

# The Life of an Outbreak Investigation – From First Case to the Courthouse

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CDC Foodborne Outbreak Response Team - Lexi Palacios

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FDA Office of Regulatory Affairs – Chris van Twuyver

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Legal Perspective – Shawn Stevens

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Discussion/Audience Questions



# How Does CDC Solve Outbreaks of Foodborne Illness?

**Lexi Palacios, MPH - Foodborne Outbreak Response Team**

Food Safety Summit

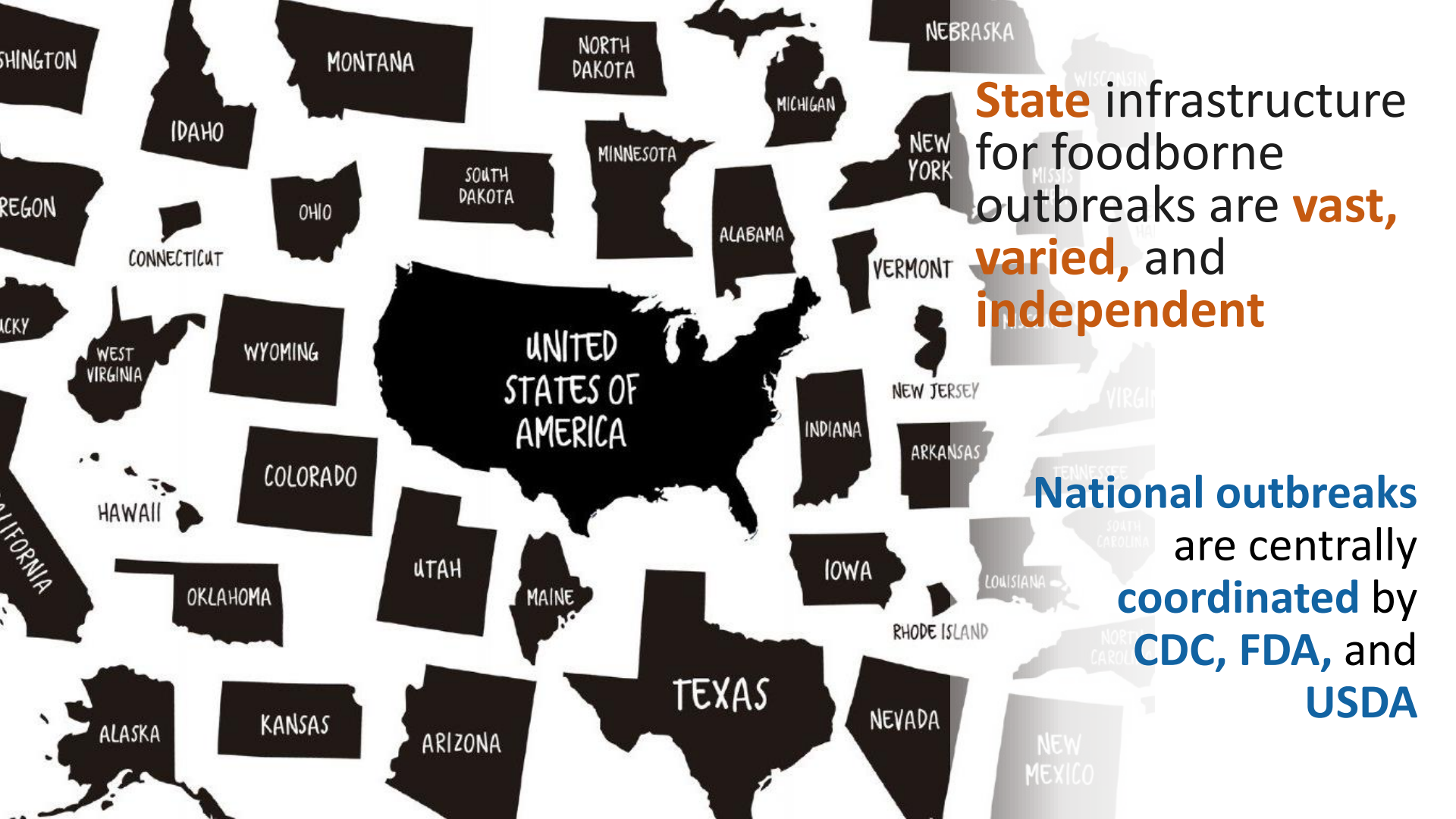
May 7, 2024

# Foodborne Infections in the United States: Common, Costly, Preventable

- **Annual burden of foodborne illnesses**
  - 48 million illnesses
  - 128,000 hospitalizations
  - 3,000 deaths
  - \$15 billion USD in direct medical costs
- **Over 1,000 reported outbreaks each year**

**1 in 6** 

About 1 in 6 (or 48 million)  
people gets sick each year  
from contaminated food.



**State** infrastructure for foodborne outbreaks are **vast, varied, and independent**

**National outbreaks** are centrally **coordinated** by **CDC, FDA, and USDA**

# U.S. Roles and Responsibilities in Foodborne Outbreak Investigations



**Lead national public health agency**

**Disease surveillance**

**Outbreak detection**

**Epidemiologic investigation and communications**

**State and local health and agriculture departments**

**<3000 local health jurisdictions**

**Collect food histories**

**Retail sampling, facility and farm investigations and product/regulatory actions**

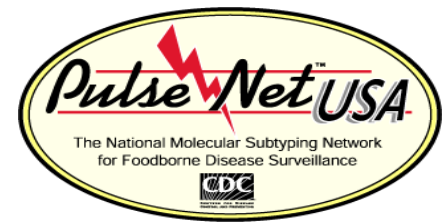
**Federal regulatory agencies**

**Product recalls, regulatory actions and communications**

**Food and environmental testing**

**Product traceback and facility inspections**

# PulseNet



**National molecular subtyping network for foodborne disease surveillance**

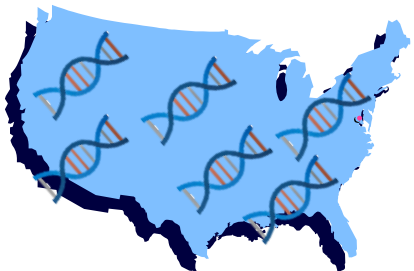
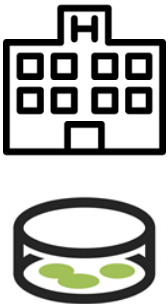


