

ER220 Traceback Investigations

“Train-the-Trainer”



Development Timeline



- Stakeholder Call – Feb. 24, 2012
- 1st Focus Group Meeting – May 10, 2012
Job Task Analysis (JTA)
Course Content Review
- 2nd Focus Group Meeting – July 10, 2012
JTA Verification
Draft Course Outline
- Report to Stakeholders – August 20, 2012

Job Task Analysis (JTA)

DACUM Chart – Developing A Curriculum



A	Develop Project Plan	A-1 Review Project Assignment	A-2 Develop Traceback Timeline / Flowchart	A-3 Identify Immediate Objectives	A-4 Assemble Project Team	A-5 Coordinate Individual Responsibilities	A-6 Review Product/Hazard References
		A-11 Schedule Firm Visit	A-12 Schedule Farm Visit	A-13 Coordinate Sample Plan (with labs)	A-14 Verify Project Plan		
B	Conduct Traceback Investigation	B-1 Conduct Traceback Interviews	B-2 Conduct Traceback Walk-Through	B-3 Document Manufacturing Process Flow	B-4 Collect Traceback Records	B-5 Assess Traceback Records	B-6 Time-Bracketing Implicated Product (receive & ship)
C	Conduct Manufacturing Environ. Assessment	C-1 Conduct Environmental Interviews	C-2 Conduct Firm Walk-Through (process flow)	C-3 Collect Samples (product, environ.)	C-4 Assess Production Records	C-5 Track Personnel Movement	C-6 Track Implicated Product Movement
		C-11 Compile Environmental Team Findings	C-12 Report Environmental Team Findings				
D	Conduct Farm Environ. Assessment	D-1 Implement Bio-Security Procedures	D-2 Complete Farm Questionnaire	D-3 Review On-Farm Food Safety Plan	D-4 Conduct Additional Interviews	D-5 Map Possible Contaminant Sources	D-6 Survey Farm
		D-11 Track Farm Input Movements	D-12 Track Personnel Movements	D-13 Track Equipment Movements	D-14 Verify Sanitation Procedures	D-15 Evaluate Wildlife / Pest Controls	D-16 Collect Farm Samples
E	Communicate Findings	E-1 Compile Findings	E-2 Finalize Flowchart & Timeline	E-3 Prepare Compliance Findings	E-4 Conduct Firm Closeout Meeting	E-5 Provide Sample Results (to firm per District policy)	E-6 Draft Investigation Report

Course Outline



I. Developing the Project Plan

A. Review Project Assignment – (Background / Incident Package)

1. Assignment to FDA District Office
2. Request for Assistance to State/Local Regulatory Partner

Group Exercise Packet A – First Case Histories

B. Determine Information Needed

Group Exercise Packet B – Sample Assignments

C. Assemble Project Team

1. Defined Project Team – Engage Various Agencies/Partners/Experts
2. Review Product/Hazard References
3. Review Establishment History for Each Firm
4. Coordinate & Assign Individual Responsibilities – Divide Workload

D. Logistics* (*as needed)

1. Develop Safety Plan (if needed)
2. Determine Project Logistics
3. Gather Investigation Supplies
4. Schedule Visit With Firm / Schedule Farm Visit (if appropriate, per protocols)
5. Coordinate Sampling Plan w/Lab(s) / Identify Shipping Points & Logistics

E. Verify Project Plan

1. Share schedules
2. Exchange/Verify Contact Information

Group Exercise Packet C – Additional Case Histories

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The First “Train-the-Trainer” Opportunities

