

Fruit & Vegetable Industry Advisory Committee

Food Safety Working Group

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Anatomy of an outbreak investigation

Disease Surveillance

Epidemiological investigation

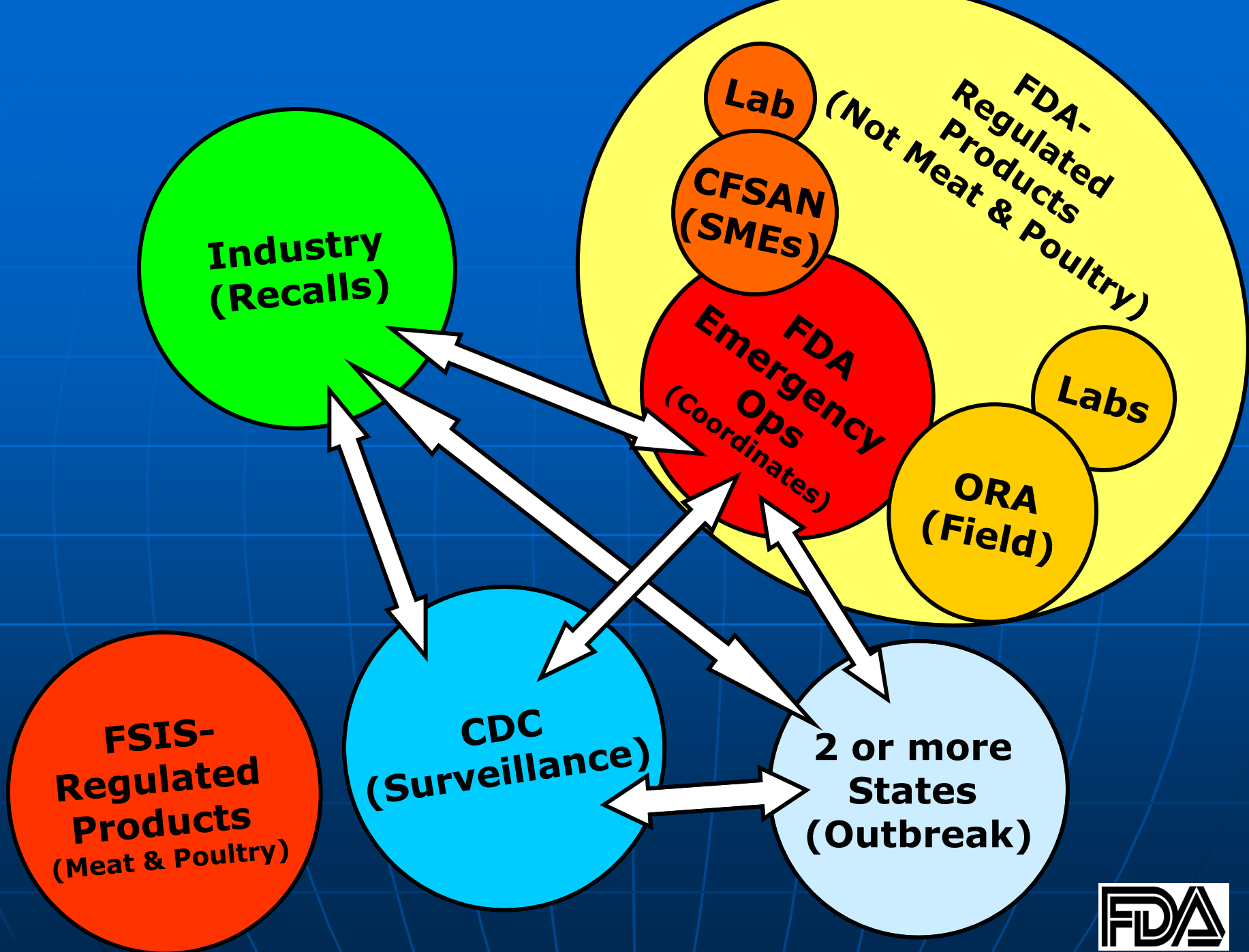
Laboratory analysis

Environmental investigation

Traceback / Traceforward

Manufacturer / Processor / Farm investigation



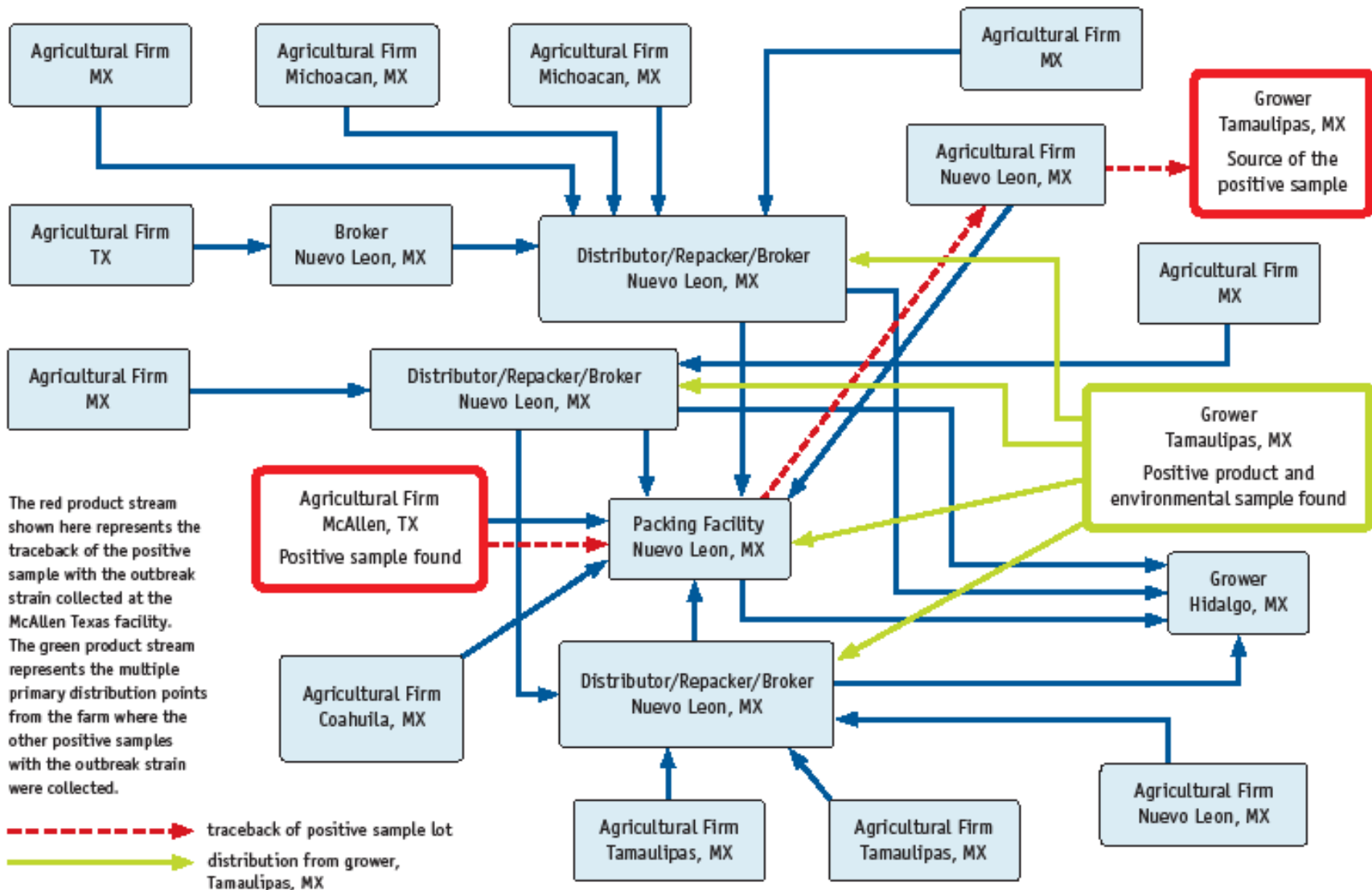


FDA Traceback Process



Salmonella Saintpaul Outbreak Traceback & Distribution

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



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



FDA Traceback Objective

- **Find convergence or commonality**
- **Identify source & distribution of implicated food & remove from commerce**
- **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 & identify shipments & suppliers of interest
- From Point of Service, document each subsequent level in supply chain
- Either narrow or expand depending on:
 - records available;
 - number of shipments in time frame of interest; &
 - ability to link shipments & items within the shipment forward & back

