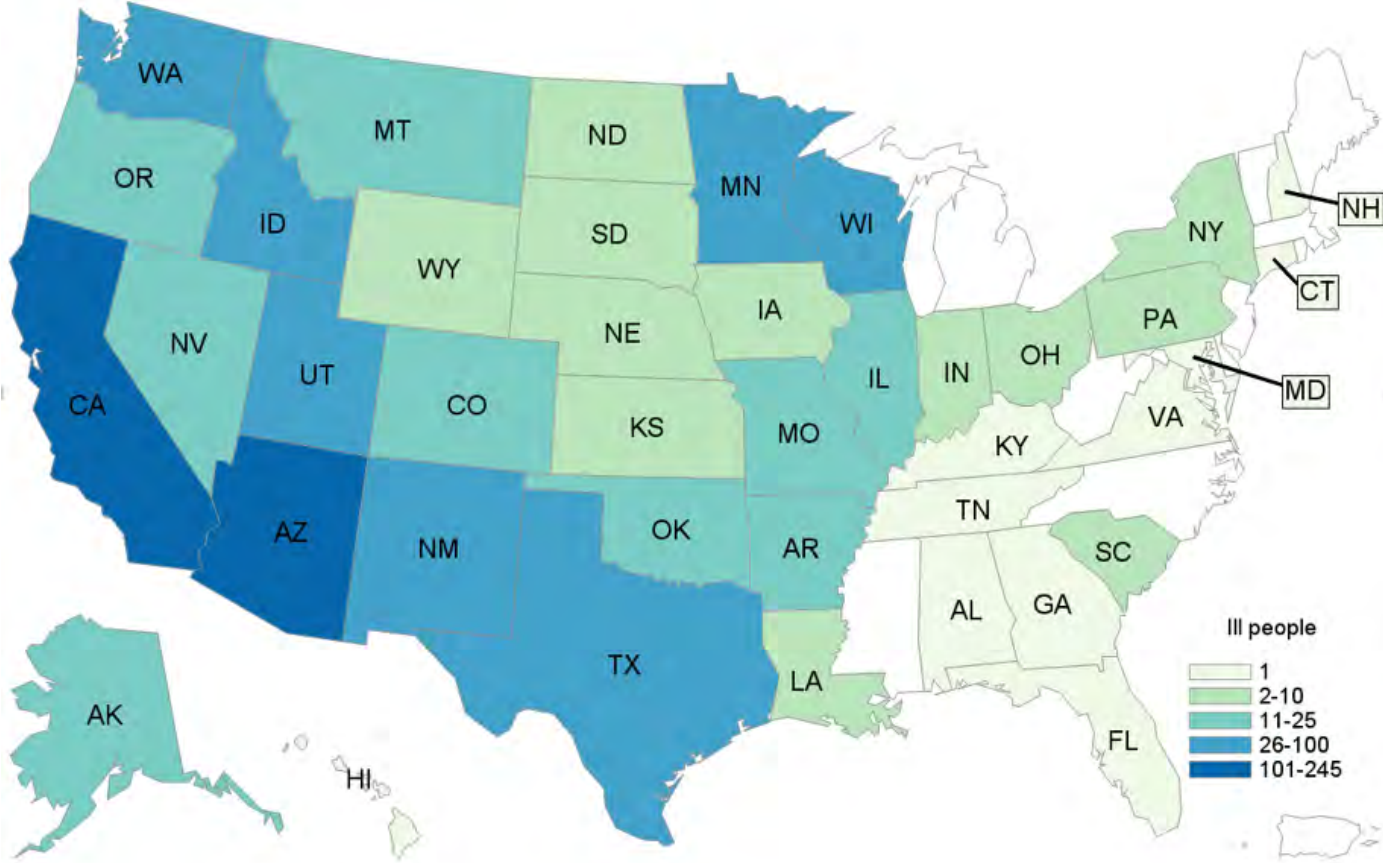
Restaurants and retailers who have purchased any recalled fruits and vegetables should do the following:

- Do not serve or sell the recalled product.
- Wash and sanitize any crates or other containers where the recalled product was held or sold.
- Wash any surfaces where recalled product may have come into contact, such as refrigerator drawers, counter tops, cutting boards, storage containers, and utensils, with an appropriate and effective cleaning solution.
- Sanitize the surfaces with a solution of chlorine bleach and hot water or another appropriate sanitizer, following the instructions provided on the label.

