



JOHN B. SANFILIPPO & SON, INC.

Mock Recall Procedures

The Global Source for Nuts

2008 NPSA Annual Meeting
Brenda Cannon
VP Innovation and Quality Systems
John B. Sanfilippo and Son, Inc.



Food Recalls

- May, 2004
 - Raw Almonds – 18 million pounds – Salmonella
- February, 2007
 - Peanut Butter – Product dating back to 2004
- March, 2007
 - Dog and Cat Food – Contaminated Wheat Gluten from China
- September, 2007
 - Frozen Hamburger – E. Coli – 21.7 million pounds
- February, 2008
 - Ground Beef – 143 million pounds – Safety and Animal Abuse Violations
- June, 2008
 - Nationwide Raw Tomato – Salmonella
- August, 2008
 - Sliced Meats and Prepared Sandwiches– Listeria – Six deaths confirmed and nine deaths under investigation

Out of business





What is a Food Recall?

- Procedures used to identify and recover potentially adulterated, misbranded and/or hazardous foods in order to prevent potential food safety problems or economic fraud.
- The current reference for recalls is the Code of Federal Regulations, Title 21, section 7.40, the "Recall Policy."





What can Prompt a Recall?

- Allergens
- Bacterial Contamination
- Chemical Contamination
- Communicable Diseases
- Undeclared Ingredients
- Foreign Objects
- Packaging Defects
- Misbranding
- Illnesses identified by the State Health Dept or CDC
- Tampering or tampering threats
- In-house sabotage
- Supplier's notification
- Real or fraudulent consumer claims





Decision to Recall

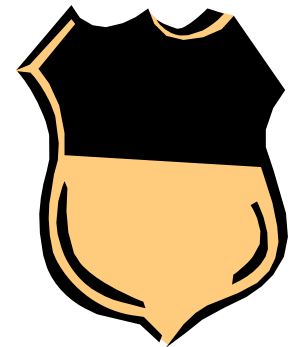
- A recall, unless otherwise determined by law, is a voluntary action
- The officers and employees of a food company have a legal and ethical responsibility to ensure that their products are safe, sanitary and accurately labeled
- Protect Brand, Protect Confidence of Consumer, Protect Employees and Shareholders and Protect Future of the Company





Government Agencies Which Deal with Food Safety Issues

- FDA (Food and Drug Administration)
- USDA (United States Department of Agriculture)
- FSIS (Food Safety and Inspection Service)
- APHIS (Animal and Plant Health Inspection Services)
- State and Local Agencies
- EPA (Environmental Protection Agency)
- FBI (Federal Bureau of Investigation)





Regulatory Basis of Food Recalls

- Federal agencies such as the FDA or FSIS do not “order” recalls – they “request” recalls
- Federal agencies can take stringent actions when a food product poses a significant health risk and a manufacturer does not launch a voluntary recall or the voluntary action is ineffective
- If company initiated recall, everything possible must be done to put the recall into motion promptly and not wait for the regulatory agency to review or approve the recall strategy
- It is in the best interest of a food manufacturer to fully cooperate with federal agencies.
- A food manufacturer should initiate a recall when requested by a federal agency although it is not required
- Before an agency formally requests a recall, it has evidence capable of supporting legal action





Classifications of Recalls

- Class I - a “reasonable possibility” that the product will cause serious adverse health consequences or death (Salmonella, Listeria, Botulism, product tampering, mislabeling)
- Class II – temporary or medically reversible adverse health consequences or the probability of serious adverse health consequences are remote (Undeclared sulfites, FD&C Yellow #5 or #6, unapproved additives or ingredients)
- Class III – violate federal regulations but are unlikely to cause adverse health consequences (Minor labeling problems, incorrect weight or volume declarations, produced under unsanitary conditions)





Before the Recall – Emergency Prevention and Planning

- Establish Recall Team and Recall Coordinator
- Develop a sensible and workable recall plan
- Identify risks and problem areas (Probability and severity of a problem, exposure to a problem)
- Implement effective measures to reduce or eliminate risks
- Test procedures and plans with Mock Recalls





Prerequisites of a Food Safety Program

- Raw Material Inspection Program
- Integrated Pest Elimination Program
- Sanitation Program
- Preventative Maintenance Program
- HACCP – Hazard Analysis and Critical Control Points
- GMP's – Good Manufacturing Practices
- Quality Management System
- Food Security Program
- Microbiological Monitoring Programs
- Environmental Monitoring Programs
- Finished Product Inspection Programs
- Documentation Policies
- Thorough Employee Training Programs





Mock Recalls are Critical

- An actual recall is not the time to test your recall/traceability system
- Bioterrorism Act mandates traceability in support of recalls or severe penalties can be imposed
- Test accuracy of documentation of code dates and lot numbers, quantity of cases produced and locations shipped
- Test system for “one-up, one-down” traceability
- Without mock recalls, will not know if your system works
- Always find things that don’t work
- Must be able to trace all product. In Class I or Class II recalls, a missing case or two of product can be critical
- JBSS policy for all plants, conduct 2 mock recalls annually and more if requested by customers
- 100% of product recalled in less than 4 hours
- Continually strive to improve – Goal is 100% in less than 2 hours





