Crisis Management
In the
Food Industry

Mock Recall/Tracebility
Crisis Management Introduction

**Definition: Crisis management** is the process by which an organization deals with a major event that threatens to harm the organization, its stakeholders, or the general public.

Most individuals when asked about crisis management will think to recent environmental, political and financial based crisis events;

- Tornados in the Midwest
- Hurricane Katrina
- Strike
- San Francisco Earthquake
- Stock Market Collapse
- Transportation

Most organizations are very good about developing a contingency plan for these threats to their business. The question is, how often are they tested for effectiveness before the crisis?

**Acts of God, financial worries aside, a food manufacture must ask themselves, will our crisis management plan protect our organization if a RECALL occurs?**
Crisis Management flow chart (product related example)

NOTIFICATION OF A PROBLEM
Received by:
- Consumer Services Deptartment
- Sales
- Distribution
- Regulatory Body (Health Dept, FDA, DOA)
- Factories, Employee

Assess Information
- Crisis Manager Corporate
- Crisis Manager Factory
- Corporate Legal

Is this a crisis?

YES

- Notify Executive Level Management
- Call crisis committee
- Notifies other Markets involved
- Start Logbook

NO

Manage through routine QA procedures

Steps
1

Steps
2-3

Steps
4-6

Steps
7-10

Steps
11-12

Step
13

Step
14

Crisis Committee:
- Reviews data and information
- Assesses risks (Quality, Food Safety, Regulatory)
- Start action plan
- For product Crisis defines level of action (withdrawal or recall)
- Evaluates media & consumer perception and Set communication plan
- Communicates to Internal and local external stakeholders

1) Internal Withdrawal: our W/Hs & Distributors
2) Trade withdrawal: from retailers
3) Public recall: from consumers level

Ongoing monitoring and review of Crisis management actions from Crisis Committee

Completion of recall. Final report and lessons learned Evaluation of Crisis management

Initiate corrective actions (Process Owner)
Steps for Crisis Management Action

Step 1 Collect information
Step 2 Assess situation
Step 3 Decision tree (is this a crisis – yes/no)
Step 4 Alert Producing Factory Management and Functional Hierarchy
Step 5 Notify other markets
Step 6 Maintain a log book of activities, actions, dates, times, contacts
Step 7 Review Data
Step 8 Formulate Action plan
Step 9 Define level of action (withdrawal or recall)
Step 10 Communication to Stakeholders
Step 11 Ongoing monitoring
Step 12 Review of Crisis management actions from Crisis committee
Step 13 Completion of recall. Final report and lessons learned
Step 14 Evaluation of Crisis management
<table>
<thead>
<tr>
<th>Class 1</th>
<th>A reasonable probability that the use of or exposure to a product will cause serious adverse health consequences or death.</th>
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</thead>
<tbody>
<tr>
<td>Class 2</td>
<td>Use of or exposure to a product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.</td>
</tr>
<tr>
<td>Class 3</td>
<td>Use of or exposure to a product is not likely to cause adverse health consequences.</td>
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The Reportable Food Registry (RFR, or the Registry)

Any registered Food Facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States under section 415(a) of the FD&C Act (21 U.S.C. 350d) are required to report when there is a reasonable probability that the use of, or exposure to, an article of food will cause serious adverse health consequences or death to humans or animals. Reporting to the RFR is compulsory for class I recalls and optional for class II and III.
The Reportable Food Registry (RFR, or the Registry)

Class 1
Reporting to RFR is COMPULSORY

Class 2
Reporting to RFR is OPTIONAL

Class 3
Reporting to RFR is OPTIONAL
Types of Food Safety Actions

Market Withdrawal
• Removed from the supply chain
• No consumer action
• AKA “trade recall”

Product Recall
• Removed from the supply chain
• Consumers advised to take actions
  • “Do not consume the product”
  • “Return the product”

Product Recovery
• Internal removal or correction of products that:
  • Remain in direct control of the manufacturer
  • Primary distributor under firm’s control
Who is impacted when a food product is found unsafe?

- **Employees**: Loss of work – shutdown of factory
- **Customer**: Loss of sales
- **Manufacture**: Loss of customers
- **Litigation**: Claims and penalties
- **Supply**: Loss of supplier inventory
- **Employees**: Loss of work – shutdown of factory
- **Friends**: Loss or worry, concern for own safety
- **Family**: Loss or illness of a loved one, financial burden
- **Employees**: Reputation, concern for customers
- **Financial**: Loss of sales
- **Reputation**: Loss of consumer trust
- **Confidence**: Loss of Trust
- **Individuals**: Illness, sickness, loss of life or quality of life
- **Coworkers**: Extra workload, concern for personal health
- **Friends**: Loss or worry, concern for own safety
- **Consumer**: Loss of work – shutdown of factory
- **Supply**: Loss of supplier inventory
- **Confidence**: Loss of Trust
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Have you noticed these headlines?

**Los Angeles Times**

Salmonella peanut product recall grows
More than 125 products have been pulled back. The outbreak has sickened hundreds and may have killed six.

**CBS 6**

Cantaloupes linked to deadly multistate salmonella outbreak
By the CNN Wire Staff
(CNN) – Two deaths and multiple cases of illness across 20 states have been linked to cantaloupes contaminated with salmonella, according to the U.S. Food and Drug Administration.

