

Recall Execution Effectiveness: Collaborative Approaches to Improving Consumer Safety and Confidence



About FMI

Food Marketing Institute (FMI) conducts programs in public affairs, food safety, research, education and industry relations on behalf of its 1,500 member companies—food retailers and wholesalers—in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores and 14,000 pharmacies. Their combined annual sales volume of \$680 billion represents three-quarters of all retail food store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from more than 50 countries. FMI's associate members include the supplier partners of its retail and wholesale members.

About GMA

The Grocery Manufacturers Association (GMA) represents the world's leading food, beverage and consumer products companies. The association promotes sound public policy, champions initiatives that increase productivity and growth and helps to protect the safety and security of the food supply through scientific excellence. The GMA board of directors is comprised of chief executive officers from the association's member companies. The \$2.1 trillion food, beverage and consumer packaged goods industry employs 14 million workers, and contributes over \$1 trillion in added value to the nation's economy. For more information, visit the GMA Web site at www.gmaonline.org.

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GS1 US is a not-for-profit organization dedicated to the adoption and implementation of standards-based, global supply-chain solutions. More than 200,000 businesses in 25 industries rely on GS1 US for trading-partner collaboration and for maximizing the cost effectiveness, speed, visibility, and traceability of their goods moving around the world. They achieve these benefits through GS1 US solutions based on GS1 global unique numbering and identification systems, bar codes, Electronic Product Code-based RFID, data synchronization, and electronic information exchange. GS1 US also manages the United Nations Standard Products and Services Code® (UNSPSC®). www.GS1US.org.

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May, 2010

Dear Industry Stakeholders:

Consumer safety is the number one priority for GMA, FMI and GS1 US members—without it, nothing we do is possible. We take our responsibility for the products we manufacture and sell seriously and want consumers and policy makers to know that we are vigilant when it comes to safety and consumer protection.

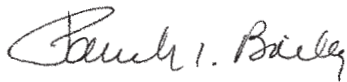
As part of our culture of continuous improvement, GMA, FMI and GS1 US have undertaken a thorough evaluation of the systems used to identify and remove recalled products from the supply chain. To date, this effort has resulted in two significant initiatives.

First, our industry launched the Rapid Recall Exchange last September. It is an innovative service designed to accelerate the recall notification and product removal process between trading partners. It currently serves more than 85 percent of supermarket sales volume and we continue to promote adoption of this valuable tool in other channels of retail trade such as food service, mass, drug and convenience store formats.

Recall Execution Effectiveness: Collaborative Approaches to Improving Consumer Safety and Confidence, published in partnership with Deloitte Consulting LLP, represents the second phase of our proactive effort to improve the recall process and provide recommendations for enhanced manufacturer-retailer recall execution. Specifically, the report focuses on current practices and opportunities in five key areas of the recall process: issue identification, recall notification, product removal/destruction, product replacement and feedback loop.

The efficiencies and insights gained from this report are important tools in the industry-wide quest to improve product safety and recall programs. Initiatives such as this one, combined with the industry's commitment to working with the Administration, Congress, Food and Drug Administration, U.S. Department of Agriculture, Centers for Disease Control and other stakeholders to strengthen our product safety net, are critical to bolstering consumer confidence in the brands and products they rely on everyday.

Sincerely,



Pamela G. Bailey
President and CEO
Grocery Manufacturers Association



Leslie G. Sarasin
President and CEO
Food Marketing Institute



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GS1 US

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Introduction

Objectives and Scope

This study examines the food and consumer packaged goods recall practices of both U.S. manufacturers and retailers and identifies opportunities to improve recall execution.


The scope of our research focuses on the response step of the “Prevention — Intervention — Response” framework used by the Food and Drug Administration (FDA) in its Food Protection Plan of November 2007, and specifically addresses Class I recall practices.

Practices discussed in this report that trading partners can consider in their efforts to work more effectively in the event of a recall are defined within the following key steps:

- **Issue identification:** Identification and investigation of affected products by manufacturers.
- **Recall notification:** Notification to all stakeholders (customers, regulators, consumers) about a recall, its status and necessary actions.
- **Product removal and destruction:** Removal of a recalled product from the supply chain and complete and proper disposal of the recalled product.
- **Product replacement:** Shelf replenishment to ensure consumer satisfaction.
- **Feedback loop:** Collaborative practices and knowledge sharing internally within organizations and externally with suppliers, retail partners and third parties.

In this report, we discuss current and leading practices for both manufacturers and retailers at each step of the recall execution process (Figure 1), and make both short- and long-term recommendations for improvement. Specific attention is paid to the identification and notification steps of the process, because — according to a recent Deloitte poll¹ and this study — companies view these as the most challenging steps and the biggest opportunities for improvement.

Figure 1. Product recall execution – Key steps



	Issue Identification	Recall Notification	Product Removal and Destruction	Product Replacement	Feedback Loop
Step Description	Process of identifying issues, escalating and triggering product recalls	Process of notifying consumers, employees, suppliers, and regulatory bodies of product recalls	Process of removing from the shelf and disposing of the recalled products	Process of replacing the recalled products on the shelf with a new product, brand, or SKU	Process of incorporating ‘lessons learned’ into future preventive / reactive recall practices
Step Objective	Minimize time required for issue detection, investigation and decision making to protect consumers	Provide all constituents with the required recall information as quickly as possible	Remove and destroy products as thoroughly and rapidly as possible to protect consumers	Replace the product on shelf, with minimal consumer harm and manufacturers / retailers negative impact (financial and brand related)	Continuously improve organization, processes, metrics and overall ability to execute recalls effectively

The geographical scope of this study is the United States only.

Approach and Methodology

The findings in this study are based on the analysis of:

- Survey responses from 54 companies, representing approximately \$152 billion in manufacturer sales and \$329 billion in retailer 2008 annual sales. Retailer survey respondents represent 47 percent of Super 50 all-commodity volume (ACV)².
- 29 industry interviews (15 manufacturers, 10 retailers and four service providers).
- Interviews with Deloitte subject-matter specialists (technology, retailer supply chain, manufacturer supply chain, regulatory and risk, food and product safety).

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The surveys and interviews were conducted from September through November 2009. The findings qualified to be included in this study if they were mentioned by three or more respondents as a part of the survey or interviews.

In addition, this study draws upon publicly reported company data, results from a recently conducted Deloitte poll³ and other published materials.

The current and leading practices outlined in this report are examples of practices cited by survey respondents or interview participants. These practices are options that companies should consider as they develop their own recall execution procedures. Ultimately, each company must determine what practices are most compatible with its products, manufacturing processes, distribution systems and available resources. The leading practices outlined in this report usually represent innovative or differentiated recall execution approaches. For that reason, they may be especially helpful as companies seek to improve recall efficiency and effectiveness. However, other approaches may be deemed equivalently or more effective in certain circumstances.

Because the study focuses on Class I recalls, those companies that have never had a Class I recall shared their plans, processes and procedures for Class I recalls. Thirty-five percent of the manufacturers interviewed have had a Class I recall in the past.⁴

Figure 2. List of survey respondents, manufacturers and retailers

Manufacturers	Retailers
<ul style="list-style-type: none"> • Bumble Bee Foods, LLC • Campbell Soup Company • Caroline Pride Foods, Inc. • Citrus World, Inc. • Clement Pappas & Co., Inc. • CMI, Inc. • Coca-Cola Enterprises, Inc. • Coca-Cola North America • ConAgra Foods, Inc. • Energizer Holdings, Inc. • General Mills, Inc. • H.J. Heinz Company • Hormel Foods Corporation • Kellogg Company • Kraft Foods, Inc. • Land O’Lakes, Inc. • Mt. Olive Pickle Company, Inc. • Ocean Spray Cranberries, Inc. • Pharmavite LLC • Pinnacle Foods Group LLC • Reser’s Fine Foods, Inc. • Snyder’s of Hanover, Inc. • Sun-Maid Growers of California • The Clorox Company • The Dial Corporation • The Hershey Company • The JM Smucker Company • The Procter & Gamble Company 	<ul style="list-style-type: none"> • Associated Food Stores, Inc. • Associated Grocers, Inc., Baton Rouge, Louisiana • Brookshire Grocery Company • Costco Wholesale Corporation • Dorothy Lane Market, Inc. • Hannaford Bros. Co. • Harris Teeter, Inc. • K-VA-T Food Stores, Inc. • Mars Supermarkets, Inc. • Meijer, Inc. • Nash-Finch Company • Publix Super Markets, Inc. • Potash Bros. Market • Riesbeck Food Markets, Inc. • Roundy’s Supermarkets, Inc. • Safeway, Inc. • Schnuck Markets, Inc. • Stater Bros. Markets, Inc. • SuperValu, Inc. • Target Corporation • The Great Atlantic & Pacific Tea Company, Inc. • The Kroger Co. • The Stop and Shop Supermarket Company • Wegmans Food Markets, Inc. • Winn-Dixie Stores, Inc. • WinCo Foods, Inc. Total: 26
Total: 28	Total: 26

Report Organization

The study is organized into the following sections:

Section 1: Call to Action — Current food and product safety complexities and the increased need for companies to focus on improved recall execution.

Section 2: The State of Recall Execution: Current and Leading Practices — Successful practices today in key areas of recall execution.

Section 2.1: Identification Process — Steps companies follow to minimize time required for issue detection, investigation and decision-making to protect consumers.

Section 2.2: Notification Process — Steps companies follow to minimize time required to notify consumers, customers, stores and regulatory authorities.

Section 2.3: Removal and Destruction Process — Ways companies make the removal and destruction processes more effective.

Section 2.4: Replacement — Actions companies take to replace the product on shelf, with minimal consumer harm and financial and brand impact.

Section 2.5: Feedback Loop — Ways companies improve organization, processes, metrics and their ability to execute recalls with speed and efficiency.

Section 3: Recommendations — Opportunities to improve recall management practices across three dimensions: a) communication and collaboration, b) processes, organization and metrics, and c) technology.

Appendix — Detailed data that supports the statistics presented throughout the study, plus additional reference materials.

Background: What Are Recalls?

Product recalls are defined differently by companies, industry bodies and regulatory agencies. Below are two commonly accepted definitions:

The FDA definition: Recalls are actions taken by a firm to remove a product from the marketplace. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority.⁵

The Food Safety and Inspection Service (FSIS) definition: A recall is a firm's action to remove product from commerce (e.g., by manufacturers, distributors or importers) to protect the public from consuming adulterated or misbranded products.⁶

Per the FDA's definition, recalls include those product violations that would result in government legal action. (For example, because of potential risk to consumers.) Under the FSIS definition, any regulatory violation due to product adulteration or misbranding would result in a recall.⁷ Companies need to work closely with the FDA and FSIS on a case-by-case basis to determine whether an issue with a product warrants a recall. Once an agreement is reached that a product needs to be recalled, the next step is to classify it based on potential health hazard.

- **Class I recall:** A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. For example, salmonella in peanuts.
- **Class II recall:** A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote. For example, allergic reactions due to undeclared ingredients.
- **Class III recall:** A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences. For example, minor labeling violations.⁸

A recall may be triggered by manufacturers, distributors or retailers, depending on who is responsible for the violation. For example, a manufacturer may not have processed the product correctly, while a distributor or retailer may not have stored the product under appropriate sanitation conditions. Ultimately, a successful recall entails strong collaboration between all players in the value chain, as well as with regulatory agencies.

Acknowledgments

Deloitte would like to express its appreciation to Grocery Manufacturers Association, Food Marketing Institute and GS1 US for the opportunity to assist in developing this study on such an important topic to the U.S. food and consumer packaged goods industry. Special thanks go to the GMA, FMI, GS1 US leadership team and the Joint Industry Shelf-Forward Recall Working Group for their commitment, time and contribution to this effort.

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Deloitte, GMA and FMI would like to recognize the many individuals from consumer product manufacturers and retailers who supported the research by completing the survey and/or participating in interviews. In addition, we would like to thank the service provider companies that contributed to this study by providing data and participating in the interviews: RQA Inc., Carolina Logistics Services (Inmar), and GENCO Damage Research.

Call to Action — Why Focus on Recall Execution Now?

Rising Number and Complexity of Product Recalls

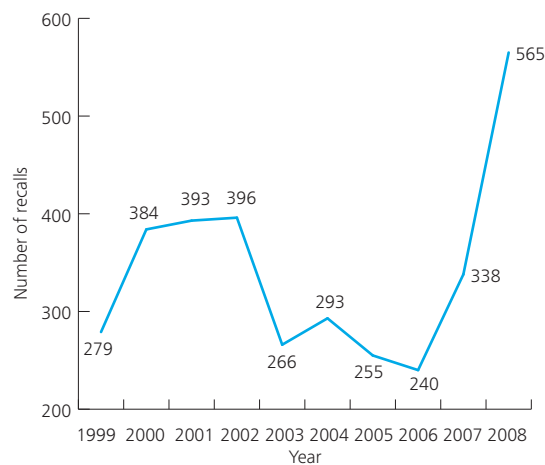
The number of product recalls has more than doubled since 1999 and appears to be accelerating. From 2007 to 2008, food and beverage recalls increased by 60 percent (Figure 3). The greatest increase was in recalls linked to Salmonella contamination and undeclared allergens. Recalls related to salmonella increased most noticeably — from 25 in 2007 to 240 in 2008.⁹

Many factors contribute to the increase in recalls — the growing complexity of the U.S. value chain, tighter regulatory requirements, improved early pathogen detection methods and enhanced testing techniques. Since improvements in these areas are expected to continue, manufacturers and retailers should be prepared to handle recalls effectively.

Recently the complexity and size of the recalls also have increased, thanks to the power of modern supply chains that can quickly distribute millions of product items from point A to point B within hours. Unfortunately, contamination spreads just as quickly. For example, in 2009, a salmonella outbreak for products manufactured by the Peanut Corporation of America led to a recall involving more than 1,000 different products,¹⁰ starting with bulk peanut butter, spreading to crackers and cookies, and finally engulfing products as diverse as kettle corn, Pad Thai and trail mix.¹¹

Based on this study, it was found that the average cost of a recall to participating food and consumer product companies is \$10 million, in addition to brand damage and lost sales. Needless to say, this study could not attempt to calculate the tremendous human costs involved in some product recalls. However, with the growing numbers, complexity and costs — both in human terms and to the industry — involved in today's product recalls, it is no surprise that managing these recalls more efficiently has become a top priority for the entire industry.