Mock Recall Exercise

- FDA notifies JBSS of positive salmonella results on random testing of Pecan Pieces
- Company recall coordinator is notified
- Convenes recall team (includes company attorney)
- Initiate investigation and compile all production, shipping, quality, customer and other pertinent information
- Check for existing inventory in warehouses and place on Hold
- Trace all product to shipping destinations
- Obtain samples/products for lab analysis
- Develop recall strategy and continue to investigate
- Notify FDA
- JBSS initiates formal product recall
- FDA classifies a Class I Recall





Press Release Sample

- John B. Sanfilippo & Son, Inc. of Elgin, IL is recalling Pecan Pieces, because it has the potential to be contaminated with *Salmonella*, an organism which can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with *Salmonella* often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with *Salmonella* can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis and arthritis.
- The Pecan Pieces were distributed through retail stores and direct delivery to customers in Texas, Oklahoma, and Nevada on June 30, 2008.
- The product was shipped in 30 LB cardboard cartons. The exterior cartons were labeled 57045 Natural Pecan Pieces Lot code 8106TL7H.
- No illnesses have been reported to date.
- The recall was as the result of a random testing by the FDA which revealed that the finished products contained the *Salmonella*. The company has suspended distribution of the product as FDA and the company continues their investigation.
- Consumers who purchased the pecan pieces should contact the store where they purchased the product to determine if their product is involved in the recall. Consumers with questions may contact the company at (847) 289-1800.





Product Trace



- Determine all item numbers involved and item descriptions
- Determine JBSS lot numbers
- Examine current inventory for suspect products
- Determine dates shipped and ship to locations
- Electronic tracking is performed using reports that show transactions per order (purchase order, work order, sales order), or transactions for a JBSS lot number.
- If electronic tracking is not available, documentation from receiving, production, and shipping is utilized to gather necessary information





Step By Step Procedure

- Obtain item number, description and code date
- Identify JBSS lot number (work order or production reports)
- Run reports by lot numbers or work orders
- Work order will identify inputs (raw materials) and outputs (finished product)
- Trace finished product – issue report by lot number showing customer orders
- Issue report showing order number, date and quantity shipped and ship to location
- Trace raw material – issue report showing raw material lot number and date of finished product packaging
- Unable to trace back to grower and receipt of in-shell pecans due to bulk storage in silos





Trace by Work Order

WO	Site	Type	Eff Date	Type	Item Number	DESCRIPTION	Loc Qty Change	UM	LP	Lot
57045	aa01	ISS-UNP	04/15/2008	CARTON	44638	CTN FISHER PECAN BULK	-50.00	EA		
57045	aa01	ISS-UNP	04/15/2008	CARTON	44638	CTN FISHER PECAN BULK	-97.00	EA		
57045	aa01	ISS-UNP	04/15/2008	MISC-PKG	46406	LINER,POLY 17X16X26.5 .9 MIL 375/CS	-50.00	EA		
57045	aa01	ISS-UNP	04/15/2008	MISC-PKG	46406	LINER,POLY 17X16X26.5 .9 MIL 375/CS	-97.00	EA		
57045	aa01	ISS-UNP	04/17/2008	MISC-PKG	46406	LINER,POLY 17X16X26.5 .9 MIL 375/CS	-49.00	EA		
57045	aa01	RCT-WO	04/15/2008	PECAN	57045	PECAN PCS, RAW FANCY MIDGET	1,470.00	LB	06720433	8106TL7H
57045	aa01	RCT-WO	04/15/2008	PECAN	57045	PECAN PCS, RAW FANCY MIDGET	1,470.00	LB	06720434	8106TL7H
57045	aa01	RCT-WO	04/15/2008	PECAN	57045	PECAN PCS, RAW FANCY MIDGET	1,470.00	LB	06720435	8106TL7H
57045	aa01	RCT-WO	04/17/2008	PECAN	57045	PECAN PCS, RAW FANCY MIDGET	1,470.00	LB	06720436	8106TL7H