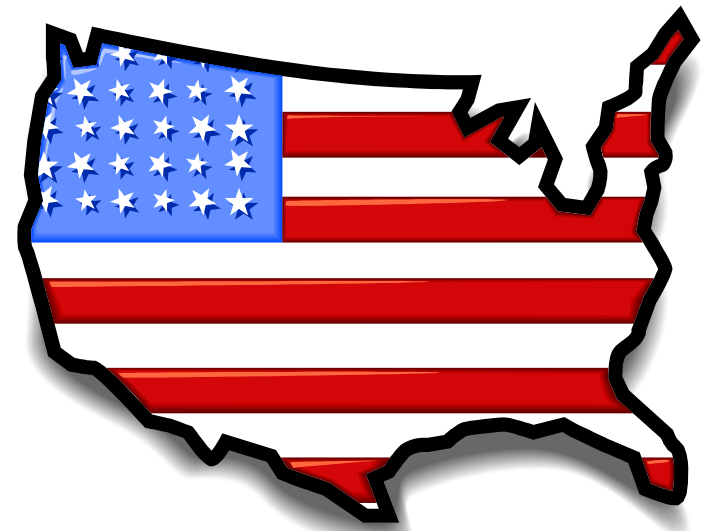
Pilot Course: January 29 - February 1, 2013
Washington, DC

2nd Course: April 30 - May 3, 2013
Walnut Creek, CA

3rd Course: August 6-9, 2013
Indianapolis, IN



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FY14 - "Train-the-Trainer" Continues...

1st Course: January 14-17, 2014
Jacksonville, FL

2nd Course: April 22-25, 2014
Dallas, TX

3rd Course: August 12-15, 2014
Springfield, MA



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FY15 – More "Train-the-Trainer"

1st Course: January 2015
Seattle, WA

2nd Course: May 2015
Harrisburg, PA

3rd Course: August 2015
St. Louis, MO



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FY16 – Yet MORE "Train-the-Trainer"

1st Course: January 2016
Richmond, VA

2nd Course: May 2016
Denver, CO

3rd Course: September 2016
Minneapolis, MN



ER220 Traceback Investigations



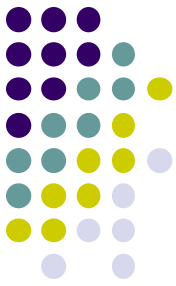
FY17 – Yet MORE "Train-the-Trainer"

- 1st Course: January 2016
Los Angeles, CA
- 2nd Course: May 2016
Memphis, TN
- 3rd Course: September 2016
Providence, RI



This is YOUR course...

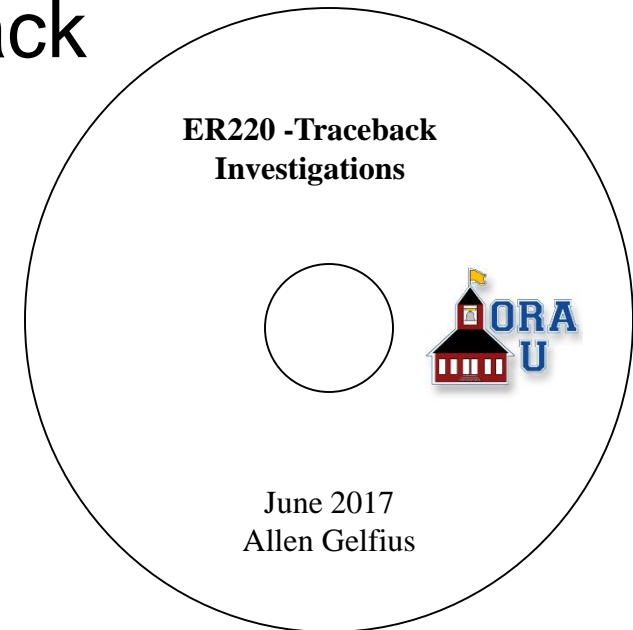
- Make the most of it
- Feel free to ask questions
- Accept the overwhelming
- Network and share experiences



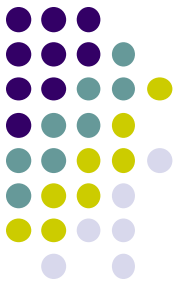
ER220 Course CD



- Agenda & Course Support Documents
- PowerPoints with Speaker Notes
- Exercise Guidance
- Case Study with Actual Traceback
(Redacted Records)
- Roster of Participants



Anatomy of an Outbreak investigation



Disease Surveillance

Epidemiological investigation

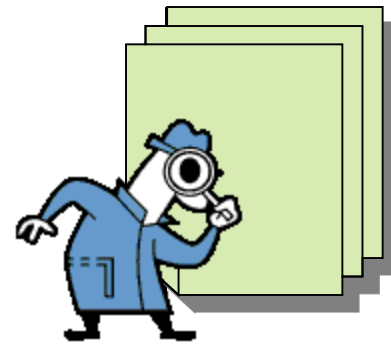
Laboratory Analysis

Environmental investigation

Traceback / traceforward

Product investigation

What is an FDA Traceback?



