

# Illness Response and Traceback Investigations

## 2023 Interstate Seafood Seminar and Gulf and South Atlantic Shellfish Conferences

|

Kim Norgren and Mike Pearson  
USFDA

# Objectives

- Requirements for the Authority
- Why the concern?
- Receiving of complaint or illness
- Initial Investigation
- Notification requirements
- Time requirements
- Traceback
- Trace forward
- Recall
- Reporting

# Illness Response Traceback & Trace Forward



Identify  
Illness or  
Outbreak



Notify FDA



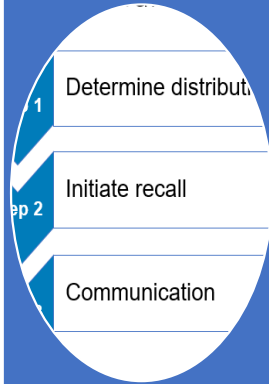
24 Hours



Retail  
&  
Restaurants



Illness  
Traceback



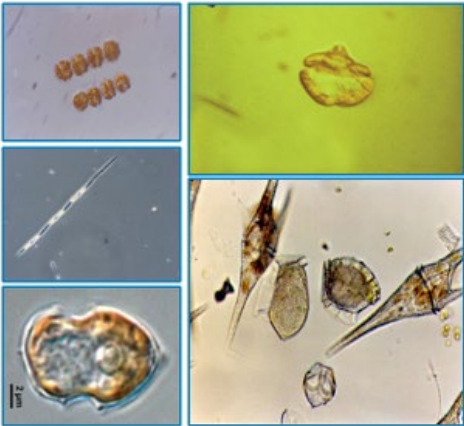
Illness  
Trace  
Forward



# Why the Concern?

## Pathogens & Toxins

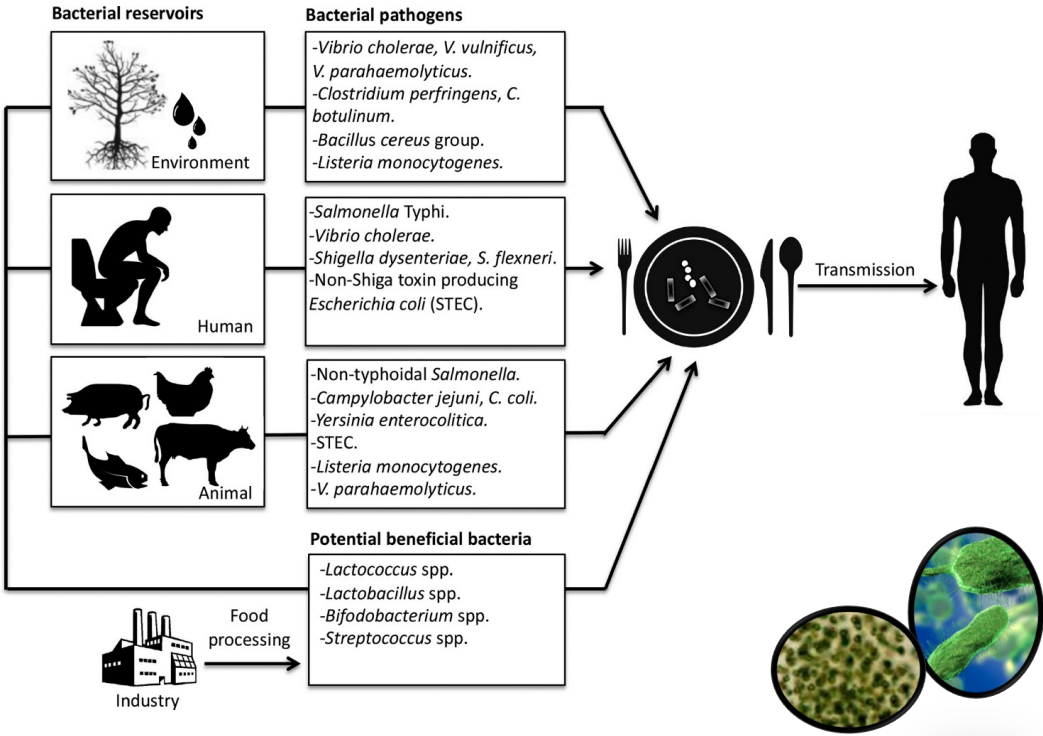
### Marine Biotoxins



### Cyanobacteria



### Human Pathogens



# Why the Concern?

## Poisonous or Deleterious Substances

**Point Source**



**Discarded military munitions in shellfish harvest areas**



**Non-Point Source**



**Petroleum and hydrocarbons**



# Why the Concern?

## Post-Harvest Contamination & Illegal Harvesting

### Post-Harvest Contamination



Model Ordinance Chapter II. @.04 B. (5)

