

Developing a Vision for Enhanced Foodborne-Illness Source Attribution Information

The Role of Product Tracing: today and tomorrow



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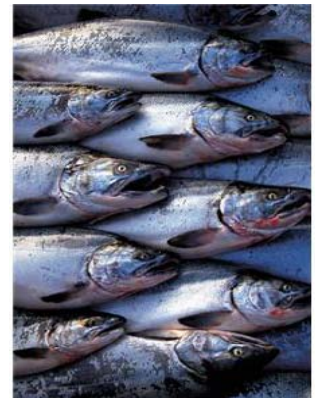
Overview

- Role of Product Tracing in Outbreak Investigations
- IFT – FDA Product Tracing Pilots

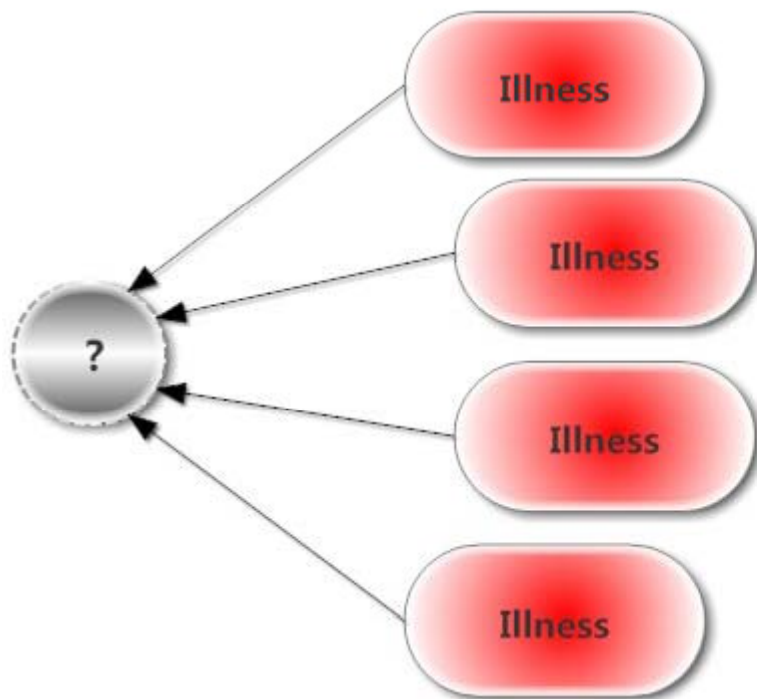


Outbreak Investigation

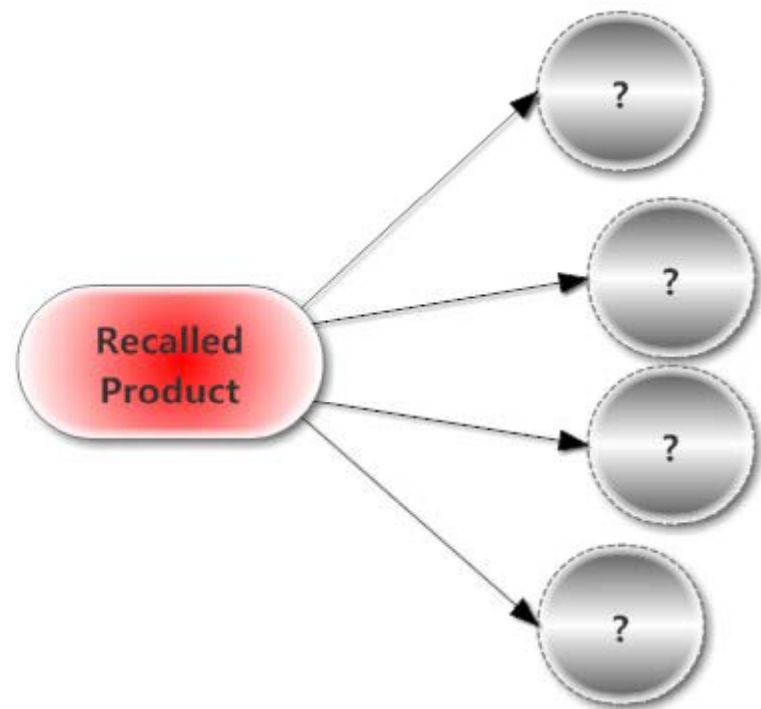
- People get ill from something they ate
- Go to doctor?
- Doctor collects samples?
- Reported to public health?
- Samples further distinguished (molecular techniques)
- Outbreak recognized
- Go back to people and ask what they ate
- Try to find common product
- **Try to find common source of the product – convergence**
 - **This is the regulatory traceback**



