Illness Response and Traceback Investigations

2023 Interstate Seafood Seminar and Gulf and South Atlantic Shellfish Conferences

FDA

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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



Pathogens & Toxins

Marine Biotoxins



Cyanobacteria



Human Pathogens





Poisonous or Deleterious Substances

> Model Ordinance Definitions, B. (87)





Non-Point Source



Discarded military munitions in shellfish harvest areas



Petroleum and hydrocarbons





Post-Harvest Contamination & Illegal Harvesting

Post-Harvest Contamination









Illegal Harvesting







Outbreak Examples



Illness Response Tracebacks





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

Illness Investigation

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

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state	city	County/Parish	E - f a x: 40 4 - 23 5 - 17 3 5 Ontons f and Disses Control a 4 Prevention Enteric Disasce Epidemiology Branch 1500 CEInon Reak, MS C09 Atlanta, GA 10333	Consumption Date			
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. Date of birth	(MM/DD/YYYY):	4. Age: 3. NNDSS C	ase ID 4. Case state ID (required)	Prepared - raw cooke			
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/. cholerae non-O1		V. vulnijicus—VUL	detected case (no lab results)				
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Other, specify:			If species identified as mulitple or other, please specify:	5. Did patient take an antibiotic as treatment for this illness? 🔛 Yes 🔛 No 🔛 Unknown			
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	-	ng Con	ditions	Other:			



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

NSSP

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

<u>Or</u>

 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

Model Ordinance Chapter II @.01 B. and @.01 E.

Steps for the Authority

1.Notify the FDA Shellfish Specialist

1.<u>Within twenty-four (24) hours</u> 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



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

•Observe shellfish storage and handling practices







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: Point of Sale or Service Investigation:



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Effective tracebacks may require patience!

Point of Sale or Service Investigation:

TAGS

DEALER NAME Dealer Address City, State Zip Code	CERT. NO.	STOMERS sggs, fish, lamb, Individuals with ods are consumed ath official for
ORIGINAL SHIPPER'S CERT. NO. IF OTHER THAN ABOV	VE:	RETAILERS, INFORM YOUR CUSTOMERS cooking foods of animal origin such as beet, eggs, fish, lamb helfish reduces the risk of foodborne liness. Individuals with th conditions may be at higher risk if these foods are consum ecooked. Consult your physician or public health official for nation.
HARVEST DATE:		RETAILERS, INFORM YOUR CU: y cooking foods of animal origin such as beet, is shellfsh reduces the risk of foodborne liness. afth conditions may be at higher risk if these for laroodised. Consult your physician or public he multion.
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TYPE OF SHELLFISH:		a of anima s of anima es the risk may be at reult your
QUANTITY OF SHELLFISH:		RETAIL Ing foods sh reduo ndtions r kied. Con no.
THIS TAG IS REQUIRED TO BE ATTACHED UNTIL CON IS EMPTY OR IS RETAGGED AND THEREAFTER KEPT CHRONOLOGICAL ORDER, FOR 90 DAYS. RETAILERS: SHELLFISH FROM THIS CONTAINER SOLD OR SERVED	ON FILE, IN DATE WHEN LAST	RETAILERS, INFORM YOUR CUSTOMERS Throwaphy cooking foods of animal origin such as beet, eggs, fish, lamb, poutry, or shellfsh reduces the risk of foodborne liness. Individuals with certain health conditions may be at higher risk if these foods are consumer naw or undercooked. Consult your physician or public health official for further information.

Point of Sale or Service Investigation:





Labels Perishable Keep Frozen Wild Product of USA Burl's Oysters 923 S. Shell Drive, St. Bernard, LA 70085 Cert. No. LA-139 SP Individually Quick-Frozen Oysters Original shipper's cert if different from above: Best if used by date: 07/08/17 Harvest Location: LA Area 19 Type of shellfish: Oysters Quantity of shellfish: 72 CT box Lot# 5439 Processed to reduce Vibrio vulnificus bacteria to non-detectable levels. Consumer Information: There is a risk associated with consuming raw oysters or any raw animal protein. If you have chronic illness of the liver, stomach or blood or have immune disorders, you are at a greater risk of serious illness from raw oysters and should eat oysters fully cooked. If unsure of your risk,

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THIS LABEL IS REQUIRED TO BE ATTACHED UNTIL CONTAINER IS EMPTY OR RETAGGED AND THEREAFTER KEPT ON FILE IN CHRONOLOGICAL ORDER FOR 90 DAYS. RETAILERS: DATE WHEN LAST SHELLFISH FROM THIS CONTAINER WAS SOLD OR SERVED

consult a physician.