- **Documents the distribution through the supply chain, and the source(s) of a product that has been implicated in a foodborne illness investigation.**

REGULATORY TRACEBACK

- Collect hard copy records at each firm

INFORMATIONAL TRACEBACK

(“Epi Traceback”)

- Collect information via phone, email, etc.

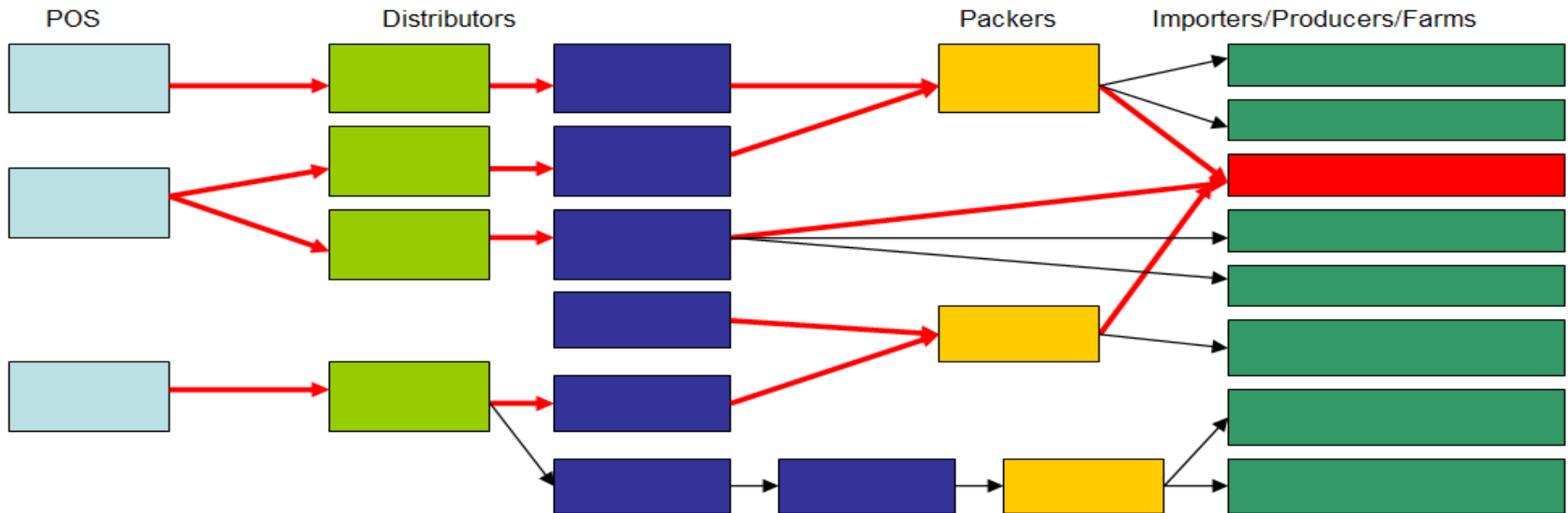
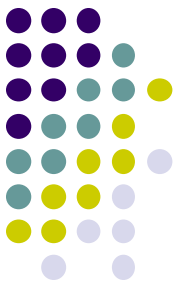
**Salmonella enteritidis – Chicken or the Egg?
Multi-state Outbreak January-April 2013**



TRACEBACK INVESTIGATION TIMELINE (DRAFT)