**Detects foodborne disease clusters using whole genome sequencing**



**Separates outbreak cases from sporadic cases**

# Flow of Whole Genome Sequence Data From Patient to CDC

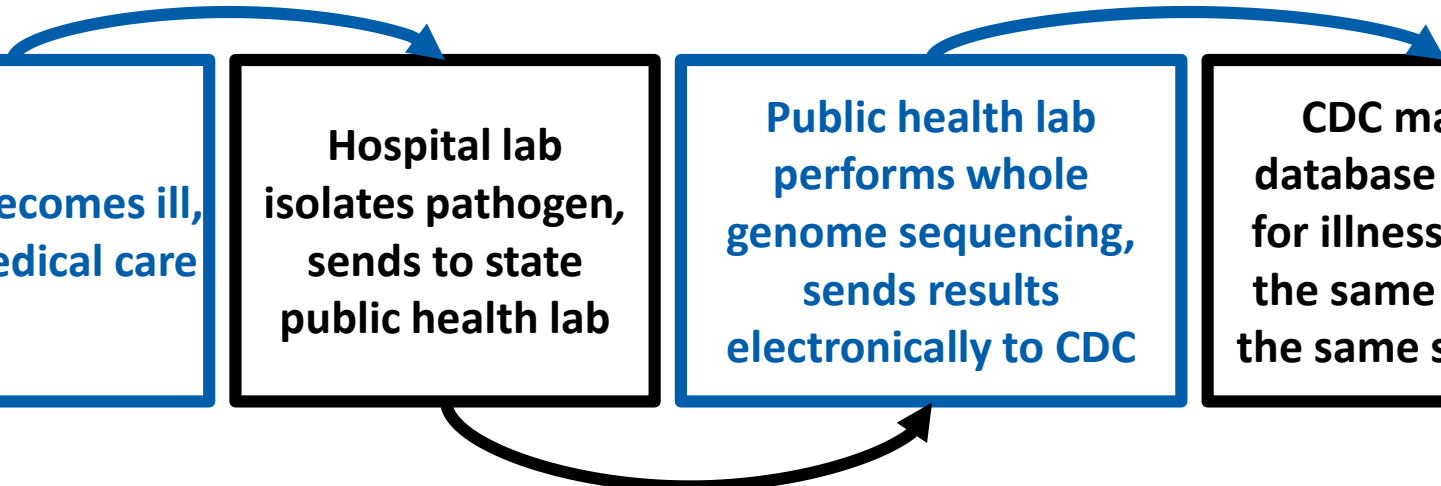


Person becomes ill,  
seeks medical care



Hospital lab  
isolates pathogen,  
sends to state  
public health lab

Public health lab  
performs whole  
genome sequencing,  
sends results  
electronically to CDC

CDC maintains  
database and looks  
for illnesses around  
the same time with  
the same sequencing



# Timeline for Reporting Foodborne Illnesses

Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
					1 	2
3 	4 	5 	6 	7 	8 	9
10	11 	12	13 	14	15 	16
17	18	19	20 	21	22 	23
24	25 	26	27	28	29	30
31						



# Solving an Outbreak - Three Pieces of the Puzzle



Epi  
What are people eating?



Traceback  
Is there a common source?



Lab  
Is the same bacteria in food/  
environment?

# EPIDEMIOLOGIC



- Person, place, time
- Has the strain caused outbreaks before?
- What foods did people eat before they got sick?
- What restaurants, grocery stores, or events did sick people go to?