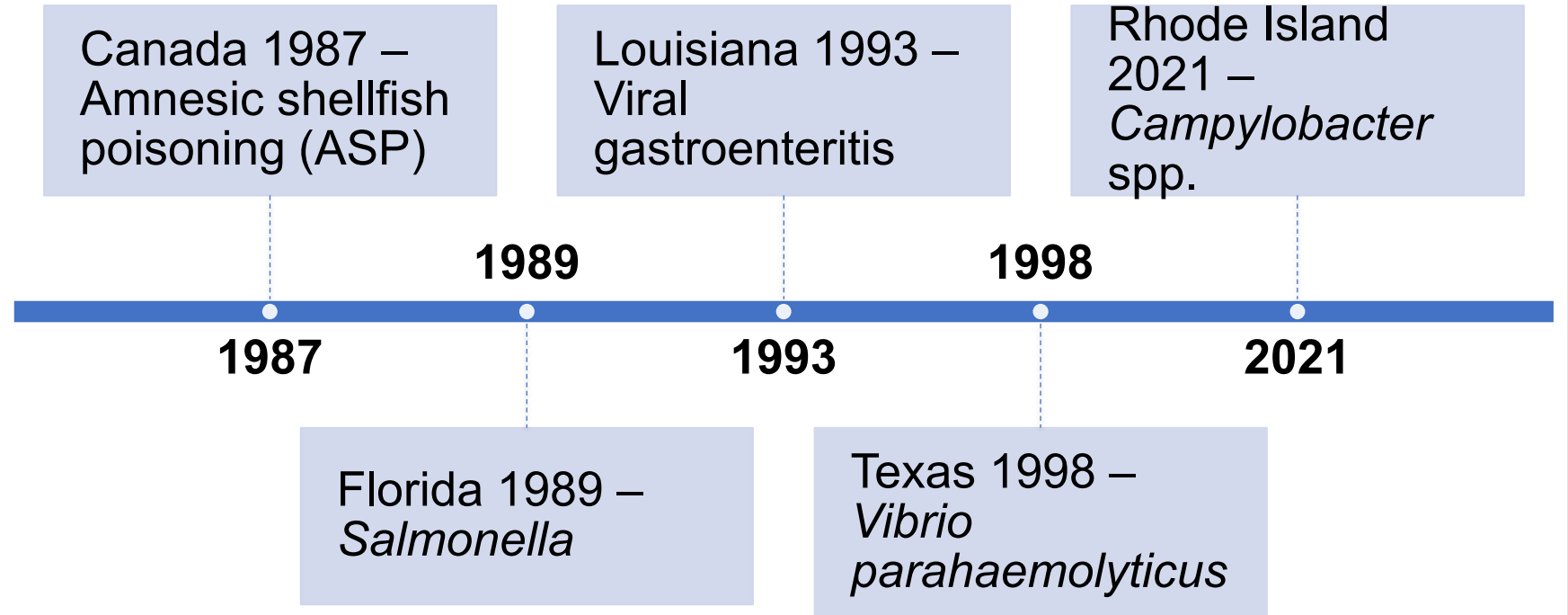
### Illegal Harvesting



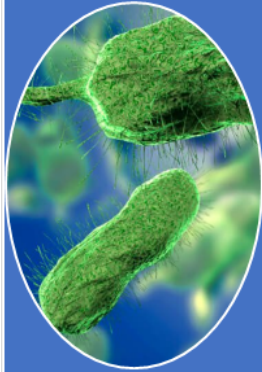
Model Ordinance Chapter II. @.04 C.

# Why the Concern?

## Outbreak Examples



# Illness Response Tracebacks



Identify  
Illness or  
Outbreak



Notify FDA



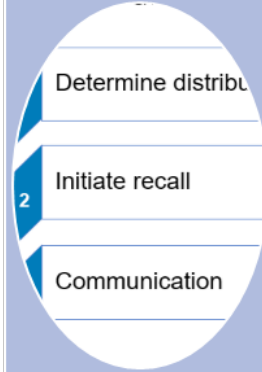
24 Hours



Retail  
&  
Restaurants



Illness  
Traceback



Illness  
Trace  
Forward



# Receiving Illness Complaints

- Notification from a variety of sources and through different mechanisms
- Follow written protocols for collecting and reporting illnesses



# F. Epidemiologically Implicated Outbreaks

Chapter I. @.01  
Administration



- Written protocol with State agencies responsible for collecting epidemiological information
- Procedures to ensure all shellfish related illnesses are reported to the shellfish Authority(s)
- Procedures for investigating incidents of shellfish borne disease.

# Illness Investigation

**Illness complaint received;  
investigation conducted by  
the appropriate agency(ies):**

**Onset date  
/ time**

**Symptoms  
of illness**

**Food  
consumed**

Illness  
Investigation  
(continued)

# Additional information includes:

Other exposure, such as skin or wound contact

Pre-existing medical conditions

Medications (including antacids)

# COVIS and Other Illness Reports

State: \_\_\_\_\_ Year: \_\_\_\_\_  Age: \_\_\_\_\_ Sex: \_\_\_\_\_ Last Name: \_\_\_\_\_

**CDC** CHOLERA AND OTHER VIBRIO ILLNESS SURVEILLANCE REPORT  
OMB 0920-0728

REPORTING HEALTH DEPARTMENT

State: \_\_\_\_\_ City: \_\_\_\_\_ County/Parish: \_\_\_\_\_

**1. PATIENT CASE INFORMATION**

1. First 3 letters of patient's last name: \_\_\_\_\_ 2. Sex:  M  F  Unk

3. Date of birth (MM/DD/YYYY): \_\_\_\_\_ 4. Age: \_\_\_\_\_ 5. NNDSS case ID \_\_\_\_\_ 6. Case state ID (required) \_\_\_\_\_

5. RACE:  American Indian/Alaska Native  White  
 Black or African American  Other  
 Native Hawaiian or other Pacific Islander  Unknown/not provided

6. Ethnicity:  Hispanic/Latino  
 Not Hispanic/Latino  Unknown/not provided

7. Occupation: \_\_\_\_\_

**2. LABORATORY INFORMATION**

Use the **Vibrio Species key** to indicate which species were positively identified by culture or CIDT result as applicable.

