Anatomy of an outbreak investigation

- Disease Surveillance
- Epidemiological investigation
- Laboratory analysis
- Environmental investigation
- Traceback / Traceforward
- Manufacturer / Processor / Farm investigation
2 or more States (Outbreak)

FDA-Regulated Products (Not Meat & Poultry)

ORA (Field)

Labs

CFSAN (SMEs)

FDA Emergency Ops (Coordinates)

Industry (Recalls)

FSIS-Regulated Products (Meat & Poultry)

CDC (Surveillance)
FDA Traceback Process
Salmonella Saintpaul Outbreak Traceback & Distribution
Partial view of the traceback & distribution of peppers from Mexico: July 16 – July 22, 2008

The red product stream shown here represents the traceback of the positive sample with the outbreak strain collected at the McAllen Texas facility. The green product stream represents the multiple primary distribution points from the farm where the other positive samples with the outbreak strain were collected.

* traceback of positive sample lot
* distribution from grower, Tamaulipas, MX

Grower Tamaulipas, MX
Source of the positive sample

Grower Tamaulipas, MX
Positive product and environmental sample found

Agricultural Firm
Michoacan, MX

Agricultural Firm
MX

Agricultural Firm
TX

Agricultural Firm
MX

Agricultural Firm
Coahuila, MX

Agricultural Firm
McAllen, TX
Positive sample found

Agricultural Firm
Nuevo Leon, MX

Distributor/Repacker/Broker
Nuevo Leon, MX

Packing Facility
Nuevo Leon, MX

Distributor/Repacker/Broker
Nuevo Leon, MX

Agricultural Firm
Nuevo Leon, MX

Grown
Tamaulipas, MX

Agricultural Firm
MX

Agricultural Firm
Mex

Agricultural Firm
Mex

Agricultural Firm
Mex

Agricultural Firm
Mex

Agricultural Firm
Mex

Grown
Hidalgo, MX

Health and Human Services / U.S. Food and Drug Administration
JULY 31, 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
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

POS       Distributors      Packers       Farms

Diagram showing the traceback flow from POS to distributors, then to packers, and finally to farms.
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

Salmonella

E. Coli O157:H7
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
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
• 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
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

- 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

<table>
<thead>
<tr>
<th>EVENT ID</th>
<th>EVENT NAME</th>
<th>POINT SOURCE</th>
<th>EVENT DATE</th>
<th>LOGISTICS</th>
<th>QUANTITY</th>
<th>EVENT DETAIL</th>
<th>EVENT ADDRESS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Product Creation</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>2</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>3</td>
<td>Product Receipt</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>4</td>
<td>Case Produce</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>5</td>
<td>Product Date to Consumption</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

Possible Sources of Data:

- Calculated
- Can be printed by user on site
- Calculated
- Can be obtained from hosts

Definitions:

- Product Identifier: The numeric code used to designate a specific product, which may include unit size, case configuration, etc.
- Retail Ready Date: Two by, "Best by," "Use-by," "Expiration date" or other date appearing on a container intended for retail sale.
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
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.
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
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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