Anatomy of a Recall
Five Steps Toward Food Safety Preparedness

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Preparing for the FDA Inspection
"I'm not quite ready to order. My lawyers are still studying the menu."
Don’t Trim Inspection of Meat - Beef It Up
– October 7, 2007
Food Poisoning For Profit?
Companies Are Acting For Their Own Benefit
When It Comes to Product Safety
– May 24, 2007
How Flawed Is Your Fish?
– May 16, 2007
“Topps Meat To Close Down After Meat Recall
Big Frozen Hamburger Maker Goes Out Of Business
After E. Coli Scare.”
Public Perception

- Regulatory Efforts Inadequate, To Date
- Food Producers are Profit, Not Safety, Motivated
- Consumers are Suffering and Dying as a Result
The New Environment

• Regulatory Inspections are:
  – More numerous
  – More aggressive
• Formerly Cooperative Atmosphere is Adversarial
• Decision Cycle is Compressed
Recommended Inspection SOP

- Create Written Document
  - Make it Plant or Product Specific
  - Be Able to Defend It Publicly
- Designate/Train Inspection Coordinators and Back-Ups
- Have QA/Reg. Affairs/Counsel on Stand-by During Inspections
- Employ Document Retrieval and Duplication System
  - Green (Must Surrender These On Request)
  - Yellow (Agency May Be Entitled To These On Request)
  - Red (Agency is Not Entitled)
- Document the Inspection
- Assign Follow-Up Responsibilities
Mechanics of the Inspection

- Written Notice (Form 482)
  - Routine
  - For Cause
  - Survey
- Broad (but not unlimited authority)
  - May:
    - Enter With No Prior Notice
    - Request Many Types of Operational Documents
    - Take Sample Product to Test
  - Generally May Not:
    - Take Product Formulations
    - Take Other Trade Secret Information
    - Take Photographs
Results of the Inspection

• Perform a High Level Exit Interview
• Notice of Inspectional Observations (Form 483)
• Establishment Inspection Report
• Reply in Writing that:
  – Follow up is welcomed
  – Corrective Actions have been implemented
  – All requests for information/documents have been fulfilled
Do Mock Inspections

• Train Inspection Coordinators
• Test Your SOPs
• Inspect Your Facilities
• Consider Including Counsel for Privilege Purposes
Developing An Effective Recall Plan
Agency Authority

• FDA’s Limited Authority To Order Recall
  – Infant Formula
  – Medical Devices
  – Human Tissue Products
• FDA’s “Voluntary Recall” 21 CFR §7.40(b)
• USDA’s More Expansive Authority
Delays in Recall Decisions

- May Encourage Seizure Under 21 USC § 334
- May Expand Scope of Eventual Recall
- Agency Indecision May be Detrimental
  - Open Box Rule
  - Absence of Written Requests for Documents
- Consider Recall Insurance To Cover Risk
Receiving the Call

• Identify the Weakest Link in your Company
• Have a Recall Decision Team in Place
• Assemble the Recall Decision Team Immediately
• Begin Assembling Available Data Immediately
Recall Decision Team

- CEO/Decision Maker
- Quality Assurance Representative
- Distribution/Sales
- Production/Operations
- Communications/Press Relations
- Counsel
- Regulatory Affairs
Real Time Data Accessibility

• QA Data
• Customer Complaint Data
• Have Laboratory On Retainer/Standby
• Production/Distribution Information
Define the Problem

- Trace Ingredients
- Trace Packaging Components
- Identify Potentially Affected Lots
- Retain/Segregate Product Still Under Your Control
Push the Red Button

- Form Letters to Accounts
- Software Lockouts In Distribution Centers
- Enforce No Sale Mechanisms at Retail Level
Determine Disposition Guidelines

- Have Reclamation Team on Standby
- Negotiate Retailer Assistance in Advance
- Get Agency Buy-In
- Balance Competing Interests
  - Public Health Concerns
  - Causation Evidence
  - Spoliation of Evidence
- Consider Testing of Returned Product
References

• 21 CFR § 7, Subpart C (FDA Guidance)
• Effective Recall Management for Food Service Distributors, IFDA (April, 2005)
Root Cause Analysis
Team of Two Headed Monsters
Case Assessment:
Food Borne Pathogen Litigation

- CDC suspects epidemiological link
- Consider Voluntary Recall (working with FDA or USDA)
  - FDA/USDA Site Inspection
  - Public Relations consideration:
    - Determination regarding recall, if any
    - Public statements
  - Cause-Origin Team formed:
    - Scope of recall, if any
    - Continuation or halting of operations
- Implement and disseminate Legal Hold notices
- Onsite Investigation
  - Fact Witness Interviews
  - Ensure Preservation of Evidence
  - Involve Consulting Microbiologist and Manufacturing Expert
  - Root Cause Document Collection
- Affirmative Defense, Cross Claims, Counterclaims & 3rd Party Defendant Analysis
  - ID Potential Third Parties
  - Review vendor contracts/indemnity provisions
  - Explore cross-contamination issues
- Public Relations consideration:
  - Determination regarding recall, if any
  - Public statements
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  - Determination regarding recall, if any
  - Public statements
Root Cause Analysis – Competing Interests

