

Framing the Issue: *FDA Perspective* Product Tracing

Sherri A. McGarry
Center for Food Safety and Applied Nutrition
Food and Drug Administration



Overview

- Federal Register Notice
- Anatomy of outbreak investigation
- Product Tracing Process
- Product Tracing Challenges
- Summary



Federal Register Notice

FDA Perspective

Context

- Foods for humans & food for animals
- Existing authorities and regulations
 - FFDCA
 - 21 CFR
 - Public Health Service Act
- Need to go beyond for faster, more targeted product tracing

Whole Chain Traceability

Considerations for Effective Product Tracing Systems

- Key information elements
 - Who manufactured the product
 - Who's sending forward and who's receiving
 - Way to link info internally and externally through the supply chain
 - Date shipped and recd
 - Physical location food shipped and recd
 - Quantity, how packaged



FDA Issues and Questions

■ Core Information Elements

- Lot codes or other identifier
- Shipment identifier
- Where should info reside (packaging, records)
- At what stages or stages in the chain
- Standardized set of info elements

FDA Issues and Questions

■ Records

- Lot code or other identifier
- Who should maintain beyond current requirements
- Linking record, standard format
- Electronic, human readable

■ Transmitting trace data to FDA

FDA Issues and Questions

- Role of Risk
- Costs, Benefits, and Feasibility
- Outreach, education on current requirements

Anatomy of an Outbreak investigation

Disease Surveillance

Epidemiological investigation

Laboratory Analysis

Environmental investigation

Traceback / traceforward

Source investigation

FDA Traceback Process

FDA Traceback Objective

- Find convergence or commonality
- Identify source and distribution of implicate food and remove from consumers
- Determine potential routes and/or source of contamination to prevent future illnesses

Traceback process

- Based on epidemiological data, select cases/clusters to trace
- Collect records at Point of Service and identify shipments and suppliers of interest
- From POS info, document each subsequent level in supply chain
- Either narrow or expand depending on:
 - records available;
 - number of shipments in time frame of interest; and
 - ability to link shipments and items within the shipment forward and back

