RECALL – The word that brings shudders to the food industry

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Goal of the Food Industry

• To produce safe and wholesome foods

How to Insure Safe Food is Distributed

• Develop and follow programs
  – Identify products accurately
  – Document procedures
  – Validate results with third-party audits
• Know where your products come from and where they go (traceability)
  – Trace forward; trace back (product identification is key)
  – Raw materials, ingredients, packaging
• During crisis, respond quickly

But sometimes, things go wrong…

And When Things Go Wrong

• Usually at very inconvenient times

Then It Hits the News (Noose)!

• Adverse publicity almost instantaneously
And Even If The Story Is Inaccurate, or Not Even True
You still get unwanted exposure:
“A lie can travel halfway around the world while the truth is putting on its shoes.”
(Mark Twain)

Public Health Issue-Botulinum Toxin
Bolthouse Farms Carrot Juice, 450-ml and 1-l bottles, “Best if used by”
November 11, 2006
- Improper refrigeration may have caused the development of C. botulinum toxin

Public Health Issue-Salmonella
- Outbreaks: 2001, 2004
- Resulted in mandatory pasteurization of raw almonds by September 1, 2007

2006 Spinach Outbreak
Over 200 illnesses and one death....

High Profile Outbreaks
- Jewell Dairy Salmonella (1985)
- Jalisco Cheese (1985)
- Jack-in-the Box E. coli 0157:H7 (1993)
- Schwann’s Ice Cream Salmonella (1994)
- Japanese Radish Sprouts (1996)
- Odwalla Apple Juice (1998)
- Pre-Cut Spinach (2007)
- Tomatoes then peppers (2008)
Costs of Recall

- **Direct costs**
  - Product and package loss
  - Retrieval
  - Destruction
  - Cleaning
  - Potential health risks
  - Lawsuits and legal issues
  - Human time

- **Indirect Costs**
  - Potential reduction in demand and sales
  - Decrease in share value

Source: Resende-Filho et al., June 19, 2007

$ Losses To The Industry

<table>
<thead>
<tr>
<th>Produce</th>
<th>Est. Revenue Loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spinach 2006 E. coli O157:H7</td>
<td>$350 million (shippers &amp; growers)</td>
</tr>
<tr>
<td>Peanut butter 2007 Salmonella</td>
<td>$140 million ($55 million in lost sales)</td>
</tr>
<tr>
<td>Tomatoes/Peppers 2008 Salmonella</td>
<td>&gt;$100 million (growers)</td>
</tr>
</tbody>
</table>

Recalls are expensive!

US FDA Recall Policy 21CFR7.40

- Recall: “…removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration.”
- Therefore, recall is the
  - Prompt removal of contaminated, mislabeled products, or sick animals from the market (includes proper disposal)

US FDA Recall Policy 21CFR7.40 (cont’d)

- Objective of a recall: “…to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.”

US FDA Recall Policy 21CFR7.40 (cont’d)

- Voluntary action by food manufacturers and distributors
- “…an alternative to a FDA-initiated court action…”
Different from Seizures or Other Court-Actions

- That are done by US FDA when
  - Firm refuses to undertake a recall
  - A recall is ineffective
  - The agency believes a recall would be ineffective
  - Violation is continuing

US FDA Enforcement Policy

- 21 CFR 7.41 – 21 CFR 7.59 (Guidance on policy, procedures, and industry responsibilities)
  - Sec 7.41 Health hazard evaluation and recall classification
  - Sec 7.42 Recall strategy
  - Sec 7.45 FDA requested recall
  - Sec 7.46 Firm initiated recall

US FDA Enforcement Policy (cont’d)

- 21 CFR 7.41 – 21 CFR 7.59
  - Sec 7.49 Recall communications
  - Sec 7.50 Public notification
  - Sec 7.53 Status Reports
  - Sec 7.55 Termination
  - Sec 7.59 General industry guidance

Health Hazard Evaluation and Recall Classification (21 CFR 7.41)

- Ad Hoc FDA committee will determine
  - Has disease or injury occurred?
  - Are there conditions that will expose humans or animals to a health hazard?
  - Will humans or animals be exposed to a health hazard?
  - Who are expected to be exposed?
  - How serious are the hazards?
  - What is the likelihood of occurrence?
  - What are the consequences of occurrence?

