Safety Assurance and Traceability Of Materials through the Supply Chain

Roger Clemens, DrPH
Chief Scientific Officer
Horn
Adjunct Professor, Pharmacology & Pharmaceutical Sciences
USC School of Pharmacy
Attack of the Killer Tomatoes

• 2008 - multi-state outbreak of *Salmonella Saintpaul*
  – Over 1,440 people were infected with the same genetic fingerprint of *Salmonella Saintpaul* in 43 states, the District of Columbia, and Canada between April and August 2008
  – 286 persons were hospitalized
  – Two deaths may be attributed to this outbreak
  – Ultimately, tomatoes were vindicated; jalapeño peppers were the culprit

1978 Film
directed by John De Bello
“How” is the Cantaloupe Question

- A total of 123 persons infected with any of the four outbreak-associated strains of *Listeria monocytogenes* have been reported to CDC from 26 states.
- Twenty-five deaths have been reported.
- Consumers should not eat whole or pre-cut Rocky Ford-brand cantaloupe from Jensen Farms.
- Cantaloupes that are known to NOT have come from Jensen Farms are safe to eat.
- Sales of California (Mendota) and Arizona (Maricopa) cantaloupes plummeted >80% even though their fruit was perfectly safe to eat.

Accessed October 18, 2011
Traceability in the Food Supply

“...the traceability of food products and the ability of food facilities to provide information about their sources, recipients, and transporters are essential to ensuring the safety of our Nation’s food supply.”

Daniel R. Levinson
Inspector General
Office of the Inspector General
U.S. Department of Health and Human Services

Testimony presented to The House Committee on Appropriations, Subcommittee on Agriculture, Rural Development, Food and Drug, 2009
The ‘Teeth’ of FDA’s Food Safety Law

• [FSMA] directs the agency [FDA] to oversee food safety in a way that applies “the best available science and good common sense to prevent the problems that can make people sick.”
  
  – Margaret Hamburg, MD
  Commissioner, FDA

• “[FSMA] gives the food companies strong additional incentives for keeping their products safe, and that helps us achieve the new law’s goal, which is to protect consumers from unsafe food.”
  
  – Michael R. Taylor, JD
  Deputy Commissioner for Foods, FDA

Accessed September 30, 2011
Regulatory Science Initiative

• “We are neither effectively translating these scientific discoveries into therapies nor fully applying our knowledge to ensuring the safety of food and medical products.”

• We must encourage the use of new methods to evaluate nutrient content, chemical contaminants and the effect of processing on food.

• Regulatory science is “needed to assess and evaluate the product’s safety, efficacy, quality, and performance.”

Dr. Margaret Hamburg
Commissioner U.S. FDA
SOT 50th Annual Meeting and ToxExpo™
March 2011
21st Century Toxicology

- ENSURING THE SAFETY AND QUALITY OF FOOD AND MEDICAL PRODUCTS HAS NEVER BEEN MORE COMPLICATED.

- We must advance the field of regulatory science, use new tools, including functional genomics, proteomics, metabolomics, high-throughput screening, and systems biology.

- We must develop new science to protect the safety of our food supply: for example, to identify the effect of food production, processing, preparation, and use on nutrient content, toxic contaminant generation, and inactivation of naturally occurring toxins.

HHS Traceability Assessment*

• Only 5 of the 40 products purchased could be traced through each stage of the food supply chain

• For 31 of the 40 products, HHS was unable to trace these products through each stage of the food supply chain

• For four products, even likely handling facilities could not be identified

* New York City, Chicago, San Francisco, and Washington, DC. The products—selected in consultation with FDA officials—including bottled water, ice, milk, eggs, yogurt, flour, oatmeal, tomatoes, leafy vegetables, and juice.

http://www.hhs.gov/asl/testify/2009/03/t20090326a.html
Accessed August 5, 2011
HHS Recommendations

• FDA should have statutory authority to strengthen the existing records requirements regarding lot-specific information.
• FDA should require processors, packers, and manufacturers to create lot-specific information—and maintain it—if it does not exist.
• FDA should have additional statutory authority to require food facilities to further strengthen the traceability of food products.
• FDA should work with the food industry to develop guidance on traceability.
• FDA should address issues related to mixing raw food products from a large number of farms.
• FDA should have statutory authority to request facilities’ records at any time
• FDA should conduct education and outreach activities to inform all segments of the food industry about its records requirements.
Food Safety Modernization Act
PUBLIC LAW 111–353—JAN. 4, 2011

• Requires information on foodborne outbreaks associated with fruit and vegetables 5 years prior to the Act and recommendations on traceability

• Requires cost of compliance report and risk/benefits, including requirements provide adequate assurance of traceability in the event of intentional adulteration, including by acts of terrorism within 1 year of the Act

• Requires import application to include traceability of articles of food

Traceability

- Epidemiological investigations
- FDA to establish a product tracing system to receive information that allows FDA to effectively track and trace food for consumption in US
- FDA conduct pilots of produce and processed food sectors with 180 days
Traceability Recordkeeping

- Additional recordkeeping for high-risk foods
  - FDA to establish a list of high-risk foods
  - FDA to issue NPRM (Notice of Proposed Rulemaking) on expanded record-keeping requirements for high-risk foods
The Supply Chain

