

Improving Product Tracing: *FDA Perspective*

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Overview

- Product Tracing Process
- Product Tracing Challenges
- Product Tracing Policy Initiatives
- Next Steps

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 implicated food and remove from consumers
- Determine potential routes and/or source of contamination to prevent future illnesses

Traceback process

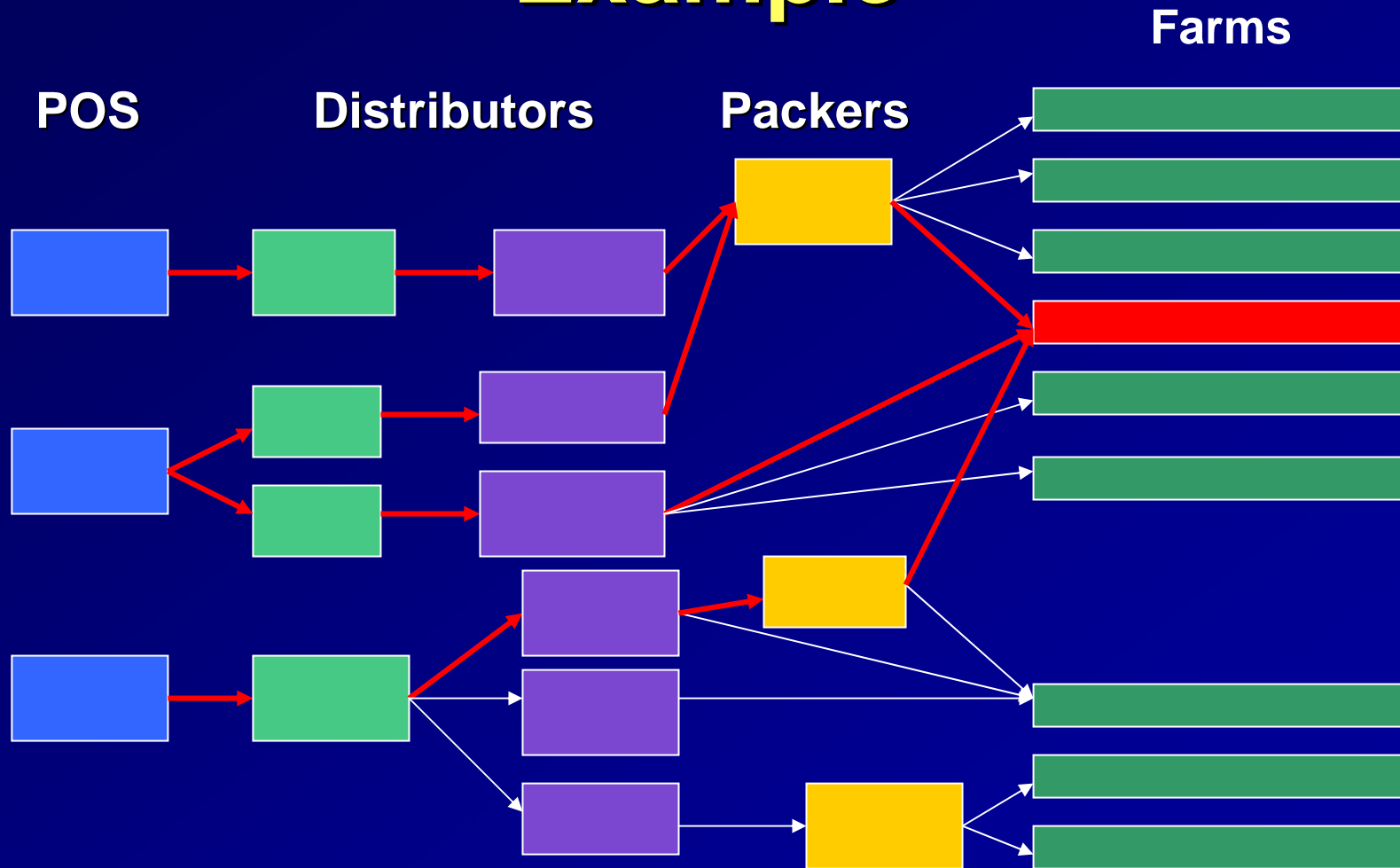
- Based on epidemiological data, select cases/clusters to trace
- Collect records at Point of Service and identify shipments and suppliers of interest
- From POS info, document each subsequent level in supply chain
- Either narrow or expand depending on:
 - records available;
 - number of shipments in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