Health Hazard Evaluation and Recall Classification (21 CFR 7.41)

- Based on the assessment, a recall classification will be assigned relative to the degree of health hazard:
  - Class I
  - Class II
  - Class III

Types of Recall

- Product Recalls
  - Class I
  - Class II
  - Class III
- Not included in public notifications
  - Market Withdrawals
  - Stock Holds
  - Mock Recalls
Class I Recalls

- Reasonable probability that the use of, or exposure to, a violative product cause serious adverse health consequences or death
- Examples: food pathogens, allergens
- Public warnings
- Maximum efficacy check likely

Class II Recalls

- Involve products that may cause temporary or reversible health consequences
- Probability of serious adverse health consequences is remote
- Public warning likely
- Intermediate effectiveness checks

Class III Recalls

- May not involve public warning
- Wholesale or retail level
- Effectiveness checks are minimal
- Affected products have no health hazards

Market Withdrawals

- This is a situation where no violation is involved or the violation is minor and product is not subject to seizure under current FDA or USDA policy or guidelines.

Stock Recovery

- Involves the recovery of products that remain under the complete control of the manufacturer and its clients, regardless of the severity of the problems.
- For example, most of Multiple Organics products are dried, shelf stable ingredients. Such a retrieval could be possible.

Recall Summary

<table>
<thead>
<tr>
<th>CLASSIFICATION</th>
<th>RETRIEVAL LEVEL</th>
<th>EFFECTIVENESS CHECKS</th>
<th>PUBLIC WARNING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td>Consumer</td>
<td>100% at retail</td>
<td>Yes</td>
</tr>
<tr>
<td>Class II</td>
<td>Retail or more</td>
<td>90 – 100% at retail</td>
<td>Yes</td>
</tr>
<tr>
<td>Class III</td>
<td>Wholesale or more</td>
<td>Variable</td>
<td>Sometimes</td>
</tr>
<tr>
<td>Withdrawal</td>
<td>Company Criteria</td>
<td>Company Assessment</td>
<td>No</td>
</tr>
</tbody>
</table>
Who Identifies the Problem?

- Regulatory Agency
- Consumer
- Physician
- Field Sales Staff
- Customer Service
- Others

Who Determines the Severity of the Problem?

- Quality Assurance or Technical Group evaluates the concern
- Is the concern of public health significance?
- Their evaluation results determine the next steps.

If Product is a Suspected Health Concern

The following actions must be started simultaneously:

- Confirm the presence or absence of a health concern
- Notify management
- Trace all suspect products
- Collect & review production or quality records
- "HOLD" product in company control

If Product is a Confirmed Health Hazard

- Initiate recall
- Sales & Marketing - Notify buyers; pick up product; isolate product
- Confirm coverage with insurance company
- Marketing - Public relations
- Purchasing - Work with suppliers if issue is supplier-related
- Human Relations - Work with staff
- Production - Assist in investigation; stop operations

Firm-initiated Recall (21CFR 7.46)

- Firm should notify FDA with required information.
- Firm action will be considered by FDA as a recall when the product involves a violation subject to legal action.

FDA-requested Recall (21CFR7.45)

- Except in limited circumstances (e.g., infant formula), a firm need not initiate a recall even when at FDA’s request.
Recall Strategy (21CFR7.42)

- Recall Plan (entails a Recall Program)
- Should include
  - Depth of recall: level in the distribution chain (consumer, retail, wholesale)
  - Public warning: general or using specialized media
  - Effectiveness checks: level A (100%), level B (10-99%), level C (10%), level D (2%), level E (0)

Recall Program

- Documented procedures developed and maintained by a Recall Coordinator
- Staff training
- Must be practiced regularly as a company
  - Goal: to have recalled products within 24 hours of first alert

Recall Program => Addresses Recall Needs

- Assesses personnel needs
- Needs management support
- Needs a Recall Action Group
  - Recall Action Coordinator
- Requires team effort

Recall Action Team or Retrieval Team

- Coordinator
- Technical Representative
  - QA, R & D, Laboratory, Contractor
- Warehouse & Distribution
  - Warehouse, receiving, distribution, marketing, customer service
- Communication
- Legal

Recall Action Team or Retrieval Team (cont’d)

- President/CEO
- Financial Staff
- Public Relations
- Legal Staff
- Outside Help (if needed)

Recall/Retrieval Structure
How to Recall the Product
- When out-of-compliance food inadvertently reaches any part of the food chain, including the consumer, the product needs to be recalled.
- Traceback or tracking systems or traceability
  - Used to trace the route of contaminated food or sick animals in the food chain

Traceback or Tracking Systems or Traceability
- Initiated by the food producer or manufacturer
- Offer additional safety reassurances to food
- Used in post-market monitoring (e.g., unintended health effects)
- Important in insuring liability and compensation