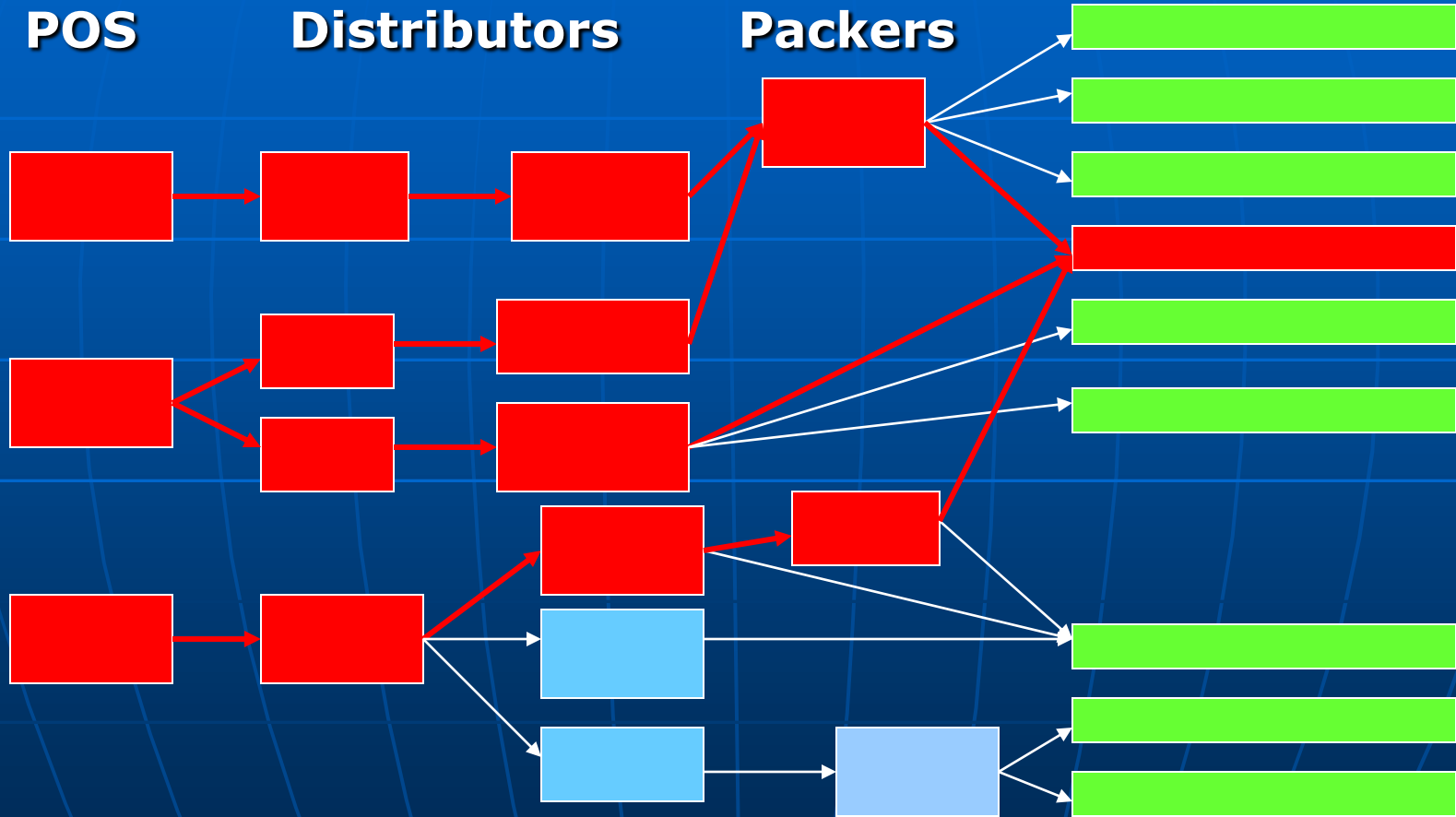
Traceback Flow Diagram

Farms

POS

Distributors

Packers



International Traceback

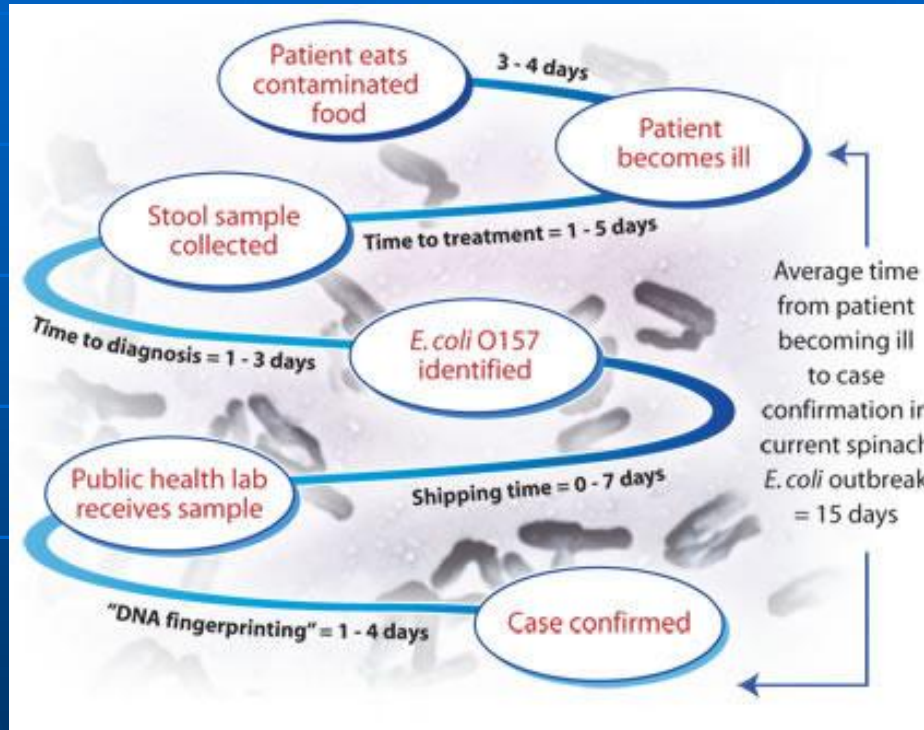


- **Use Registration and Prior Notice information**
- **FDA makes requests to conduct on-site investigations in cooperation with the foreign government**
- **Obtain records to close the link to the source**