	February														March															
	M 8	9	W 10	11	F 12	13	14	M 15	16	W 17	18	F 19	20	21	M 22	23	W 24	25	F 26	27	28	M 1	2	W 3	4	F 5	6	7	M 8	
AT Spamps, PA, CA																														
FROM Sea One, PA			20							22							20								15		22			
FROM Samuels & Sons, PA		15										15												15						
AT Sea One, PA																														
FROM MMI Food, CA																	440 + 484													
FROM JFC Intl, MD		20+ 30																												
AT MMI Food, CA																														
FROM Her Cheng Fishery Co, Taiwan		7524 + 2610																												

Traceback Investigation Flow Diagram



Point-of-Service

Date and time food prepared
 Date and time food served
 Delivery rcpt date, time, qty
 Stock rotation
 Menu and recipes
 Food turnover/shelf-life
 Inventory
 Food product identifiers
 Product/Environmental sampling
 Ordering practices

Distributors

POS deliveries
 Incoming deliveries
 Product identifier info/Lot #
 Stock rotation
 Bill of Lading
 AWB
 Transportation time

Packers

Distributor deliveries
 Incoming deliveries
 Product identifier info/Lot #
 Stock rotation
 Bill of Lading
 AWB
 Transportation time

Importers/Producers/Farms

Custom Entry Number
 Invoice
 Bill of Lading
 Date of Production
 Amount of Product
 Production conditions
 Lot #

Key Points



- CONFIDENCE
 - Leadership must have confidence in the trace
- TEAMWORK
 - Select a leader of the team
 - need more than one set of eyes on a traceback leg
 - experienced/trained staff on the traceback team
- DOCUMENTATION
 - Bills of lading, invoices, etc – more than just Excel spreadsheets from firms
 - Ownership/Responsibility for collected records



What are the steps?

1. Decide whether to trace or not
If yes, is it one or more products?
2. Determine clusters to trace
3. Determine the time period to bracket to collect information
4. Collect the information/records, send asap
5. Decipher and analyze
6. Connect the dots / Identify Convergence

Decide what clusters to trace...



Ideally those with:

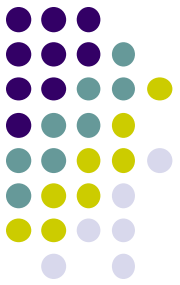
- 4 or more cases in a cluster, the larger the better
- 3 distinct geographic areas
- Good food historians, and/or key cases w unique histories, and minimal exposures before onset
- Documented food exposure – receipts, shopper card
- Varying types of establishments (groc, restaurant)
- Not complicated with food-handler issues

Traceback Challenges

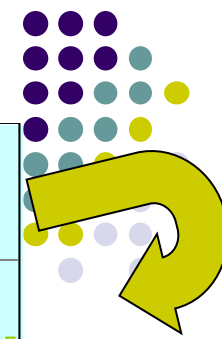


- Limited Resources (staff, budget, time, etc.)
- Logistics & Support (distance to travel, admin. support, travel limitations)
- Technology Limitations
- Multiple Commodity Responsibilities (regulatory work beyond foods)
- Competing Outbreaks
- Limited Experience (knowledge and/or training in tracebacks)

Traceback Challenges (contd.)



- Ongoing outbreak; need to act fast
- Large numbers of sporadic cases
- Poor consumer recollection of consumption history and lack of specific product information
- Multiple product varieties identified
- Multiple products w/multiple ingredients identified
- Multiple sources of same product at POS
- Lack a rapid and rigorous mechanism to link shipments (or *item of in a shipment*) from farm to table, factory to fork, boat to throat, etc...



