Product Tracking Systems for Fresh Produce

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Anatomy of an Outbreak investigation

Product Investigation

Traceback Investigation

Traceback Challenges

Trace Initiatives

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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

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

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

The red arrows indicate the source of the positive sample.

Health and Human Services / U.S. Food and Drug Administration

JULY 31, 2006
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

1 - 3 Days

Patient Eats Contaminated Food

Time to contact with healthcare system = 1-5 days

Patient Becomes Ill

Stool Sample Collected

Time to diagnosis = 1 - 3 days

Salmonella Identified

Shipping time = 0 - 7 days

Public Health Lab Receives Sample

Serotyping and "DNA fingerprinting" 2-10 days

Case Confirmed as Part of Outbreak
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
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
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

- Ellen Morrison, Director, FDA Office of Crisis Management
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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