Trace by Lot Number

Lot/Serial	Type	WO	Site	Eff Date	Item Number	DESCRIPTION	Loc Qty Change	UM	LP
8106TL7H	RCT-WO	57045	aa01	04/15/2008	57045	PECAN PCS, RAW FANCY MIDGET	1,470.00	LB	06720433
8106TL7H	RCT-WO	57045	aa01	04/15/2008	57045	PECAN PCS, RAW FANCY MIDGET	1,470.00	LB	06720434
8106TL7H	RCT-WO	57045	aa01	04/15/2008	57045	PECAN PCS, RAW FANCY MIDGET	1,470.00	LB	06720435
8106TL7H	RCT-WO	57045	aa01	04/17/2008	57045	PECAN PCS, RAW FANCY MIDGET	1,470.00	LB	06720436
8106TL7H	ISS-WO	583443	aa01	06/05/2008	57045	PECAN PCS, RAW FANCY MIDGET	-30.00	LB	06720433
8106TL7H	ISS-WO	582929	aa01	06/04/2008	57045	PECAN PCS, RAW FANCY MIDGET	-305.00	LB	06720433
8106TL7H	ISS-WO	581035	aa01	05/19/2008	57045	PECAN PCS, RAW FANCY MIDGET	-900.00	LB	06720433
8106TL7H	ISS-UNP	kb57045	aa01	04/17/2008	57045	PECAN PCS, RAW FANCY MIDGET	-1,470.00	LB	06720434
8106TL7H	ISS-SO	373749	AA01	08/01/2008	57045	PECAN PCS, RAW FANCY MIDGET	-330.00	LB	06910299
8106TL7H	ISS-SO	373360	AA01	08/04/2008	57045	PECAN PCS, RAW FANCY MIDGET	-390.00	LB	06922979
8106TL7H	ISS-SO	371638	AA01	07/23/2008	57045	PECAN PCS, RAW FANCY MIDGET	-210.00	LB	06931863
8106TL7H	ISS-SO	371471	AA01	07/21/2008	57045	PECAN PCS, RAW FANCY MIDGET	-270.00	LB	06910294
8106TL7H	ISS-SO	371471	AA01	07/21/2008	57045	PECAN PCS, RAW FANCY MIDGET	270.00	LB	06910294
8106TL7H	ISS-SO	371471	AA01	07/21/2008	57045	PECAN PCS, RAW FANCY MIDGET	-270.00	LB	06910294
8106TL7H	ISS-SO	370320	AA01	07/14/2008	57045	PECAN PCS, RAW FANCY MIDGET	-150.00	LB	06916795
8106TL7H	ISS-SO	369566	AA01	07/08/2008	57045	PECAN PCS, RAW FANCY MIDGET	-120.00	LB	06883875





Summary Data

- The trace for item number #57045 - Lot Code 8106TL7H has been completed.
- 5580 pounds were produced; 5580 pounds were traced; 100% in 2 hours and 35 minutes
- Issued to Work Orders
- 900 lbs were used to make item 75008 (Customer A) Lot Code 8140TOA Of the 30 cases produced there are 3 at AA05 (Customer A Warehouse).
- 30 lbs were used to make item 75008 (Customer B) Lot Code 8157SB7B. This was only one case and is in inventory in Selma.
- 1470 lbs were recased into item KB57045 Lot Code 8108TL7H. 49 cases (1,470 lbs) remain in inventory. 98 cases (2,940 lbs) were issued to work orders for Customer C items.
 - Work order 586512 used 1,470 lbs in the production of 1,920 cases of item 03451 (12/2.25 Pecan Cookie Pcs) Lot Code 8182SC7B. None in inventory.
 - Work order 586736 used 600 lbs in the production of 2,304 cases of item 03451 (12/2/25 Pecan Cookie Pcs) Lot Code 8182SC7B. None in inventory.
 - Work order 586744 used 870 lbs in the production of 312 cases of item 03457 (12/10 Pecan Cookie Pcs) Lot Code 8183SD7A. 4 cases in inventory.
- The remainder was used to make item 03451 (Customer C - 12/2.25 Pecan Cookie) Lot Code 8154SD7C. There were 768 cases produced and there is none in inventory.
- Retail Sales Orders
- 369566 Customer D - 4 cases of 57045 Lot Code 8106TL7H
- 370320 Customer E - 5 cases of 57045 Lot Code 8106TL7H
- 371471 Customer F - 9 cases of 57045 Lot Code 8106TL7H
- 371638 Customer G - 7 cases of 57045 Lot Code 8106TL7H





Recall Conclusion

- Maintain recall log
- Daily reports to FDA on recall activities
- JBSS conducts effectiveness checks
- FDA conducts effectiveness checks
- JBSS determines disposition of product
- JBSS recommends disposition to FDA
- FDA agrees to disposition
- Recall officially terminated by FDA once all reasonable efforts made to correct the violative product and remove it from sale





Summary

- The officers and employees of a food company have a legal and ethical responsibility to ensure that their products are safe, sanitary and accurately labeled
- Fully cooperate with federal agencies
- Have all prerequisites of a Food Safety Program in place
- Identify all risks and potential problem areas and implement measures to reduce those risks
- Establish a product identification and tracking system
- Ensure record keeping and documentation is impeccable
- Establish a mock recall team and action plan
- Conduct frequent mock recalls – an actual recall is not the time to test the effectiveness of your recall plan
- “One-up, one-back” traceability
- At all times, be prepared!!