Recall & Traceability
- Statutorily required of some products but all products must involve these.
- Protect the business
- Different issues for distributor than a producer
  - Reliance on vendors & warehouse operations
  - Lot sizes may be variable
  - Mixed pallets

Commitment to Traceability
- Needs total management support

How to Trace the Product
- Product identification is critical in tracing the product through distribution from supplier to consumer.
- Rigid coding system preferred
- Test the system through mock recalls
  - Evaluate performance at post mock-recall meetings

Product ID⇒Tracking⇒Recall
- Proper identification of product is a prerequisite to tracking & recall.
- Plan ahead. A crisis is not the time to find that your recall program doesn’t work.
Required Label Information

- Legibility
- Establishment
- Product
- Pack Date
- Pack Year
- Shift or Period

Identifying Initial Source

- Critical information
- Use accurate and recorded product identifications linking successive packaging and transport/storage configurations.

Product Labels

- Code allows traceability to date of production, but labels allow the manufacturer or distributor to be contacted
  - Manufactured by:
  - Distributed by:
    - Distributors work with manufacturers to put their labels on items.

Product Labels (cont’d)

- Clear contact information including:
  - Company name
  - Phone, preferably a toll free number
  - Address
  - Email or web address

Other Product Information

- Product type
- Packaging
- Labeling
- Shelf life
- Lot number
- Date processed/received/rotated
- Inventory
- Shipping and handling information

Facility Designation

- Differentiate plants
- Needed for troubleshooting
**Case Codes & Pallet Tags**

- Case codes should be the same as for individual product containers
- Universal Product Codes (UPC) & scanners may be used for tracking
- Pallet tags should delineate what is in pallet

**Tracking Finished Product**

**OBJECTIVE:** To ensure that all products shipped by the firm may be tracked to the customer in the event that there are problems. This procedure shall be used for tracking products as part of a recall exercise.

**DEVELOP & USE YOUR TRACKING FORM**

**Mock Recall**

- Simulated recall exercise to test readiness
- Should mirror what would happen in the event of a real recall
- Standard:
  - 100% of product tracked within 4 hours
- Recall Action Team shall meet and review exercise when it is complete
- Records of discussions shall be maintained
Mock Recall (cont’d)

- Be proactive
- Seamless, not a fire fighting exercise
- Have backups

Recall Communications (21CFR7.49)

- Lists the necessary information for a recall
- Gives instructions on product handling

Role - Communications

- Responsible for communicating with the media, consumers, and regulatory Agencies
- Instructs all employees to refer all questions to Communications
- Statements are pre-evaluated and pre-approved by the Recall Action Team and Legal Counsel

Contact List

- Detailed contact lists shall be developed, documented and maintained on a regular basis.
- Quarterly at least
  - All team members
  - All warehouse and distribution centers
  - All clients
  - All vendors

Communicating the Problem

- Radio, television, & print media
- Full details on product
- State what is known and NOT known and what the company is doing to address uncertainties
- Instructions on how to handle suspect product
- Be open & honest

Group Exercise

- Recall Action Team Members:
  - Take 15 minutes to jot down your duties
  - Include types of documents, locations and key contacts
  - This will become the basis of your work instruction.
  - Discuss the duties
Public Notification (21CFR7.50)

- Published in the weekly FDA Enforcement Report
  http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm
- Then click on Recalls, Market Withdrawals, & Safety Alerts

Recall Termination (21CFR7.55)

- Depends on the hazard
- By FDA when all reasonable efforts had been made to remove or correct the product
- Requested by the firm demonstrating effectiveness of the recall

Recall Status Reports (21CFR7.53)

- By the initiating firm to the FDA usually at 2-4 week intervals
- Discontinued upon termination of the recall

General Industry Guidance (21CFR7.59)

- Prepare a contingency plan and test its effectiveness
- Use product identification that will positively identify the lot and facilitate effective removal of violative lots
- Keep records beyond product shelf life and expected use (e.g., 3 years total)

Salmonella in HVP

- Considered a major product recall due to public health impact (Salmonella Tennessee)
  - Used worldwide in many products
- Given expanded coverage on http://www.fda.gov/Safety/Recalls/MajorProductRecalls/HVP/default.htm
- February-April 2010
- Some say it is potentially the largest recall in US history

A Case Study

Salmonella in Hydrolyzed Vegetable Protein (HVP)
**Salmonella Tennessee**

- Symptoms
  - Fever
  - Diarrhea (may be bloody)
  - Nausea
  - Vomiting
  - Abdominal pain
  - If the organism enters the bloodstream, may cause arterial infections
- Can survive in dry products