# Generating Hypotheses About the Source



# National Hypothesis Generating Questionnaire (NHGQ)

Deployed when no  
common food is  
identified in initial  
interviews

Over 300  
questions about  
food and animal  
exposures

NHGQ standardizes  
questions asked  
across ill people



Can help investigators identify one or more leading hypotheses

# Focused/Supplemental Questionnaires



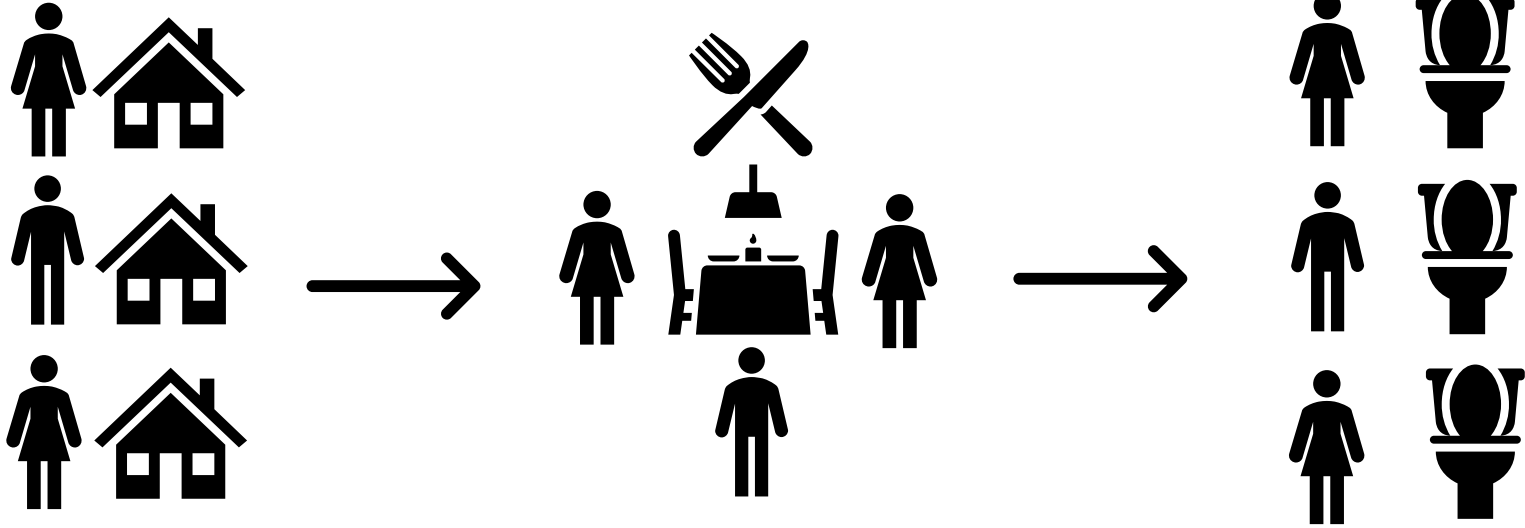
# Focused/Supplemental Questionnaires



# Focused/Supplemental Questionnaires



# Illness Sub-Clusters



Two or more people who do not live in the same household

Report eating at the same restaurant location or common event

Illness sub-clusters suggest the food causing the outbreak was served there

Drastically reduces the number of possible food sources



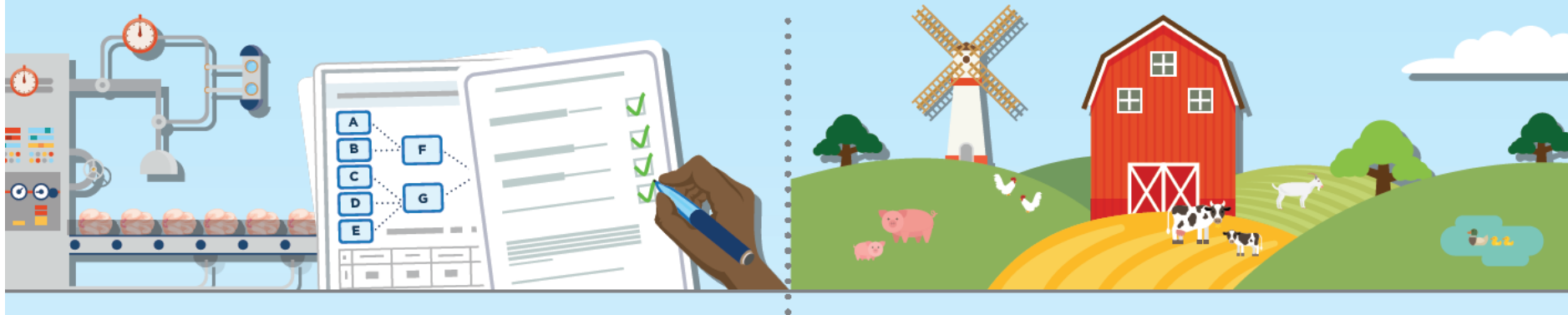
## How to Decide What is Unusual?

- Food frequencies reported by ill people are compared to food consumption data from healthy people
- 2018-2019 FoodNet Population Survey is food consumption data from 40,000 respondents in 10 states



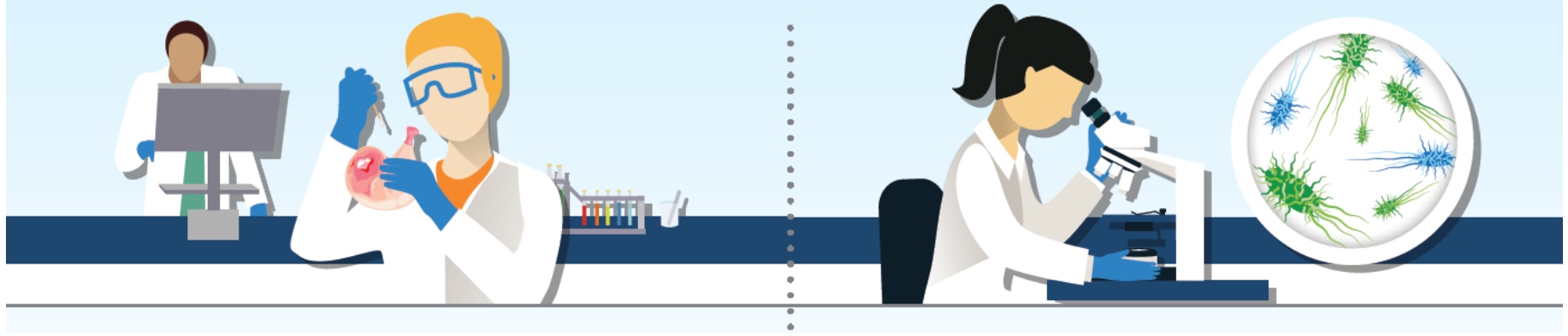
**If food frequencies reported by ill people are significantly higher than the FoodNet Population Survey, it can indicate what foods could be causing illness**

# TRACEBACK



- Use shopper cards and receipts from ill people to verify purchase information
- Review records collected from restaurants or stores where ill people ate or shopped
- Identify common point of contamination in the distribution chain
- Inspections in food production facilities, farms, or restaurants

# FOOD & ENVIRONMENTAL TESTING



- Food collected from an ill person's home, a retail location, or food production environment can be tested for the bacteria causing illness in an outbreak
- Whole genome sequencing is conducted on the bacteria to see if it has the same DNA fingerprint as bacteria found in ill people

# Communications

- During an outbreak, people look to credible, trustworthy sources of information about what to do
  - Many risks are invisible (bacteria)
  - Emotional connection to our food
  - Much of the public cannot understand the information themselves



**Trust is essential for risk communication around food**

# Communications

- All members of the team assess available data:

Level of Public Health Concern

- **Lower**
- **Higher**

Specificity of Public Health Concern

- **Low specificity**
- **Medium specificity**
- **High specificity**

- Using these considerations, the team decides on the approach
- Iterative process and data is assessed continuously

**When applied consistently, a communication process leads to stronger trust, credibility, and transparency**

# Confirming the Outbreak is Over

- CDC will close an investigation after reports of illness stop
- Other information is considered
  - Reporting delays for the bacteria and other factors that affect reporting
  - Whether the source of contamination was identified and mitigated



**FDA Coordinated Outbreak Response and  
Evaluation Network (CORE) – Traceback  
101**



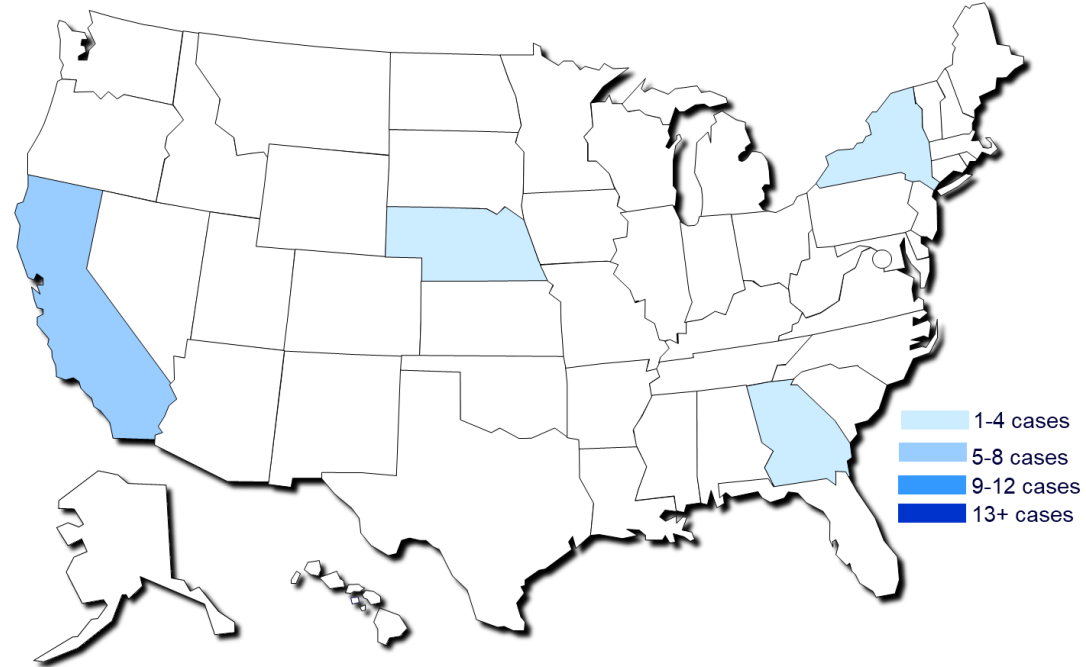


# Outbreak Scenario

This is a **fictious** outbreak investigation scenario and is loosely based on multiple past investigations. All data are to be used as an example.