Figure 3. Number of food and beverage recalls by year



Source: Food Industry Report, April 15 2009

Growing Consumer Risk and Awareness

Recently, consumer attention is shifting to the issues of food and product safety. According to Centers for Disease Control and Prevention, 76 million Americans are impacted by food-related issues each year, including 325,000 hospitalizations and 5,000 deaths from foodborne illnesses.¹²

Another recent consumer study found that 73 percent of consumers surveyed feel that the number of food-related recalls had increased, 76 percent are more concerned about foods they eat than they were five years ago, and 57 percent have stopped eating a particular food because of a food recall.¹³

Shifting demographics and changing consumption patterns reinforce the need for the industry to pay attention to this issue. Consider the following statistics:

- Consumption of raw products is increasing very rapidly. For example, fresh spinach consumption grew 180 percent between 1992 and 2005.¹⁴
- The U.S. population is becoming more susceptible to foodborne illness — 20 to 25 percent of the population is comprised of the elderly, children and pregnant women — the highest risk categories.¹⁵
- By 2015, it is estimated that one in five Americans will be over the age of 60 and, therefore, more susceptible to certain types of infections. As more Americans live longer with chronic illnesses, including cancer and diabetes, vulnerability will only increase.¹⁶

Furthermore, society at large is exhibiting a strong interest in both the drivers of product recalls and in the steps companies should take to minimize the number of consumer health-related incidents. This has been demonstrated by a series of documentaries and articles developed over the past few years, as well as an increase of focus from consumer advocacy groups dedicated to communicating the risk associated with product recalls. For example, the Consumer Federation of America, consisting of 300 consumer groups and representing more than 50 million Americans¹⁷, is very active in food and product safety.

Significant Impact on Share Price and Market Value

Wall Street keeps consumer packaged goods (CPG) companies on their toes. This study found that the day after a recall announcement, the stock price of the affected company underperforms the sector index by an average of 2.3 percent.¹⁸ In fact, a company with poor recall execution processes could see declines of up to 22 percent within two weeks after the recall announcement.¹⁹

In addition, the study found that the way a company manages product recalls and how it communicates to the public have a direct impact on its stock price. Therefore, it behooves companies to be prepared to execute recalls quickly and with great efficiency.

Increasing Pressure From Trading Partners

As the industry focuses more attention on product recall management, individual companies face increasing pressure from trading partners to improve recall execution processes. The pressure varies from timely notification to effective removal and destruction of recalled product. The complexity of the modern supply chain (e.g., high number of SKUs, globalization of sourcing) also puts an additional burden on manufacturers to capture data and track ingredients, not just within their own four walls, but also up and down an expanded supply chain.

Given the number of recalls, retailers are also playing a more proactive role in the quality assurance of national brand items. Some retailers have started conducting tests on suppliers' products to detect food safety issues, especially on products that are deemed to be risky. For example, Wegmans Food Markets, Inc. conducts internal testing to detect mercury levels in swordfish and tuna.²⁰ Some other retailers add a clause on testing of incoming products in their transaction agreements or buyer specifications with suppliers.

The State of Recall Execution: Current and Leading Practices

Identification

In a recent poll, 42 percent of company representatives surveyed agreed that identification is the most important step in increasing effectiveness of recall execution.²¹ In fact, early identification and timely escalation of an issue are critical in preventing delays throughout the entire recall process.

Currently, manufacturers typically take from 0.5 to 72 hours²² to complete the identification process, measured from the moment an issue is detected to the moment a recall decision is made. Interestingly, there is a correlation between manufacturer size and the time required to run the identification process. Smaller organizations with few facilities (those with less than \$700MM in revenue and fewer than 15 facilities) complete the identification process in between 0.5 and 17 hours. Larger organizations take 32 hours²³ on average, because they need more time to make cross-functional decisions and trace more products through more facilities and numerous different distribution channels.

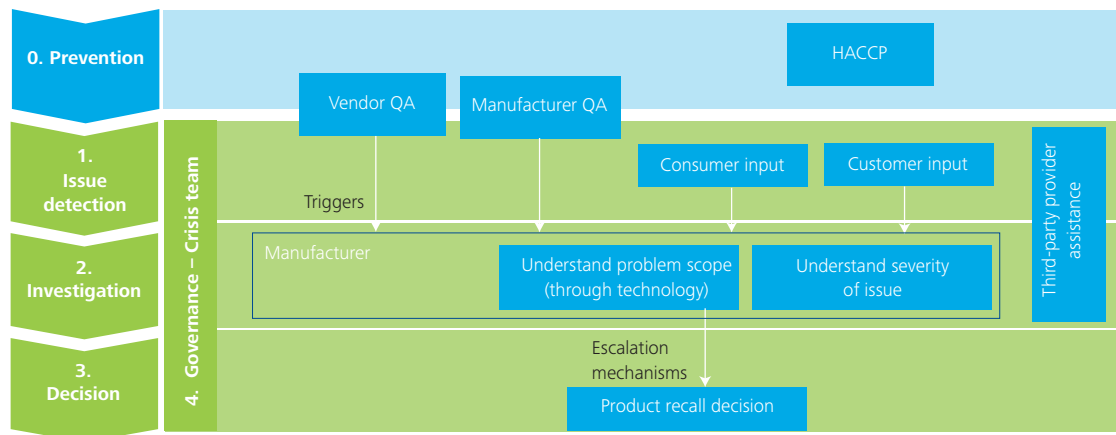
In some cases, including some recent high profile recalls involving fresh produce and seasonings, identification of a specific product that needs to be recalled occurs only after a protracted epidemiological investigation by CDC, FDA/FSIS and the states links human illnesses to a particular food or ingredient. At that point the decision to recall is generally preordained and little investigation is required by the food company other than to rapidly identify the lots of product that need to be recalled.

Companies need to deploy processes and systems that allow for structured and swift identification and escalation of recall issues across the following areas of identification:

- 1. Prevention:** Inhibits food safety issues through quality assurance processes; while not formally part of the identification process, prevention is important because gaps can lead to food safety problems.
- 2. Issue Detection:** Starts from the time a potential food safety issue is reported based on pre-defined triggers until an investigation is launched.
- 3. Investigation:** Determines the severity and scope through laboratory tests. Technology is used to locate the product.
- 4. Recall Decision:** Completes the identification process by reaching an internal decision that a recall should take place. The decision is typically made by a senior level executive.
- 5. Governance:** Helps ensure that crisis teams are involved from issue detection to investigation.

These areas of Identification, and activities within each, are graphically depicted below in Figure 4.

Figure 4. Key identification areas and activities



Prevention and Issue Detection — A Stitch in Time Saves Nine

Companies implement quality assurance (QA) processes to prevent food safety issues altogether, or, if an issue exists, to identify it as early as possible. Prevention can limit the number of recalls, as well as their severity. In this study, 81 percent of manufacturers represented in the survey already have a standard quality assurance (QA) procedure in place,²⁴ which helps prevent food safety issues and recalls. However, due to imperfections or failures of the QA process, recalls still happen. See the callout box on the right for select recall reasons.

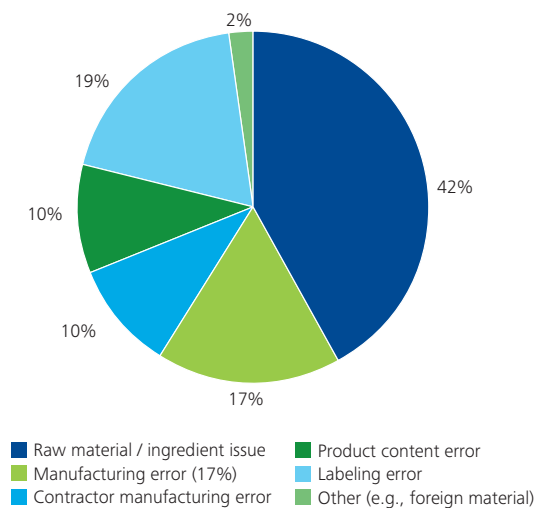
Selected Recall Reasons:

- Microbial contamination
- Misbranding (e.g., undeclared allergens)
- Foreign material contamination
- HACCP plan failure
- Chemical contamination
- Illegal pesticide or drug residues
- Packaging defects
- Worker illness or disease
- Intentional contamination

Source: GMA Product Recall Manual, 2010

The survey data shows that 42 percent of recalls stem from supplier-related raw material issues, and 56 percent stem from internal process issues, including manufacturer error, labeling error and product content error (Figure 5). These statistics indicate that companies may want to consider evaluating their need to improve QA processes within their organizations and at their supplier base.

Figure 5. Root causes of product recalls, manufacturers



Q. What caused the product recalls?
N = 14

Within their own quality assurance processes, companies may have clearly defined triggers for the detection of product issues early in the manufacturing process. Companies employ a multi-pronged testing approach to discover any raw or source material, any manufacturing process that might adversely affect public health in any way. Raw material or product found to have contamination levels exceeding defined limits are rejected prior to reaching the finished product phase, thus reducing the number of recall incidents.

Today, one of the standard ways of integrating triggers into the manufacturing process is a preventive program called HACCP (Hazard Analysis Critical Control Point), already implemented by many manufacturers. Based on our survey results, 88 percent of manufacturers represented have integrated HACCP with their supply chain processes across all their facilities.²⁵

Common Recall Triggers

- Detection of a pathogen
- pH value change on retained samples
- Micro testing of in-line product
- Micro testing of finished goods
- Misinformation and labeling
- Positive *Listeria monocytogenes*
- Harmful substance levels, e.g., pesticide, melamine
- Product tampering or sabotage

However, purely integrating HACCP with supply chain processes is not the same as having a comprehensive HACCP program that allows for immediate detection of an issue. A comprehensive HACCP program employed by leading companies includes these characteristics:

- Uses integrated technology systems rather than paper-based or spreadsheet systems.
- Communicates potential issues on a near real-time basis. For example, if the temperature of a product goes above a certain limit, the sensor would detect the temperature change, set off an alarm / alert and shut off the production line automatically.
- Extends beyond the company's facilities and goes all the way back to the raw material source (including farmers for agricultural products).

To help ensure quality outside their four walls, most manufacturers have supplier audit programs in place that require suppliers to provide a Certificate of Analysis indicating the completion of testing in compliance with quality standards. Most manufacturers also use third-party auditors to validate supplier quality.

However, simple intermittent audits may not be comprehensive enough. Without providing visibility into all the day-to-day operations of a supplier, these audits can easily miss an issue. Companies that are more advanced in managing quality:

- Work with third parties to tailor quality audits for different types of processing, materials and equipment.
- Define global quality standards for common processes and equipment.
- Run mock recall exercises at suppliers' facilities and reflect results in their audit scores

Issue Detection — Consumer Complaints Matter

Manufacturers typically receive consumer complaints through direct channels (such as the consumer hotline, email and web form email) or indirectly from retailers. Collecting consumer feedback helps companies quickly detect potential product issues.

Most companies in our study — 77 percent of manufacturers and 74 percent of retailers²⁶ — have a standard metric for consumer complaints, such as the number of complaints per week. Furthermore, these companies evaluate metrics, such as severity of issue, frequency of consumer complaints and consumer complaint hierarchy. These metrics, which differ from company to company, are typically defined based on a company's recall experience.

While no single metric is optimal for the whole industry, forward-thinking companies have started leveraging predictive techniques that use an understanding of the data patterns in prior recalls to help identify potential recall issues early in the

HACCP (Hazard Analysis Critical Control Point)

is a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product.

Source: FDA

Leading Practice: Technology-Enabled Prevention

A manufacturer implemented an integration and control system with scanning technology which matches the bar code on labels with container codes. If an issue is found during the matching process, the assembly line is halted. This system has reduced alleged labeling related complaints by 97 percent.

Source: Food Safety Magazine, "Building a World-class Allergen Control Program, Part 2," January 2009. <www.foodsafety-magazine.com>

Leading practice: Supplier audits

A large company conducts regular facility audits of all of its suppliers. As part of the scored quality audit, the company performs mock-recall exercises to determine the supplier's ability to identify a specific, theoretically contaminated, batch of raw material. The time taken to identify the batch and fax the applicable Certificate of Analysis impacts the supplier's audit score. The company uses the audit scores to annually evaluate its suppliers and award future business.

Leading practice: Investigating consumer complaints

Manufacturers can thoroughly investigate consumer complaints by either setting up a hotline internally or by using a third-party provider. Regardless of the method used, upon receipt of consumer complaints, the internal team or third-party provider reviews the data and issue to determine if the manufacturer could have a potential product recall issue. The results of this initial detection are promptly submitted to the dedicated recall team.

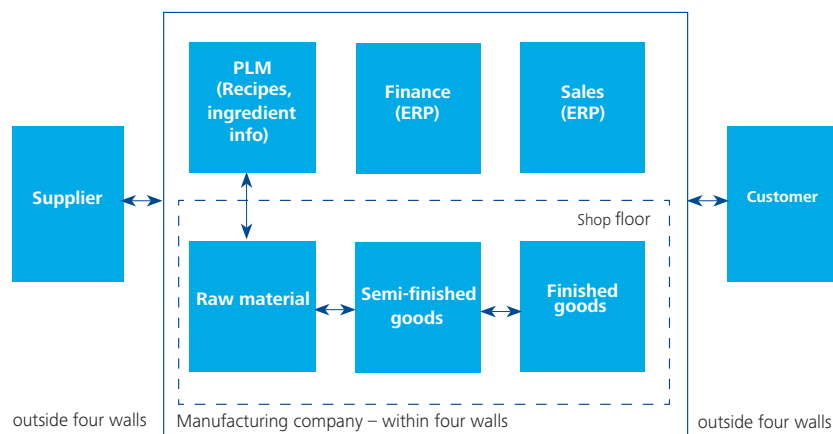
process. Predictive analytics are already prevalent in other parts of the consumer products industry. For example, companies use consumer demographics to identify which consumer segments will buy a new product.

Investigation — Four Walls Ecosystem Is not as Simple as it Seems

Once an issue has been detected, manufacturers must be able to identify both 1) the location of the product and other products that may have been affected within the four walls of the company and 2) the location of the product one step forward and one step backward in the supply chain.