Trace Forward

Trace Back
Challenges

- The complexity
  - Distribution systems – broad and fast

- Supply chain unknowns
  - Suppliers - suppliers
  - Brokers sources

- Inconsistent record keeping
  - Extent of records
  - Electronic vs paper

- Changing names of products

- Different systems of tracking

- Repacking of products
IFT-FDA Traceability Report
Key Findings

1. Food production and distribution are global and complex

2. Technology to trace exists, and continues to evolve

3. Most firms believe they are in compliance with “Bioterrorism Act” (2002; maintaining 1-step up/back records)

4. The lack of common data elements in the supply chain may not provide complete product tracing
   • A lot of information is recorded, but not linked

5. Paper recordkeeping is prevalent, dominant
IFT-FDA Traceability Report
Key Findings

6. There are many industry initiatives, current and in development: The private sector is willing to improve.
   • Some wish to lead; not have a solution imposed upon them
   • Some want to wait see what happens; what is agreed upon (reference to FSMA)
   • Many fear there won’t be a “level playing field”

7. Traceability costs vary and tend to be inaccurately estimated
IFT-FDA Traceability Report

Overarching Issues

• Paperwork generally lacks complete information
  – No standards exist for capturing/expressing information

• Within a facility, internal systems often differ and are not electronically linked – not interoperable

• Companies receive different information from different suppliers, and have to provide different information to different customers

• “Lot” – meaning is confused and internal tracing is prevented
Canadian Integrated Food Safety Initiative (April 2009)

• Food Safety Systems Development
  – focuses on the development of food safety systems by national organizations

• Canadian Industry Traceability Infrastructure
  – focuses on the development and implementation of traceability processes and systems by national organizations.
  – Committed $4.45 MM (CND$) to traceability initiatives (thru 2011)
  – $1.6 MM (CDN$) in the Canadian Cattle Identification Agency (CCIA) in support of implementation of its national livestock traceability system
Canadian Industry Traceability Infrastructure (April 2009)

• Activities
  – Systems development
  – Industry systems implementation

• Objectives
  – develop or enhance traceability capacity for agriculture and agri-food products through specified stages of production, processing, and distribution

• Expectations
  – To assist governments and industry to better control the economic effect of animal health, plant health, food safety, and other emergencies
  – To proactively gain access to markets requiring traceability

Accessed August 5, 2011
EU Food Traceability
(Updated June 2007)

• Effective 2002, traceability compulsory for all food and feed businesses

• The food and feed production chain often involves many steps, from the import or primary production of a product to its sale to the final consumer.

• At every stage, food and feed businesses, Member State competent authorities and the EU have clearly defined roles and responsibilities and need to respond appropriately when a risk is identified.
# EU Food Traceability
(Updated June 2007)

<table>
<thead>
<tr>
<th>Overall Responsibilities</th>
<th>Actions Taken When a Risk is Identified</th>
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<tr>
<td><strong>Food and Feed Businesses</strong></td>
<td>• Identify and document information on products “one step forward and one step back” in the food chain.</td>
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<td>• Immediately withdraw the affected products from the market and, if necessary, recall them from consumers</td>
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<td>• Destroy any batch, lot or consignment of feed that does not satisfy food safety requirements</td>
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<td><strong>Member State Authorities</strong></td>
<td>• Monitor production, processing and distribution of food and feed products to ensure that operators have traceability systems in place</td>
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<td>• Fix and enforce appropriate penalties for operators that do not meet EU requirements on traceability</td>
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<td><strong>The EU</strong></td>
<td>• Establishes sector-specific legislation on traceability as appropriate</td>
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The Rapid Alert System for Food and Feed (RASFF)

• The RASFF network, in place since 1979, was enhanced by the General Food Law in 2002.
• Members of the network are the 27 Member States, the European Commission, the European Food Safety Authority, Iceland, Liechtenstein and Norway.
• This warning system supports the traceability system by enabling the rapid exchange of information whenever a risk to food or feed safety is identified.
• If a member of the network becomes aware of a potential risk to human health, it notifies the European Commission, which immediately transmits this information to the other members – and beyond – so that corrective action can be rapidly taken.

http://ec.europa.eu/food/food/rapidalert/index_en.htm
Accessed August 5, 2011
The Rapid Alert System for Food and Feed (RASFF)

• Food is complex and global
• Food safety is everyone’s responsibility
• Food safety guidelines must involve all stakeholders
• Food safety activities must be transparent

• Food safety involves continual communication among stakeholders
• Food safety systems, such as TRACES*, must “link” and be shared bidirectionally
• Food safety requires global commitment and cooperation

* TRACES: (TRAde Control and Expert System) risk management tool for animal health and public health

http://ec.europa.eu/food/food/rapidalert/index_en.htm
Accessed August 5, 2011
Conclusion

• Traceability → identification of common source and distribution channels

• FDA pilot projects (2) in collaboration with FDA, USDA, and IFT
  – Processed foods
  – Agriculture produce (raw fruit and vegetables)

http://www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm
Accessed November 10, 2011