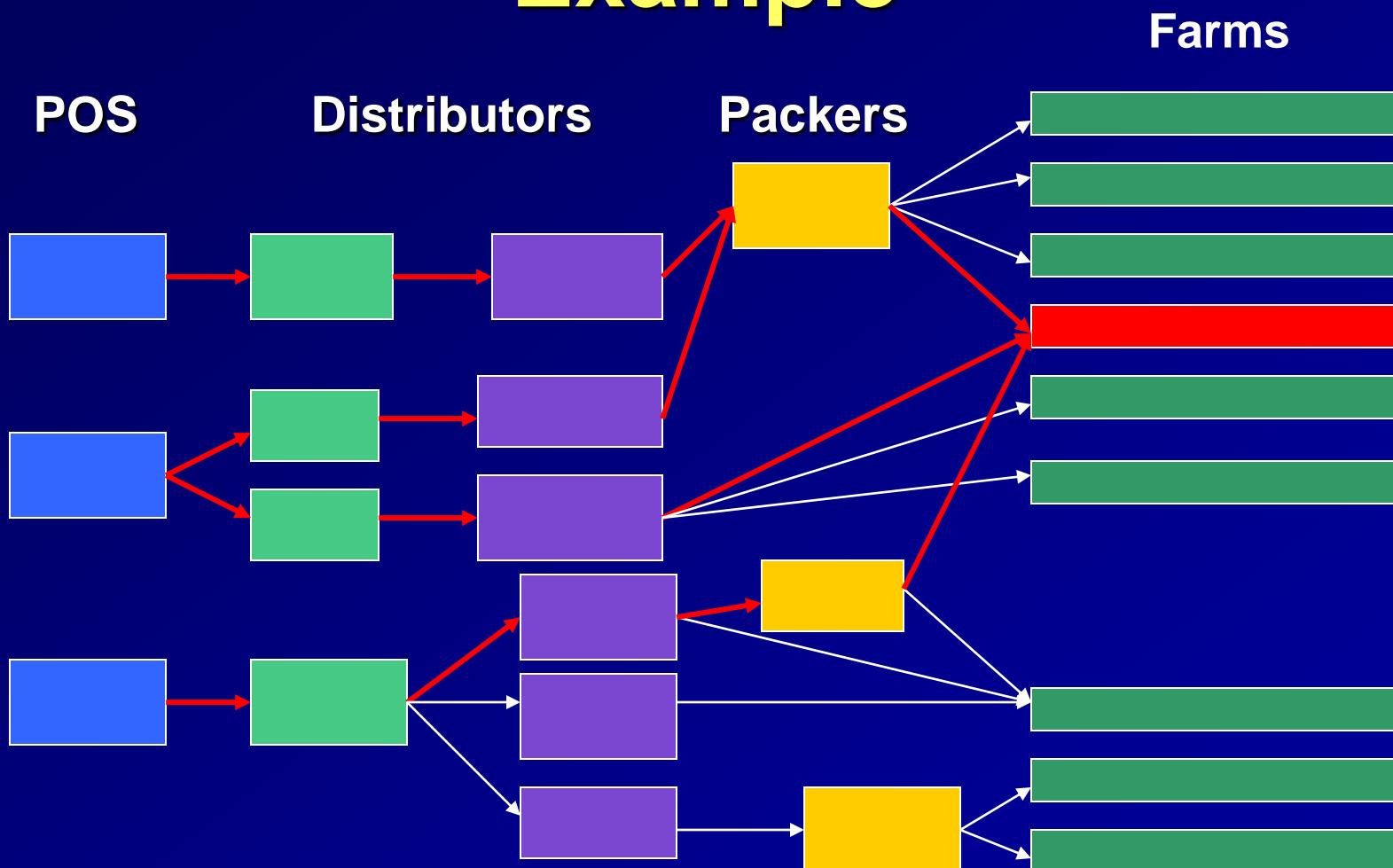


Further Steps

- Each step identify shipments of interest based on time frame and linking documents
- Develop flow diagram and time lines
- Don't see common sources until several levels or at very end so no way to know early on if the trace will be conclusive



Traceback Flow Diagram Example



What's Critical?

- Illness exposure information, clusters
- Records with date of receipt
- Records that are legible
- Records with an identifier or other means to connect next level in supply chain
- Turn around time and pattern of buying
- Industry provides records in timely fashion



Trace over the Border

- Use Registration and Prior Notice info
- FDA requests assistance to conduct onsite investigations in cooperation with foreign government
- Obtain records to close the link to the source