Most companies surveyed say that tracking products outside their four walls is the key challenge for their organization, as well as for the industry. However, companies need to focus on their internal systems and processes as well so they can be more effective in pinpointing the affected lot and ingredient, in identifying location, and in fixing the manufacturing processes that led to the product contamination.

Figure 6. Manufacturing company technology system architecture



Information technology can play a critical role in this process. Using a cake product as an example, if the issue is with a raw material ingredient (e.g., flour), then the manufacturer should be able to determine which supplier provided the contaminated flour. Without automation and integration of data capture from raw materials to finished goods, companies are not able to easily locate the products within a reasonable timeframe.

Currently, 31 percent of manufacturers represented in our study can locate necessary information about affected lots within two hours.²⁷ Seventy eight percent of manufacturers can locate lot information within eight hours. Those companies that take longer than eight hours may want to take steps to improve their technology capabilities.

Even though most companies have at least partially automated their data capture capabilities, only 18 percent fully automate data capture throughout the entire production chain from raw materials to finished goods (Figure 7). This inhibits a company’s ability to identify the lot number of the affected products quickly.

To run effective and timely investigation processes, manufacturing companies may consider:

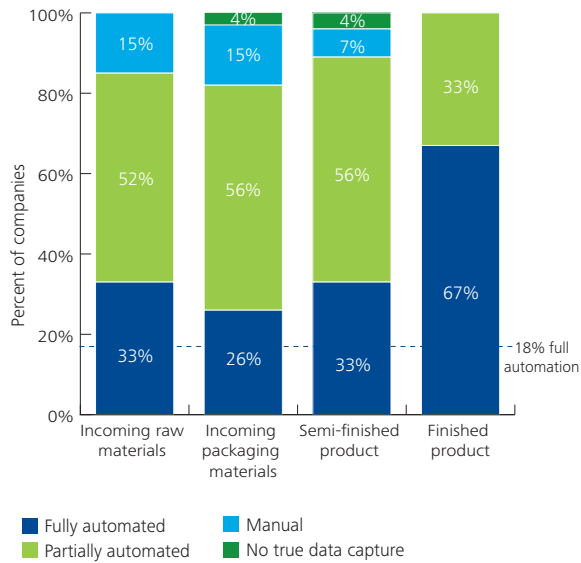
- Automated data collection systems and process discipline for the real-time capture of lot numbers and associated lot characteristics for all materials / products on the shop floor. For incoming raw materials, required data includes the lot number, the vendor lot number, the date of manufacture and any associated quality characteristics specific to the lot.
- For products produced in-house, data required includes the

Leading Practice: Internal Audits Test Ability To Identify Lots

A manufacturer runs scenarios to test its technology capabilities every quarter. Examples of scenarios tested include:

- Bottom-up tracking of poor quality packaging material through the supply chain based on the vendor lot number.
- Top-down tracking based on metal detected in a finished product at the customer.
- Related bottom-up tracking based on root cause of the metal.
- Bottom-up tracking of all products that contain a certain allergen and all customers that have received these shipments.

Figure 7. Level of data capture automation, manufacturers



Fully automated: Receipt and consumption transactions are performed on the shop floor using shop floor data collection devices such as scanners, weighing scales linked to computer systems, etc. Receipt of finished goods is completely automated.

Manual: Receipt and consumption transactions are manually written down on the shop floor. The actual transactions are performed in an office based on the data that has been written down. Receipt of finished products is manual.

Partially automated: Processes span an entire spectrum and are anywhere between fully automated and manual. For example, certain types of raw materials may be manual, but others might be automated.

Q. What is the level of automation of data capture and reporting for lot tracking of different materials on the manufacturing floor?
 N=27

internal lot number, date of manufacture and quality sampling data specific to the lot at the time of production and at the time of shipment.

- Ability to trace material movement and consumption by lot through the entire manufacturing process, both on the processing side and the packaging side.
- Automate recall reporting capabilities to enable top-down and bottom-up analysis and issue detection.

As part of the investigation process within four walls, companies need to be able to track ingredients and allergens easily and then map them back to the products in which they are used. To build on the example above, it is important to determine which other products use the same contaminated raw material ingredient.

Based on this study, at least half of the companies represented do not have capabilities to fully track ingredients and allergens across the one step up (to raw materials suppliers) and one step down (distributors, retailers) supply chain. This is likely the result of how information technologies are currently built and deployed. Typically, allergen data is stored in a Product Lifecycle Management System (PLM), and only 37 percent of manufacturers in our study integrate data between their PLM system and supply chain management system.²⁸ Some supply chain management systems can be designed to store one allergen in the data characteristics of a product. However, if a given product contains more than one allergen, supply chain systems are not designed to handle that kind of information and thus may need to be integrated with PLM.

Leading companies use middleware technology to integrate their PLM and supply chain management systems to:

- Translate R&D data effectively (such as formulations, specifications, recipes) to manufacturing data (such as bills of materials and routings).
- Provide better visibility to key ingredients and allergens through the manufacturing process, thus eliminating the need to maintain data in multiple systems.
- Improve version management processes to help ensure that the right version of the product bill of material and recipe is being used for purchasing and production.
- Automate packaging design collaboration with critical vendors.

Leading Practice: Integration of Product Life-Cycle and Supply Chain Management Systems

A manufacturer communicates packaging design changes with vendors as purchase orders are placed. Right versions of the label designs and artwork are automatically linked to the purchase orders based on the receipt date of the purchase order. Engineering change management processes drive the update of critical production master data, such as BOMs and routings.

Issue Detection to Decision — Collaboration Is Key

During the identification phase, cross-functional crisis teams can play a critical role. They can lay out the investigation plan, collect information, provide liaison among multiple departments in the organization to collect the necessary data and make escalation recommendations.

Currently 85 percent of the companies surveyed have dedicated recall teams.²⁹ However, not every recall team is equally effective. The following may be considered by companies in their efforts to run more structured and effective investigation processes:

- Involve the team from the moment the government notifies the company of a problem or an issue is detected through the investigation and decision-making processes.
- Structure the team so that it is cross-functional in nature (including supply chain, quality assurance, legal, etc.) to enable effective communication across the organization, as well as escalation of high severity recalls. (See Exhibit 12, Appendix 1 for information on cross-functional teams at surveyed manufacturers.)
- Clearly define the roles and responsibilities of the recall team before a recall to help ensure accountability and to help mitigate the complexities of coordinating with a large team spanning different departments.
- Have the crisis team collaborate with vendors during high-profile recalls; today 74 percent of surveyed manufacturers include vendors in their recall processes.³⁰

Some leading companies:

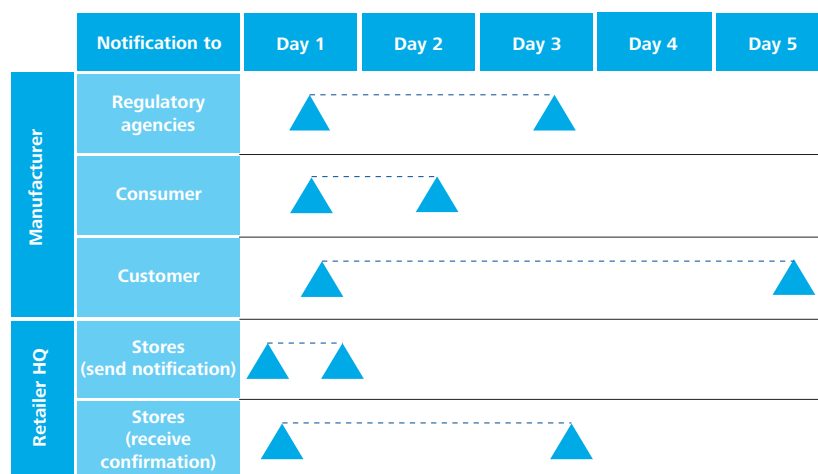
- Conduct thorough consumer complaint investigations internally or outsource certain areas of investigation, such as product identification and testing, to third parties. Both options meet the objective of rapid issue detection and investigation.
- Use outside experts to act as an independent checkpoint for decision making process.

Notification

In a recent poll³¹, notification was rated as the second most important step (after identification) in increasing effectiveness of recall execution. A poorly executed notification can delay the timely removal and destruction of products, jeopardize public health and negatively affect the company's market value and reputation.

According to our study, on average, manufacturers take one to five days to notify *all* constituents of a product recall from the moment an internal decision about a recall is made. Once retailers have been notified by manufacturers, the retailers complete the notification process, sending notification to their stores and receiving confirmation that the stores have been notified. The retailer notification process on average is accomplished within several hours or up to several days (see Figure 8). When a value chain includes additional constituents between the manufacturer and the retailer, such as a distributor or wholesaler, the information can be further delayed.³²

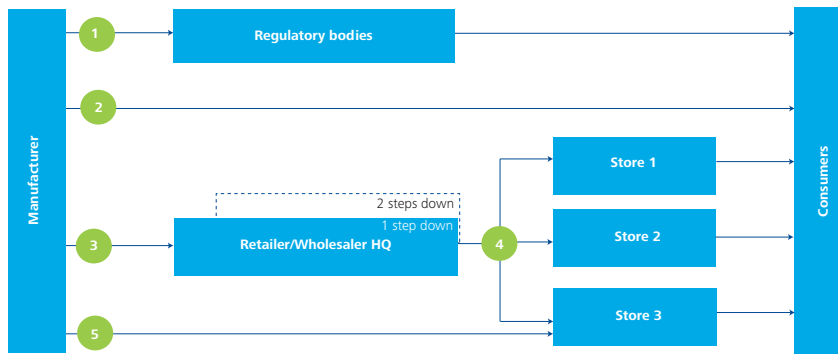
Figure 8. Notification time, days: manufacturers and retailers



According to this study, industry companies are working hard to improve notification procedures and policies. Some 54 percent of manufacturers and 65 percent of retailers surveyed say they have made significant improvements in notification procedures and policies over three years ago.³³ And, asked if the focus on improvement should be continued, 46 percent of manufacturers and 43 percent of retailers surveyed say they expect significant change in the notification procedures and policies over the next three years.³⁴

This survey found that participating companies with more mature recall execution processes and shorter notification cycles tend to engage in more notification activities, such as setting up a hotline for consumer questions or publishing information about a recall on the company website.³⁵ This finding suggests companies may consider engaging in a comprehensive set of activities to help ensure that all the constituents are properly informed across notification channels, as graphically represented in Figure 9.

Figure 9. Notification channels

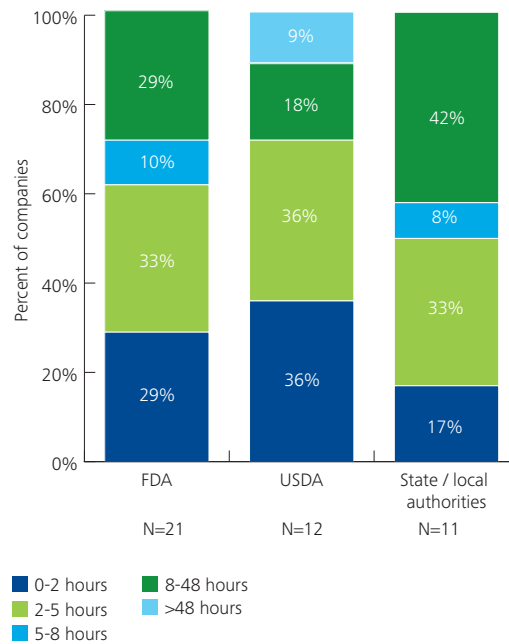


1. Manufacturer notifies regulatory bodies
2. Manufacturer notifies consumer
3. Manufacturer notifies customer HQ
4. Customer HQ notifies stores
5. Manufacturer notifies stores

Manufacturer Notifies Regulatory Bodies — Collaborate to Protect Consumers

Our study found that most companies surveyed are quite effective in working with regulatory agencies — 72 percent of manufacturers surveyed notify the FDA and/or USDA of a recall in eight hours or less (Figure 10). Those companies that notify the FDA in more than eight hours may need to be aware of the FDAAA (Food and Drug Administration Amendment Act of 2007) regulatory requirement, which requires notification of any reportable situations (Class I recall) to the FDA within 24 hours.

Figure 10. Manufacturer notification timelines: FDA, USDA and state authorities



Q. From the point of recall decision within your company, how quickly are the following stakeholders notified?

In September 2009, the FDA significantly simplified the information submission process. Today, any manufacturer can submit the information to the FDA through the FDA Reportable Food Registry — an electronic portal that is intended to foster swift communication between companies and the FDA.

The 2008 Farm Bill contains a provision that would require FSIS-inspected establishments to notify FSIS if adulterated or misbranded products have entered the marketplace. To date, FSIS has not implemented regulations to carry out this provision. However, meat, poultry and egg product manufacturing companies should still notify and work with FSIS to ensure they are taking all the necessary measures to protect consumers.³⁶ Based on our study, 72 percent of meat, poultry and egg product manufacturers notify FSIS within eight hours or less from the time the issue was detected.

Like FSIS and FDA, most state authorities do not have mandatory recall authorities. However, most states expect recalling companies to have recall information readily available and inform the state promptly once a recall decision has been made. Leading manufacturers already proactively inform state authorities. Based on our study, 39 percent of manufacturers responded to the question about notifying state authorities, and 58 percent of them said they do so within eight hours or less (Figure 10).

Appendix 5 contains links to useful FDA and FSIS resources that can assist recall team members understand the FDA and FSIS requirements.

Information Submitted to FDA Through Reportable Food Registry

- The registration numbers of the responsible party under section 41 5(a)(3) [21 USC § 350d(a)(3).
- The date on which an article of food was determined to be a reportable food.
- A description of the article of food, including the quantity or amount.
- The extent and nature of the adulteration.
- If the adulteration of the article of food may have originated with the responsible party, the results of the investigation required under by FFCA Sec. 417 (d) (1)(B) or (7)(B), as applicable and when known.
- The disposition of the article of food, when known.
- Product information typically found on packaging, including product codes, use-by dates and names of manufacturers, packers or distributors sufficient to identify the article of food.

Source: "GMA Product Recall Manual," January 2010

Manufacturer Notifies Consumer — A Reassured Consumer Can Be Your Best Ally

Some companies may not be adequately prepared to notify consumers during a recall. In this case, timelines tend to extend and the risk to consumer safety increases. Furthermore, shareholder value and public confidence can take a hit. For example, based on our analysis, in 2002, the absence of adequate communication with the consumer resulted in a 2 percent stock price decline (index adjusted) for a large manufacturer of multiple products one day after a Class I recall of one of its product. Five years later, the company had another Class I recall event, but experienced no negative impact on its stock price because the company effectively harnessed multiple communication channels to inform the public.

