



American Spice Trade Association

Leading Practices In Recall Preparedness

Roger Lawrence
Vice President, Quality Assurance
McCormick & Company, Inc.

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Where Recall Fits in the Food Safety Plan

- *PREVENTION – Build quality and food safety in from the start.*
- *INTERVENTION – Verify preventions with focused inspection, risk-based surveillance and testing.*
- *RESPONSE – Immediate response if compromised product reaches the market. Can be in the form of a withdrawal or a recall.*

Philosophy

- Supported from the top with three fundamental messages:
 - Vital to brand protection.
 - Cuts across all functions.
 - “All Hands on Deck” when the occasion arises.

Elements of Discussion

- Policy / Procedure
- Organization
 - Incident Management Committees
 - Hierarchy
- Planning
 - Ongoing Training
 - Mock Recalls
- Execution
 - Communication
 - Decision-Making

Recall Policy / Procedure

- Formal written policy.
- Establishes that our foremost, overriding concern is the safety of the consumer and protecting the public health.
- Defines:
 - Committee structure.
 - Incidents that trigger process to kick-in.
 - Investigative process.
 - Decision-making process.

Incident Management (Recall) Committee Structure

- Exists at business unit and corporate levels.
- Chair – Quality Assurance Head.
- Members – General Manager and cross section of function heads (manufacturing, sales / marketing, legal, corporate communications).
- Roles and interrelationship clearly defined.
- CEO has the final word (more later).

Incidents that Trigger the Process

- Actual or Potential Serious Health Hazards
- Actual or Potential Large Volume or \$ value loss or correction.
- Actual or Potential Adverse Publicity
- Actual or Potential Adverse Customer or Employee Relations
- Regulatory Infraction
- Actual or Potential Recall or Withdrawal of Raw or Packaging Material from a Supplier

Risk Analysis Model

- Know the definition of adulteration in the FD&C Act.
- Requires a model and constant, ongoing training to refine performance of the analysis.
- Should become “Institutionalized” i.e. the common language of risk in the organization.
- Analysis is absent of cost / benefit and tradeoff considerations.

Risk Analysis Focus

- **Food Safety Questions** (HACCP, Adulterants, Product Design)
- **Regulatory Compliance Questions** (Regulation Interpretations, Labeling, GMP's, Allergens)
- **Quality Parameters** (Your Requirements – Internal, Customer Requirements – External)

Severity Index – *Assessment of the Consequences*

- **Severity Index 4**
- **Severity Index 3**
- **Severity Index 2**
- **Severity Index 1**

Probability - *Likelihood that the hazard or situation will occur in the product.*

- **Probability Score 3**
- **Probability Score 2**
- **Probability Score 1**

Risk = Severity Index X Probability Score

	Risk Score			
	Severity = 4	Severity = 3	Severity = 2	Severity = 1
Probability = 3	Red	Red	Yellow	Yellow
Probability = 2	Red	Yellow	Yellow	Green
Probability = 1	Yellow	Yellow	Green	Green

Risk Score	Box Color
High	Red
Medium	Yellow
Negligible or No Risk	Green

How an Investigation Plays Out

- First Communication
- Interaction of Recall Committees
- Accurate, Comprehensive and Fast Due Diligence is achieved Through Deployment of all available Resources to develop a Recommendation.
- Process runs its course regardless of the recommended action even if it is “No Action”.
- Real Power of the Process
 - Collective Thinking, Input and Decision Making.

Ongoing Preparation

- Training
 - On boarding Quality Assurance members
 - Annual QA Conferences
- Mock Recall
 - Conducted annually.
 - Required of all plants: wholly owned, joint ventures, licensees and copackers.

SUMMARY

- They say there are two kinds of companies: Those that have had a recall and those that will.
- Wisdom is like a comb that Mother Nature gives you after you have lost all your hair.
- Those who have never considered a market action are at the greatest risk of being like a “deer stuck in the headlights”.
- The possibility of not adroitly handling an event can be catastrophic.
- Having a policy, a process and rehearsal is the best insurance a company can have.

END