Traceback

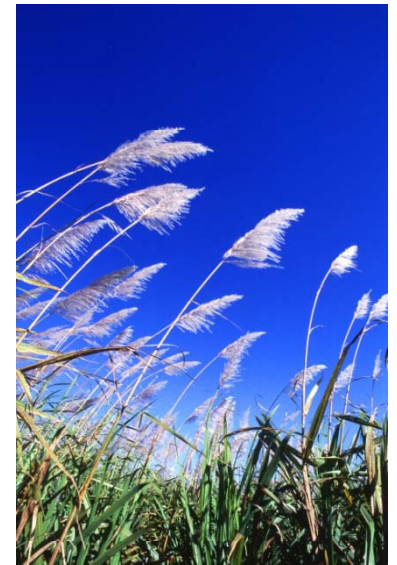


Recall



Traceability is not recall

Product Tracing	Recall
Conducted by regulators: balance making quick decisions with building a regulatory case	Conducted by industry: protect public health and protect their firm and bottom line
Implicated product not known – reliance on epi	Specific product(s) known-
Objective: identify points of convergence in supply chain to rule in/out suspects	Objective: remove product from the marketplace
Relies on good recordkeeping by industry	Relies on good recordkeeping by industry



From the last meeting highlights:

- “The scoping meetings are intended to provide a platform for bringing together government and industry representatives in the early stages of a foodborne illness outbreak investigation to share information and collaboratively develop a more detailed analysis of the outbreak. The goals of these meetings are to **provide CDC with critical information about food production and distribution....**”

Is Traceback Solely “After the Fact”?

- Today: No
 - Root cause analysis can help prevent future issues
- In the future: No
 - Can supply chain visibility help rule in/out certain products/brands?
 - Instant, accurate knowledge of supply chains can help inform epi



Tracebacks Today

- Often can't find point of convergence
 - Many reasons, to be studied by pilots
- Without convergence, may not “definitively” know the food
- = unsolved case
- = no food attribution



Pilot Requirements

- Task issued to IFT Sept 6, 2011; final report due June 6
- Objective
 - more rapidly and effectively trace back product = greater likelihood of tying an outbreak to food
- 2 Pilots: Produce and Processed food
 - Collaboration platform
 - Cost/benefit evaluation



Key Questions

- What data are really needed to trace products?
- How can we ensure accuracy?
- How can we GET it quickly?
- How can we ANALYZE it quickly?



General Approach

- Solicit Stakeholder input
 - Products, collaboration platform, use of existing systems, initiatives, cost data sources
- Baseline study- What is the process, what makes it difficult/easier, where are the hang-ups
 - Qualitative- discussions with traceback investigators
 - Quantitative- evaluation of previous investigations
- Solicit participants
- Conduct tests
- Evaluate results and cost

Testing Data

<u>CTE</u>	<u>Description</u>	<u>Date</u>	<u>Time</u>	<u>Event Location</u>	<u>Trading Partner</u>	<u>Item</u>	<u>Lot/Batch /Serial Number</u>	<u>Quantity</u>	<u>Unit of Measure</u>	<u>Order Number</u>	<u>Order Type</u>	<u>Transfer Number</u>	<u>Transfer Type</u>
Receiving	Accepting a shipment from another facility	x	x	x	x	x	x	x	x	x	x	x	x
Transformation	Changing the identity (such as a new item identifier , description, GTIN or batch identity) or characteristics (types of packaging, configuration of contents, etc) of a product												
T1	Items input into a transformation process	x	x	x	x	x	x	x	x	x	x		
T2	Items output from a transformation process	x	x	x		x	x	x	x	x	x		
Shipping	Releasing product from one facility to another	x	x	x	x	x	x	x	x	x	x	x	x

Next Steps: How can we improve speed and accuracy?

- Evaluate results based on
 - Speed to convergence/resolution
 - Mapping speed of analysis to practices (current state)
 - Assessing speed of analysis when industry uses a template
 - Evaluation of collaboration platforms
 - Speed
 - Accuracy

After Report Completion

- FDA report to Congress- early July
- IFT intends to publish report
- FDA must have 3 public meetings
- Rulemaking process



Questions?



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