# Cluster of *Salmonella* Infections is Identified

- 12 *Salmonella* Urbana infections
- 4 states
- 67% female
- Median age 48 years
- 4 hospitalizations
- Onset dates: April 2-April 9, 2024
- Highly related by WGS



# Initial Food History Information

States use questionnaire to interview cases to obtain food, water, and animal exposure information



CDC schedules a call to discuss outbreak including state partners with cases, FDA, and USDA



States enter food history data from initial interviews into web-based data sharing platform, SEDRIC

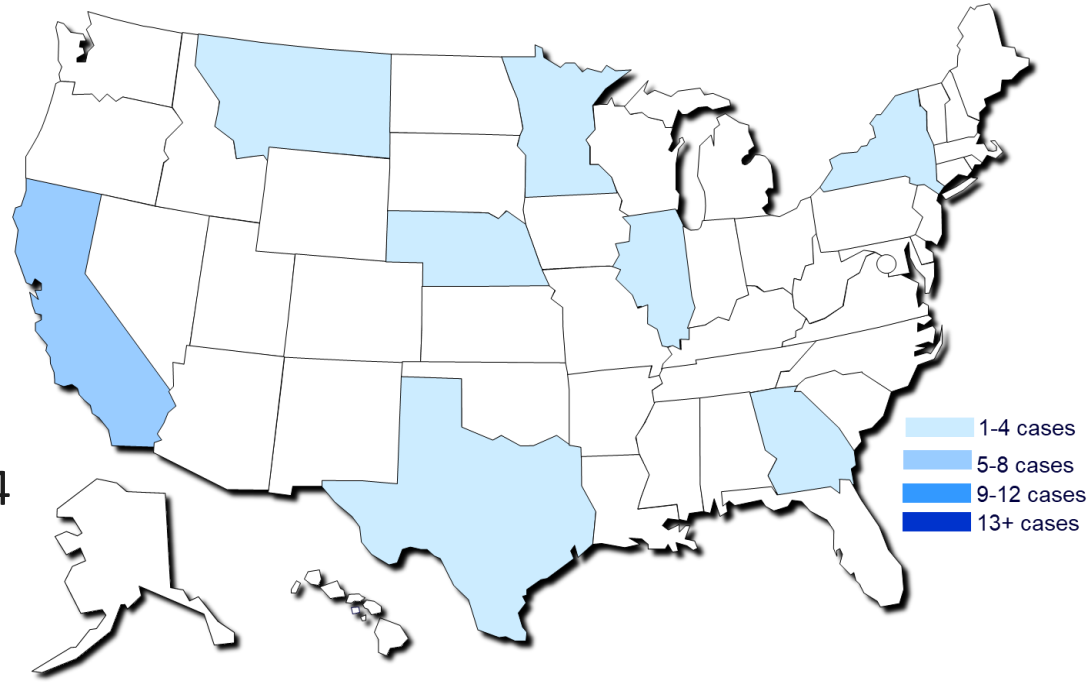


- No obvious foods in common
- Deployed NHGQ
- Requested shopper card details



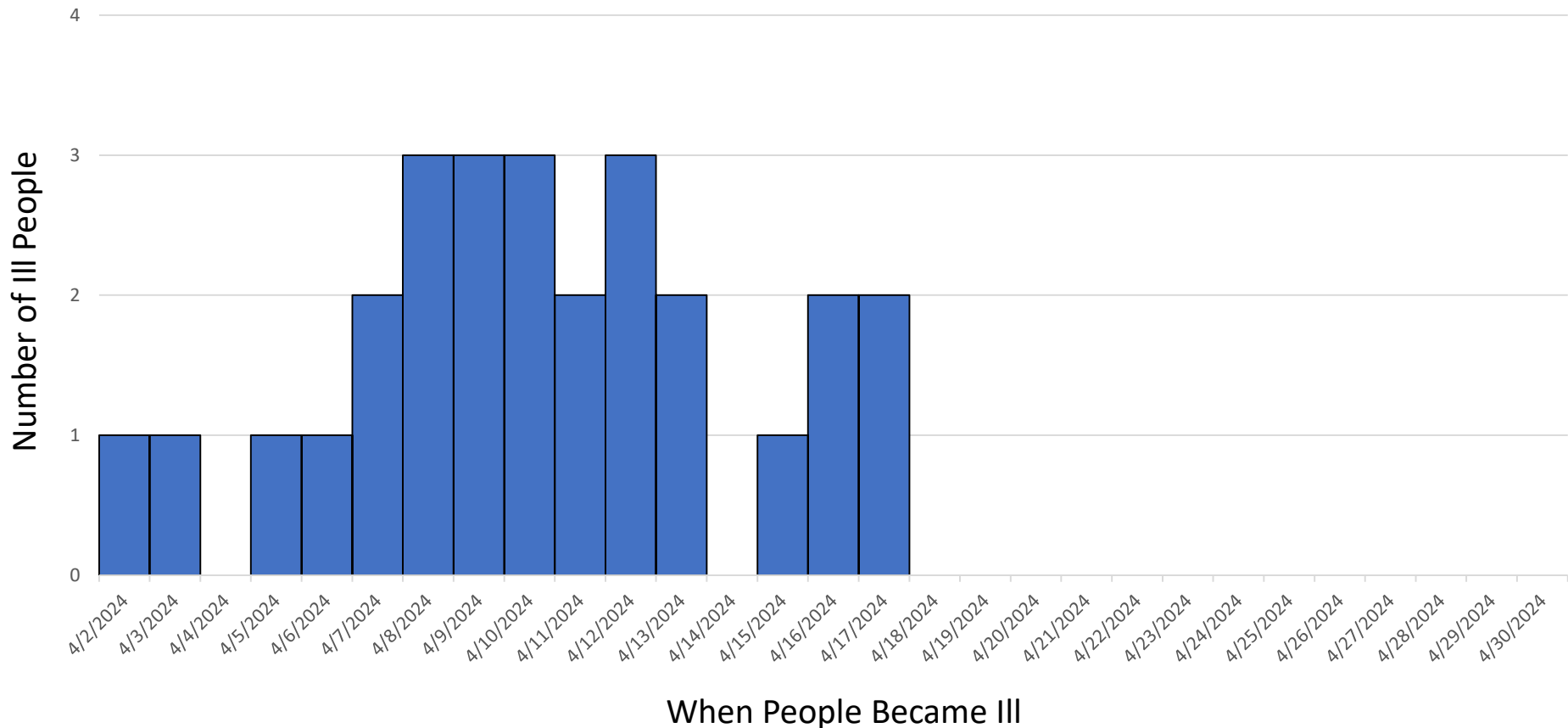
# Updated Case Information

- 25 *Salmonella* Urbana infections
- 8 states
- 65% female
- Median age 49 years
- 10 hospitalizations
- Onset dates: April 2-April 16, 2024