- Uncover causational evidence
- Publicly announce cause
- Implement remedial measures
- Spoliation of evidence
Team of Two Headed Monsters

Counsel Involvement Critical, But Not All Counsel are Created Equal

• Regulatory Framework
• Litigator
Team of Two Headed Monsters

- Facility Quality Control/Assurance Manager
- Plant Manager
- Maintenance Manager
- Human Resources Representative
- Consulting Expert
Evidence Assessment

- Witness Interviews
- Managerial Team Meetings
- Collection of Key Documents
- Monitor Agency Interaction
- Implement Measures to Ensure Preservation of Evidence
Attorney Client Privilege – Worth Protection to Prevent Plaintiff Mantra

• Sales over Safety
• Profits over People
Resist “Jumping the Gun”

- Complete evaluation of evidence
- Double check that your documents support your causational theory
- Get Agency Buy-in
- Identify Remedial Measures
- Disseminate accurate, complete, timely information
Changing Roles

• Former routine, cooperative Agency relationship will change
• No such thing as “confidential” agency communication
• Monitor document disclosure and dissemination of information
Consider Alternative Causes

- ID Potential Alternative Causes (packaging vendor, suppliers, transporters, subcontractors)
- Assess Viability of Third-Party Claims
- Review Vendor Contracts
- Put Vendors/Suppliers on Notice (preservation of evidence)
Corporate Communications: Keep it from Spinning Out of Control
The Ultimate Test of the Relationship

• Will the public view you as
  – Able to respond in the face of adversity
  – Deserving of their long term trust and confidence?

• Or
  – Putting profits over the health and safety of your customers?
Public Perception, Part Two

• Public will forgive
  – Mistakes, accidents, acts of nature
  – Not knowing everything right away
  – Reasonable efforts to protect a company

• Public will not forgive
  – Intentional or reckless acts
  – Equivocation
  – Inaccurate information
  – Being lied to
The “Will Rogers Rule”

“People have to think that you care before they care what you think.”
Spinning Out of Control – A Recipe

• Fail to resolve inherent tensions
  – Communications vs. legal
  – Food safety vs. liability
• Give inaccurate or misleading information
• Provide different information to different audiences
• Delay in responding
• LOSE CONTROL OF THE MESSAGE
THE MESSAGE

- Consumers
  - Press
  - The Board
  - Employees
- Regulators
- The Public
- Trade Associations
- Investors
- Third Party Allies
- Competitors
- Government
- Business Partners
- Customers
- Suppliers
- Insurers
- Potential Employees
The Challenge: Information that is

• Complete
• Timely
• Accurate
• Not an admission of liability
Developing the Message: All Hands on Deck
Elements of the Message

• Identification of the product
  – Amount
  – Labeling (Visual or link to web)
  – Product Codes
  – Other (Batch, run, origin)

• Geographical scope
The Message, cont’d

• Statement of the Problem
• Proposed Disposition of Product
  – USDA – “Throw it Away”
  – Refund: Keep Bar Code?
• Contact
  – Media
  – Consumer
The Message, cont’d

• Expression of Concern
  – Opportunity to reinforce relationship of trust
    • But, can be an admission in court
  – Touchstones: responsibility and reassurance
    • Responsibility ≠ fault
  – Do you point the finger?
    • No Pyrrhic Victories
    • Be ready for the follow-up question
Going Forward

• Speak with one voice
• Maintain control of message
  – Provide additional information as needed
• Keep team advised of media requests
• Coordinate any changes to basic message with team
Preparation

• Identify Recall Team
  – Including potential outside consultants
• Establish Media Contact Policy
• Create Lists – And Maintain Them!
  – Media
  – Regulators
  – Other stakeholders
• Review Mission Statement
Legislative Inquiries and Governmental Inspections
Investigative Offshoots

- 110th U.S. Congress
- FDA’s Office of Criminal Investigations (OCI)
- U.S. Attorney Criminal Investigations
- Investigative Journalist
Congressional Inquiries

• Document Requests
• Witness Testimony
• FOIA
Criminal Search Warrants

- Entry May Not Be Refused
- Scope of the Warrant
- Employee Rights
- Observe the Activity
- Document/Copy What is Seized
- No Obligation to Answer Questions
- Have an Attorney De-brief Interviewees
Investigative Journalist

- Preparation is the Key
  - No Surprises
- Typical Sources
  - FOIA Requests
  - Plaintiffs’ Attorneys
  - Congressional Staff
  - Disgruntled Employees
  - Competitors
- Get Your Position Heard
  - No “No Comments”