**Basic Food Flavors, Inc.**

- Manufacturing HVP since 1980
- HVP is a flavor enhancer
  - Imparting meaty or savory taste (umami)
  - Available in liquid, paste, vacuum dried granules, spray dried powder, Identity Preserved Non-GMO forms
  - Found in ~10,000 packaged, processed foods

Source: [http://www.basicfoodflavors.com/](http://www.basicfoodflavors.com/)

**Some HVP Applications**

- Beef
- Chicken
- Pork
- Snacks
- Soups
- Stews
- Gravy
- Sauces
- Dips
- Salad dressings
- Spice rubs
- Seasonings

**The HVP Recall**

- HVP by Basic Food Flavors, Inc.
  - In liquid and paste forms manufactured after September 17, 2009
  - Including foods using this HVP if not cooked before serving (e.g., snacks, dips)
- As of March 24, 2010, no foodborne illness from this HVP or products using this HVP had been reported.

**Inspection History of Basic Food Flavors, Inc.**

- 1990: by US FDA; no violations
- 1996: by US FDA; one violation; company took voluntary action
- 2009: by a State contractor; no violations

**New Law on Reporting Problems with Food**

- September 2009: US FDA established the Reportable Food Registry (RFR) that mandates food industry to report within 24 hr of detection any problems with a food product
- February 5, 2010: Upon testing HVP purchased from Basic Food Flavors, Inc., a customer reported detection of *Salmonella.*
Inspecting Agency’s Response

- February 12, 2010: US FDA and the Nevada State Health Department began investigations
  - Later found contamination of one lot with Salmonella Tennessee
  - Also found Salmonella in the processing plant
- Set up a database of products containing this HVP
  [Source: http://www.accessdata.fda.gov/scripts/HVPCP/]

Inspecting Agency’s Response (cont’d)

- March 4, 2010: US FDA issued a press release about the firm-initiated recall
  - Industry must destroy or recondition recalled this bulk HVP
  - Recall foods containing this HVP
  - Issued consumer instructions
    - Check list of recalled products on FDA website
    - Follow cooking instructions for all foods
    - Report symptoms of foodborne illness

Inspecting Agency’s Response (cont’d)

- April 1, 2010: about 177 products containing this HVP have been identified
  - Database is searchable by brand name, product name, or a combination
  - Each product (e.g., bouillon, frozen food, gravy mix, sauce and marinade, etc.) may have been manufactured by several processors

Inspecting Agency’s Response (cont’d)

- Brands included
  - McCormick
  - Durkee
  - French’s
  - Pringles
  - Quaker
  - Safeway
  - Fresh Food Concepts
  - Hawaiian
  - Great Value
  - Trader Joe’s
  - Herbox
  - Garden Harvest
  - Publix
  - Kroger
  - Dean’s
  - Great Nut Supply

Inspection Form 483

- Observations of the inspection team, not a final FDA determination
- Listed FDA’s own Salmonella findings

Inspection Form 483 (cont’d)

- January 21, 2010: company received COA showing positive for Salmonella
- January 21-February 15: company continued distribution
- January 21-February 20: company continued manufacture under the same conditions without microbial contamination control

Source: [http://www.fda.gov/Safety/Recalls/MajorProductRecalls/HVP/ucm203784.htm](http://www.fda.gov/Safety/Recalls/MajorProductRecalls/HVP/ucm203784.htm)
Inspection Form 483 (cont’d)

- Detailed significant issues in the plant
  - Lack of microbial contamination control during manufacture, packaging, and storage of foods
  - Failure to conduct cleaning and sanitation procedures
  - Inadequately installed plumbing and inadequate drainage
  - Plant construction and design do not allow floors to be adequately cleaned and kept in good repair.

Source: http://www.fda.gov/Safety/Recalls/MajorProductRecalls/HVP/ucm203784.htm

Basic Food Flavors’ HACCP Plan

<table>
<thead>
<tr>
<th>HACCP Plan</th>
<th>Date of Evaluation</th>
<th>Product Area</th>
<th>CCP</th>
<th>CCP - ASSIGNED TO</th>
<th>Risk</th>
<th>CCP - PRIMARY PERSON</th>
<th>CCP - SECONDARY PERSON</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic Flavors</td>
<td>February 2010</td>
<td>HVP paste and powder</td>
<td>CCP-1</td>
<td>CCP-1</td>
<td>CCP-1</td>
<td>CCP-1</td>
<td>CCP-1</td>
</tr>
</tbody>
</table>


Basic Food Flavors’ Response (cont’d)

- February 26, 2010: began notifying its customers of a recall of all HVP in liquid and paste forms it had manufactured from September 17, 2009
  - February 27, 2010: Kroger recalled products
  - Mid-March 2010: Company still refused to comment on the recall

Source: http://www.foodproductiondaily.com/QualitySafety/BasiceFoodFlavors%27%20response%20to%20the%20recall

Basic Food Flavors’ Response (cont’d)

- March 17, 2010: Company broke its media freeze to FoodNavigatorUSA
  “While it is unclear whether FDA is suggesting in the Form 483 that Basic Foods knowingly shipped adulterated product, the language used by the agency and reported by the press has created that implication. We, therefore, consider it important to clarify that Basic Foods has not knowingly shipped into commerce any product the Company believed had the potential to contain Salmonella.”