<i>V. cholerae</i> —CHL	<i>V. cholerae</i> non-O1, non-O139—CHN	<i>V. parahaemolyticus</i> —PAR	<i>V. vulnificus</i> —VUL
<i>V. vulnificus</i> —VUL	<i>V. vulnificus</i> —VUL	<i>V. vulnificus</i> —VUL	<i>V. vulnificus</i> —VUL

3. Laboratory results (If more than one specimen is tested, complete one row per specimen. If more than two specimens are tested, please use additional sheets and attach additional sheet. CIDT indicates a culture-independent diagnostic test.)

1. Specimen one: Date collected: \_\_\_\_\_ Received at public health laboratory?  Yes  No  Unk If yes, State lab ID: \_\_\_\_\_

Specimen source: \_\_\_\_\_ Culture result:  Pos  Neg  Unk  Not Done CIDT result:  Pos  Neg  Unk  Not Done

Specimen Site: \_\_\_\_\_ If positive, species identified: \_\_\_\_\_ Name/type of diagnostic test used: \_\_\_\_\_

If Other, specify: \_\_\_\_\_ If species identified as multiple or other, specify: \_\_\_\_\_ If species identified as multiple or other, please specify: \_\_\_\_\_

- Etiologic Agent
- Symptoms
- Pre-existing Conditions

- Seafood consumed
- Consumption Date
- Prepared - raw, cooked

State: \_\_\_\_\_ Year: \_\_\_\_\_ Age: \_\_\_\_\_ Sex: \_\_\_\_\_ Last Name: \_\_\_\_\_

**3. CLINICAL INFORMATION**

1. Date illness began (MM/DD/YY): \_\_\_\_\_ 4a. Admitted to a hospital overnight for this illness?  Yes  No  Unknown

2. Duration of illness (Days): \_\_\_\_\_ 4b. If yes, admission date (MM/DD/YY): \_\_\_\_\_

3a. Did patient die?  Yes  No  Unknown 4c. Discharge date (MM/DD/YY): \_\_\_\_\_

3b. If yes, date (MM/DD/YY): \_\_\_\_\_

5. Did patient take an antibiotic as treatment for this illness?  Yes  No  Unknown

If yes, name (antibiotic): \_\_\_\_\_ Date began antibiotic (MM/DD/YY): \_\_\_\_\_ Date stopped antibiotic (MM/DD/YY): \_\_\_\_\_

1. \_\_\_\_\_ 2. \_\_\_\_\_ 3. \_\_\_\_\_

Signs and symptoms:

	Yes	No	Unk	Medical history (optional for probable cases):	Yes	No	Unk
Vomiting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Diarrhea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Visible blood in stools	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Abdominal cramps	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Abdominal pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fever (>100.4F or 38 C)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Muscle pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Muscle pain	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Septic shock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Septic shock	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Cellulitis (Site: _____)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Cellulitis (Site: _____)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Bullae (Site: _____)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Bullae (Site: _____)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Sequelae (e.g. amputation, skin graft) (Type: _____)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sequelae (e.g. amputation, skin graft) (Type: _____)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other (ear pain, discharge, rash, etc.): _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (ear pain, discharge, rash, etc.): _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Additional signs and symptoms comments: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Additional signs and symptoms comments: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	If yes to any of the above conditions, specify type: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If yes to any of the above conditions, specify type: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**4. EPIDEMIOLOGY SECTION**

1. Was this case part of an outbreak?  Yes  No  Unk

2. If yes, please describe (include NORS ID if available): \_\_\_\_\_

3. PulseNet cluster code (if available): \_\_\_\_\_

# Illness reports

## All illness reports are evaluated for:

- **Etiologic information:** Are symptoms and incubation period of the illnesses consistent with the suspected pathogen or agent?
- **Epidemiologic information:** Does the information indicate a commonality—an association between the shellfish consumed and suspected pathogen or agent?

