Challenges to Implementing Product Traceability

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Hilton
Anaheim, CA

By
Gale Prince
gale@galeprince.com
Under Magnifying Glass
In the end it was ...
Or was it both?
Recent Food Safety Problems

• 2006 Produce Safety was the top news story
  – Spinach
• 2007 Product safety was the top news stories
  – Peanut Butter
  – Pet Food
  – Canned Chili
  – Ground Beef
• 2008
  – Ground Beef
  – Tomatoes and Peppers
• 2009
  – Peanut Butter
  – Pistachios
  – Alfalfa Sprouts
  – ???????
Product Recalls Are Becoming More Massive

- 25 million pounds
- 22 million pounds
- 1.8 million pounds
- 143 million pounds
- Over a year’s production of peanut butter
- All production codes of chili sauces
- Multiple brands by multiple manufacture’s of pet food
- Over 600 different food products recalled in Europe
  - all related to one adulterated minor ingredient
- Over 400 different food items recalled in US
  - all related to one supplier
Product Recalls Are Costly

• Preliminary recall costs reported by firms of recent recalls:
  – $56,000,000
  – $35,000,000
  – $60,000,000
  – $30,000,000
  – $37,000,000
  – $103,000,000
  – Some firms ceased business

• These costs do not include litigation costs
• Nor does it include the cost in lost sales
• Nor the cost of re-establishing the business
• Nor does it include the swings in stock market
Why the Change?

- Concentration of food production
- Increased batch size
- Product changes
- Changes in food distribution
- The Consumer has changed
- Science has changed
- Epidemiology has changed
Food Net Sentinel Sites

Represents about 15% of US population

* Shiga toxin-producing Escherichia coli.
† The position of each line indicates the relative change in the incidence of that pathogen compared with 1996–1998. The actual incidences of these infections can differ. Data for 2008 are preliminary.

Source: MMWR April 10, 2009
Center of Disease Control
Pulse Net

PulseNet USA
The National Molecular Subtyping Network
for Foodborne Disease Surveillance

CDC
Electronic Communications
CDC Outbreak Response and Surveillance Team (ORST)
October 2006*

#Cases of *Salmonella* Tennessee (outbreak type)
by month, USA 2004 - 2006

* Preliminary data

Slide Compliments of Dr. Art Liang Center of Disease Control and Prevention
December 2006*

# Cases of *Salmonella* Tennessee (outbreak profile) by month, USA 2004 - 2006

* Preliminary data

Slide Compliments of Dr. Art Liang Center of Disease Control and Prevention
January 2007*

# Cases of *Salmonella* Tennessee (outbreak profile) by month, USA 2004 - 2006

* Preliminary data

Slide Compliments of Dr. Art Liang Center of Disease Control and Prevention
Confirmed cases (N=453)* of *Salmonella* Tennessee infection by state—United States, 2006-2007

*Figure 1

*Preliminary data

*Confirmed cases with date of illness onset reported as of 1:00 p.m. EDT on March 14, 2007.

Slide Compliments of Dr. Art Liang Center of Disease Control and Prevention
Peanut Butter 2009

Cases infected with the outbreak strain of *Salmonella* Typhimurium, United States, by state, as of March 1, 2009 at 9pm ET (n=677)

Source: CDC 030609
Peanut Butter 2009

Infections with the outbreak strain of *Salmonella Typhimurium*, by date of illness onset*
(n=662 for whom information was reported as of March 1, 9pm EDT)

Date of illness onset

*Some illness onset dates have been estimated from other reported information

Source: CDC 030609
PCA Peanut Product Related Recalls
Jan 10 – Mar 31, 2009

Other Food Companies Recalls

~ 500 Recalls Involving > 3,900 Products as of 3/31, 9 Deaths

Source: CDC & FDA & News Releases
Protecting Your Brand and Bottomline

Preventive Food Safety Programs
Protecting your brand and bottom-line

Food Safety Programs

Traceability
Bioterrorism Act of 2002

- Food Facility Registration
- Prior Notice on Food Imports
- Maintenance of Records
- Administrative Detention
2005 FDA Rules on Records Maintenance

- Trace product **one step back and one step forward**
- Included **lot codes** of food products and packaging at each step in distribution
- Included name of transporter and driver in each step of distribution
Definitions of products covered

• Food
  – Human and animal
  – Ingredients and processing aids
  – Packaging with food contact surfaces
  – Dietary supplements
  – Infant formula
  – Beverages including alcoholic beverages
  – Candy and gum
  – Live food animals
Records

- Does not require duplication of information in current existing records
- Does not require all the information to be in one set of records
- Record must be made at the time of action
  - At the shipping and receiving dock
  - During the processing and production steps
- Records must be available at point of activity
Food Manufacturers

- Identification of the source and lot code of each ingredient used to make every lot of finished product
  - Ingredients
  - Processing aids
  - Packages with food contact
Records access

- A single record is not required
- Information can come from multiple existing records
- Reproduction of a modified record at a later time is not allowed
- FDA has authority to review and copy certain records
Record access

• Must be made available to FDA within 24 hours of their request
• Authority to review and copy
• At any point in the system
Records access