Figure 11. Comparison of two different communication approaches

Dimension	Recall A	Recall B
Total cost of recall	\$10 MM	\$28 MM
Press Release	None immediately, some notification to public later	Yes, very detailed, issued immediately (included next steps for consumers, hotline number, problem with product)
Use of other public notification channels	No	Yes
Tone of public notification (according to press)	Emotionless and unfeeling	Reassuring and constructive
Overall press coverage	Negative	Positive
Recall management	Poor (in a month recall is extended to more volume)	Excellent (identified all units involved immediately, shut down plants)
Results	2% drop in stock price	No impact on stock price

Example: Proper Consumer Communication Reassures the Public

A company had two incidents of Class I recalls. For the first recall the company was caught off guard and did not adequately notify its consumers. The company saw an immediate share drop of 2 percent versus a sector index. For the second recall a few years later, the same company provided detailed reassuring communication using multiple channels. The share price did not change after the second recall. The details are provided in the table above: (Figure 11)

When a recall decision is made, a company should be quick to deliver the appropriate message to the public, based on its pre-developed crisis communication strategy — a strategy that may include:

- Generic message to the public by recall class that can be customized to a specific recall.
- Level of information to be shared based on severity of recall / by recall class.
- Designated spokesperson.
- Priority communication vehicles (e.g., press release, hotline).
- Alternative ways of communication (e.g., retailer loyalty database) by recall class.
- Execution guidelines for communication vehicles.
- Role of legal department.
- Third-party and public relations agency involvement.

Important communication vehicles include press releases and consumer hotlines. In the event of a Class I recall, all companies included in our study published a press release. However, it takes 0.5 to one day³⁷ to issue a press release, which means companies may miss the next morning media cycle. Manufacturers can compress this timeline by tapping into their crisis communication strategy and leveraging pre-defined press release templates published on the FDA Web site. These templates, together with key guidelines in the crisis communication strategy, can also help minimize the coordination time to get a press-release approved by the FDA.

The press release message matters. As a general rule, to minimize negative public reaction companies should be open with consumers, keeping consumers informed on what is happening and the steps that the company is taking to correct the situation. Additionally, companies may consider the guidelines presented in Figure 12 in their efforts to become more effective in communicating with consumers and in avoiding common pitfalls.

Figure 12. Do's and Don'ts to consider in communicating to consumers

Do...	Don't...
<ul style="list-style-type: none">• Create public trust by stressing what your company is doing to monitor, manage and reduce risk• Respond to issues as rapidly as possible• Communicate compassion and concern for potentially affected consumers• Provide detailed information through multiple channels such as website, 800 number, etc.• Use third party experts and other credible sources to support the message• Make sure your audience perceives that they have an opportunity to make an informed choice• Provide the full UPC barcode number in communication to consumers	<ul style="list-style-type: none">• Expect scientific facts or statistics alone to reduce public anxiety• Forget to communicate to internal employees• Let inaccurate or misleading claims go unchallenged• Cover up the problem and fail to acknowledge it

Source: The Food Institute, "Food Products Recall Manual," 2009; Survey and interview participants.

Among our survey participants, 89 percent of manufacturers use hotlines to support consumers through the Class I recall process and to answer the consumers' questions.³⁹ However, many of these hotlines may lack sufficient capacity or well-trained agents. Consumers can become even more frustrated if an agent does not have comprehensive information about the recall or about next steps. Long wait times can also aggravate consumers. Leading companies have made a targeted effort to maximize the quality of the hotline experience and provide comprehensive advice to consumers in the case of a recall.

As an additional communication channel, retailers' loyalty cards are a useful way to notify consumers. Our study found that it takes retailers from two to 48 hours to notify 80 percent of their loyalty card consumers.³⁹ The short timeframe and targeted nature of this vehicle makes it a valuable additional source of communication. Currently less than 50 percent of retailers have loyalty card programs and issues of consumer privacy and accuracy of the contact information still limit this option.⁴⁰

Examples of ways leading retailers have used their loyalty card programs:

- Inform consumers at the point of sale (e.g., indicate on their receipts that a product purchased in the past is being recalled and how the consumer can return it).
- Proactively reach out to consumers who have bought the recalled product by phone, mail or e-mail. For example, one retailer made more than 1.5 million automated phone calls and mailed letters to consumers in the peanut butter recall case.⁴¹ Retailers inform consumers about the affected U.P.C./lot numbers and explain how to return/destroy the product.

Manufacturer Notifies Customer HQ — The Seemingly Simple Can Be Complex, Yet Critical

This study indicates that surveyed manufacturers at times can take from one to five days⁴² to notify direct customers. Some smaller retailers reported during our interviews that in some instances they do not receive notification from manufacturers at all, especially since manufacturers have no visibility to many of these stores and depend on wholesalers and distributors to notify smaller customers in their supply chain.

These delays in customer notification can occur due to multiple reasons, including:

- Lack of clarity on the exact information that needs to be provided.
- Inability to reach customers due to lack of contact information. Forty five percent of manufacturers participating in the study either do not store customer recall team contact lists, or they update the lists only once a year or less frequently.⁴³
- Limited means to control execution. Although those manufacturers that have had a Class I recall in the past require that the account manager / sales team confirm that a customer has been notified, 23 percent of all manufacturers surveyed still do not require their manager/teams to do so.⁴⁴ Also, 23 percent do not require any confirmation from their customers that they have actually received and read the notification. Having a process in place that provides a confirmation could reduce the probability that information will reach a wrong person and/or go unnoticed.⁴⁵
- Minimal 24/7 operations. Some manufacturers still do not have the ability to notify stores during after-hours (evenings, weekends, holidays).

Manufacturers may improve timeliness of their customer notification by, first and foremost, developing a checklist of exactly what information is needed to execute the recall. A sample checklist is provided in Appendix 2.

Manufacturers also should ensure that they maintain accurate customer contact lists. Since information on these lists changes often, they should be updated frequently.

Manufacturers using brokers should coordinate who is responsible for retailer notification — an agreement that should be arranged well in advance of any possible recall incident.

Leading Practice: Comprehensive Hotline Approach

One large company provides a hotline number to consumers via press release. The hotline has the following capabilities:

- High call-handling capacity (that uses Cloud technology) for the cases of elevated concern during the recall.
- Multi-language capability to cater to different demographics. Also customize message to different markets or countries, if applicable.
- Trained agents who can effectively address various concerns and provide necessary information to consumers without jeopardizing company's brand. Agents are able to address related issues. Hotline handles not only company-specific recall concerns, but also other related issues (e.g., Avian Flu).

The company is willing to absorb the high cost of the hotline to ensure that their consumers are fully informed and aware of next steps.

Leading Practice: Sales Force Accountability

A large company involves their sales force early in the recall process and holds them responsible for pushing out notifications to their respective customers. The sales team has to join sales calls to discuss any issues their customers are experiencing. The recall crisis team advises on how to handle each specific request. During the call the sales people share leading practices or concerns.

Sales teams should be held accountable for communication with retailers; they should be involved early in the process. Daily conference calls with the sales force can be used to help them respond to their customers' questions. Each account team should define recall working plans to ensure 24/7 coverage.

It is important for manufacturers to ensure that they receive from their customers a receipt of recall notification and a confirmation of the execution of the recall.

Often retailers participating in the study claim that manufacturers do not provide all the information they need to take action. One retailer commented during our interviews, "Providing me with a U.P.C. number and telling me that it was shipped between May 1 and May 15 to one of our distribution centers is not enough and is unacceptable."

It is suggested that manufacturers provide specific information on which U.P.C. / lot number is affected, exactly when it was shipped, and to which distribution center. Some participating retailers indicate that a picture of the product helps their stores find a product faster. Currently, only 56 percent of the surveyed manufacturers provide photographs of the recalled product to their customers.⁴⁷ Moreover, some manufacturers surveyed (22 percent) do not provide instructions on the product's removal and/or destruction instructions to retailers.⁴⁸ Some participating retailers say that instructions are provided to them too late, after the product has been removed and placed in storage.

Rapid Recall Exchange

An industry portal that applies industry expertise and successful practices to standardize product recall and withdrawal notifications between retailers/wholesalers and manufacturers.

It provides the following benefits to the participants:

- Prompt, targeted and accurate information exchange during a recall.
- Time savings on information aggregation
- Consistent, reliable communications.

Features include:

- Up-to-date customer contact information.
- Two-way messaging.
- Email alerts about new information.
- Comprehensive, prioritized information with U.P.C. bar codes and product images for easy identification, as well as the ability to add other specific product codes.
- Confirmation of customer notification.
- Universal notification of Class 1 recalls.
- Standardized form, process and instructions apply industry leading practices including product removal and reimbursement instructions.
- Ability to conduct mock recall scenarios.
- Customer service support including 24/7 technical assistance.

Rapid Recall Exchange

The Rapid Recall Exchange was created launched in September 2009 by industry leadership organizations FMI, GMA and GS1 US to ensure prompt, accurate and secure product recall and withdrawal notification for all sizes and types of retailers, wholesalers, distributors and manufacturers in the U.S. food and consumer products industry. It was designed to address the challenges suppliers, whether they be manufacturers, wholesalers or distributors, have in notifying their customers and the challenges retailers, wholesalers and distributors have in receiving effective notification. At press time, over 160 companies had subscribed, including 90 retailers that together process 85 percent of all supermarket purchases in the United States today (measured in revenue). Suppliers using Rapid Recall Exchange with their customers know what information is needed for effective recall execution, need not maintain contact lists for these customers and receive verification of receipt along with the ability to receive feedback from their customers on recall execution progress. Of those surveyed in this study, 40 percent of retailers and 30 percent of manufacturers were using Rapid Recall Exchange.⁴⁶

The above recommended leading practices were incorporated into the design of the Rapid Recall Exchange. For example, manufacturers can insert UPC codes, pictures and other identifiers; the Rapid Recall Exchange provides manufacturers with confirmation of notification; and, the system includes the capability for retailers to communicate the progress of recall execution back to the manufacturers.

Although still in its early stages, all interviewed retailers and manufacturers say that the Exchange will become a more viable solution for the industry once reasonable levels of participation are achieved. Broad adoption of Rapid Recall Exchange is expected to improve in the months and years ahead, although there will always be some industry companies that do not subscribe. For this reason, many of the processes involved in a product recall that would be eliminated for companies using Rapid Recall Exchange are detailed in this study in their entirety. (It is also interesting to note that the Exchange can be used not only for recalls but also for removal of any product from the supply chain.)

Manufacturers can help ensure retailers are enabled to remove the products by sending them a customer letter with all

the information needed for retailers to execute the recall. Again, using Rapid Recall Exchange, retailers can document any of their own specific recall data requirements and post these guidelines with the Exchange for manufacturers to access. And while the Exchange gives standard information on the product being recalled, including removal and destruction instructions and reimbursement instructions, any specific, detailed special retailer requirements also are noted. However, for those companies not using the Exchange, these customer letters can be pre-developed before the recall and customized to each distributor's specific requirements. The letter could include:

- **Comprehensive information about a recall and product affected.** A sample checklist of information to be provided to retailers is presented in Appendix 2. While the details differ from recall to recall, this sample could serve as a guide to manufacturers.
- **Removal and destruction instructions.** Refer to Appendix 3 for sample destruction guidelines.
- **Reimbursement instructions at the time of notification.** These should specifically state how customers will be reimbursed (specific lots, U.P.C.), as well as the evidence and documentation the retailers need to provide.
- **Sample "next in the chain" customer letter** that can be passed to other constituents in the supply chain. This can help the customer take quick and easy action.

Leading Practice: Customer Letter

A large manufacturer sends a five-page letter to each customer. The letter is tailored to customer needs based on recall specifics and customer information requirements. In general the letter contains information on potential impact to consumer, key characteristics of the recalled product (e.g., U.P.C., lot, date, distribution center where the product was shipped), and reason for recall. The letter also provides detailed instructions on how to handle the recalled product (e.g., where to ship) and reimbursement instructions. It also provides a 24/7 contact information for the customer recall team to use in the case of questions.

Customer HQ Notifies Stores — Quick Coordination Is Key to Jumpstarting Removal

Retailers surveyed often find out about a recall from a source other than the manufacturer, such as the media, private notification services, FDA/USDA Web sites, or other companies.

When participating retailers receive information from sources other than the manufacturer, they struggle to execute the rest of the notification process. They know about a recall but have little information to provide to their stores. They must contact the manufacturer, and this may cause unwanted delays. Broad adoption of Rapid Recall Exchange is expected to improve the notification process and enhance two-way communications during recall execution.

According to our study, after actionable recall information is received, the retailer can take up to 24 hours to send the notification to the stores.⁵⁰ Depending on the method used, it can take a long time for information to reach the individual store itself. Some smaller retailers or distributors use "snail mail" or fax, which adds to the lag in communication. Also, retailers generally need to contact all stores because they may not have the visibility to know which store has an affected lot number. Independent stores buying products from wholesalers or non-industry channels also need to be notified.

Another potential cause for delays in store notification is the lack of a closed-loop process between retailer HQ and the store level. Specifically, 23 percent of surveyed retailers do not require confirmation that their stores have received the recall notice.⁵¹ In interviews, many retailers said they do not have a designated person at store level responsible for recall execution, that notification is sent to the general attention of the store. This may leave notifications unnoticed and delay actual product removal.

Leading retailers use the following approaches to facilitate timeliness of store notification:

- Build on-going relationships with the crisis teams of key, high-volume vendors; exchange crisis team contact information and share recall requirements during annual or semi-annual planning sessions.
- Identify a single point of contact to support recalls at stores.
- Provide recall execution training to a single point of contact.
- Use automated systems for transmission of information to stores.

- Run 24/7 recall operations or have plans on how to handle a recall during the weekend. Identify a back up recall manager to ensure coverage at all times.
- Notify stores independently of whether the stores have the affected product.
- Require stores to send a confirmation of receipt:
 - Require confirmation in any format, at a minimum. In this case, reconciliation of information takes a long time and significantly delays action to be taken.
 - Send out surveys to stores requiring the stores to provide confirmation of receipt as well as status of removal. In this case, reconciliation is a much simpler process but still requires HQ labor.
 - Have an automated system requiring store managers to input some type of personal identification as verification of receipt. This automated system aggregates all the data into dashboards and communicates in compliance metrics by store to customer HQ.