## Definition of an Outbreak

- two or more persons **not from the same household...**

Or

- **one or more persons** in the case of marine biotoxins



## Determine if Outbreak has Occurred

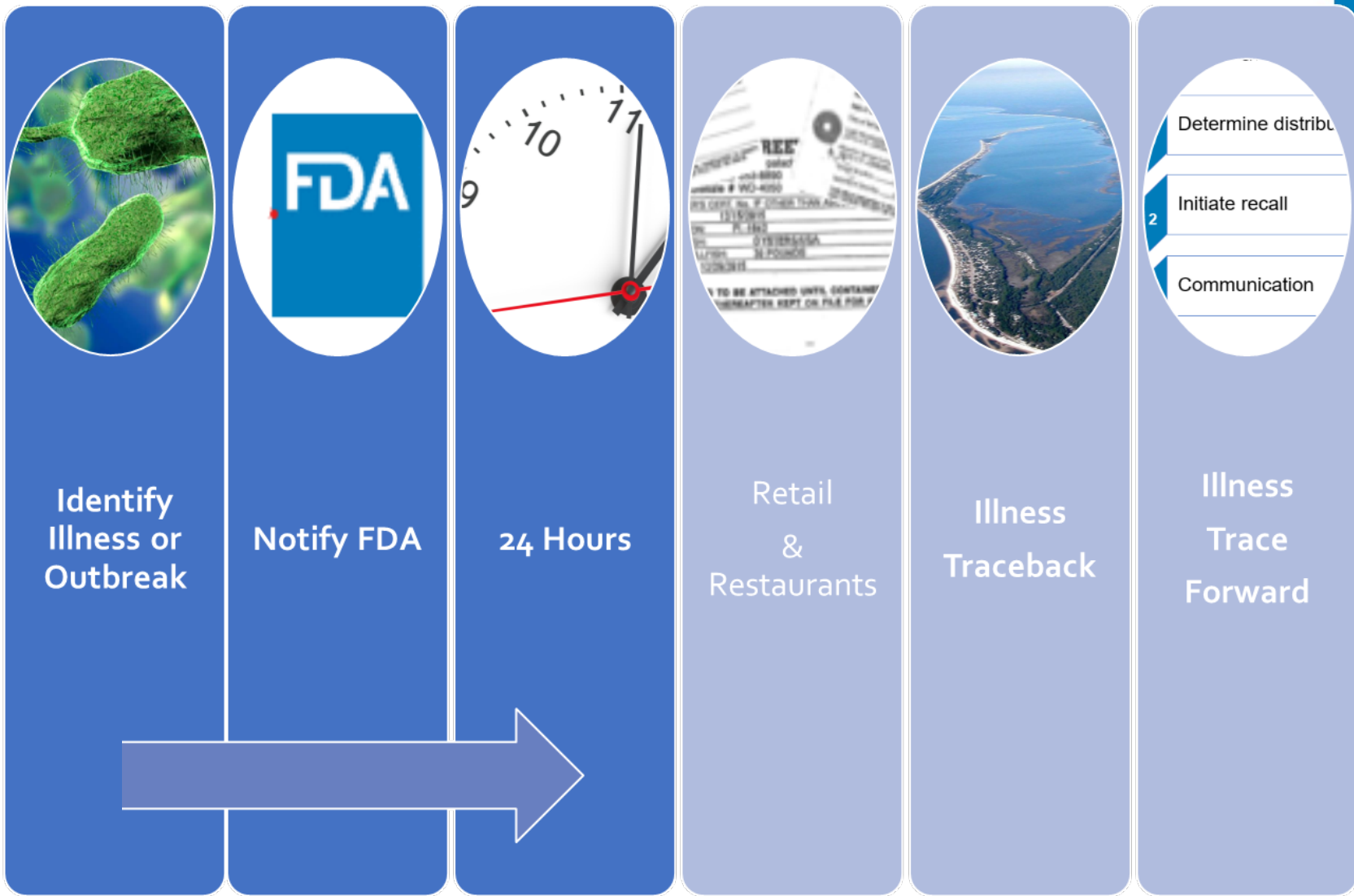
The **state** epidemiologist (where outbreak occurs) determines if an **epidemiological association** exists by reviewing:

- Food history
- If disease has potential or is known to be transmitted by shellfish
- If symptoms and incubation period are consistent with suspected etiologic agent





# Illness Response Tracebacks



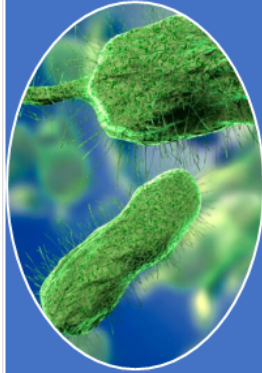
# Outbreak Identified

## Steps for the Authority

1. Notify the FDA Shellfish Specialist
1. Within twenty-four (24) hours determine whether the illness is growing area related or is the result of post-harvest contamination, mishandling, or illegal harvesting from a closed area



# Illness Response Tracebacks



Identify  
Illness or  
Outbreak



Notify FDA



24 Hours



Retail  
&  
Restaurants



Illness  
Traceback



Illness  
Traceback



## Point of Sale or Service

# Investigation Procedures

- Inspect facility(ies)
- Collect and photograph tags and documents related to implicated shellfish
- Maintain open communication between public health officials and their state shellfish authority

# Point of Sale or Service Investigation:

## Questions & Observations



- **Ask** open ended questions

- **Observe** shellfish storage and handling practices



## Point of Sale or Service Investigation:

### Documents

**Collect, scan, or photograph documents related to the implicated shellfish:**


- Shellstock tags and labeling
- Invoices
- Delivery tickets
- Bills of lading
- Cooler temperature records (if available)
- **Focus on documents related to timeframe** of reported shellfish consumption