Further Steps

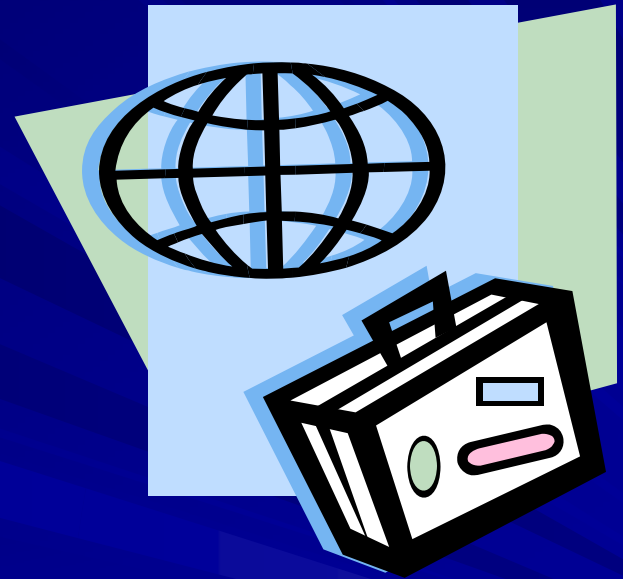
- Each step identify shipments of interest based on time frame and linking documents
- Develop flow diagram and time lines
- Don't see common sources until several levels or at very end so no way to know early on if the trace will be conclusive

Traceback Flow Diagram Example



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



What's Critical?

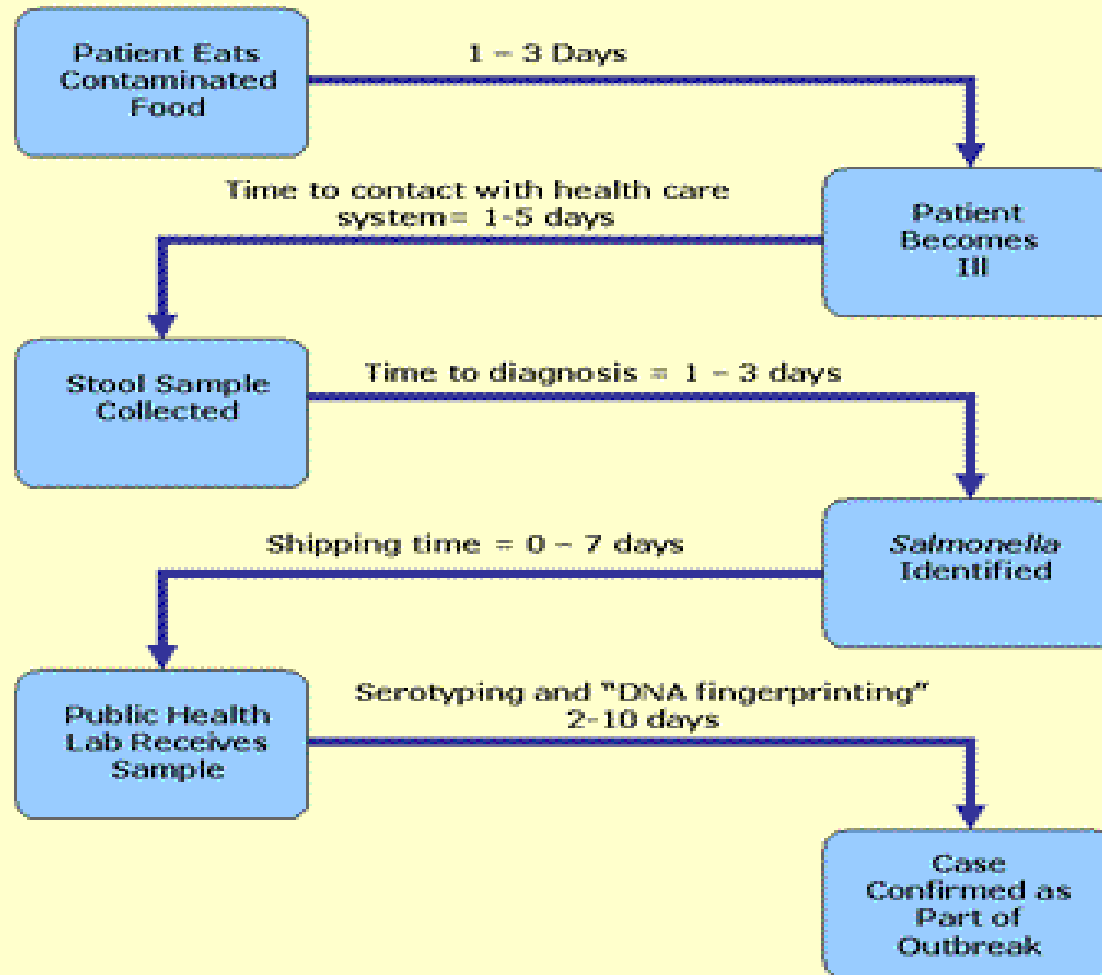
- Illness exposure information, clusters
- Records with an identifier or other means to connect next level in supply chain
- Records with ship date and receipt date
- Records that are legible
- Turn around time and pattern of buying
- Industry provides records in timely fashion