Manufacturer Notifies Stores — Smaller Stores: Stronger Support

Typically manufacturers pass the notification information to their customers and rely on them to pass it down the value chain. Our study confirmed that manufacturers surveyed do not have full visibility to the store level. Only 39 percent of suppliers have some type of store-level information, which may or may not be complete and, therefore, usable for recall notification.⁵²

This “pass one step down” approach can work with larger retailers and distributors with good communication with their stores. However, smaller stores, such as convenience and independent stores, are usually the last ones to get the information, because there are simply too many touch points between them and the manufacturer. As a result, the product can be left on the shelf longer than in other channels. Although these smaller stores typically account for only 6 percent of a manufacturer’s business,⁵³ leaving even a small amount of recalled products on the shelf can be extremely risky for consumers and for the company’s reputation.

Manufacturers may consider leveraging existing distribution channels to streamline the communication to smaller stores by:

- Providing incentives to trading partners for timely notification of their stores in the form of additional trade promotion discounts or other incentives.
- Enabling distributors to communicate with their stores by providing them with timely and comprehensive information, such as a letter to forward on to their customers.
- Considering the adoption of incentive mechanisms, such as those used in the health care and life sciences industry, where manufacturers provide incentives to retailers to be more rigorous with notification, data tracking and reporting back to manufacturers.

Suppliers using direct store delivery (DSD) to c-stores could use their sales force teams to distribute information.

Some leading manufacturers attempt to help facilitate the notification process by employing third parties to notify stores, using their own or outsourced telemarketing teams, or having their sales force run effectiveness checks. Here again, the Rapid Recall Exchange can be a solution. If small operators subscribe to this service, they will receive direct notification of recalls at the same time large retailers are notified.

Leading Practice: Automated Notification That Helps Ensure Accountability

One of the leading retailers in the recall execution space implemented a unique system that:

- Helps ensure timely delivery. Allows HQ to put out a broadcast report (notification) to all distribution centers (DCs), which in turn sends it to all the stores through the system. The system is fully automated, and there are pre-determined distribution lists for these notifications.
- Helps ensure accountability. As a follow-up technique, the automated system can then detect which stores are missing removal confirmation / responses. If a store has not responded, a message goes out to the store manager’s superior. In order to help ensure verification of action and promote accountability, DC and store managers must respond with their name and Social Security numbers keyed into the system.

Leading Practice: Prompt Notification to Smaller Stores

Leading manufacturers provide immediate notification to stores by using internal and external telemarketing teams. The telemarketing teams have contact lists of retailers and stores that usually carry the company’s product. (This list can be obtained through services such as TDLinx.) Then they use these lists to notify small stores of a recall. If store managers/contacts are not available, the telemarketing teams follow up before reporting unresponsiveness back to the recall team.

In some cases, telemarketing teams update contact information on their lists on a continuing basis. Telemarketing teams can also follow up with the recall teams in case of customer questions.

Removal and Destruction

The removal and destruction step of the recall execution process covers physically removing a recalled product from the shelves, racks, freezers, etc. and disposing of it in ways that guarantee consumer safety. During this step — which is the most expensive step in the recall process — it is important to focus on speed, efficiency and thoroughness, while controlling the costs and complexity.

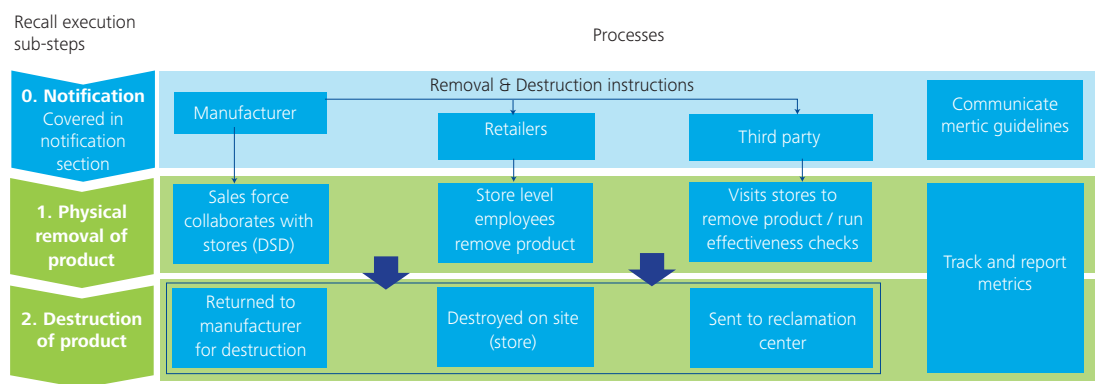
For the surveyed manufacturers, this step accounts for 67 percent⁵⁴ of the total cost of a product recall; for retailers, the cost is 53 percent⁵⁵ of the total. In most cases, retailers are reimbursed by manufacturers, but some participating retailers suggest that they still carry additional overhead costs (e.g., labor, signage).

The complexity of this step for retailers results from the need to locate the affected lot or U.P.C. number quickly, from the sheer number of products in stores — since the average U.S. retail food and grocery store has more than 46,000 SKUs⁵⁶ — and from the coordination of personnel at the store level. Manufacturers usually are not directly involved and, therefore, have limited visibility or control over the actual process.

This section addresses some of the complexities of this step and discusses how companies can engage in effective removal/destruction practices.

The removal and destruction steps and key activities are graphically represented in Figure 13.

Figure 13. Removal and Destruction steps and key activities



U.P.C. and Lot Number Considerations

The primary goal for both manufacturers and retailers is to ensure swift removal of the product and guarantee consumer safety. The secondary objective is to minimize costs associated with removal. Determining whether to remove the affected product lot or the entire U.P.C. impacts both objectives.

Manufacturers participating in the study prefer that retailers remove by lot number to minimize the loss of sales of non-recalled products, which may fall under the same U.P.C. Seventy percent of manufacturers in our study say they provide the lot number information to their customers during notification.⁵⁷

However, retailers may resist removing specific lots of the product for several reasons:

- It is difficult to track lot numbers of product at the store level; in fact only 12 percent of the retailers in our study have the technology to do so (i.e., they can identify the stores that carry products from specific lots).⁵⁸ The moment a national brand product reaches a customer warehouse,

Definitions: U.P.C. and Lot Number

U.P.C. or Universal Product Code is a scannable bar code that identifies the company and product name with encoded information to be scanned and decoded, expediting the receiving, picking, invoicing, sale and shipment of goods.

Sample UPC number — 644209420957 (6 - Number System Assignment; 44209 — Manufacturer Code; 42095 — Item Code; 7 - Check Digit)

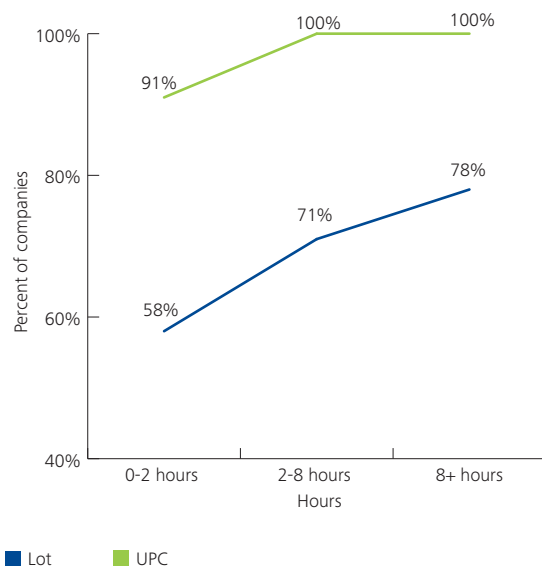
Lot number: The lot number is not scannable. It is the most granular identification number assigned to a particular quantity or lot of material from a single manufacturer to identify a product. It is much more specific than the U.P.C. because it contains concrete information, such as batch, date produced, etc.

Sample Lot number — JS01S-1204-08 (JS — Producer Initials; 01 — Production Location; S — Soybeans (Product); 1204 — Date of Shipment; 08 — Year of Production)

manufacturer lot information is often lost and not cross-referenced with the retailer's/wholesaler's internal codes. In contrast, 85 percent of the surveyed retailers have the technology to track U.P.C. numbers of products at store level.⁵⁹

- The lack of the technology to automatically scan the lot number on the product makes it difficult for retailers. Typically, to locate an affected lot number on the shelf, store employees must manually check every item, which can both increase the odds of making an error and reduce the speed of product removal. The surveyed retailers report that it takes up to eight hours to find 71 percent of products with a specified lot number. However, within 2 to 8 hours, they are able to locate all products with the specified U.P.C. (Figure 14).
- Retailers find that leaving product on the shelf that is identical in appearance to the recalled product, but from a different lot, confuses consumers who often think that the store is continuing to sell recalled product. Even if it is a different lot, consumers will avoid purchasing this product.
- Too often a recall is expanded to include different lots. For retailers, this increases work load and chance of error since the same product must be checked again for lot number identification.
- Consumers do not always pay attention to lot number details and will return product and expect a refund or replacement.
- State inspectors do not always have all of the lot number details and will cite retailers for failing to execute the recall. The burden to prove the lot numbers is placed on the retailers who often choose to simply remove the product than give the appearance of disagreeing with the regulators.

Figure 14. Time taken to locate lot number and UPC, retailers



Q. On average, how long does it take your company to locate the lot # and UPC that needs to be recalled?
N=24

Despite these facts, some participating retailers still remove products manually by lot. It is no surprise that many retailers opt for removing products by U.P.C. And because most manufacturers are also interested in removing the contaminated product from the shelves as fast as possible, they — under specific circumstances — agree to make exceptions to their recall guidelines and reimburse retailers for the entire U.P.C. However, many participating manufacturers contend that they lose non-affected products.

According to our study, smaller retailers and convenience stores prefer to remove product by lot number because they have smaller inventory to sort through and also want to minimize lost sales.

There is no standard practice on whether a company should use U.P.C. or lot number. The primary objective is to remove the product quickly; minimizing costs is secondary. However, certain methods are used by leading companies today that allow for timely removal by lot number even in the absence of advanced technology:

- Using dolphin scanners allows for a partially automated way to identify lot number and reduce errors. (See leading practice sidebar.)
- Hiring third-party recall facilitators to remove recalled products.

Also, manufacturers can motivate retailers to remove by lot by negotiating trade promotions.

In the DSD channel, manufacturers can consider coordinating the removal process with retailers to avoid mistakes, misunderstandings or duplicate effort. During our interviews, some retailers indicated that the DSD removal process could be better coordinated; sometimes the manufacturer sales force would remove the product from the retailer's shelf without prior agreement. In fact, 23 percent of the surveyed retailers said that collaboration with manufacturer's direct-store-delivery personnel required improvement.⁶⁰

There are also a number of potential long-term technology solutions that can be adopted by retailers and manufacturers to mitigate challenges associated with lot removal:

- 2D bar-code systems — Allow for storage of more information (across the width and height of the bar code) than the 1 D barcode systems. Therefore, companies using 2D bar-code systems can store additional information, such as lot numbers, expiration dates, etc. Although a 2D scanning system is known to be more expensive than a U.P.C. scanning system, industry research indicates that the price of 2D bar-code scanners has dropped dramatically, costing only 25 percent more than linear barcode scanners.⁶¹
- Electronic Product Code (EPC) — Initially developed by MIT Auto-ID Center and currently managed by EPCglobal, Inc., a subsidiary of GS1, the EPC is the next standard for tracking products through the supply chain. Each manufacturer can use it to store a variety of information that the current bar code is not able to carry, thus enabling effective tracking of the product through the supply chain.⁶² While cost is a major hurdle for this radio frequency code, several large companies are making a significant push for the adoption of this technology. As it becomes more widespread and more research is conducted, the costs of EPC technology is expected to fall.

Extensive Training, Education Help Forge Ahead

Given the number of products at stores and the difficulties in locating affected products, store employees can find it challenging to remove recalled products efficiently. Some retailers stated that high employee turnover and language barriers further exacerbate the situation. As a result, removal instructions and processes may not be followed with 100 percent accuracy at all times. This is often more significant in smaller stores, convenience and independent stores. It is not surprising that 43 percent of manufacturers in our study say that they need additional support in dealing with indirect customers.⁶³

Leading Practice: Use of Dolphin Scanners to Facilitate Lot Identification

A leading retailer implemented a system where all recall instructions and information (U. P.C. / lot / reason for recall / date of manufacturing, etc.) are loaded in a database. Each employee working on product removal is then given a handheld Dolphin scanner that is connected to this database. The employee uses the device to scan the U.P.C. of the product that needs to be removed. All instructions/information that are associated with the particular lot number that needs to be removed are pulled from the database and presented on the handheld device.

Learning From the Pharmaceutical Industry: Technology to Facilitate Removal by Lot

In the pharmaceutical industry, bar code readers such as the Ariel Expiration Date and Lot Number Tracking System are able to scan the lot number and expiration dates. This system is highly automated and labor efficient. It uses lightweight portable bar-code readers to capture lot and expiration dates as they are stocked or removed. One can also view lot numbers on any item that has been received into the system and see whether it is in circulation at the facility.

Source: http://www.onariel.com/Expiration_%20Date-Lot_Number_Tracking.htm

Leading Practice: Training Store Employees

A leading retailer saw a lack of training and education at the store-employee level. To fill this gap, the manufacturer created an easy-to-understand training manual that includes the required removal steps, the do's and don'ts, and the potential removal errors to avoid. The training manual is easily available for all store personnel.

To mitigate these issues, some retailers and distributors in this study:

- Provide standard operating procedures training to the liable person at the store and issue a certificate of course completion. Leading retailers and distributors in our study say they provide the training materials in multiple languages.
- Ensure product return policies include specific direction to consumers for recalled products and integrate the recalled product return process into the retailers recall standard operating procedure
- Dedicate resources at the store level to remove the products from the shelves for all recalls.
- Include product removal accuracy as a performance metric for store personnel.
- Use internal systems and technology to track completion of removal.
- Organize events to educate stores on FPS (food and product safety) procedures and specifically on recalls.
- Hire third parties to give extensive training to key staff on product removal of the right product SKU. Then the trained staff can cost-effectively train the other employees in the store

**Leading Practice:
Ensure Removal Accountability**

To introduce accountability at the store level, a retailer sends a survey to each store manager to keep track of the product removal process. Specifically, store managers are required to indicate the amount of product removed at their store. If this information is not received, or if the information indicates delays in the removal process, immediate action is taken.

