

# Recall Risk Management: Compressing the Value Chain



**Craig W. Henry Ph.D.**

**Senior Vice President and Chief Operating Officer,  
Scientific and Regulatory Affairs**

**GMA/FPA Association**

**Washington, D.C.**

**IS/LD Conference**



**2007**



## Key Success Factors

1. Take Responsibility
2. Be Aware of Regulatory Authorities
3. Pre-Test Your Recall Program
4. Get the Facts; All the Facts
5. Communicate Early, Regularly, Completely
6. Follow up with Effectiveness Checks
7. Reassess and Confirm



# 1. Take Responsibility

- Legal responsibility
  - For product safety and wholesomeness rests with the officers and employees of a food manufacturing company
  - Have corporate counsel involved



## Take Responsibility

- Although not required by regulation\*, prudent companies should have, as an adjunct to a HACCP or food safety plan, a recall program to deal with potentially hazardous product inadvertently released into commerce
- Under the Bioterrorism Act all companies are responsible for the traceability of their products
- At the minimum, one step forward and back



## 2. Regulatory Authorities

### FDA and FSIS

- FDA and FSIS
  - Have authority to seize or condemn product not in compliance
  - Temporary State embargo
  - Can issue press releases if products represent a hazard
  - Under the Bioterrorism Act they must have appropriate cause to conduct investigations
  - **In view of recent food borne outbreaks involving produce this authority may be expanded**

# Regulatory Authority

## FDA

- FDA
  - Public Health Security and Bioterrorism Preparedness and Response Act of 2002 – Final Rule
  - Requires records for
    - Immediate previous sources
    - Immediate subsequent recipients of food
  - Provides detention authority



## Regulatory Authority States

- Most states have authority
  - To seize or hold product suspected of contamination or adulteration
  - However, most states do not conduct a records review
  - Therefore if a company's traceability program is insufficient then regulatory action is expected to be utilized to protect the public



## Federal Mandates

- Low-acid Canned Food regulations
  - Require companies to have an effective recall program
    - 21 *CFR* 108.35(f)
    - 9 *CFR* 318.311 &
    - 9 *CFR* 381.311
- But neither Agency has mandatory recall authority
  - Except for FDA-regulated infant formula



## Year-to-Date FSIS Recall Information

- FSIS now communicates recall information through only one document.
  - For Class I and Class II recalls, a news release is issued
  - For Class III recalls, info is found in a Recall Notification Report, or RNR on the website



# Year-to-Date FSIS Recall Information

- Statistics
  - 13 open cases at this time
  - 15 recalls so far in 2007
    - 5 – *Listeria monocytogenes*
    - 4 – Undeclared allergens
    - 3 – Underprocessing
    - 2 – *E. coli* O157:H7
    - 1 – Mislabeling
  - 34 recalls in 2006
  - 52 recalls in 2005
  - About 75% are from small or very small firms



# Year-to-Date FSIS Recall Information

- Sharing recalled product distribution lists
  - California law
    - Effective July 1, 2007
    - Notification of all consignees for Class I and II recalls in CA
  - FSIS proposal
    - FPA objected
    - Under Secretary says they will move ahead
- Visit with Recall Management Department staff and build rapport and their confidence in your product
- Visit with the state and federal agencies



## Federal Mandates

- FDA
  - 21 *CFR* 7 Subpart C (7.40 through 7.59)  
Recall Guidance
  - infant formula recall policy
    - in 21 *CFR* 107 Subpart E (107.200 through 107.280)



# Federal Guidelines

- FDA
  - Guidance for Industry
  - Questions and Answers Regarding the Final Rule on Establishment and Maintenance of Records – Sept 2, 2005



# Federal Guidelines

- FSIS
  - Procedures for recall of meat and poultry products are found in
    - FSIS Directive 8080.1, Rev. 4, dated May 24, 2005
  - Similar procedures would be applied to processed egg products



## 3. Pre-Test Your Recall Program

- Company recall preparedness
  - Thoroughly test your recall program
  - Most companies do easy
    - “non-branching” mock recalls are typical
    - Use a “branching” mock recall involving an adulterated imported ingredient used in multiple final products
    - Sudan I and raw almonds have tested many programs recently



# Imported Food Products

- Today, food companies universally utilize internationally sourced ingredients
  - The recall team must harmonize with the purchasing department
  - It is imperative to verify all aspects of letters of guarantee and certificates of analysis
  - Random occasional testing of ingredients = early warning system
- This issue arose with the spinach recall of 2006
  - **FDA found very poor record keeping and even availability**



## 4. Get the Facts; All the Facts

- In many cases Corporate Management expects regional operations to “have all records ready”
- Accumulate sufficient facts to properly characterize the issue
  - Have disease or injuries occurred from the use of the product.
  - Assess severity of hazard presented to targeted consumers especially those at greatest risk, e.g., children, the elderly, immunocompromised individuals, etc.



## Get the Facts

- Accumulate sufficient facts to properly characterize the issue
  - Assess level of exposure to the public and seriousness of the health hazard
  - Assess of the likelihood of occurrence of the hazard.
  - Assess the consequences (immediate or long-range) of occurrence of the hazard.