FDA 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


- 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



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

Fruit Growers, Co.		Invoice No. 9260
1985 Fruitplant Avenue		To: Tomato Distribution Co. 22 Loveapple Way Toma, TO 00001
ORDER NUMBER 8506		
Shipment Date 04/25/2008		
Destination 04/25/2008		
Est. Arrival 7		
Pallet count		
Description		
Tomatoes, Size '35'		

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!	

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

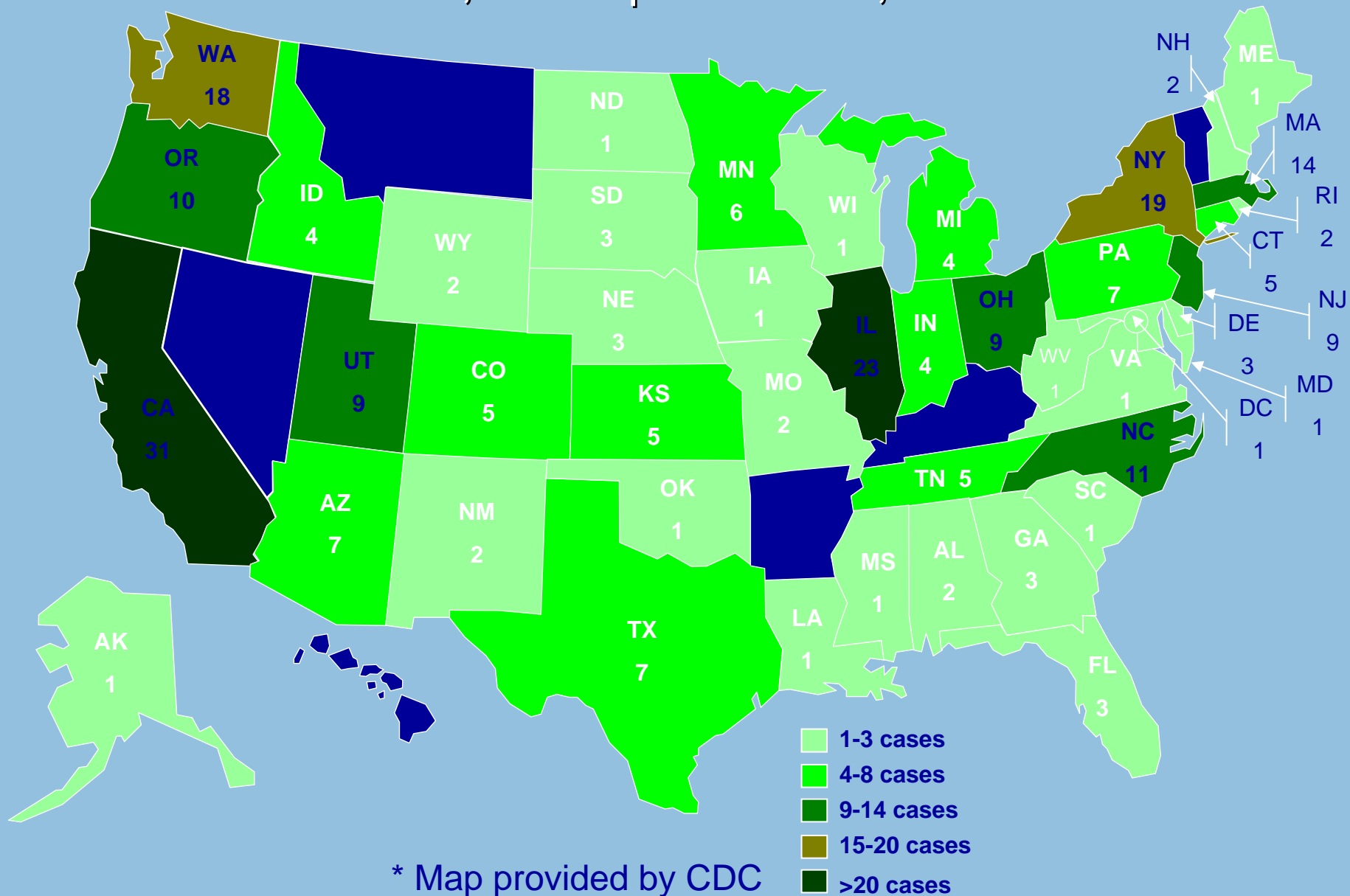
S. Montevideo outbreak

Salami products coated with
red and black pepper



Epidemiology

Total # Cases 252, 51 hospitalizations; 44 states and DC



Specific to Montevideo outbreak

- Data Silos not connecting in supply chain
- Receiving records w/o lot or other identifier
- Cross-contamination potential
- Parent lot relationship to sub-lots
 - Carrying or linking data thru supply chain
- Foreign industry practices not well known
- Following physical flow of product

Preliminary: subject to change



Key Areas for Improvements

- Product Connectivity /Linkages



- Documentation



- Speed

An interoperable system to rapidly link product (or ingredient) from farm/manufacturer to form

Product Trace Policy and Initiatives



Product Tracing for Foods

- High priority for the Administration and for Congress
- Reportable Food Registry – Sept, 2009
- 2 IFT Reports released in Dec, 2009.
Industry “best practices” and tomato
traceback exercise
- FDA & USDA held public meeting-Dec '09
- Joint docket w/USDA closed March 2010



Product Trace Public Meetings

- 2008 - Two Public Meetings - PRODUCE
- 2009 – FDA FSIS joint Public Meeting

