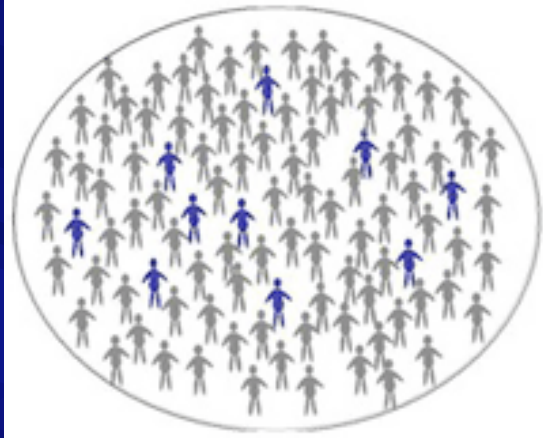


Product Tracking Systems for Fresh Produce

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Anatomy of an Outbreak investigation



Product Investigation



Traceback Investigation

Traceback Challenges



Trace Initiatives



Epidemiological Association with Food

Investigation of an Outbreak of *Salmonella* Saintpaul Infections Linked to Raw Alfalfa Sprouts

Highlights

- CDC is collaborating with public health officials in many states and the FDA to investigate a multistate outbreak of human infections due to *Salmonella* serotype Saintpaul linked to eating raw alfalfa sprouts.
- FDA and CDC recommend that consumers not eat raw alfalfa sprouts, including sprout blends containing alfalfa sprouts, until further notice because the product has been linked to *Salmonella* serotype Saintpaul contamination. Other types of sprouts have not been implicated.



SOURCE: <http://www.cdc.gov/salmonella/saintpaul/alfalfa/>

Product Investigation – Goals

- Obtain specific product information that will enable product removal and inform consumers
- Use epidemiological information to investigate “best” cases or clusters of illness to traceback
- FDA investigates all points in distribution chain to determine where in the chain the product was contaminated and how

Product Investigation

- **Focus on time period of interest**
- Lot and batch info
- Review process flow
- Review processor records
- Collect samples – product and environmental
- Conduct **traceback** & forward (distribution)
- Determine if other products may present risk

FDA Traceback



The method used to determine and document the distribution and production chain, and the source(s) of a product that has been implicated in a foodborne illness investigation.

Purposes:

1. Identify the source and distribution of implicated food and remove contaminated product from marketplace,
2. Distinguish between two or more implicated food product, and
3. Determine potential routes and/or sources of contamination in order to prevent future illnesses.

Pairing Exposure and Point of Service

- Rely on state and CDC epidemiological investigation to implicate the food causing illness
- Local, state, and/or FDA may collect point of service records based on exposure dates of ill consumers
 - Review to determine shipments and suppliers of interest