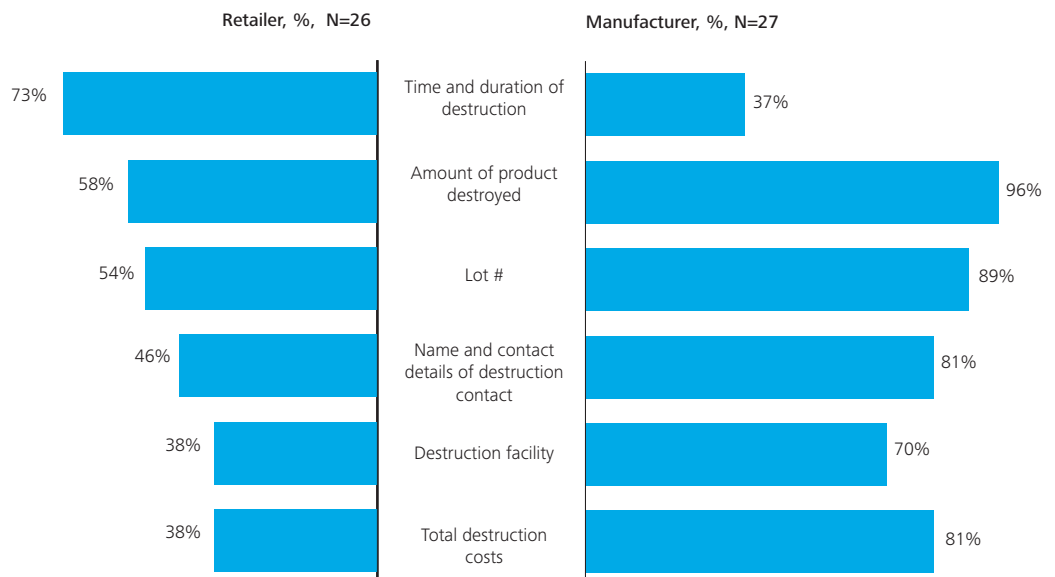
To address the small store challenges, manufacturers could provide informational / educational materials on the importance of product removal, preferably in multiple languages. These materials could be distributed to smaller stores via distributors / wholesalers, directly during effectiveness checks, or via targeted campaigns.

Metrics — The Need for Transparency

Measuring the amount of removed and destroyed product is extremely important for both retailers and manufacturers, as their ultimate and shared goal is to protect consumers. Retailers also use these metrics to develop claims for reimbursement. Manufacturers want to see the metrics to identify and address gaps in the removal process and to meet regulatory requirements and FDA and FSIS follow-up confirming that the products have been removed from the marketplace.

Manufacturers today have limited visibility into the status of product removal/destruction at stores. According to the surveyed retailers, it takes anywhere between one and 36 hours to remove 80 percent of a recalled product from the shelf.

Figure 15. Information tracked in product destruction, manufacturers and retailers



Q. What information do you track on product destruction?

Yet, surveyed manufacturers report that it takes between two and 150 days.⁶⁴ This discrepancy could result from the fact that manufacturers do not have direct visibility into the removal process and rely on retailers to provide this information to them. Also, manufacturers that report longer removal timeframes sometimes have to wait until the retailer sends the reimbursement claim to obtain the number of the products removed / destroyed. To avoid long wait times, some surveyed manufacturers use their sales force, broker network or third-party service providers to run checks and collect the information.

Manufacturers and retailers rarely align on metrics that they collect. Figure 15 demonstrates the types of metrics that retailers and manufacturers track on product destruction. In this study, only 58 percent of retailers track the amount of product destroyed compared to 96 percent of manufacturers. In fact, the survey indicates that retailers often do not pay as much attention to the destruction metrics as do manufacturers; retailers often destroy product at stores and do not record or keep track of what has been destroyed. In contrast, participating manufacturers carefully track metrics for the products destroyed at their own facilities or at outsourced reclamation centers.

Some leading manufacturers participating in the study are able to improve their visibility to the removal and destruction step of the recall process by:

- Discussing and determining the removal and destruction metrics that need to be tracked in the annual planning discussions with key retailers.
- Working closely with their retailers throughout the removal and destruction process, especially communicating status and actions taken for DSD products.
- Using sales force / broker networks / third-party providers to run effectiveness checks and tracks metrics at stores

When deciding whether to employ third-party providers, a sales force or both, companies may consider the advantages and disadvantages of each method, as represented in Figure 16:

Leading Practice: Sales Force Plays a Key Role in Removal at Smaller Independent and C-Stores

Recognizing the importance of the smaller retailers in the removal of product recalls, a manufacturer takes a proactive approach. Following the communication of removal instructions, the manufacturer sends the sales force out to take a random sample of smaller format stores to provide follow up on the required procedures and steps.

The company then conducts a weekly conference call with the entire sales force to address issues faced by their respective stores and answer any questions posed by smaller retailers.

Leading Practice: Following Up with Smaller Stores

Leading manufacturers follow up on removal and destruction with smaller format retailers by either subscribing to a database similar to the AC Nielsen TD Linx or outsourcing this service to a third party. TD Linx database has a list of all registered stores in the United States based on distribution pattern data, enabling manufacturers to identify stores that could have the affected product.

Leading Practice: Tracking Metrics Through Sales Force or Third-Party Providers

One manufacturer tracks the progress of removal and destruction through its sales force. Specifically, each sales team includes a member from the logistics division who tracks metrics associated with the removal process such as time taken or amount of product removed.

To follow-up, the sales team or a third-party provider then conducts effectiveness checks, ensures accuracy of metrics and closes any gaps.

Figure 16. Pros and cons of using sales force vs. third-party recall facilitators to track metrics

	Sales Force	Third-party recall facilitators
Pros	<ul style="list-style-type: none"> • No extra costs • Strong understanding of product • Existing relationship with store employees 	<ul style="list-style-type: none"> • Extensive experience with recalls • Systems and tools to automate data capture and reporting • Extensive capacity: large network of resources located all over the country
Cons	<ul style="list-style-type: none"> • Lack of automated tools to track and report status and metrics • Limited capacity • Potential misalignment of incentives (incentivized to sell, not to remove products) • Difficulty in reconciling data at the HQ level 	<ul style="list-style-type: none"> • Cost – particularly for smaller companies • Resistance from certain retailers • Limited control over process when outsourced

Replacement

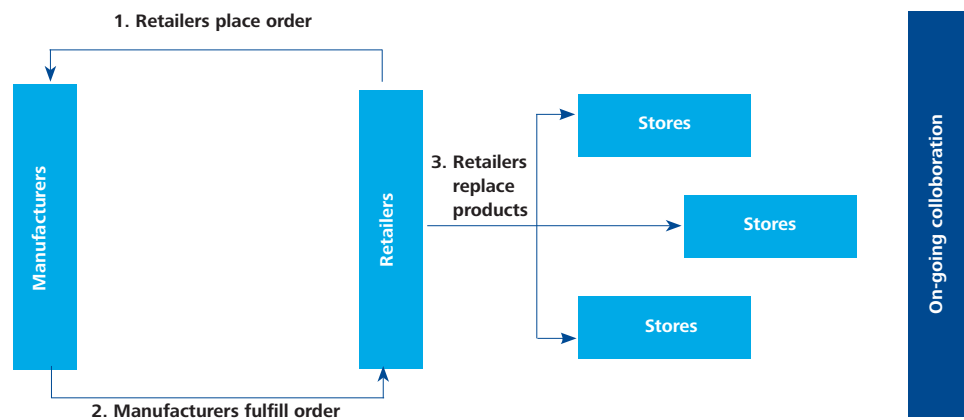
The objective of the replacement step is to put a substitute product safe for consumption on the shelf as quickly as possible and resume business as usual. (The replacement process is graphically represented in Figure 17 — see note below). Delays in replacement can result in lost sales for the manufacturer and the retailer — 12 percent and 27 percent respectively, according to our study.⁶⁵

For retailers surveyed, the replacement process takes anywhere from one to 30 days depending on whether they have unaffected product available at their stores or distribution centers.⁶⁶

To minimize lost sales, 42 percent of the retailers participating in our study fill shelf space with alternative products in the category.⁶⁷ This practice can be detrimental to manufacturers, who could lose share to competitor products. To help mitigate this, manufacturers may consider building replacement options into their response plans.

This section addresses some of the complexities of the replacement step in the product recall process, and describes how trading partners can collaborate to improve its timeliness.

Figure 17. Replacement process



Prompt Coordination Puts Products Back on the Shelves

After a recalled product has been removed from the shelf, retailers place an order for a replacement product — ideally automatically — through regular replenishment steps. Depending on their supply chain flexibility and inventory strategies, manufacturers may or may not be able to fulfill these orders in a timely fashion. Currently 69 percent of manufacturers participating in this study build an emergency production plan and develop a timeline of when the product will be returned to the shelf.⁶⁸

Manufacturers can help improve the timeliness of product replacement by working with supply chain partners to develop contingency plans. It is also important to ensure that all customers have received the substitute product and to track whether all customers have submitted a replacement order. Currently, 62 percent of surveyed manufacturers can monitor customer warehouse levels and the percentage of recalled products that have been removed.⁶⁹

In an effort to be better prepared, leading manufacturers have implemented flexible supply chain initiatives, such as:

- Qualify a set of plan B supply or execution vendors to use when/if current production is not possible; this could include alternate raw-material suppliers, backup manufacturing capacity, alternate distribution channels.
- Conduct scenario planning with these vendors to determine replacement activities in the event of a recall.
- Manage capacity levels across their entire production network to enable a quick response to unforeseen demand.

Leading Practice: Leveraging Alternative Suppliers

When a large beverage manufacturer experienced an issue with one of its raw material ingredients, it collaborated with its vendors to obtain replacement raw material within days and ran extra shifts in the plant to replace the product for its customers right away.

- Leverage strategic relationships with transportation companies to track and expedite delivery.
- Develop and implement scientifically based safety stock policies for raw materials and finished goods — particularly if associated vendors are categorized as risky.

Effective Replacement: Tighter Collaboration

To avoid delays, miscommunication or duplication, the two stakeholders in the replacement process — the manufacturer and the retailer — need to collaborate.

As mentioned, 69 percent of the manufacturers participating in the study develop a timeline of when the product will be returned to the shelf. In many cases, however, they do not communicate this timeline to the retailers; 85 percent of the surveyed retailers say they ask manufacturers for the replacement timelines.⁷⁰ Manufacturers may need to be more proactive in communicating this information. Only 42 percent of retailers participating in this study build a timeline for store managers of when the recalled product will be available and when it needs to be put back on shelves.⁷¹ When they receive a timeline from manufacturers, retailers may consider developing their own internal timeline to facilitate communication and ensure accountability.

In some cases, retailers receive the replacement shipment before recalled products have been destroyed or completely removed from the store or warehouse. When this happens, the recalled product could be mixed with the replacement product. Leading manufacturers in our study proactively address this problem by marking new batches with a different label.

Leading Practice: Differentiated Packaging

After a food recall, a large manufacturer added a “new batch” sticker on all its replacement shipment, thereby helping ensure that retailers could always immediately tell if the product was part of the replacement batch.

Retailers need confirmation from the manufacturer that the problem with the recalled product has been resolved and the replacement product can be used safely. In our study, 54 percent of manufacturers surveyed forward to retailers an FDA letter confirming that the product recall case has been closed.⁷² Manufacturers and retailers could communicate the status of the replacement process more effectively. According to the retailers surveyed, it takes on average 12 days to replace 80 percent of the product, whereas manufacturers surveyed report that it takes on average 45 days.⁷³ This discrepancy arises because manufacturers are typically informed of the replacement status only well after the fact.

Leading companies surveyed work closely with their business partners to conduct joint replacement planning sessions either during the semi-annual planning cycles or during an off-cycle meeting. These planning sessions are used to define the following:

- A timeline in which the manufacturer can deliver a replacement product back to stores, although this often varies on a case-by-case basis.
- Interim shelf space plans for retailers and plan B planogram (e.g., the manufacturer’s products that can be substituted if product A has been removed).
- Frequency of communication of metrics and status of replacement.

Leading Practice: “Reverse Recall”

According to a leading retailer, once it receives a written verification that the product is safe, the recall team issues an electronic “reverse recall” that notifies all parties involved in the initial recall that the new product may now move through the pipeline. Holds are discontinued, store personnel remove red tags from shelves, and stop-sale is removed from point-of-sale registers.

Leading companies use either internal resources or third-party services to track metrics related to the number of products replaced. Among companies participating in this study, only 27 percent⁷⁴ of manufacturers and 8 percent⁷⁵ of retailers surveyed use a third-party vendor for replacement-metrics tracking.

Feedback Loop

The feedback loop is the practice of incorporating lessons learned into the recall processes and procedures. With the number of recalls increasing every year, companies want to improve their recall practices and reduce food safety risks continuously. They can do so by learning from their own and their trading partners' recall experiences, by running simulation exercises or mock recalls, and by participating in various industry initiatives.

Our study found that companies that identify and apply lessons learned after a recall tend to be more sophisticated in overall recall execution. Many manufacturers and retailers (71 percent and 48 percent, respectively) engage in some feedback loop activities.⁷⁶

This section describes the existing and leading practices companies use to capture lessons learned and improving their recall processes. Improvement opportunities occur in three categories:

- Prepare: Conduct mock recalls to identify gaps in the recall process
- Follow up: Identify lessons learned from previous recalls
- Share: Transfer knowledge within the organization and with other companies

Prepare — Replicate a Real-Life Scenario

Mock recalls are exercises conducted by companies to assess their recall procedures and responsiveness. For manufacturers, mock recalls are critical since most have limited actual recall experience. Retailers, on the other hand, participate in hundreds of recalls per year and do not believe they have to run mock recalls to evaluate their preparedness.