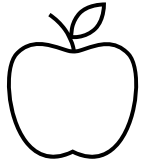


# When People Became Ill

This chart shows when the 25 people in this *Salmonella* outbreak became ill



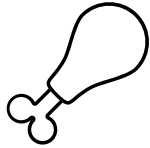
## Initial NHGQ Results



65%



75%



90%

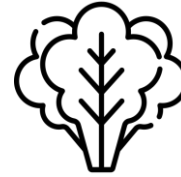


85%

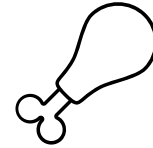
## PopSurvey Rates



59%



80%

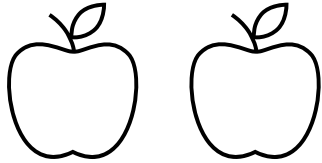


88%

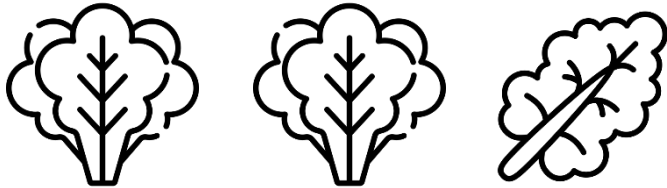


78%

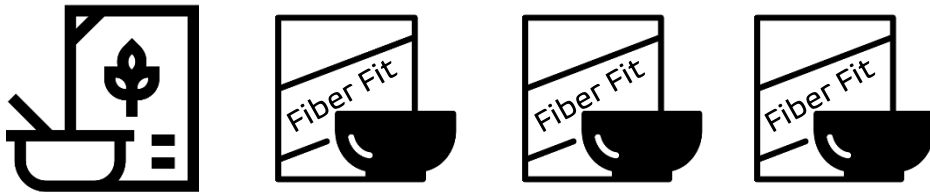
# Collected 4 Shopper Records



1 Red Delicious, 1 Granny Smith

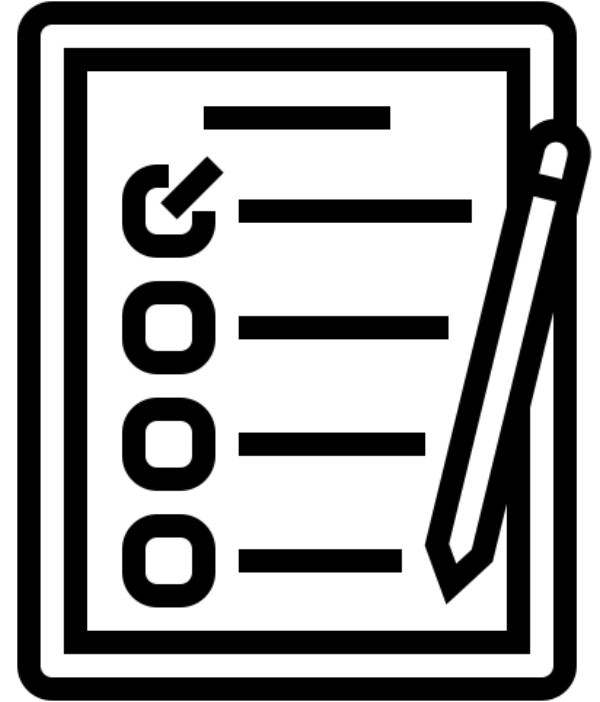
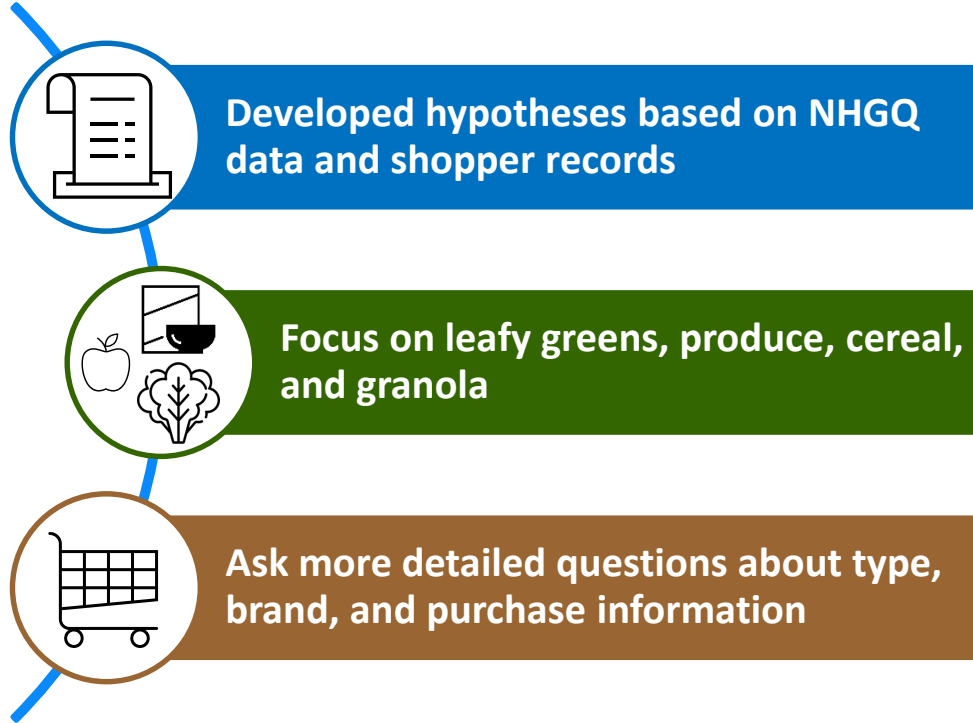