FDA Traceback Challenges

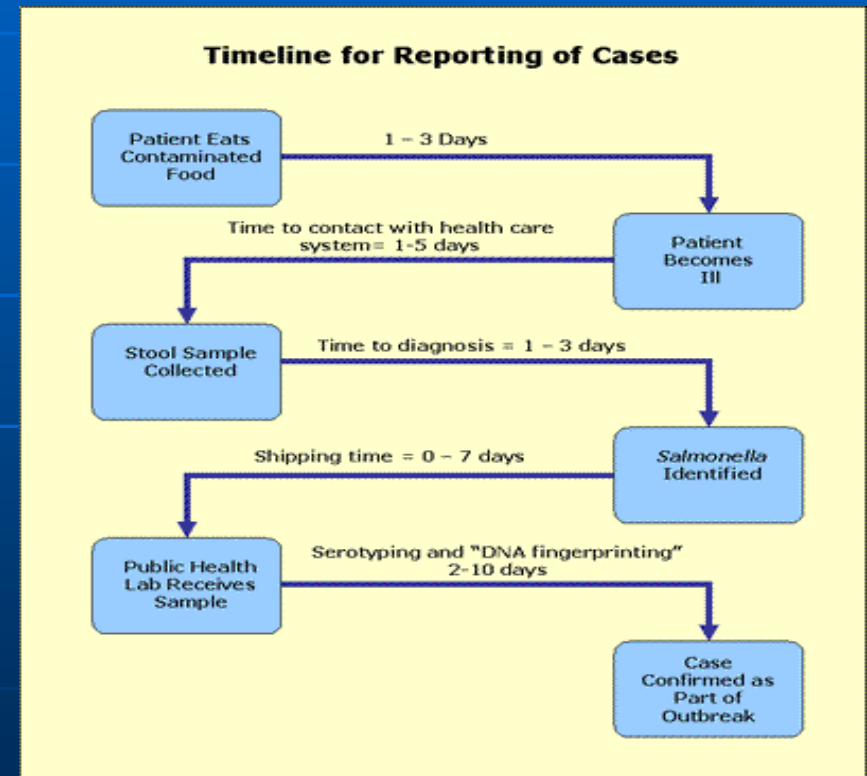


Typical Timeline of 5 to 28 days for Reporting Cases



***E. Coli* O157:H7**

Salmonella



Traceback Challenges

- **If an ongoing outbreak; need to act fast**
- **Large numbers of sporadic cases**
- **Poor consumer recall of food history & lack of specific product information**
- **Multiple product varieties identified**
- **Multiple products w/multiple ingredients identified**