# Point of Sale or Service Investigation:



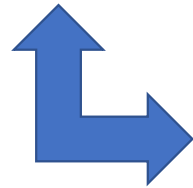
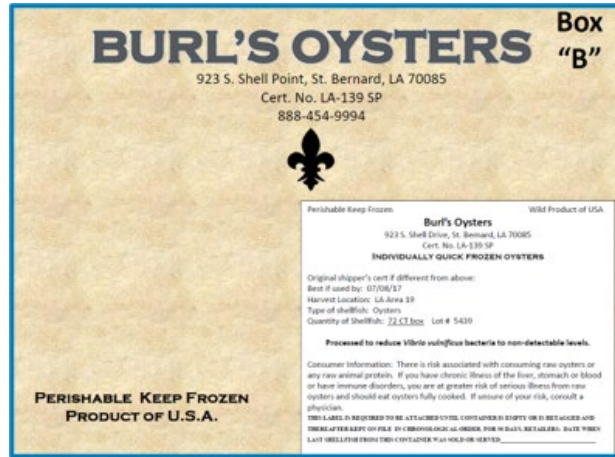
**Effective tracebacks may require patience!**

# Point of Sale or Service Investigation: TAGS

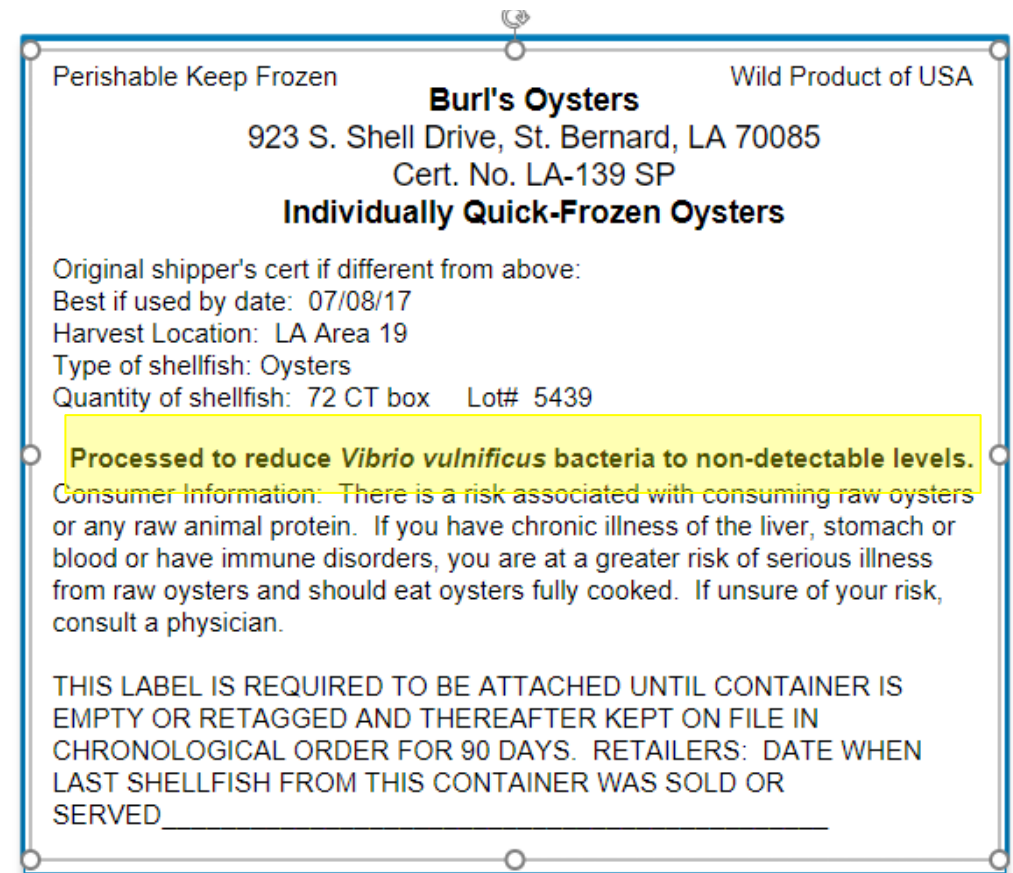
	DEALER NAME <span style="float: right;">CERT. NO.</span> Dealer Address City, State Zip Code	<b>RETAILERS, INFORM YOUR CUSTOMERS</b> Thoroughly cooking foods of animal origin such as beef, eggs, fish, lamb, poultry, or shellfish reduces the risk of foodborne illness. Individuals with certain health conditions may be at higher risk if these foods are consumed raw or undercooked. Consult your physician or public health official for further information.
	ORIGINAL SHIPPER'S CERT. NO. IF OTHER THAN ABOVE:	
	HARVEST DATE:	
	HARVEST LOCATION:	
	TYPE OF SHELLFISH:	
	QUANTITY OF SHELLFISH:	
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT ON FILE, IN CHRONOLOGICAL ORDER, FOR 90 DAYS. <b>RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER SOLD OR SERVED (INSERT DATE)</b> _____		



# Point of Sale or Service Investigation:



## Labels



Point of Sale or Service Investigation:  
Other Documents

Example Document "A"