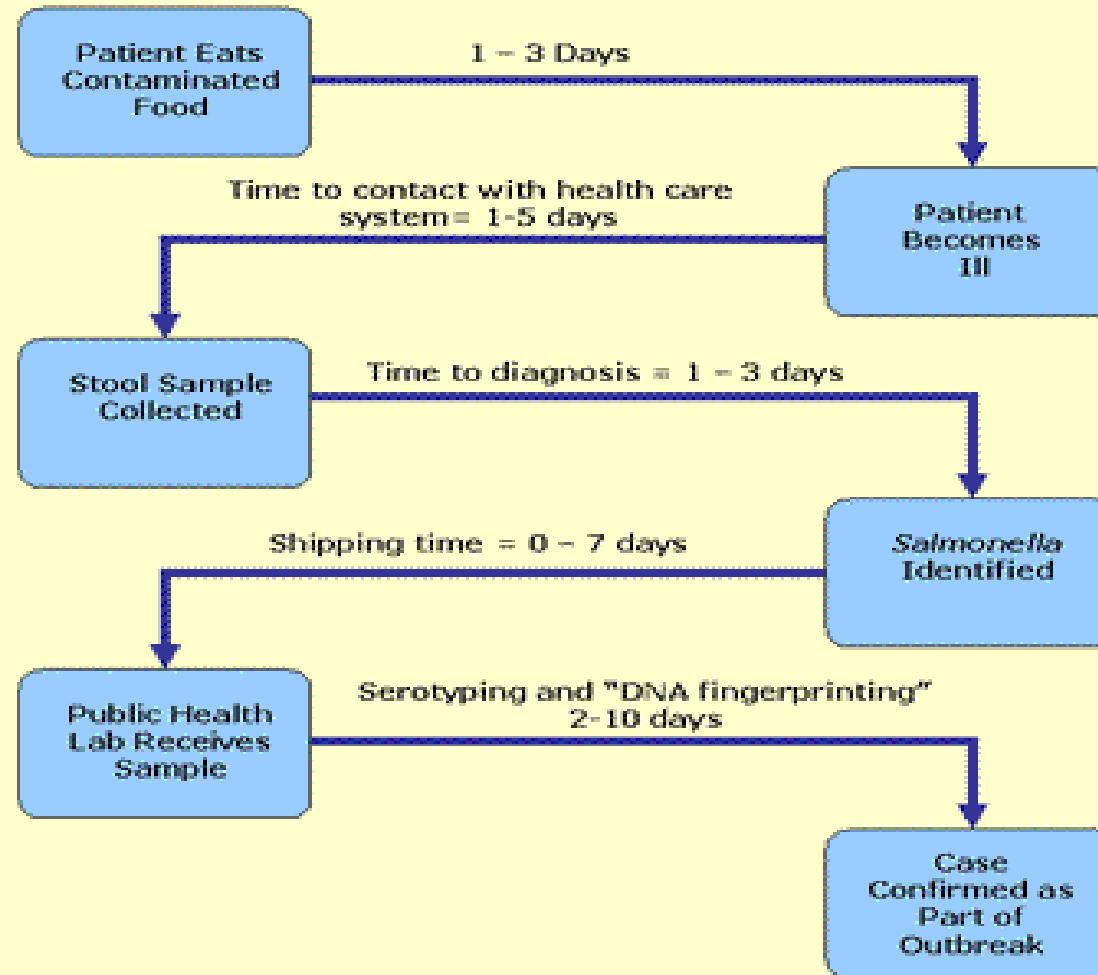
FDA Traceback Challenges

Broad Traceback Challenges

- Competing priorities
 - H1N1
 - Economic
- Varying resources and expertise
- Reluctance and time
 - Where's the positive sample?
 - Epi? What's that?



Timeline for Reporting of Cases



Source: CDC

Traceback Challenges

- an 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



Traceback Challenges

- Billing address versus shipment info
- From DC to Retail
 - Unclear what was shipped where
 - Turn-around at DC/warehouse
 - Ability to narrow shipments of interest
 - Connecting incoming and outgoing



Product Tracing Challenges

- Perishable product
- Lack of rapid connectivity
- Lack of unique identifier
- Repacking and co-mingling
- Addresses, ship and receipt dates
- Packaging (ie. cases) gone
- Product no longer available
- Producing states importing as well



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	50173		

the restaurant		Date	Invoice #	
5/5/08	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	BILL TO
8 Gourmet Lane	Foodtown, USA	8 Gourmet Lane
301-555-5923	301-555-5923	301-555-5923
	ORDER NUMBER	SHIP DATE
34511		5/3/2008
Cartons / Manifest / Product		Size
44 / Beefsteak Tomato		4X5
44 / Beefsteak Tomato		4X5
44 / Beefsteak Tomato		4X5
44 / Beefsteak Tomato		4X5
86 / Beefsteak Tomato		4X5
44 / Beefsteak Tomato		4X5
44 / Beefsteak Tomato		4X5

Fruit Growers, Co.

Shipper:	FIRM		ORDER NUMBER	Invoice No.
Fruit Haulers R Us			8506	9260
Consignee:			To:	
Fruit Growers, Co.			Tomato Distribution Co.	
1985 Fruitplant Ave.			22 Loveapple Way	
Pick, EM 00005			Toma, TO 00001	
	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	

Customer Service at [Phone] with any questions or comments.
THANK YOU FOR YOUR BUSINESS!

Summary

- Food contamination events are being detected earlier
- A rapid and interoperable product tracing system may reduce illness
- Need for a standardized approach globally
- Advance preventive food safety policies from lessons learned from these events
- Communication and collaboration is Key

Submit data and comment to Docket