Product Tracing - 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

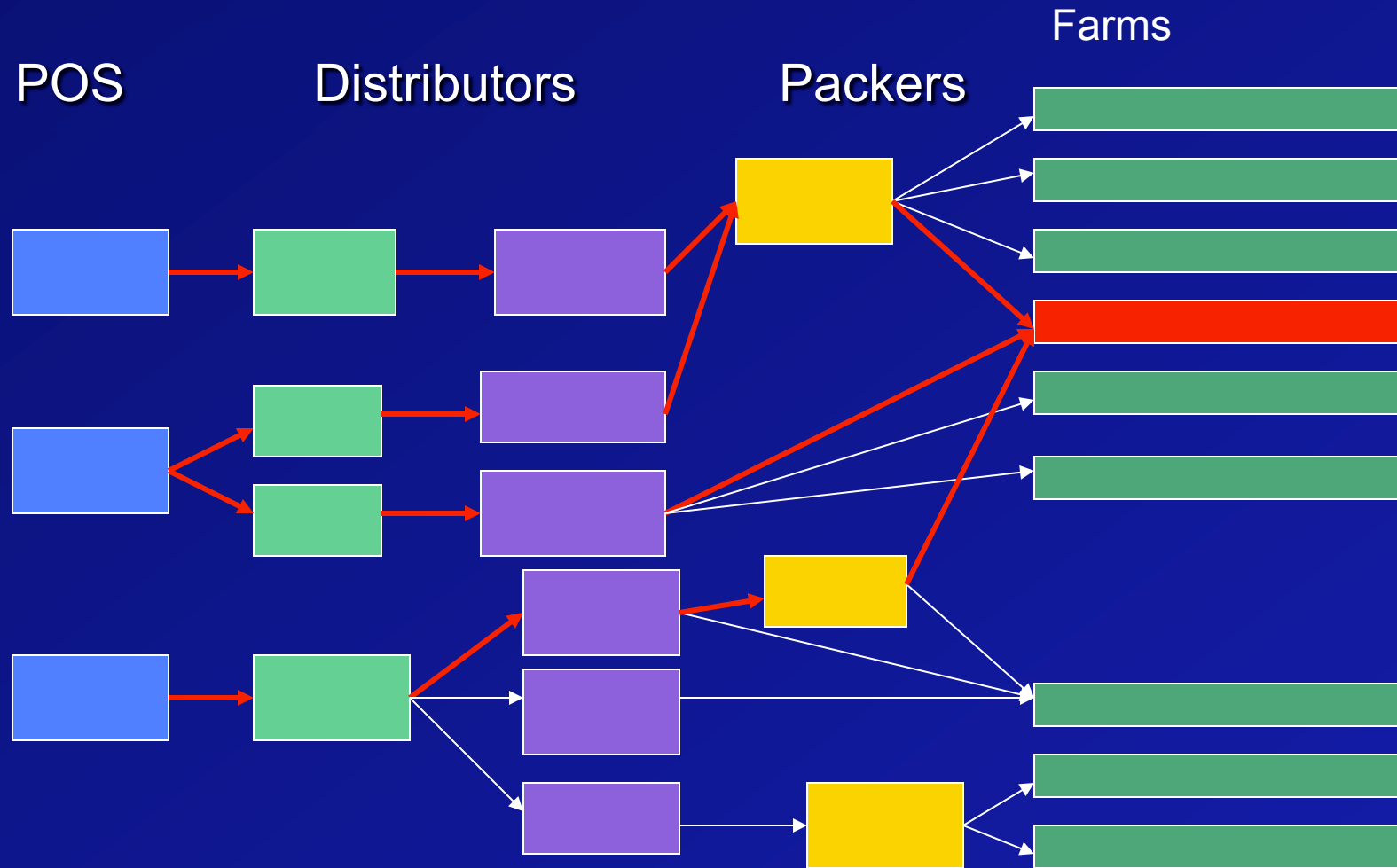
Traceback process – Next Step

- Next level in supply chain
- Identify shipments and suppliers of interest at warehouse, distributor level
 - Critical info: same as before
 - Can either narrow or expand depending on:
 - info 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



Further Source Investigation



Reducing Risk to consumers

- Recall – voluntary industry removal of product from marketplace
- Invoke record access under BT Act, if needed
- Getting the message out to stakeholders

Goal

Obtain specific product information that will enable product removal from the marketplace and inform consumers

Industry Role

- Earlier information may limit scope
- Mobilize industry before we knock on the door
- Explore ways to overcome legal issues



Note: FDA will continue to reach out earlier than in the past

Salmonella Saintpaul Outbreak

Tomatoes/Hot Peppers
2008



Roma and round



Complex and evolving –

Epidemiological information led to multiple and multi-ingredient vehicles

Early Sequence of Events

- Late May - CDC gave FDA an early alert of S. Saintpaul illnesses in NM & TX
 - tomatoes likely vehicle
- CDC notifies FDA - tomatoes implicated
- FDA initiates traceback investigation
- June 3 – Consumer advisory for NM & TX raw red round and roma/plum tomatoes

COMMUNICATIONS

➤ **w/Industry**

- Reached out early-on for harvest/distribution
- FDA hosted routine calls, daily at one pt

➤ **w/State partners**

- Reached out for help identify harvest areas
- FDA hosted 50-State conference calls

➤ **w/Consumers**

- press briefings, consumer groups

What to Trace?