Basic Food Flavors’ Response (cont’d)

- Form 483 of the company issued March 9, 2010 by the US FDA (FoodNavigatorUSA)
  “After receiving the first private laboratory analytical results [dated January 21] indicating the presence of Salmonella in your facility, you continued to distribute HVP paste and powder products until 2/15/2010. Furthermore, from 1/21/2010 to 2/20/2010, you continued to manufacture HVP paste and powder products under the same processing conditions that did not minimize microbial contamination.”

Basic Food Flavors’ Response (cont’d)
• Their website does not contain any progress report on the recall. There is no information on:
  – Company responses to the recall
  – What the company is doing to insure no product contamination in the future
  – What stage the recall is at

Unwanted Exposure (cont’d)
• The Daily Green, April 27, 2010. “HVP, a Non-Food, Continues to Cause More Food Recalls”
  • “…the industrialized food system and how easily it can sicken us, rather than nourish us.”
  • “…food manufacturers, it doesn’t sound like a farm, does it?”
  • “…how weirdly disgusting our food system is.”

Unwanted Exposure (cont’d)
• March 13, 2010 Pacifica Riptide
  “They documented dirty utensils and equipment-mixers and tubing coated with brown residue-and cracks and fractures in the floor, as well as standing water on the floor-all conditions where bacteria can breed. In one area where paste mixers and belt dryers were positioned, FDA inspectors noted "standing, grey/black liquid" in the drain near the area where the hydrolyzed vegetable protein was turned from paste to powder. "We sensed an odor in the vicinity of this drain," the inspectors wrote. Enough said? “
Source: http://www.pacificariptide.com/pacifica_riptide/

Unwanted Exposure (cont’d)
• March 12, 2010 Care2 Healthy and Green Living
  “We will now attempt to scare you into walking away from the processed food.”
  “Thousands of types of processed foods—including many varieties of soups, chips, frozen dinners, hot dogs and salad dressings—may pose a health threat because they contain a flavor enhancer that could be contaminated with salmonella.”

Lessons Learned

How the US FDA Minimized the Risk of Foodborne Illness
• Immediately began investigations after report of detection of Salmonella on RFR
• Communicated with the company
• Issued press release about the recall

Source: U.S. Food and Drug Administration
How the US FDA Minimized the Risk of Foodborne Illness (cont’d)

• Set up online Q&A for consumers, Q&A for the industry
• Set up online database of recalled products and brands
• Posted online public documents about the investigation and recall
• Posted online appropriate contacts

How the Company Minimized the Risk of Foodborne Illness

• Voluntarily recalled all involved products but not sufficiently timely
  – Form 483 cited their continuing to manufacture and distribute for more than 3 weeks after receiving confirming lab results of Salmonella

To Minimize the Risk of Foodborne Illness, the Company Should Have…

• Known what to do when the investigators knock
• Ceased production and distribution while confirming lab results
• Had a tested Crisis Management Program and a trained Crisis Management Team

To Minimize the Risk of Foodborne Illness, the Company Should Have…

• Had tested Recall Program and a trained Recall Team
• Announced recall to the industry and the consumers immediately upon verification (in different languages)
• Publicized on their website events and activities related to the recall

To Minimize the Risk of Foodborne Illness, the Company Should Have…

• Promptly returned media calls (only by designated company communication persons)
• Within the company
  – Checked coverage of insurance policy
  – Reviewed supplier qualification procedures and supply contracts
  – Obtained criminal law advice

Communicating the Problem

• Radio, television, & print media
• Full details on product
• State what is known and NOT known and what the company is doing to address uncertainties
• Instructions on how to handle suspect product
• Be open & honest
Group Exercise

• Recall Action Team Members:
  – Shall we do a mock recall?
  – Use your notes from the first exercise and let’s go.
  – Select a product to track.

Thanks to Jennifer Thomas of US FDA for her kind assistance.

Mahalo nui loa! Maraming salamat po!

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