2 Vitality Greens romaine, 1 store brand spinach



1 Healthy Harvest Cereal  
3 Fiber Fit Cereal

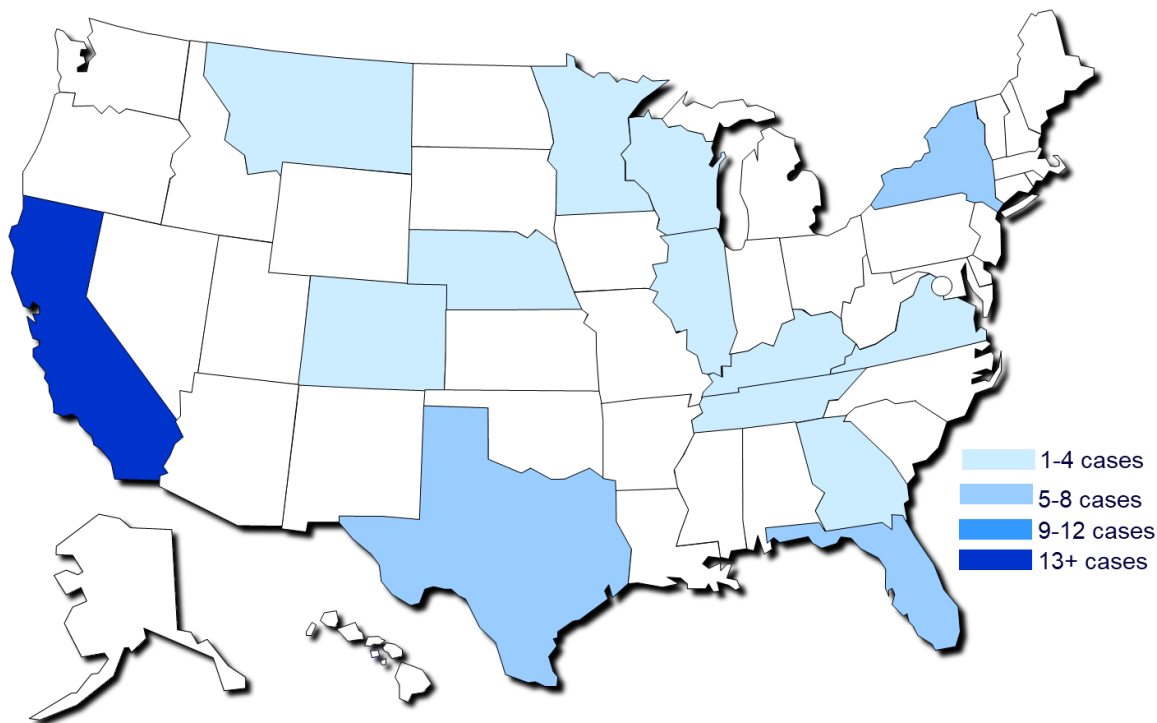
# Deploy a Focused Questionnaire





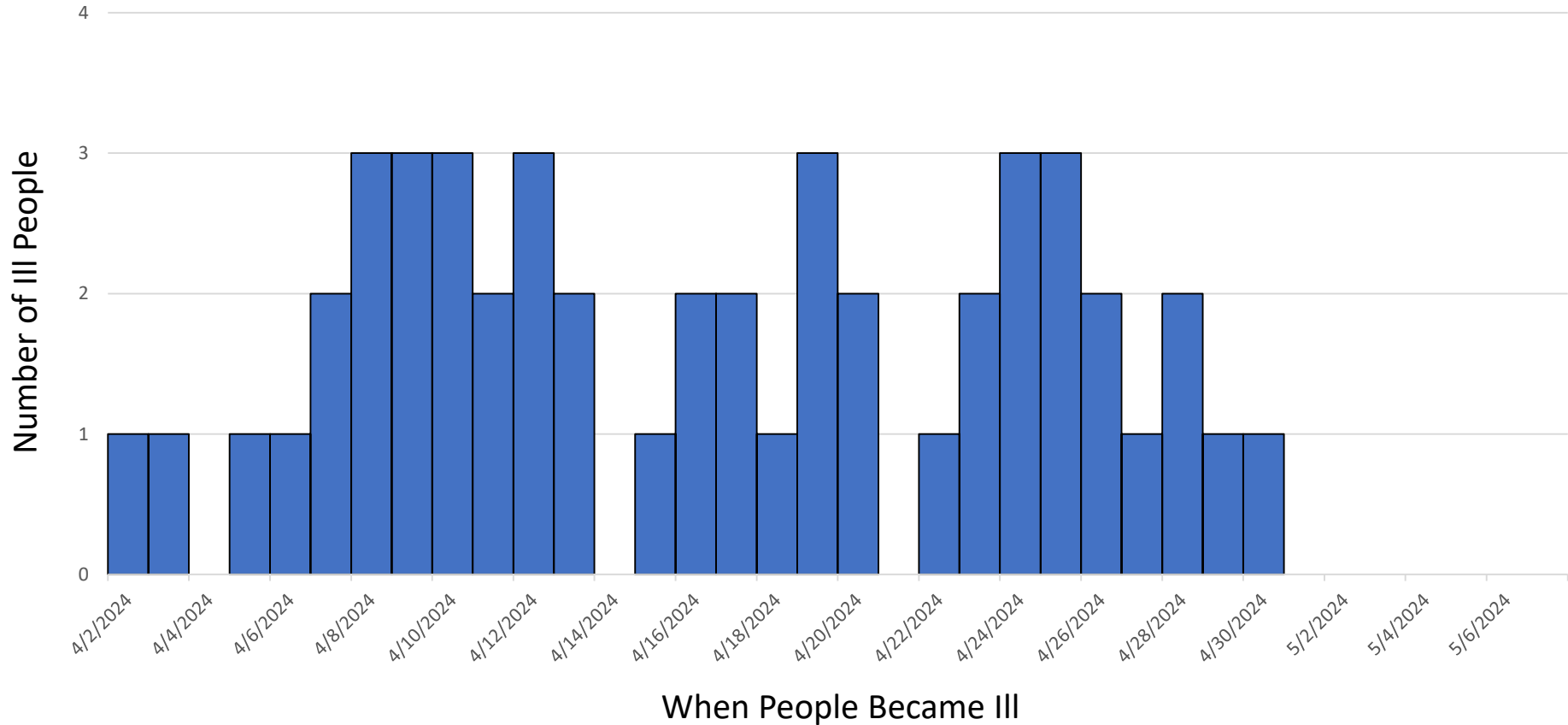
# Updated Case Information

- 49 *Salmonella* Urbana infections
- 14 states
- 63% female
- Median age 53 years
- 19 hospitalizations, 1 death (CA)
- Onset dates: April 2-April 30, 2024



# When People Became Ill

This chart shows when the 49 people in this *Salmonella* outbreak became ill



# Focused Questionnaire Results from 27 Ill People



24/27 (89%) of ill people report eating cereal - this is **significantly higher than the 69% of healthy people in the PopSurvey**



9 ill people reported Healthy Harvest Cereal



12 ill people reported Fiber Fit Cereal



3 ill people reported cereal, but couldn't remember the brand

# Product Sampling

- Illinois and Colorado collected samples of opened cereal from ill people's homes
- Minnesota and New York collected samples from retail stores reported by ill people

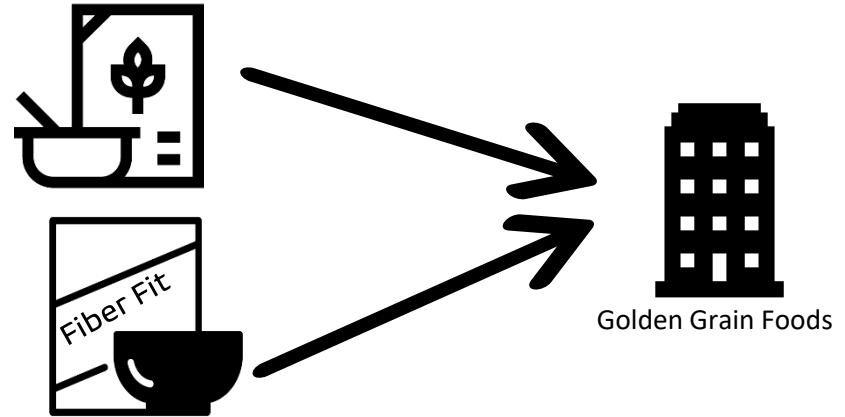
Agency	Samples Collected	Collected From	Product Sampled
Illinois	2	Patient's home	Healthy Harvest
Colorado	3	Patient's home	Fiber Fit
Minnesota	4	Retail store	Healthy Harvest
New York	4	Retail store	Fiber Fit