Point of Sale or Service Investigation:

Other Documents



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Point of Sale or Service Investigation:

Documents



Ensure Copies Are Legible



Simple Traceback



Complex Traceback



Traceback Diagrams:

Simple (if you're lucky!)

Complex (common) 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 multisource)

Illness Response Traceback & Trace Forward



Trace Forward Steps





Trace Forward Steps:

Transaction records

Step 1

Shellfish harvest and sale records

Determine distribution

- Purchase records
- Transportation records
- Invoices, bills of lading (BOL)
- Bulk tagging



Customer list

Trace Forward Steps 1

Transaction records

The Shellfish Dealer (State-123-SS) ABC Drive SE Anyhoo, State 12345

CUSTOMER LIST

NAME	EMAIL	PHONE	ADDRESS
That Shellfish Place	HeyU@heyu.com	010-010-0011	ZYX A Street Anyhoo, State 12345
Everyone Loves Shellfish			
It's a Shellfish Thing			
Oyster-a-go-go			
Bivalves R Us			

Transaction Record

The Shellfish Dealer (State-123-SS) ABC Drive SE Anyhoo, State 12345

TRANSACTION RECORD

NAME	QUANTITY	TYPE OF SHELLFISH	HARVEST AREA	HARVEST DATE	DATE SOLD
That Shellfish	5- 10LB	Oysters-	Shellfish Bay		
Place	BAGS	Pacific			
Everyone Loves	10- 5LB	Oysters-			
Shellfish	BAGS	Pacific			
It's a Shellfish	20- 5LB	Oysters-			
Thing	BAGS	Pacific			
Oyster-a-go-go	10-5LB	Oysters-			
	BAGS	Pacific			
Bivalves R Us	5-10LB	Oysters-			
	BAGS	Pacific			

Bill of Lading

Date:					В	LL	OF	LAD	ING		Page 1 of		
Name:			SHIP F	ROM				Bi	II of Lading	g Number:			
Address													
City/Sta	ite/Zip:						-	_		BAR CODE S	SPACE		
SID#:			SHIP	70		F	OB: C						
Name:			SHIP		ion #:				ARRIER NAM				
Address	5:						Seal number(s):						
City/Sta			1			CAC:	(-)-						
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City/Sta	ite/Zip:							Fr	eight Char arked otherw	ge Terms: (freight chu	arges are prepaie	d uniess	
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Trace Forward Steps 2:

Transaction records



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



- 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, ISSC, and the Authorities in other states involved in the recall





Recall Requirements

Dealer Recall Plan Requirements

 Dealers shall adopt written procedures for conducting recalls of adulterated or misbranded shellfish products.

2) Dealers shall follow their written recall procedures.



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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

	ECKLIST FOR RECA	ALLS, CLOSURES AND SPEC	CIAL EVENTS	
Specific Event:		Date Office Notified:	Date Office Act	tion
Date of Event:	Initiated:			
	Task		Staff Initials	Date
nitial shellfish related illness or	atbreak/hazardous event	reported by:		
Name:	Title:		1 1	
hone:	Organization	n:		
Office Director informed of out	break/event: No V	íci		
ood Safety Manager informed				
Growing Area Manager inform	ed of outbreak hazardous	Vevent: No Yes		
icensing and Certification Mar No 🛛 Yes		sak/ hazardous event:		
Recall Required: 🗌 No 🗌 Yei				
Assistant Secretary informed of				
Notification to FDA Regional S	hellfish Specialist (withi	in 24 hours of Notice):		
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Alert to Media L No L Tes (r yes, attach press reicas	c)		
Notification to Epidemiology /	Public Health Laboratory	r: (obtain tracking #) Phone: (ent	er number)	
Person Contacte	d	Tracking Number(s)	Staff Initials	Date
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LHJ /Tribe	Phone #	Person Contacted	Staff Initials	Date
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Illness Response Traceback & Trace Forward







Questions?