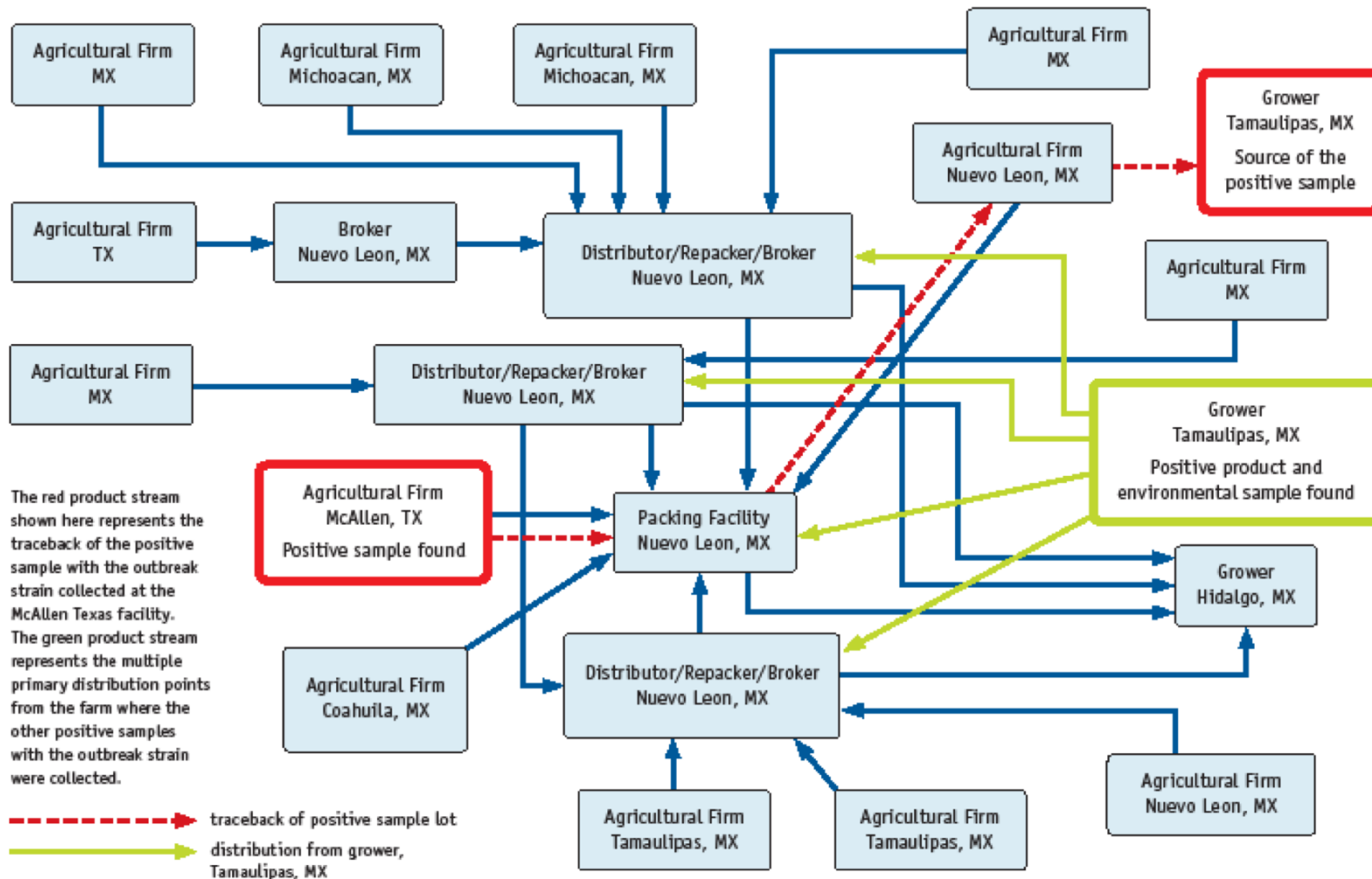
- Select geographically diverse to triangulate
 - Strengthens evidence for commonality
- Prefer cluster vs sporadic case traceback
- No clusters so select cases with the best:
 - Exposure info, receipts to document dates, good food historians, etc
- FDA & CDC collaborate to identify best cases to trace