# Additional Purchase Records and Traceback

Collected 10 total purchase records - 6 records showed Healthy Harvest and 4 showed Fiber Fit

FDA traced Healthy Harvest and Fiber Fit cereal brands to a single production facility owned by **Golden Grains Food**

FDA initiated an inspection of the production facility



# Product Sampling Results

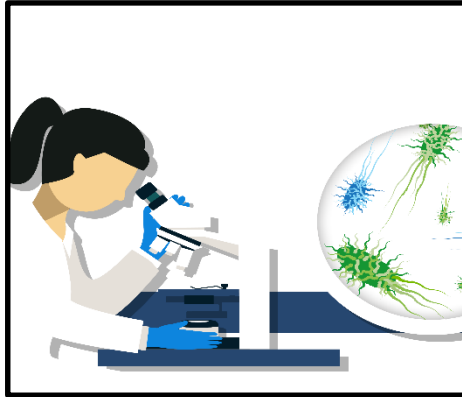
- Healthy Harvest cereal from an IL patient's home – positive for *Salmonella* Urbana
- Fiber Fit cereal from a NY retail chain – positive for *Salmonella* Urbana
- **All positive samples are sequenced and match the outbreak strain**

Agency	Samples Collected	Collected From	Product Sampled	Sample Results
Illinois	2	Patient's home	Healthy Harvest	Positive
Colorado	3	Patient's home	Fiber Fit	Negative
Minnesota	4	Retail store	Healthy Harvest	Negative
New York	4	Retail store	Fiber Fit	Positive

# FDA Inspection



Collected 10 environmental samples from non-food contact surfaces

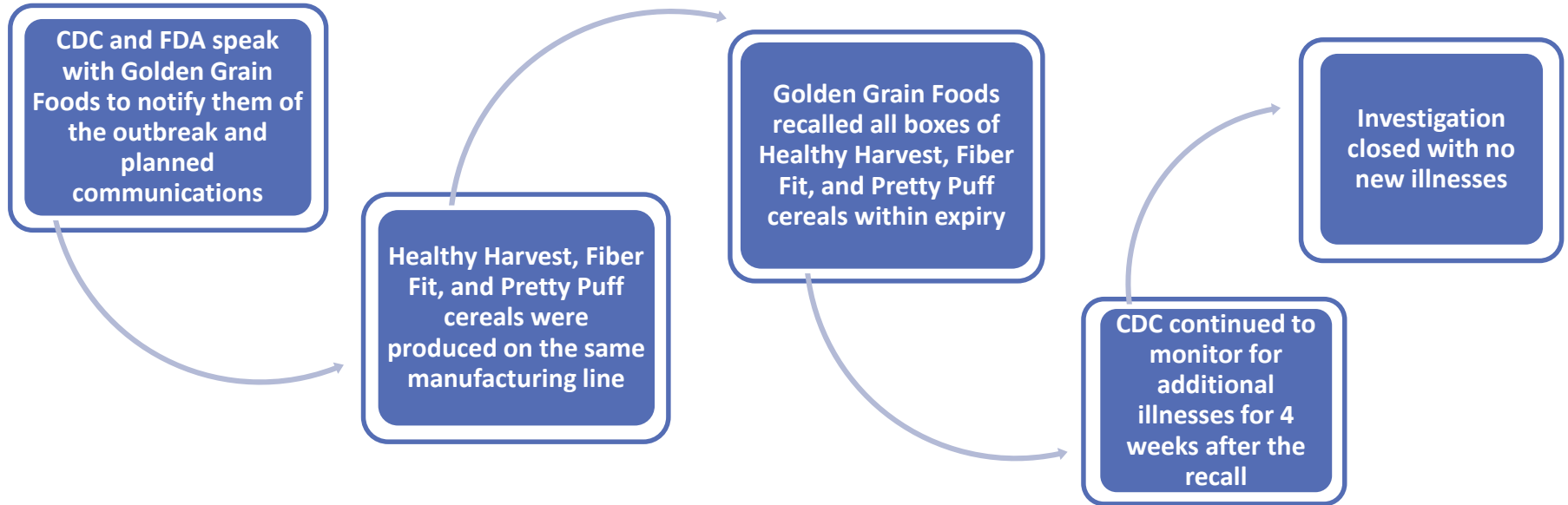


3 samples yielded the outbreak strain of *Salmonella* Urbana



Corrective actions – cleaning and sanitizing the affected areas

# Public Communications and Recall





# Thank you!

For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [cdc.gov](https://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the U.S. Centers for Disease Control and Prevention.



# Life of an Outbreak Investigation The Role of the Retailer

Food Safety Summit 2024

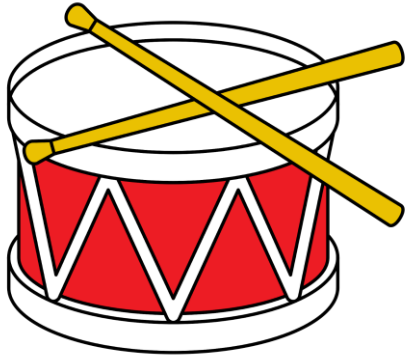
Robin Forgey  
AGMM Food Safety and Quality Assurance



# Traceback and Recall Logistics

Listen to the rumblings...