Many manufacturers in our study — 68 percent — perform mock recalls.⁷⁷ However, these exercises may or may not include comprehensive simulations that test all company policies. In some cases, production facilities might run less extensive exercises, including an inventory tracking exercise to test how accurately product locations, code numbers and quantities can be pinpointed in the event of a recall. These exercises, while valuable, are not true mock recalls since they are not comprehensive.⁷⁸

Also, many companies surveyed reported that they do not include all relevant parties in their mock recalls. (Figure 18):

- Only 37 percent of companies surveyed use their dedicated recall team during mock recalls.
- Many include supply chain and quality assurance employees but do not include legal, sales and public relations. Legal could help test the procedures and processes associated with accurately conducting the identification and replacement steps, while sales and public relations are needed during the notification and removal / destruction.
- Most manufacturers surveyed do not include external constituents in their mock recall procedures. True, it can be challenging to include customers, especially since they might conduct hundreds of actual recalls per year and, therefore, be reluctant to take the time to participate in simulated ones with multiple suppliers. However, including external constituents can greatly improve lessons learned. For example, companies can place a call to recalls teams of select retailers to establish relationships or update customer recall team contact lists without asking them to execute a full mock recall scenario.
- A limited number — 18 percent of manufacturers surveyed — include third-party facilitation companies in their mock

Leading Practice: Mock Recalls

A manufacturer conducts two kinds of mock recall exercises every year. 1) Imagining a problem with a particular product in a specific plant; the production steps are traced, as is every place the product was sent, to determine how long it would take to notify customers. 2) Conducting hypothetical case studies with different groups to show them how the process works, as well as review their responsibilities in the event of a recall.

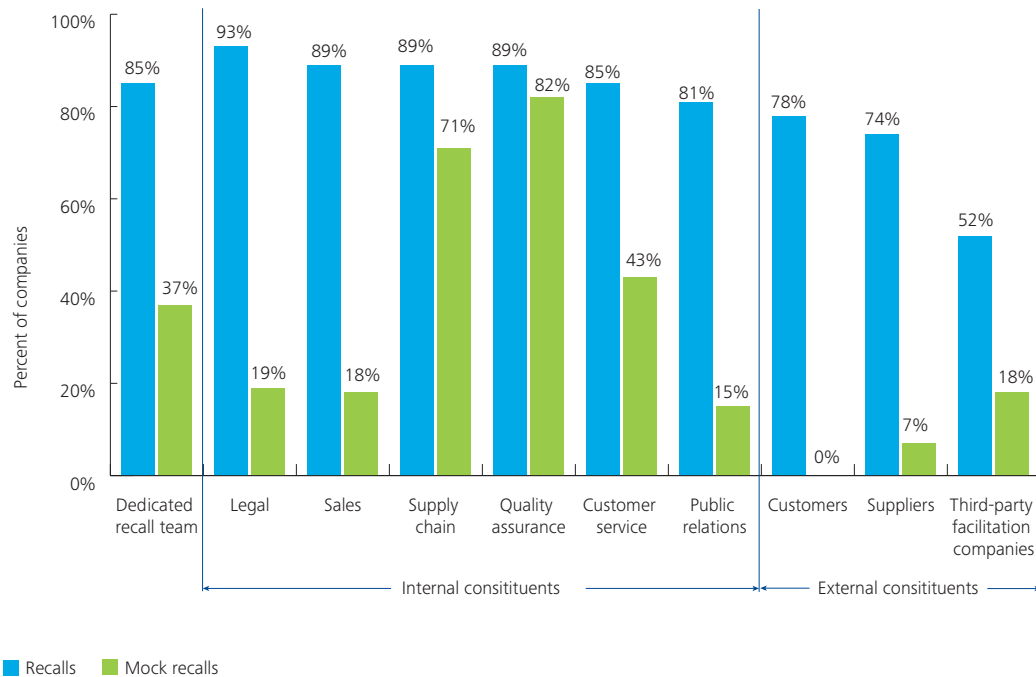
Leading Practice: Enhancing Recall Plans

Manufacturers continuously improve their recall plans by leveraging expertise of internal resources or third-party providers. Experts work with recall teams to review recall plans as well as conducting mock recalls. Regardless of the source of expertise, the primary objective is to identify gaps in recall plans by either conducting crisis simulations or sharing successful practices based on past experiences. This assistance from internal experts or third parties can be useful particularly for those companies that have limited experience with recalls.

recalls. Third parties are usually good sources of credible information and can advise on improvement opportunities when internal resources and recall experiences are limited.

- Only 7 percent of the surveyed manufacturers include suppliers in their mock recalls.

Figure 18. Internal and external constituents included during mock recalls, manufacturers



Q. Which constituents do you include in recalls and mock recalls?
N=27

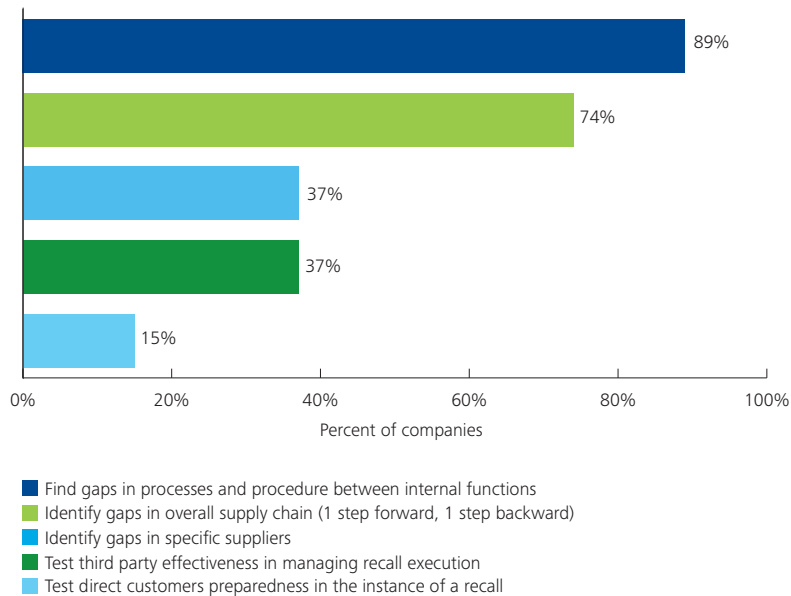
Of course, in a perfect case scenario, to be effective a mock recall should include all the constituents — internal and external. However, that could be a costly undertaking, not just in dollars-and-cents but in the deflection of resources from other initiatives. Also, given the number of recalls executed at retail, there is a reasonable probability that a real recall could occur during the mock recall causing confusion and unnecessary disruption for the retailer. For these reasons, the number and intensity of mock recalls depend on each manufacturer’s self-assessment of its preparedness. (That said, mock recalls should be a top priority for a company’s leadership and should, therefore, be a line item on the operating budget.)

Study participants (manufacturers only) shared their goals for mock recalls (Figure 19). Not surprisingly, for most companies surveyed (89 percent) the number one objective is to identify gaps in internal processes. A close second (74 percent of respondents) is to test visibility to the product location, one step forward and one step backward.

Leading companies in our study recognize that including external constituents can help them run recalls faster and more efficiently in the future. Some 37 percent of manufacturers surveyed try to identify gaps in specific suppliers’ procedures and to test third parties’ effectiveness in managing recall execution; 15 percent test direct customer preparedness.

To improve their preparedness, manufacturers may consider fully reflecting these objectives in their mock recall plans and case studies and, at the end of the exercise, measuring results and assessing performance against these objectives.

Figure 19. Mock recall objectives, manufacturers



Q. What are the objectives of the mock recall exercises you conduct within your organization?
N=27

Follow Up — Go the Extra Mile

Post-recall follow up is a golden opportunity for companies to capture lessons learned and incorporate them into their recall processes. More than 65 percent of the surveyed manufacturers perform analysis to capture internal lessons learned, assess negative impact on their businesses and update internal procedures. However, fewer than half go a step further and evaluate the performance of various customers or hold meetings with their direct customers to discuss each other's performance.⁷⁹

Retailers surveyed do not engage in follow-up procedures as often as manufacturers do because of the sheer number of recalls they manage. However, 58 percent of retailers participating in this study update internal procedures after a recall, and 48 percent capture and document lessons learned. Very few retailers (19 percent) hold follow-up meetings with their suppliers. Additionally, 19 percent update training documents, which limits the opportunity to improve product removal and destruction at the store level.⁸⁰

As these statistics suggests, there is room for improvement in collaboration between manufacturers and retailers in identifying lessons learned and uncovering key gaps in recall processes. Leading companies seek to improve their own and their trading partners' performances by soliciting feedback from them. For example, some leading manufacturers surveyed conduct post-recall follow-up sessions with the suppliers of their raw materials to ensure that any issues have been addressed and that preventive measures are in place.

Some companies choose to follow up with their constituents to assure them that the recall has been executed and the issue has been closed. Although most manufacturers and retailers provide evidence of recall completion to regulatory agencies, leading companies participating in the study choose to notify the investor community and consumers as well, especially after severe recalls that result in high consumer awareness.

Leading Practice: Identify Lessons Learned

After a recall, one manufacturer conducts meetings with the different internal constituents as well as bi-monthly conference calls with the sales people out in the field at the time and close to the action. This gives them a unique perspective on practices that did or did not work. All lessons learned are then documented and circulated within the entire organization, and status of implementation is reviewed at each post-recall meeting.

Share — Why Reinvent the Wheel?

Knowledge sharing allows for cross-pollination of effective practices across companies as well as from other industries, which is especially important since industry-level data is limited. Many companies surveyed would like to get more involved in initiatives that promote the exchange of leading practices.

When interviewed, a QA plant manager for a consumer products company said, “It would be beneficial to get best practices from leading organizations. Companies tend to keep those things close to the vest, but we shouldn’t because there are no trade secrets here.”

Leading companies participating in the study enable knowledge sharing by developing successful practices and case studies, organizing and participating in industry conferences and partnering with universities and other professional associations on training programs. Then they share their findings with their supply chain partners to ensure safer practices throughout the value chain.

Leading companies surveyed engage in the following activities to enhance knowledge collection and sharing:

- Appoint a specific individual within the company to oversee research and knowledge sharing within industry. The individual should be responsible for conducting research, participating in industry initiatives, and identifying innovative practices. The company also might host knowledge exchange events.
- Gather successful practices from other industries, such as healthcare and life sciences.
- Get involved with industry committees, trade organizations, research and educational institutions that are focused on promoting food safety.

Leading Practice: Using Signage to Communicate Recall Completion

A leading retailer collaborated with a manufacturer to develop post-recall messaging on shelves. More specifically, both trading partners identified shelf signage as an effective mechanism to inform end-consumers that the recall was now over and that products were safe to consume. The signs contained messaging around date of recall completion and hotline information to contact in case of questions. These signs were then placed by products on the shelves as well as in a notice area at the front of the store

Leading Practice: Proactive Stance on Knowledge Sharing

A large foodservice provider organizes annual conferences; attendance by direct partners (suppliers and customers) is required. This conference consists of workshops, simulations and discussion on industry-wide challenges and innovative practices, as well as one day of training on the food organization’s specific recall procedures.

Leading Practice: Establishing a Role Tied to Knowledge Sharing

To conduct research and development on industry-wide challenges, a manufacturer created a new role within the company, a person whose responsibilities include working with universities, regulatory agencies and trade organizations to improve the accuracy of finished product testing and catch quality issues before products reach the hands of consumers.

Recommendations

Our study found that companies surveyed are improving their processes and focusing on managing and executing recalls more effectively. As they continue to push ahead with improvements, however, there are golden opportunities to improve recall management practices across multiple dimensions. Particularly, companies may consider, increasing collaboration with their business partners, standardizing recall procedures and tools, and implementing effective technology to improve visibility to the product location.

Key recommendations based on this study's findings are presented here. They are divided into three categories: 1) communication and collaboration; 2) processes, organization and metrics; and 3) technology. Companies may consider these recommendations as they work hard to implement or improve their own practices in managing product recalls more efficiently and effectively.

Initiatives			
Communication and Collaboration	Collaborate with trading partners to enable early identification / prevention.	<ul style="list-style-type: none"> Investigate consumer complaints using internal resources or third-party services. Work with suppliers to conduct analysis on root causes of recalls and adjust processes / procedures accordingly. 	<ul style="list-style-type: none"> Collaborate with trading partners to track, investigate consumer complaints.
	Use multiple vehicles for notification to consumers, customers and regulatory authorities.	<ul style="list-style-type: none"> Pay close attention to meeting regulatory requirements. Consider adoption of Rapid Recall Exchange as method of notification. Hold sales teams accountable for customer communication Reach out to customers/stores using internal, external tele-marketing teams. Communicate clearly and openly. Collaborate with partners to create consistent messages to consumers. 	<ul style="list-style-type: none"> Use multiple channels for notification to consumers, such as press releases and consumer hotlines. Tap into alternative channels, such as consumer loyalty card information, to communicate to consumers. Provide rigorous training to hotline agents and ensure capacity to handle high volumes of calls and various consumer requests.
	Run comprehensive mock recalls — collaborate internally and externally.	<ul style="list-style-type: none"> Include internal employees / members of the recall management team who would be part of actual real-life recall scenario. Leverage Rapid Recall Exchange test environment for mock notifications. 	<ul style="list-style-type: none"> Include trading partners and third parties in targeted mock recalls; offer incentives for participation and develop mutual goals. Run mock recalls at vendor organizations.
	Collect and share recall execution knowledge internally and with trading partners.	<ul style="list-style-type: none"> Proactively follow up with business partners using surveys or similar methods to gather feedback on recall performance. Engage with internal experts or third parties to gather practices, recall plans and case studies used by other leading organizations. Actively participate in food and safety industry initiatives (e.g., conferences, panels, debriefs, forums). 	<ul style="list-style-type: none"> Collect and selectively use leading practices from other industries, such as health care or life sciences. Share recall execution knowledge and leading practices within the organization and with trading partners. Utilize relationships between trade associations and government officials for assistance with communication and dissemination of information.