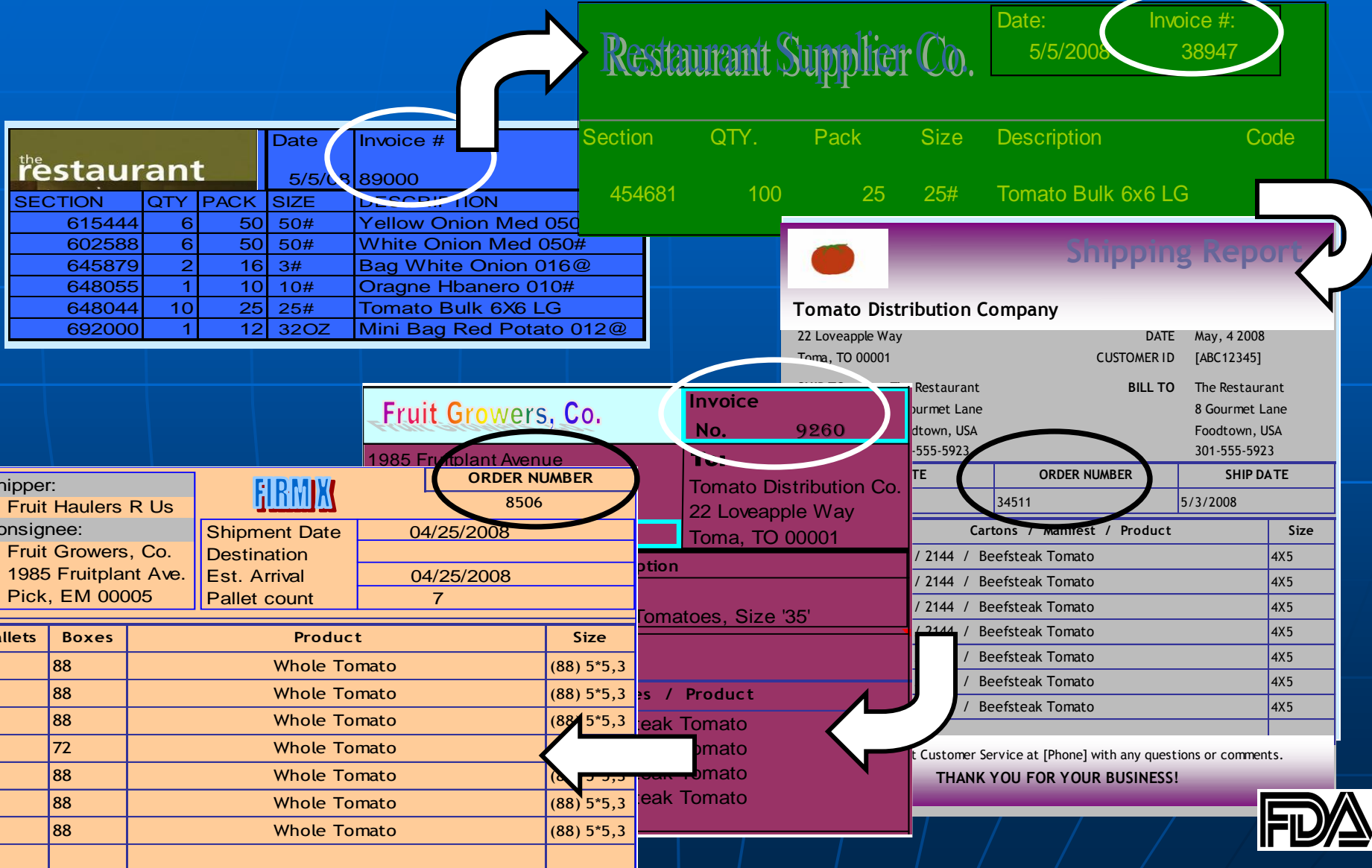


Product Tracing Challenges

- **Lack of rapid connectivity**
- **Lack of unique identifier**
- **Repacking and co-mingling**
- **Addresses, ship and receipt dates may be confusing**
- **Packaging discarded**
- **Product no longer available**



Lack of a unique **identifier** that connects the links of the chain



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@

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

Fruit Growers, Co.		Invoice No.
1985 Fruitplant Avenue		9260
ORDER NUMBER		
8506		
Shipment Date		04/25/2008
Destination		
Est. Arrival		04/25/2008
Pallet count		7
Pallets	Boxes	Product
1	88	Whole Tomato
2	88	Whole Tomato
3	88	Whole Tomato
4	72	Whole Tomato
5	88	Whole Tomato
6	88	Whole Tomato
7	88	Whole Tomato

Shipping Report		
Tomato Distribution Company		
22 Loveapple Way		DATE May, 4 2008
Toma, TO 00001		CUSTOMER ID [ABC12345]
Restaurant		BILL TO The Restaurant
Gourmet Lane		8 Gourmet Lane
Foodtown, USA		Foodtown, USA
301-555-5923		301-555-5923
ORDER NUMBER	SHIP DATE	
34511	5/3/2008	
Cartons / Manifest / Product	Size	
/ 2144 / Beefsteak Tomato	4X5	
/ 2144 / Beefsteak Tomato	4X5	
/ 2144 / Beefsteak Tomato	4X5	
/ 2144 / Beefsteak Tomato	4X5	
/ Beefsteak Tomato	4X5	
/ Beefsteak Tomato	4X5	
/ Beefsteak Tomato	4X5	
Customer Service at [Phone] with any questions or comments.		
THANK YOU FOR YOUR BUSINESS!		



Key Areas for Improvements

- **Product Connectivity / Linkages**

- **Documentation**



- **Speed**



An inter-operable system to rapidly link product (or ingredient) from farm / manufacturer to fork

Product Trace Policy and Initiatives



2009 HHS Inspector General Report