**Akbar's Oyster House**  
3822 Breezy y Lane  
Collin, MD  
MD-1212SP

**Invoice**

Date	Invoice #
2/13/2015	43014

Bill To

**Glendale Grocery**  
1950 Chestnut Place  
Denver, Colorado

Ship To

**Glendale Grocery**  
1950 Chestnut Place  
Denver, Colorado

Terms	Due Date	P.O. Number	Ship Date	Harvest Location
Due on receipt	2/13/2015	MD-1212SP	2/13/2015	MD, Ches. Bay

Item Code	Quantity	Description	Harvest Date	Lot #	Unit Price	Amount
LN400	5	Little Neck Clams - 400 CT	2/12/2015	3		
TN200	10	Top Neck Clams - 200 CT	2/12/2015	3		
CS120	2	Cherry Stone Clams - 120 CT	2/12/2015	3		
HS100BOX	5	Half Shell Oysters - 100 CT Box	2/12/2015	4		
<p>9:25 AM 41° F</p>						
<b>Total</b>						
<b>Payments/Credits</b>						\$0.00
<b>Balance Due</b>						

Signature



# Traceback Diagrams:

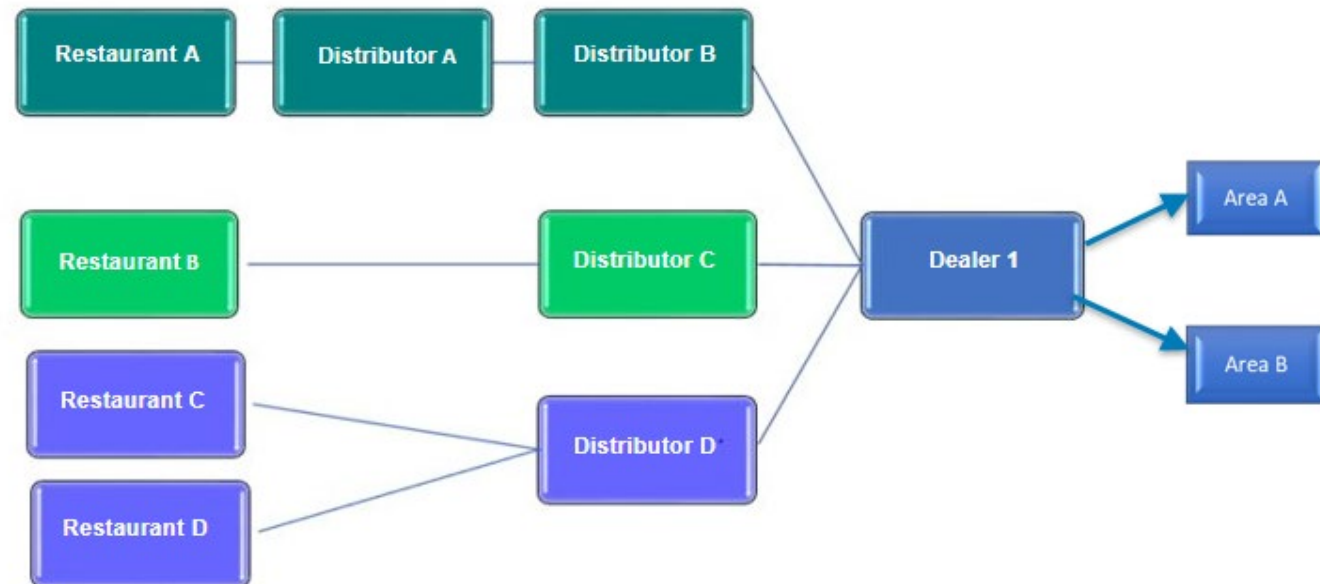
**Simple**  
(if you're lucky!)

