Product Tracing
Farm to Fork - FDA

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Overview

- FDA regulated foods in outbreaks
- Anatomy of outbreak investigation
- Traceback Process
- International Aspects
- Product Trace Initiatives
Outbreaks and Illnesses of FDA Regulated Products
Outbreaks – FDA regulated products

1996 – 2008:

- Dairy: 21
- Eggs: 207
- Proc Foods: 37
- Produce: 77
- Seafood: 114
- Sprouts: 27
Illnesses – FDA regulated foods

1996-2008:

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<th>Category</th>
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Anatomy of an Outbreak investigation

- Disease Surveillance
- Epidemiological investigation
- Laboratory Analysis
- Environmental investigation
- Traceback / traceforward
- Source investigation
FDA Traceback Process
What is an FDA Traceback?

Documents the distribution through the supply chain, and the source(s) of a product that has been implicated in a foodborne illness investigation.
**Connectivity**
The ability to link food through all points of food distribution from farm to point of sale
- field locations (lots) on a farm
- Processing & Production
  - washing/packing/re-packing
- Distribution
- Wholesalers/Warehouses
- Retail

**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.
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
Traceback

- Traceback begins at the point of service
- FDA in cooperation with state obtain point of service records based on exposure dates of the ill consumers
  - Determine shipments and suppliers of interest
- Track shipments/suppliers each step in supply chain to find common source
Traceback process

- **Narrow or expand** scope 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

- Commonality only seen several levels into supply chain or at very end = no way to know early on if the trace will be conclusive
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
Recalling Product

Traceforward
Recalls

- Track product from responsible US firm to next level up in supply chain
- Voluntary action by responsible firm
  - Removes contaminated product from market
- Foreign distribution: May not know initially
  - Sub-distribution
  - Investigation evolves…recall may expand
Communication w/Foreign Partners

General notification & updates

Outbreak:
- FDA OIP to:
  - WHO, INFOSAN
  - IHR
  - Embassies
  - Regulatory authority

Specifics

Trace:
- FDA Office of International Programs contacts foreign authority
- Sharing of information restricted unless:
  Pre-established agreement (i.e. MOA)
Traceback Challenges
Broad Traceback Challenges

- Competing priorities
  - H1N1
  - Economic
- Varying resources and expertise
- Reluctance and time
- Differing regulations and practices globally
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

- Produce: perishable
- Lack of rapid connectivity
- Lack of unique identifier

Lack of interoperable systems to rapidly link product from farm to fork
International Aspects

- FDA in constant dialogue with food regulatory authorities
- FDA requests assistance from govt to obtain records
- Regulatory actions
  - Import alert
  - Investigations
  - Sampling
Challenges

- Lack of an infrastructure for the commodity
- Varying requirements to maintain records
  - i.e. one up one back
- Resources to investigate in foreign country
- Varying levels of cooperation by foreign government and firms
- Same issues as domestically – linkage, receipt dates, addresses, etc.
Specific Outbreaks, Global aspects

- Sprouts and contaminated seed
  - Raw agricultural commodity, exemptions
  - Human vs animal feed, intended use
- Salmonella Paratyphi and raw tuna
  - Unable to inspect some of firms of concern
- Cantaloupe source investigations
  - Critical role of Ag attaché
- S. Saintpaul assoc tomato/hot peppers
Trade Restrictions

- Challenging both for US and other countries involved
- Lettuce issue on heals of spinach outbreak
  - MX trade restrictions and impact
- Melamine in dairy products in China 2008
  - US import controls were in place from previous incident
  - improvements in communication and information exchange
Global Product Trace

- EU: TRACE Project
- ISO definition, WHO efforts
- US:
  - Industry: Produce Trace Initiative
  - National Animal Identification System, USDA
  - COOL – country of origin labeling
US Food Safety Policies

- FDA opens new offices in foreign countries
  - China, India, Europe, Middle East, Latin America

- Food Safety Bills on the horizon
  - Food Safety Enhancement Act 2009
  - Food Safety Modernization Act 2009
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

Pilot study and other contracts to examine practices, make recommendations, and estimate costs
Product Trace Initiatives

- Two Public Meetings 2008
- Encourage industry efforts to improve product trace system farm to fork
- Exploring regulatory and other options
Summary

- Outbreaks are being detected earlier
- A rapid and interoperable product tracing system may reduce illness if we can identify source faster
  - Apply domestically and for imported products
  - Increase consumer confidence
- Need for a standardized approach globally
- Communication and collaboration is key