Lack of **identifier**
that connects thru chain

Restaurant Supplier Co.				Date: 5/5/2008	Invoice #: 38947
Section	QTY.	Pack	Size	Description	Code
454681	100	25	25#	Tomato Bulk 6x6 LG	501785

the restaurant		Date: 5/5/08	Invoice #: 89000	
SECTION	QTY	PACK	SIZE	DESCRIPTION
615444	6	50	50#	Yellow Onion Med 050#
602588	6	50	50#	White Onion Med 050#
645879	2	16	3#	Bag White Onion 016@
648055	1	10	10#	Oragne Hbanero 010#
648044	10	25	25#	Tomato Bulk 6X6 LG
692000	1	12	32OZ	Mini Bag Red Potato 012@

		Shipping Report	
Tomato Distribution Company		DATE	May, 4 2008
22 Loveapple Way Toma, TO 00001		CUSTOMER ID	[ABC12345]
SHIP TO	The Restaurant 8 Gourmet Lane Foodtown, USA 301-555-5923	BILL TO	The Restaurant 8 Gourmet Lane Foodtown, USA 301-555-5923
ORDER DATE	ORDER NUMBER	SHIP DATE	
5/3/08	34511	5/3/2008	
Pallet No	Cartons / manifest / Product	Size	

Fruit Growers, Co.		Invoice No. 9260
Fruitplant Avenue 00005		To: Tomato Distribution Co. 22 Loveapple Way Toma, TO 00001
April 20, 2008		

Shipper: Fruit Haulers R Us	FIRM X	ORDER NUMBER 8506
Consignee: Fruit Growers, Co. 1985 Fruitplant Ave. Pick, EM 00005		Shipment Date 04/25/2008
	Destination	Est. Arrival 04/25/2008
	Pallet count	7

Pallets	Boxes	Product	Size
1	88	Whole Tomato	(88) 5*5,3
2	88	Whole Tomato	(88) 5*5,3
3	88	Whole Tomato	(88) 5*5,3
4	72	Whole Tomato	(72) 5*5,3
5	88	Whole Tomato	(88) 5*5,3
6	88	Whole Tomato	(88) 5*5,3
7	88	Whole Tomato	(88) 5*5,3

Description	
Box, Greenhouse Tomatoes, Size '35'	
4421	
Cases / Product	
100	Beefsteak Tomato
100	Beefsteak Tomato
100	Beefsteak Tomato
100	Beefsteak Tomato

Tomato	4X5
Tomato	4X5
Tomato	4X5
Tomato	4X5
Tomato	4X5
Tomato	4X5
Tomato	4X5

[Phone] with any questions or comments.
FOR YOUR BUSINESS!

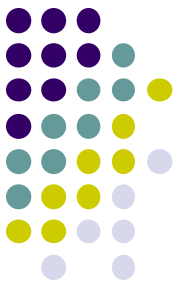


Leveraging Resources

- Integrated Food Safety System
- FDA Assistance
- Rapid Response Team
- Food Safety Task Force
- Another In-State Agency
- Neighbor State Agency
- Contract 3rd party for certain situations

Establish Contracts, MOU, SOPs before the outbreak hits

Ensure trained staff before outbreak hits

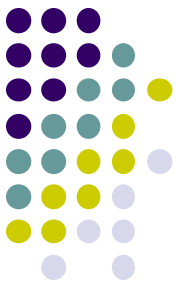


Leveraging Resources (contd.)



- FSMA required product traceability
- Food Shield
- Lab Networks (PulseNet, FoodNet, etc.)
- Palantir Web-Based Dashboard
- Training Exercises
(ER220, CDC, and other course-in-a-box options)

Important to Remember Industry Role – Engage early!



Firm(s) involved:

- Assignments – share why FDA is there
- Provide information and records
- Recall, warn consumers

Industry Association:

- Seasonality/sources
- Market patterns
- Distribution patterns
- Assist in getting support from others in industry

Important to keep industry informed and engaged!





When to apply options

- Consider each option & when to apply
- Questions that might help decide:
 - Is an investigation likely at that firm?
 - Are samples needed? Are samples possible? Do we just need records and general info?
 - Is there an adverse firm history?
 - Is there info to help narrow which food/ingredient, or do we have an implicated food/ingredient?
 - Is the firm located close to a bordering state?



Summary

- Before the outbreak hits, establish framework to garner resources when needed
- Train ahead and maintain
 - training resources and documents available
- Reach out early; continue communications

*Increase public health protection
by leveraging resources*



ER220 Traceback Investigations



Questions?

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