**Complex**  
(common)

## Simple Traceback



## Complex Traceback



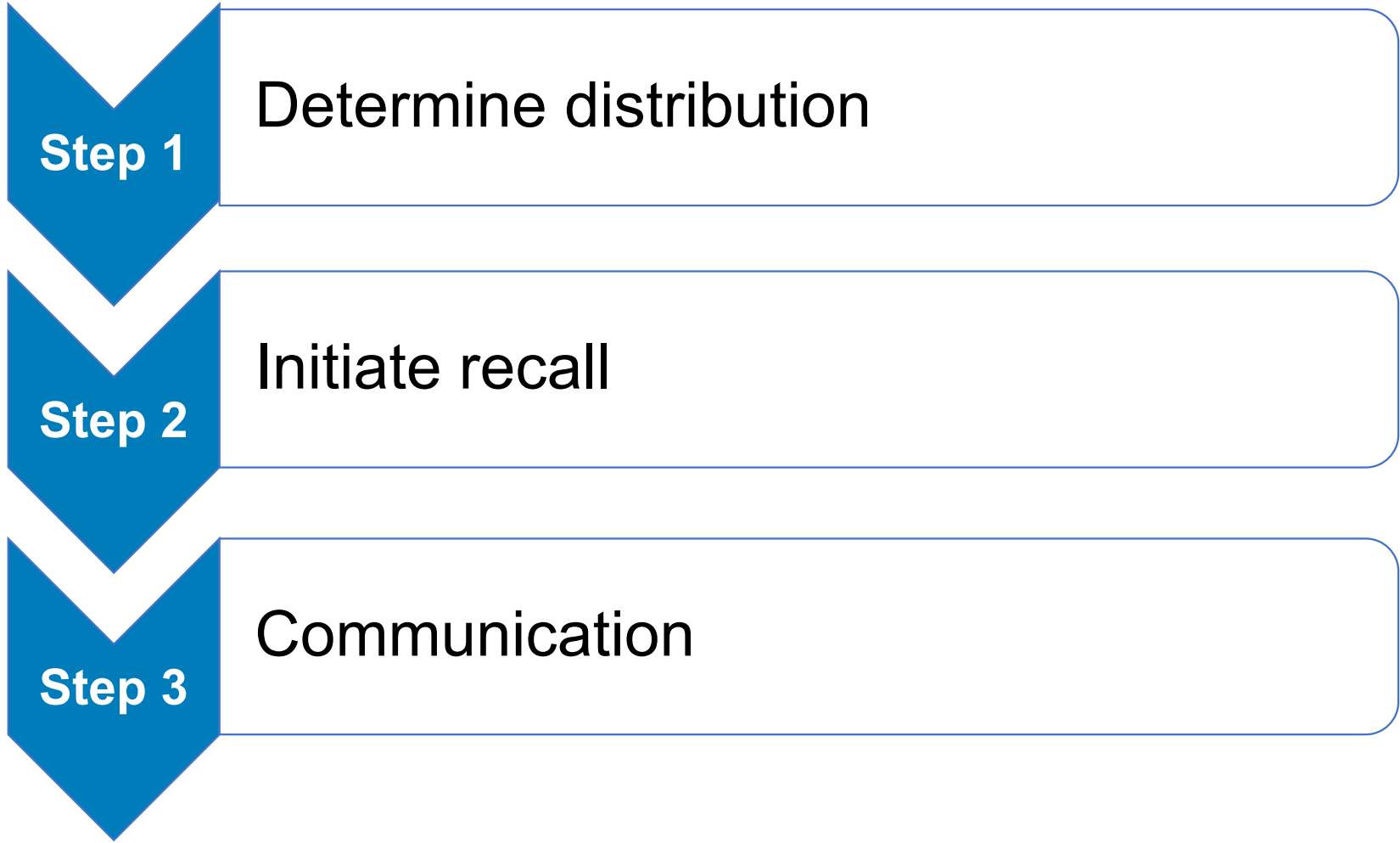
# Illness Response Tracebacks

- **Traceback** is driven by results of the retail investigation
- **Shellfish Authority:**
  - Reviews retail investigation records
  - Identifies dealers and distributors
  - Determines harvest area(s) from tags and records (single source or multi-source)

# Illness Response Traceback & Trace Forward



# Trace Forward Steps



## Trace Forward Steps:

### Transaction records



#### Step 1

#### Determine distribution

- Shellfish harvest and sale records
- Purchase records
- Transportation records
- Invoices, bills of lading (BOL)
- Bulk tagging





## Trace Forward Steps 2:

## Transaction records

### Step 2

### Initiate recall

Original dealer initiates a recall consistent with their plan:

Recall plan follows 21 CFR Part 7 and includes:

1. Timely notification of the authority,
2. Timely notification of the consignee(s) who received the affected product, and
3. Effective removal or correction of the affected product

# Trace Forward

## Steps 3:

### Communication



### Communication

- Original dealer communicates recall plan to customers.
- Original dealer notifies their state shellfish authority of distribution of implicated products.
- Trace forward must include all dealers through point of sale.

## Immediate Notification

- The Authority will immediately notify the FDA, ISSSC, and the Authorities in other states involved in the recall



Model Ordinance Chapter  
II. @.01 C. (1)

## Dealer Recall Plan Requirements

# Recall Requirements

- 1) Dealers shall adopt **written procedures** for conducting recalls of adulterated or misbranded shellfish products.
- 2) Dealers **shall follow** their written recall procedures.



Model Ordinance  
Chapter X. .04 A. (2) (c)

# Recall Effectiveness and Reporting

Monitor the progress and  
success of the recall



# NSSP Section IV Guidance Documents – Chapter V. Illness Outbreaks and Recall Guidance.

- .01 Guidance for Investigating an Illness Outbreak and Conducting Recall
- .02 Guidance for a Time-Temperature Evaluation of a Shellfish Implicated Outbreak
- .03 Guidance for Harvest Area Closure and Recall Notification
- Appendices A-G: example forms and procedures