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

TRACEABILITY IN THE FOOD SUPPLY CHAIN



Daniel R. Levinson
Inspector General

March 2009
OEI-02-06-00210

- Auditors attempted to trace 40 food products from retail to the farm
- Only 5 were fully traceable
- Problems included lack of lot specific information and commingling



Product Tracing for Foods

- **Priority for the Administration**
 - President's Food Safety Work Group
- **Reportable Food Registry – Sep 09**
- **2 IFT Reports released in Dec 09:**
Industry “best practices” and tomato
traceback exercise
- **FDA & USDA held public meeting-
Dec 09**
 - docket for comments closed Mar 2010



Product Trace Public Meetings

- **2008 - Two Public Meetings - PRODUCE**
- **2009 – joint Public Meeting by FDA and USDA - ALL FOODS**
 - Purpose was to stimulate and focus efforts on mechanisms to enhance product tracing
 - Substantive comments received from speaker panels and the public

IFT Recommendations in a Nutshell...

- **Electronic recordkeeping** is essential. In the event of a recall, the FDA needs the ability to rapidly retrieve detailed records of product movement and transformation (ingredient in another food).
- **Each participant in the supply chain is responsible for capturing in electronic format their product movements** and transformations (or using a third party), and submitting them to the FDA in the event of a recall.
- **A standardized, global nomenclature for key data elements** (such as product name, lot number, date, locations) is required.
- A company's ability to trace and record in accordance with these guidelines should be **part of a third-party audit.**



IFT White Paper Jan 2011

Product Tracing in Food Systems:

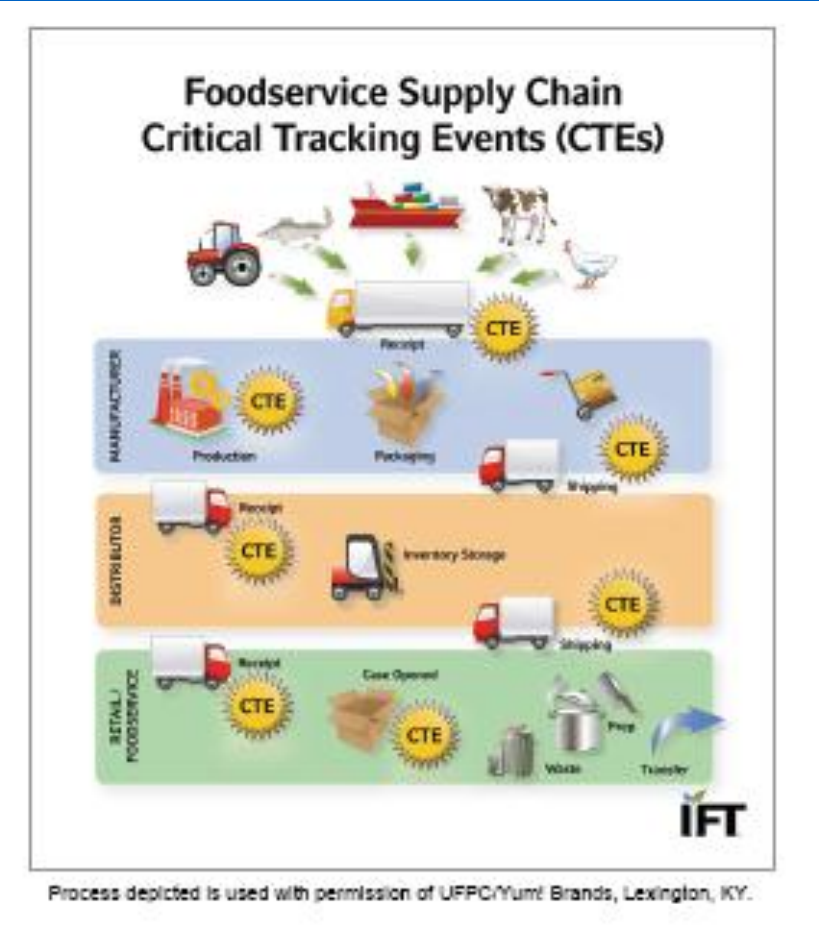
Developing a Product Tracing Plan
Using Critical Tracking Events and
Key Data Elements



- Clarifies the concepts of **Critical Tracking Events (CTE)** and **Key Data Elements (KDE)**
- The paper provides **examples and an analogy to HACCP**
- Has very **practical applications** for those looking to build their product tracing plans
- **Open for comment** through **March 1, 2011**



Key Data Elements (KDEs)



Overview of CTE KDEs

EVENT ID	EVENT NAME	EVENT DATE	EVENT LOCATION	PRODUCT IDENTIFIER	BATCH/Lot	QUANTITY	LOT CONTROL DATE	INPUT PRODUCT	INPUT BATCH/Lot	INPUT QUANTITY	INPUT/LOT CONTROL DATE	SHIPMENT NUMBER	DESTINATION ADDRESS	ORDERS ADDRESS
1 - Product Creation/Repackaging	✓		✓	✓	✓	0		✓	✓	✓	✓			
2 - Product Shipment	✓	✓	✓	✓	✓	0						0	✓	
3 - Product Receipt		✓	✓	✓	✓	✓						0		✓
4 - Case Product Inspection	✓		✓	✓	✓	✓								
5 - Product Sale To Consumer**	✓	✓	✓	✓	0	✓								

EVENT DATA
PRODUCT DATA
INPUT DATA
TRANSPORT DATA

Possible Sources of Data

Can be preset	Preset on case	Calculated	Can be obtained from inventories
✓	✓	0	0
Mandatory data elements		Optional	

*This includes product prepared for sale to consumers as well as "blend."
 **Capturing product tracking information at the point of sale to consumers is generally not possible today. Key data elements are provided to illustrate what would need to be captured to enable this in the future.

Definitions

Product identifier	The name or code used to designate a specific product, which may also include unit size, case configuration, etc.
Lot control date	"use by," "best by," "manufactured on," or other date appearing on a consumer level or individually packed item.