## Get the Facts

- Use a standardized form
  - FSIS - Directive 8080.1
  - FDA – 21 CFR 7; Product Recalls, Including Removals and Corrections – Industry Guidance
  - Submit the information in written form to expedite the process and prevent misunderstandings



## Get the Facts

- For example,
  - Ingredient being recalled for plastic foreign material -
    - Size of plastic
    - Shape of plastic
    - Color of plastic
    - Amount of plastic involved



## Get the Facts

- Assess your exposure
  - Does your process prevent entry of such foreign material due to screening?
  - Evaluate sufficient finished product
  - Determine if there is reasonable potential for risk to targeted consumer



## Get the Facts

- Know the “ship to” locations
  - Recent discussion at the state and federal level to make all consignees public information
  - It is wise to know the exact information about as many recipients as possible
  - **Big customers = Big distribution**
    - Have functional contact info
    - This was not the case during the tracking of spinach produce
    - **Consider the impact of a foreign supplied ingredient that might contain a bioterrorism agent**



## Product Tracking is Invaluable

- Reconciled raw material and batching records are a must
  - During some recent investigations on produce FDA found poor availability and
  - accuracy of records tracking product from supplier through batching for production
- This issue is more profound in the event of a bioterrorist event
- Companies must use all available tools to insure tracking of product and to protect the brand and the market



## 5. Communicate Early, Regularly, Completely

- Plan for Friday at 4pm Eastern Time
  - Regularly updated contact list imperative
  - Test the list at least quarterly after 4pm



## Notify the Proper Agency Early

- Have at least 1 back up contact number
  - Suppliers
  - Customers
  - Agencies (headquarters and districts)
    - Domestic responsibility?
    - International responsibility?



## Use All Resources

- Identify the proper Agency contacts
  - Trade associations
  - State agencies
  - FDA
  - USDA
  - International Agencies



## Move Quickly, but Effectively

- Once the facts have been accumulated and confirmed
- Use all resources to confirm the need for a recall
  - Agency with jurisdiction
  - Trade Associations
  - Consultants



# Press Releases

- Biggest problem is inaccurate information
  - FDA products – establishment writes the release
  - FSIS products – FSIS writes release but establishment has 30 minutes to review
  - Exporting country and US agency can prepare press releases



## 6. Follow up with Effectiveness Checks

- FDA Effectiveness Checks
- FSIS Effectiveness Checks
- Company Effectiveness Checks



## FDA Effectiveness Checks

- **FDA's expectation of an establishment**
  - “The purpose of an effectiveness check is to verify your recall notification letter was received by the customer, that the customer read and understood the letter and followed the recall instructions. The effectiveness check should also verify your recall reached the appropriate level in the distribution chain.”



# FSIS Effectiveness Checks

- **FSIS conducts the effectiveness check**
  - Industry responsibility - The recalling firm has the responsibility for conducting the recall and for ensuring that its actions have been effective in removing the product from the marketplace
  - FSIS verifies effectiveness using a risk-based statistical sampling plan



# Recall Program Effectiveness

- **Work closely with your customer(s)**
  - If possible, verify how your customer(s) execute a recall request
  - Know how effectively the recall is executed as far down stream as possible
  - Advantageous to all involved to verify each step of the process
  - Public health and brand name are at stake
  - **This is where a valid and reliable traceability program is paramount and invaluable in protecting the brand name**



## Confirm Product Disposition

- Confirm your customer has control of the product being recalled
  - History has shown that errors will occur during a recall
  - Product pulled from shelves or bins can be shipped without proper direction or chain of custody
  - **Compressing the value chain is exemplified when product is confirmed to be under control from “farm to fork”**



## Confirm Proper Labeling

- In the US, most companies have labels and HOLD tags in a single language, English
  - Apply **HOLD** and **WARNING** tags in the appropriate languages to avoid improper handling
  - Apply sufficiently to all sides of the pallet



## Confirm Control of Retained Product

- Product on “HOLD” ends up in another shipment due to -
  - HOLD tag on one side of pallet or “fell” off
  - No way to “lock down” recalled product to prevent unauthorized handling
  - Consider using refrigerated trailers with air brake locks
  - Federal and state agencies expect suppliers to have control of adulterated product



## Confirm Proper Disposal

- Obtain Agency approval for intended disposal of recalled product
  - Too many times a customer will ask if they can “dispose” of the recalled product to free up space and prevent reshipment
  - The Agencies can ask to supervise disposal



## Confirm Proper Disposal

- Consider the “attractiveness” of Branded product
  - Protect your brand and company name
  - Ensure labels from condemned product cannot be re-used
  - “See” the product and labels destroyed, rendering them unusable in their original form



## Trailers and Boxes Good to Go

- “Condemned” product can be further abused or mis-treated
  - “Oh just set the pallets outside by the fence, the rendering truck will be here soon.”
  - RTE product condemned or recalled for *Listeria monocytogenes*
  - “Over the fence and through the woods to someone's house it goes”
  - How close can the public get to condemnable product?



## Take Inventory and Confirm

- Communicate the status of the recall with reasonable frequency to the District Recall Manager for the Agency involved
- Maintain a good current inventory of recalled product, daily if needed
- Record the specific the Agency representative on your documentation supervising approved product disposal
- Strive to complete and terminate quickly



## 7. Reassess and Confirm

- Once the recall has been completed and terminated by the appropriate agency,
  - Recap all events and identify any shortcomings of the recall program
  - Communicate to all agencies, areas they could improve upon because they will certainly communicate this to your company
  - Correct the deficiencies and re-validate the program with mock recalls
- Confirm the effectiveness of your product traceability program
- **Product your brand throughout the food chain**





**Thank you !!!**