National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish: 2017 revision

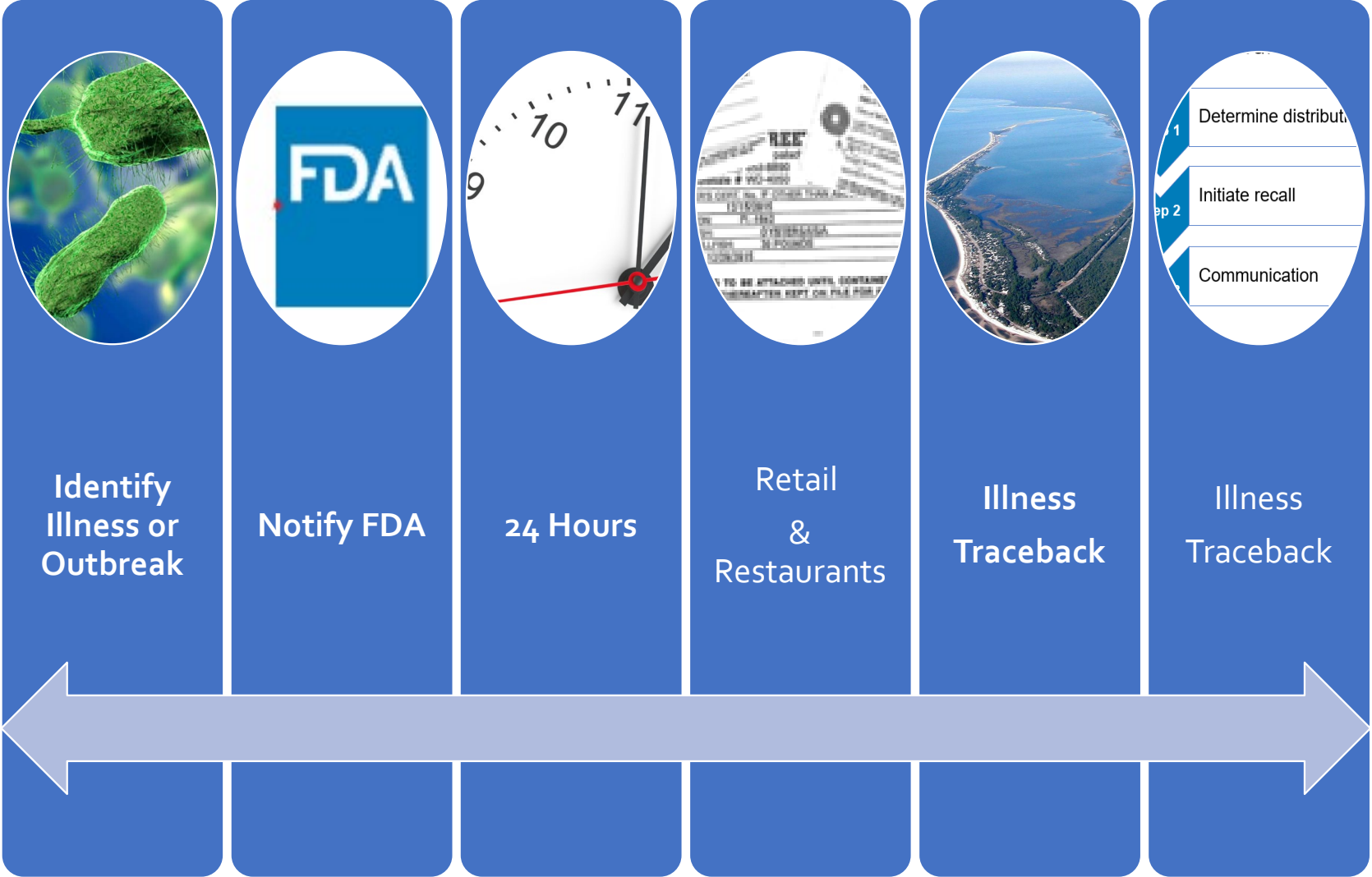
APPENDIX A

CHECKLIST FOR RECALLS, CLOSURES AND SPECIAL EVENTS

Specific Event: Date of Event:	Date Office Notified:	Date Office Action Initiated:
Task	Staff Initials	Date
Initial shellfish related illness outbreak/hazardous event reported by: Name: _____ Title: _____ Phone: _____ Organization: _____		
Office Director informed of outbreak/event: <input type="checkbox"/> No <input type="checkbox"/> Yes		
Food Safety Manager informed of outbreak/ hazardous event: <input type="checkbox"/> No <input type="checkbox"/> Yes		
Growing Area Manager informed of outbreak hazardous/event: <input type="checkbox"/> No <input type="checkbox"/> Yes		
Licensing and Certification Manager informed of outbreak/ hazardous event: <input type="checkbox"/> No <input type="checkbox"/> Yes		
Recall Required: <input type="checkbox"/> No <input type="checkbox"/> Yes Initiated on date: _____		
Assistant Secretary informed of outbreak/event: <input type="checkbox"/> No <input type="checkbox"/> Yes		
Notification to FDA Regional Shellfish Specialist (within 24 hours of Notice): <input type="checkbox"/> No <input type="checkbox"/> Yes		
Alert to Media <input type="checkbox"/> No <input type="checkbox"/> Yes (If yes, attach press release)		
Notification to Epidemiology / Public Health Laboratory: (obtain tracking #) Phone: (enter number)		
Person Contacted	Tracking Number(s)	Staff Initials Date
Notification to Local Health Jurisdiction(s) or Tribes (if more space is needed, attach page -- Attachment 1)		
LJU /Tribe	Phone #	Person Contacted Staff Initials Date
a.		
b.		
c.		
d.		
e.		
f.		
Notification to Receiving State(s) / Country(s) (if more space is needed, attach page -- Attachment 2)		
State/Country	Phone #	Person Contacted Staff Initials Date
a.		
b.		
c.		
d.		
e.		
f.		
Notification of Involved Companies (if more space is needed, attach page -- Attachment 3)		
Growers/Dealers		

Recalls, Closures, and Special Events Checklist & Appendices  
Page | 1

# Illness Response Traceback & Trace Forward





Questions ?