Originally developed by Douglas Bailey, USDA, AMS and mpXML. Used with permission.

Critical Tracking Events (CTEs)



US Food Safety Policies

- **FDA Food Safety Modernization Act**
 - FDA to conduct additional pilot studies
 - FDA has been continuously gathering data on industry practices

- **FDA is assessing requirements under the new Act and prioritizing efforts and resources**



111TH CONGRESS
2D SESSION

S. 510

AN ACT

To amend the Federal Food, Drug, and Cosmetic Act with respect to the safety of the food supply.

This Act may be cited as the
“**FDA Food Safety Modernization Act**”.



TITLE II—IMPROVING CAPACITY TO DETECT AND RESPOND TO FOOD SAFETY PROBLEMS

Sec. 201. Targeting of inspection resources for domestic facilities, foreign facilities, and ports of entry; annual report.

Sec. 202. Laboratory accreditation for analyses of foods.

Sec. 203. Integrated consortium of laboratory networks.

Sec. 204. Enhancing tracking and tracing of food and recordkeeping.

Sec. 205. Surveillance.

Sec. 206. Mandatory recall authority.

Sec. 207. Administrative detention of food.

Sec. 208. Decontamination and disposal standards and plans.

Sec. 209. Improving the training of State, local, territorial, and tribal food safety officials.

Sec. 210. Enhancing food safety.

Sec. 211. Improving the reportable food registry.



FDA Food Safety Modernization Act

Specific FDA actions related to the enhanced tracking and tracing of food include:

- The establishment of **pilot projects in coordination with the food industry** to explore and evaluate methods to **rapidly and effectively identify recipients of food to mitigate a foodborne illness outbreak;**
- subsequent establishment of **a product tracing system;**
- **feasibility and cost analyses** associated with the use of product tracing technologies;
- the establishment of **record keeping requirements.**



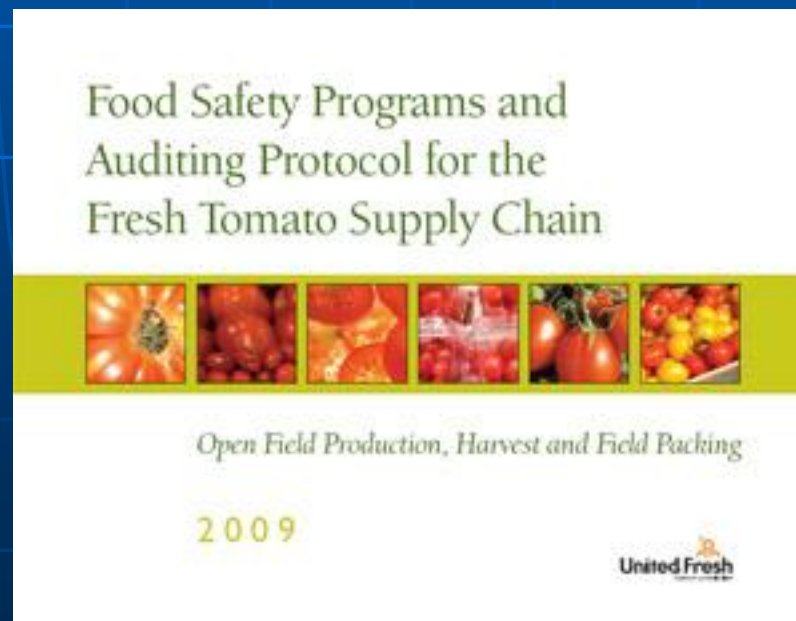
Prevention

**Government and Industry
Working Together**



Food Safety Programs and Auditing Protocol for the Fresh Tomato Supply Chain aka

The Tomato Safety Metrics



Commodity Specific Food Safety Guidelines for the Fresh Tomato Supply Chain - 2nd Edition

July 2008

**FDA is posting this industry information as a
service to industry, consumers, the media, and
other interested parties.**



**The document is available in English PDF (472KB) and en
Español (Spanish) PDF (405KB).**

Special thanks to all of the companies, agencies, trade associations and individuals who helped in developing the 2nd edition of this guidance.

Summary

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



Thank you!



Questions

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