- Records are only available under special circumstances
- Need for records must be approved by District Director or FDA Headquarters staff
- FDA inspectors do not routinely have access under routine inspections
Record access

- FDA information is subject to Freedom of Information requests thus public information
- Confidential business information may need to be separate from records which FDA is authorized to see and copy
Current Methods of Compliance

• Commercial Paper
  – Purchase orders
  – Invoices
  – Packing slips
  – Bills of Lading
  – Delivery tickets

• Internal documents
  – Quality control records
  – Production documents
  – Inventory control records
No one exact method currently used

Vary by industry, by company, by size and method of business

Method of exchanging information between parties is the essential element.
Traceability Information Silos

Farm, Processor, Distribution Centers, Retail
Traceability Report

- Were able to trace 5 of 40 items
- Lack of lot code information
- Lack of records
- 25% of facilities not aware of record keeping requirements
Current Traceback Problems

- Lack of records
- Paper work challenge
- Readability
- Does not provide a means to rapid response to a trace back
- Universal system does not exist to provide transfer of information to an electronic investigative tool
Current Proposed Legislation Traceability

- FDA Food Safety Modernization Act
  SB-519 by Durbin of IL
- FDA Globalization Act of 2009
  HR-759 by Dingell of MI
- Safe FEAST Act of 2009
  HR-1332 by Costa of CA
- Establish a traceability system for food
  SB 425 by Brown of OH
Do Consumers care about traceability?
Do Consumers Really Care?

- Pet Food Recall triggered questions on source of foods and ingredients used in human foods...
Consumer are more vocal

More rapid communications when products are not satisfactory. The 800# and www. on labels provides the food manufacturer with information.
Consumer Satisfaction is very important in today.

- Blogs
  - Consumer Generated Media
  - CGM
Consumer Reaction to Recalls

- Harris Interactive Research-April 2007
  - 79% aware of food recalls for past three years
  - 29% felt recalls were “serious concern”
  - 55% would switch brands temporarily
  - 15% said they would never purchase the recalled product
  - 21% avoid purchasing any brand made by the manufacturer of the recalled product
Consumer Reaction to Recalls

• Impact of major food safety issues on consumer purchasing decisions
  – Consumer reported they would not purchase the recall product in the future…

• 2005 - 6%
• 2006 - 38%
• 2008 - 15%

FMI Trends 2008
USDA Country of Origin Labeling

• Requires traceability as to source
• Requires documentation as to source
  – Beef
  – Pork
  – Lamb
  – Chicken
  – Goat Meat
  – Wild and Farm Raised Fish and shellfish
  – Peanuts
  – Pecans
  – Ginseng
  – Macadamia nuts
Traceability

- Needs to be in a form so an exchange of data can be synchronized with global harmonization of traceability information

- Need a common platform to transfer information as needed
Basic Traceability Elements

• Firm identification
• Product identification
• Product coding and traceability
  – Code to ID plant where packaged
  – Production line
  – Date code
  – Time (Hour, Minutes, Seconds)
• Have you done an exercise to measure ability to trace product.
  – When
  – How effective is your system?
Electronic Traceability

- Readable bar codes
- Identify company, product, plant, lot codes, etc
- Compatible with universal information exchange platform
- Compatible with current Universal Product Code (UPC #)
Electronic Tracing

An idea that was born in 1932 by a grocer Wallace Flint

UPC Bar Code
Identify company and product

First item to be scanned on June 26, 1974
GS 1

- Uniform Code Council (UCC)
  - Managed UPC in USA
- Changed name to GS 1 US
  - 2005
- Consumer package bar code
Tracking Lot Codes

Translation Sample
Global Trade Item Number (GTIN) linked with Packaging Date and Batch/Lot Number within a GS1-128 barcode

Supplier Translation
Global Trade Item Number (GTIN) linked with Packaging Date and Batch/Lot Number within a GS1-128 barcode

01 = GS1 Application Identifier (AI) for GTIN
Global Trade Item Number (GTIN)
1 0 6 1 4 1 4 1 0 0 7 3 4 6

13 = GS1 Application Identifier (AI) for Packaging Date
0 9 0 9 0 1 = Packaging date in YYMMDD format (e.g., September 1, 2009 = 090901)

10 = GS1 Application Identifier (AI) for Batch/Lot Number
5 4 3 2 1 C B S F D = Batch/Lot Number (encodes a variable length up to 20 alphanumeric characters)

2 GS1 Application Identifiers are the field of two to four digits at the beginning of an Element String that uniquely defines its format, length, and meaning. They are all identified in Section 5 of the GS1 General Specifications v.9.0 (January 2009). Parentheses surrounding the Application Identifier, AI, are not encoded within the barcode and are used for the Human Readable only.

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Traceability Information Silos

How do we link these electronically?

Download Info as needed

Farm

Processor

Distribution Centers

Retail
Tracking lot code to retail

- Bolding a digit that shows a key change in lot code information allows a distribution center to track the lot code movement to retail store.

“HOOK Number”
Voice Pick
Electronic Traceability Will Not Happen Overnight!

But...
In order to protect our brands Traceability must be enhanced!
Meeting Consumer Expectations
Thanks For Your Attention!

Gale@galeprince.com