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

Salmonella Saintpaul Outbreak Traceback & Distribution

Partial view of the traceback & distribution of peppers from Mexico: July 16 – July 22, 2008

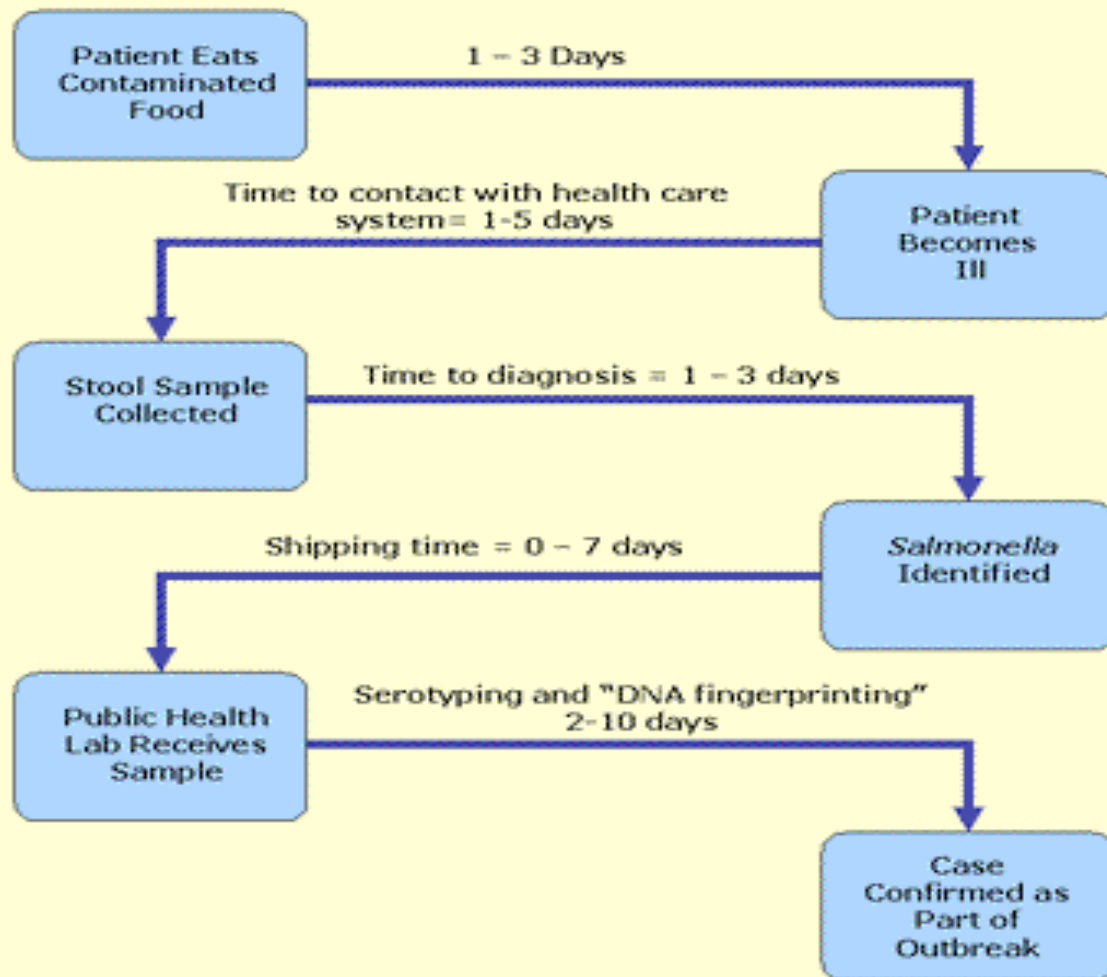


Hot Pepper Tracebacks

- Same challenges as in tomatoes
- Traceability is an issue
- Spider web of relations among points in distribution chain

Traceback Challenges

Timeline for Reporting of Cases



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

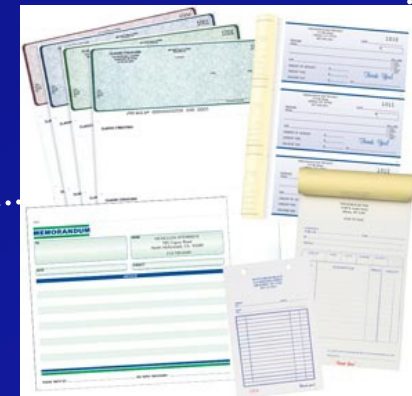


Product Tracing Challenges

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

Connectivity

The ability to link food through all points of the food distribution from farm to point of sale



Assurance

The certainty one has that the records for product received correctly match the product distributed

Linking invoices, bills of lading, etc. to production lots, boxes, cartons, cases, 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	50178

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			
22 Loveapple Way Toma, TO 00001		DATE	May, 4 2008
		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 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
Customer Service at [Phone] with any questions or comments.			
THANK YOU FOR YOUR BUSINESS!			

Fruit Growers, Co.		Invoice No. 9260
1985 Fruitplant Avenue		To: Tomato Distribution Co. 22 Loveapple Way Toma, TO 00001
ORDER NUMBER 8506		Description Tomatoes, Size '35'
Cartons / Product		Description
88 / Whole Tomato		Whole Tomato
88 / Whole Tomato		Whole Tomato
88 / Whole Tomato		Whole Tomato
72 / Whole Tomato		Whole Tomato
88 / Whole Tomato		Whole Tomato
88 / Whole Tomato		Whole Tomato