- Awareness of current investigations being conducted
- State regulators start reaching out for Member Shop Histories



# What is a Member Shop History?

- Items linked to the purchase by each membership number
- Requested by Health Dept
- Must have a limited date range and item category
- Must provide a membership number
- Signals members agreement to release this information to the Health Dept
- Limited employee access

# Our “Investigation”

April 19, 2024

NY Dept of AG requested member shop history - all food between 02/15 - 04/19/2024

Investigating Salmonella

Warehouse	Department	Item #	Description 1	Description 2	Purchase Date
401	12	1300509	KS NUT BARS W/PECANS 30CT	1.41OZ P304 SL203	4/2/2024 0:00
401	12	867221	STACYS ORGANIC PITA 28OZ	CHIP P138 T46H3 SL75	4/2/2024 0:00
401	13	993449	GAROFALO ORG VTY 6/17.6OZ	ORGANIC PASTA SL365 P144	4/2/2024 0:00
401	13	516822	KS ORG CHKN STOCK 6/32OZ	KS ORGANIC SL292 P150	4/2/2024 0:00
401	13	633561	KS ORG DICED TOM 8/14.5OZ	P240	4/2/2024 0:00
401	13	1495250	KS ORG N/S COCO WATR 9-1L	NO SUGAR P100	4/2/2024 0:00
401	13	384732	KS PURE SEA SALT 30 OZ	850G	4/2/2024 0:00
401	13	1032932	KS RAW ORG HONEY 3/24 OZ	BEARS BRAZIL T16H5 P320	4/2/2024 0:00
401	13	664511	S+HW ORG BLACK BEANS 8/15Z	ORGANIC SL365 P240	4/2/2024 0:00
401	16	1588359	CHLOE SAUVIGNON BLANC	NEW ZEALAND 12/750ML	4/2/2024 0:00
401	16	1492788	CORONADO SALTY CREW	SAN DIEGO 24/12OZ CANS	4/2/2024 0:00
401	16	1681485	DOMAINE DE TAMARY ROSE	COTES DE PROVENCE 6/750ML	4/2/2024 0:00
401	16	1134102	KS GIGONDAS	RHONE FRANCE CSPCH 797053	4/2/2024 0:00
401	16	555512	KS RUSSIAN RIVER 12/750ML	PINOT NOIR CSPCH 736971	4/2/2024 0:00
401	16	1342948	LATITUDE 33 BLOOD OJ IPA	24/12OZ CANS	4/2/2024 0:00
401	17	1114743	KS ORANGE JUICE 3/59 OZ	SL45 DOM70 T14H5 P140	4/2/2024 0:00
401	17	1462714	KS ORG A2 PROTEIN 3/64Z	3/64OZ SL30 33X4 P132	4/2/2024 0:00
401	18	1180452	ORGANIC MANGOES 5LB	ULTRA ORGANICS T7H6 P252	4/2/2024 0:00
401	19	332451	CHAOURCE FROM FRANCE	6/8.8OZ T14H18 SL21	4/2/2024 0:00
401	19	1320300	CITTERIO PROSCIUTTO	16/2-6 OZ 16T6H SL40	4/2/2024 0:00
401	19	1340976	FRENCH COMTE CUTS	14/1.4LB T11H8 SL45	4/2/2024 0:00
401	19	1340976	FRENCH COMTE CUTS	14/1.4LB T11H8 SL45	4/2/2024 0:00
401	19	1340976	FRENCH COMTE CUTS	14/1.4LB T11H8 SL45	4/2/2024 0:00
401	19	6101960	KS ORG SPIN/CHSE RAVIOLI	10/2-22 OZ 5T5H SL35	4/2/2024 0:00
401	19	2251987	KS ORG PNM HUMMUS	12/34 OZ 8T6H SL50	4/2/2024 0:00
401	19	34777	KS PARM REGGIANO 1.5# RW	20/1.5LB RW T8H11 SL120	4/2/2024 0:00
401	19	33313	POT CHEESE PIEROGI 6/3-14	KASIA'S T9H8 SL25	4/2/2024 0:00
401	19	1302599	SABATINO ORG CHKN SAUSAGE	12/36 OZ 14T4H SL45	4/2/2024 0:00
401	62	1199652	BUTTER CROISSANT 12 COUNT		4/2/2024 0:00
401	62	1199652	BUTTER CROISSANT 12 COUNT		4/2/2024 0:00
401	65	121288	ORG. BABY BELLA MUSHROOM		4/2/2024 0:00
401	65	96716	ORGANIC BABY SPINACH	453 G / 16 OZ	4/2/2024 0:00
401	65	2619	ORGANIC BANANAS	3 LB / 1.36 KG	4/2/2024 0:00
401	65	532683	ORGANIC GINGER	794 G / 1.75 LB	4/2/2024 0:00
401	65	5576	ORGANIC GRAFFITI EGGPLANT		4/2/2024 0:00
401	65	944939	ORGANIC LIVING LETTUCE		4/2/2024 0:00
401	65	944939	ORGANIC LIVING LETTUCE		4/2/2024 0:00



# Our “Investigation”

April 22, 2024

CA Dept of Health requests member shop history for 2 members - 03/29 - 04/24/24

Investigating Salmonella

April 23, 2024

Michigan Dept of Ag.requests a member shop history for 1 member - 03/15- 04/10/24

Investigating Salmonella

# Contact by the CDC

CDC reaches out and they ask us to provide traceback information for 2 distinct purchases

Member # 1234567 Item # 123075 Fiber Fit Cereal Purchased on 4/2/24 in Brooklyn, NY

Member # 3456789 Item # 123075 Fiber Fit Cereal Purchased on 4/5/24 in Alhambra, CA



# Next Steps

- Look up traceability information
- Contact the supplier
- Pull all product off the sales floor, wrap and mark “Do Not Sell”
- Block sales at the register
- Supplier has conversation with CORE
- Initiate recall procedures





# Recall Procedures

- Confirm facility involved
- Get list of Purchase Orders with the affected items/code dates
- Pull list of members who purchased the item
- Get recall letter from the supplier
- Send emails, phone calls, paper letters
  - (includes donation contacts, delivery par
- Post on website
- Notify our call center
- Destroy the affected product





Questions?

# OVERVIEW OF OHAFO

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## FIELD OPERATIONS & FDA COMPLIANCE ACTIONS

*CAPT Chris van Twuyver  
Program Division Director  
HAFW1 (WI, MN, ND, SD)*





# FoodIndustry

COUNSEL LLC

“GOING **ALL-IN** FOR FOOD AND **ALL-OUT** FOR THOSE WHO PRODUCE IT”

Shawn Stevens

[stevens@foodindustrycounsel.com](mailto:stevens@foodindustrycounsel.com)

920.698.2561

# LEGAL CONSEQUENCES

Civil, Regulatory, and Criminal



# CIVIL

**Alleged claims**

**Meritorious claims**

**Informal settlement discussions (with or without lawyers)**

**Formal and structured mediation (with lawyers)**

**Litigation, discovery, and possible trial**



# **REGULATORY**

**FDA/USDA**

**Inspections / Swab-a-thons**

**FDA Form 483s / Warning Letters**

**USDA/FSIS Notice of Intended Enforcement**

**Public Health Orders (mandating closure)**

**Potential withdrawal of licenses or registration**



# CRIMINAL

## Regulatory inspections can trigger referral to DOJ DOJ investigation – Grand Jury Subpoenas



### Elements:

1. Awareness of a condition that could make someone sick;
2. Being in a position to fix or eliminate the condition; and
3. Failing to do so.

**Penalties (per count): 1 year in prison/\$250,000 fine**





# FoodIndustry

COUNSEL LLC

“GOING **ALL-IN** FOR FOOD AND **ALL-OUT** FOR THOSE WHO PRODUCE IT”