Environmental Investigation

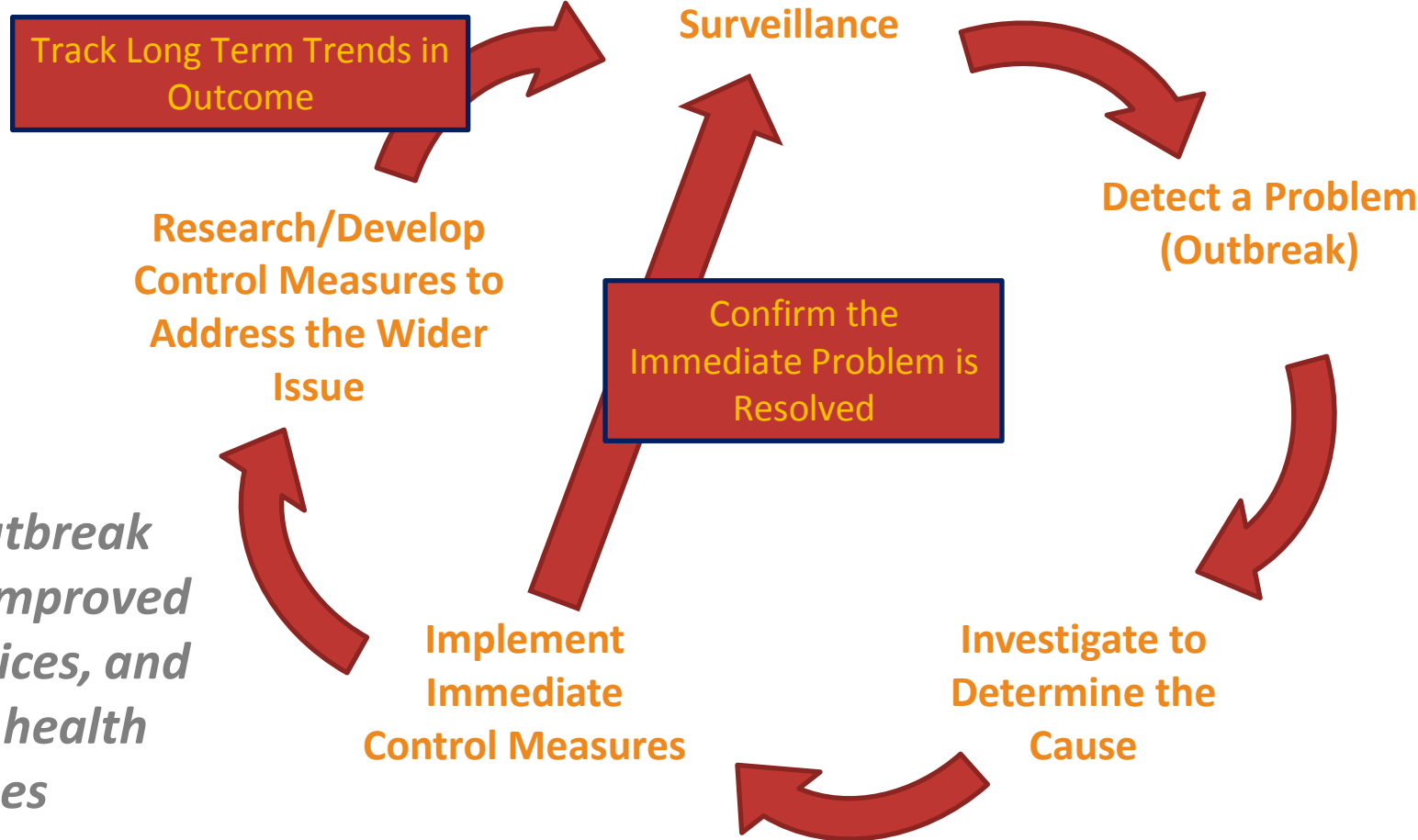
- **Issues noted during FDA on-farm inspection:**
 - Rodents
 - Waste water management
 - Equipment design
 - Storage of shipping materials
- **Root cause of outbreak never identified**

People infected with the outbreak strains of *Salmonella* Poona, by state of residence, as of March 15, 2016 (n=907)



Conclusions

Learning from Outbreaks



Industry Involvement in Investigation Process

- **Industry can play a critical role in multiple aspects of multistate foodborne outbreaks**
 - Hypothesis generation: early consultation with industry experts can help narrow down suspects based on the timing and geographic distribution of illnesses
 - Hypothesis testing: providing traceback data or sharing isolates from food/environmental testing can help confirm or refute a hypothesis
 - Pinpointing the cause: working with regulatory agencies to scope contamination events and identify/correct the cause of contamination
 - Sharing lessons: disseminating information learned during an outbreak and/or recall to others in industry

Industry Involvement in Communication Process

- **Industry can help public health craft specific, actionable advice to consumers**
 - You know how your product is labeled, where it's sold, etc.
- **Industry can communicate directly with their customers**
 - Robo-calls, printing recall notices on receipts, website announcements, etc.
- **A company's communications can provide another source of clear, accurate, and consistent messaging to the public**
 - Press releases, social media, etc.

Conclusions About Investigation Process

- Detecting, investigating, and stopping multistate foodborne outbreaks is complex
 - Requires collecting and interpreting data from numerous places
 - Decisions may need to be made in the context of uncertainty
 - Need to be both “fast” and “right”
- Close coordination is essential to ensure everyone is working together
 - Everyone should know what to expect
 - Sometimes need to “agree to disagree”