88 / Whole Tomato		Whole Tomato

Shipper: Fruit Haulers R Us		FIRMIX	
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

FDA Product Trace Initiatives

- Meeting with industry and vendors gaining better understanding of industry practices and technology available to improve the product trace system from farm to fork
- Contract to examine practices, make recommendations, and estimate costs

Product Trace Initiatives

- Two Public Meetings 2008
 - Transcripts available
 - October 16 & November 13
- Encourage industry efforts to improve product trace system farm to fork
- Exploring regulatory and other options

Key Points on Product Tracing

- Current systems need significant improvement
 - Connectivity of shipments through distribution chain
- Produce is most challenging to trace
- Industry and government are working cooperatively to improve systems

Summary

- Earlier detection and more rapid traceback may minimize illnesses in outbreaks
 - More targeted messaging if effective trace system
 - Industry plays vital role in improving systems
- Need to understand how contamination occurs to develop measures to minimize public health impact of current and future outbreaks
- Communication among all stakeholders is key in ensuring all pieces come together in protecting public health

Contact info and Acknowledgements

■ Acknowledgements

- Ellen Morrison, Director, FDA Office of Crisis Management
- Val Jefferson, Consumer Safety Officer, FDA/CFSAN

■ Sherri McGarry, 301-436-2084, Sherri.McGarry@fda.cfsan.gov

Traceback Investigations

FDA Guide to Traceback of
Fresh Fruits and Vegetables Implicated in
Epidemiological Investigations
(Updated June 2006)

http://www.fda.gov/ora/inspect_ref/igs/epigde/epigde.html