ALL FOODS

- Purpose to stimulate and focus efforts on mechanisms to enhance product tracing
- Substantive comments from speaker panels and public comment
- Positive response to holding the meeting jointly with FSIS and FDA working toward an integrated food safety system

2009 Product Trace Meeting

■ Preliminary take-aways:

- Educate industry on current product tracing requirements and compliance with those recognizing that new authorities are needed in order for FDA to determine compliance routinely.
- Broad recognition of needing to enhance the current system to more rapidly trace contaminated food products.
- Needs to be global system, standardized information, and link along the full chain.



US Food Safety Policies

■ Food Safety Bills

- Food Safety Enhancement Act 2009

 - Passed the House

- FDA Food Safety Modernization Act 2009

 - In Senate preparing for vote

❖ Pilots...



Ongoing and Next Steps

- Reviewing transcripts and written comments from public meetings
- Keep an eye on and prepare for pending legislation
- Continue to gather data and input for short and long term

General Issues

Risks related to Spices

- Dialogue with ASTA and other industry associations
- April 20, 2010, FDA issued a FR Notice requesting comments and scientific data for a Risk Profile on spices
- Tidbit relating to RFR:
 - 6% of primary RF reports spices w/Salmonella contamination (since 9/09)

Summary

- Food contamination events are being detected earlier
- A rapid and interoperable product tracing system may reduce illness if we can identify source faster
- Need a standardized approach globally
- Advance preventive food safety policies from lessons learned from these events