State and federal health officials are advising consumers to discard all cantaloupes from southwestern Indiana, as tests have found evidence of the same strain of salmonella bacteria associated with a multi-state outbreak that health officials say is still ongoing.

**Plainview Milk Products Recall Covers Many Products**
Posted by Jane Aire
Monday, July 06, 2009 11:29 AM EST
Category: Major Medical; Protecting Your Family
Tags: Foodborne Illness, Public Health, Salmonella, Recall, FDA, Contaminated...
Recent Major Product Recalls

Undeclared Allergens

2012 Honey Crunchy Corn Dogs
  (class 1 undeclared milk)
2012 Bratwurst Products
  (class 1 undeclared milk)

Foreign Objects

2012 Crunchy Chicken Strips
  (class II foreign material)
2012 Frozen Bacon Cheeseburger
  (class II foreign material)
What is a Mock Recall? Are they necessary?

- Simulation exercise
- Tests organizations effectiveness of:
  - Procedures
  - Accurate documentation
  - Product accountability
  - Timely removal of product from circulation

Practice Makes Perfect

Time is of the essence.
Public is at risk.
Heavy fines.

Time is Money
and RISK
Frequency & Timing
Best Practices

• Annually at a minimum
• More is Better
• Be Unpredictable, do not announce ahead
• Do not schedule at convenient times
• Make scenario as real as possible
• Begin simple and work for more complex
• Multi layer distribution channels

• Include ALL departments
• Test ALL aspects of Plan
• Take simulation beyond internal
• Record ALL activities
• Utilize forms and templates
• Retain documentation
• Capture and apply learning's
“Traceability Exercise”
- Accounting of the physical inventory
  - finished product (100% accounting)
  - partially finished
  - packaging
  - raw materials ingredients

(± 2% accounting)

“Mock Recall”
- Full accounting of inventory
  PLUS
- From the supply chain to the customer
Traceability Exercises

1. **Trace Forward**
   - Ingredient forward
   - Purchased $x$-pounds of an ingredient ...where did it go?
     - Into what products?
     - Is there any left in inventory?

2. **Trace Back**
   - Customer back to ingredient
   - Customer reports illness, what is product is made of?
     - Trace lot number back to ingredients, supplier, shipper, receiving records

3. **Mass Balance**
   - Account for all the ingredients
Where did it come from and where did it go?
Trace Back – Customer back to production
Trace Forward – Ingredient forward  (mass balance)

(Amount Received) + (Amount Used/Batch) + (process loss) + (other)

Batches Produced

Mass Balance = 100% ± 2% within 2-4 hours Maximum
Sometimes Recalls are the result of

1. Consumer Complaint: Presence of peanuts in an “allergen-free” candy bar

2. Local Plants Investigate: The lot number can be traced back to the correct manufacturing sites (Plants 2 and 3) and batch number: “No peanut is involved in manufacturing process.” The problem comes from the supply chain

3. The Company Investigates its Supply Chain: It lists all raw materials used in the composition of the final formula and contacts suppliers who provided ingredients for the batch

4. Supplier Identified: Suppliers are contacted and one confirms the possible presence of peanut traces in its wheat flour

5. Label Claim Changes: from “Allergen-Free” to “May Contain Peanut Traces”

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Mock Recall: What does it take to be ready?

1) Establish a Recall Team
2) Write a Recall Plan (SOP)
3) Keep accurate Production Records
4) Keep accurate Ingredient and Packaging Lot Records
5) Know your communication plan
   i. Internal – managers, staff, supplier vendors
   ii. External – customers, distributors, regulatory bodies
6) Practice Trace and Mock Exercises
ANNOUNCEMENT: “MOCK RECALL”

Annual Corporate Mock Recall for Finished Product

Mock Recall Scenario:

We have received notification from the FDA that they have received multiple reports of illness tied to our Slow Churned, Limited Edition Coconut Pineapple Ice Cream with a manufacture code date of:

BEST IF PURCHASED BY 03/09/13
049-32 002 19:36 2LAP

They have cultured the product and have come back suspect for Listeria Monocytogenes.

We must assume that any product from this run CIP to CIP is suspect.

Please commence “MOCK” recall exercise for the finished product associated to this product run CIP to CIP including all lots produced.
Steps for Initiating A Mock Recall

Basic action steps:

1. Identify problem material and batch
2. Producing market must restrict the batch – place all product on hard hold
3. Run batch transaction for traceability and find stock in supply chain and deliveries to customers.
4. Execute material balance sheet (MBS) to reconcile batch quantity in supply chain and batch quantity with customers
5. Inform Distribution Centers (DC) or importing markets and block stock
6. Check analytical results for relevant batch
7. Run List of Outbound deliveries for identification of quantities and customers affected
1. Identify problematic batch(es)

2. Restrict batch

3. Identify shipments from producing factory

4. Locally sold product?
   - YES: Inform Distribution Center(s)
   - NO: Inform importing market(s)

5. Block existing stock

6. Run Mass Balance check accounting for FP against all RM utilized

7. Identify deliveries to customer
   - Manual process
   - System supported process

Communicate to customer

Physically recall batch from the shelf
Summary

Mock Recall & Traceability Exercise

• Simulation providing necessary practice
• Prepares organizations for crisis management
• Random announcement - surprise
• Reasonable scenario
• Timing is a key element
• Mitigate risk to the company, customer and consumer
• Practice makes perfect