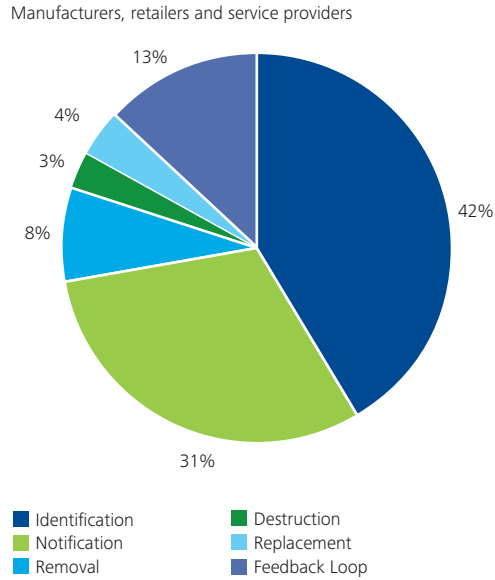
		Initiatives	
Processes, Organization and Metrics	Implement and continuously refine standard recall execution processes.	<ul style="list-style-type: none"> • Develop rigorous recall plan / recall procedures. • Develop a communication strategy with supporting checklist / templates for notification to consumer and customers. • Minimize development of trading partner-specific processes/tools; look for industry standard solutions when possible. 	<ul style="list-style-type: none"> • Include manufacturing contingency plans to recall procedures to support customer restocking requirements. • Institute rigorous mock recall processes that include both internal and external parties that would be involved in a real-life recall.
	Implement efficient processes for intelligent identification and prevention of issues.	<ul style="list-style-type: none"> • Run ad-hoc quality tests at various points in the manufacturing process. • Consistently and rigorously use HACCP through the supply chain to identify areas of exposure. 	<ul style="list-style-type: none"> • Leverage scientific / predictive techniques to understand data patterns from prior recalls and identify potential recall issues early in the process.
	Ensure accountability across the value chain.	<ul style="list-style-type: none"> • Define roles and responsibilities of the recall team and other responsible parties (e.g., store managers, sales force) in advance. • Develop incentive schemes for all responsible parties; use other methods to achieve accountability (e.g., status tracking, confirmation receipt). • Run 24/7 operations and have contact information of all back-up personnel. 	<ul style="list-style-type: none"> • Implement supporting technology to track the status of the recall process (e.g., confirmation of receipt from a store manager). • Use internal resources (e.g., sales force) or third parties to ensure effective removal and/or conduct effectiveness checks.
	Invest in training employees on recall execution practices at the corporate as well as the store level.	<ul style="list-style-type: none"> • Provide comprehensive training to cross-functional recall management teams (e.g., general recall processes, coordination with other departments, investigation techniques, communication strategies, and case studies and lessons learned). • Train store employees on standard operating procedures specific to recall execution. • Update training materials during feedback loop. 	<ul style="list-style-type: none"> • Implement recall execution company certification. • Leverage internal resources or third parties to evaluate training processes and improve them accordingly.
	Identify, track and share recall execution metrics.	<ul style="list-style-type: none"> • Discuss removal, destruction and replacement metrics with business partners as a part of annual business planning meetings. • Share notification, removal, destruction and replacement metrics that is tracked in your company with key trading partners involved during the recall execution process. 	<ul style="list-style-type: none"> • Develop contingency plans with trading partners to ensure immediate replacement. • Track all metrics related to all steps of the recall execution process to assess performance and close gaps.

Initiatives	
Technology	<p>Automate and integrate technology within and beyond the four walls of the organization.</p> <ul style="list-style-type: none"> • Utilize all capabilities of existing technologies to enable effective traceability within the organization. • Offer technology-related training to personnel responsible for recalls / lot tracking. • Automate data capture and reporting from raw materials to finished goods to track product movement across the shop floor during the identification process. • Adopt Rapid Recall Exchange for effective notification between manufacturers and retailers. • Use other resources and services (media, tracking services, Web sites) to monitor information on recalls. • Use customer portals (if those exist) to notify customer. • Use Reportable Food Registry to notify FDA. • Integrate supply chain system with the new product development system to be able to track allergens and components. • Integrate systems and processes with business partners to increase visibility. • Define common data standards for traceability internally and one step up and one step down. • Adopt systems that enable two-way notification across various constituents. • (Retailers): Use an automated system that broadcasts notification to all DCs / stores and requires recipient to verify receipt of information.

Appendix 1. Survey Results

Introduction

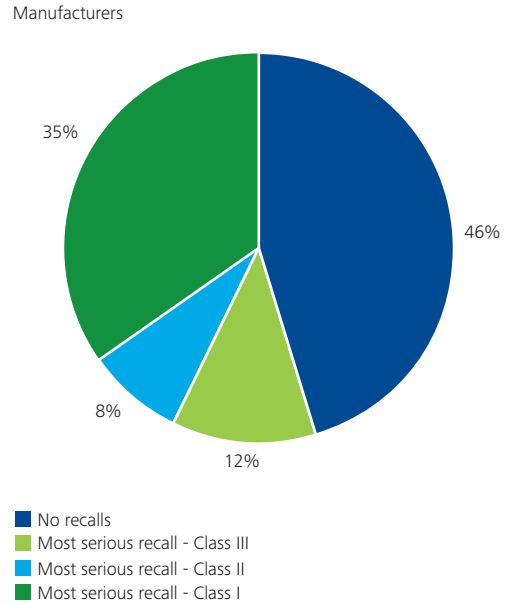
Exhibit 1. Importance of recall steps to increase effectiveness of recall execution*



Q. Which stage of the recall process needs most attention to increase effectiveness of recall execution?
N=367

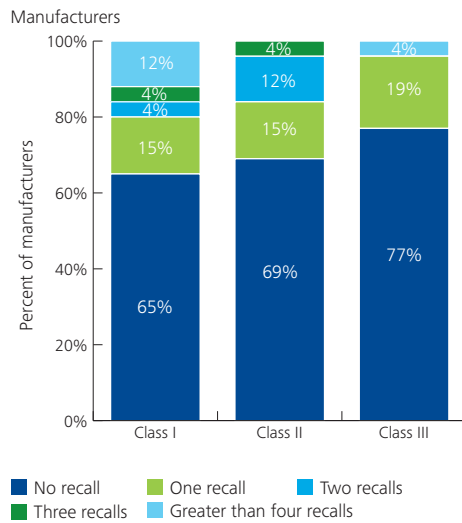
* Source: Poll conducted during the Deloitte debrief "Food Recall Prevention: Manage Risk to Protect Your Consumers and Your Brand," November 12, 2009 (367 participants – manufacturers, retailers and service providers)

Exhibit 2. Respondent profile by recall class, percent of total companies



Q. How many Class I, II and III recalls have you had in the past three years?
N=26

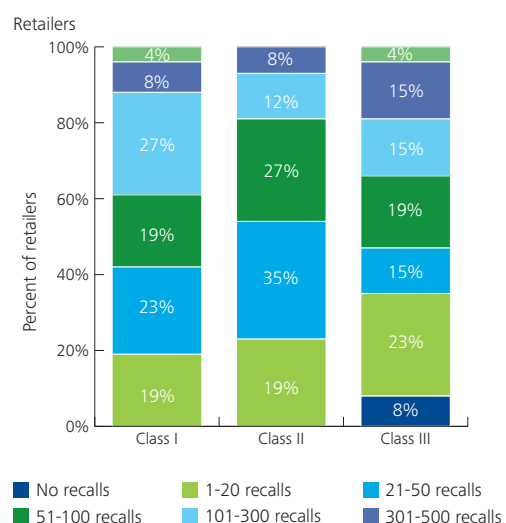
Exhibit 3. Number of recalls by class, percent of total companies



Average number of product recalls per company:
- 2 recalls in the past three years
- 0.7 recalls per year

Q. How many Class I, II and III recalls have you had in the past three years?
Class I: N=26, Class II: N=27, Class III: N=26

Exhibit 4. Number of recalls by class, percent of total companies

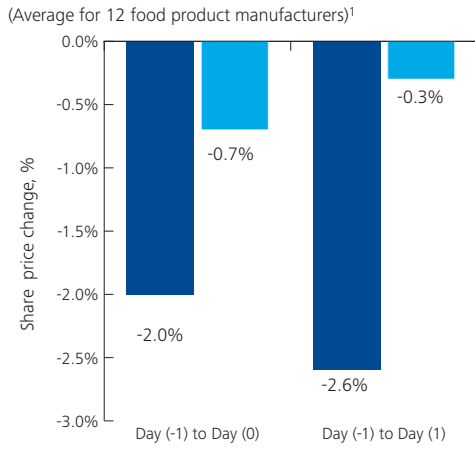


Average number of product recalls per company:
- 352 recalls in the past three years
- 117 recalls per year

Q. How many Class I, II and III recalls have you had (e.g., have you implemented) in the past three years?
N=26

Call to Action

Exhibit 5. Recall impact on share price, percent change



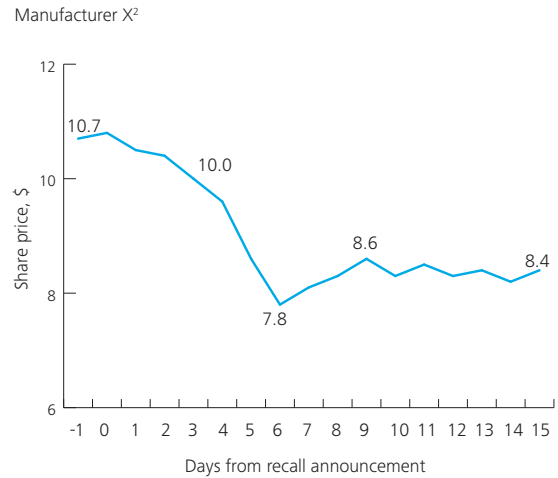
■ Recall companies ■ Consumer food product index*

- Day (-1) - day before the event
- Day (0) - day of the event (when company issues announcement on website)
- Day (1) - day after event (typically when FDA issues announcement)

* Consumer food product index reflects the average price of 21 (mid, small and large cap) food product companies in North America

^{1,2} Source: Deloitte Consulting analysis

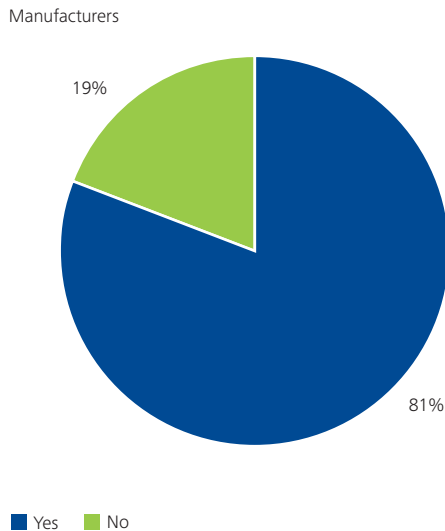
Exhibit 6. Impact of recall on share price over 15 day period



- Day (-1) - day before the event
- Day (0) - day of the event (when company issues announcement on website)
- Day (1) - day after event (typically when FDA issues announcement)

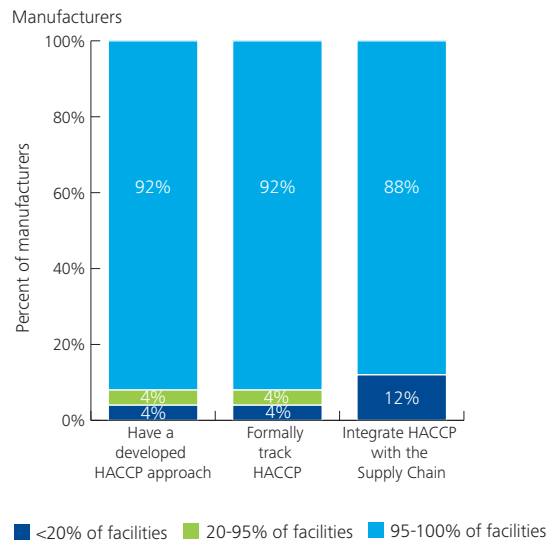
Identification

Exhibit 7. Percentage of companies that have standard quality check procedures



Q. Is there a standard quality check procedure for which certain results automatically launch an escalation process leading to a recall?
N=26

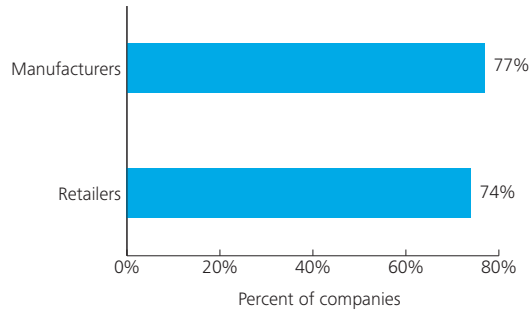
Exhibit 8. Percentage of facilities with HACCP capabilities



Q. What percentage of your facilities follow HACCP?
N=25

Exhibit 9. Percentage of companies that have standard metrics of direct consumer complaints

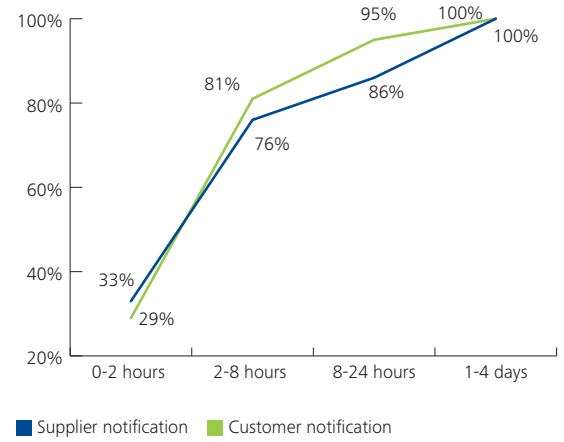
Manufacturers and retailers



Q. Are there standard metrics of direct consumer complaint/feedback that automatically launch an escalation process leading to a recall?
Manufacturers: N=26; Retailers: N=23

Exhibit 10. Time taken to identify and locate lot, percent of companies

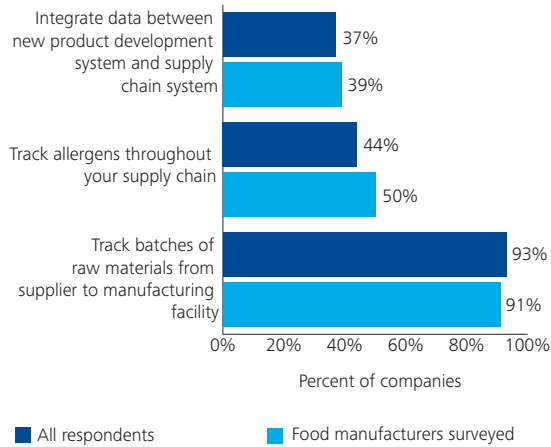
Manufacturers



Q. On average, how long does it take your company to identify and locate the lot that needs to be recalled?
N=21

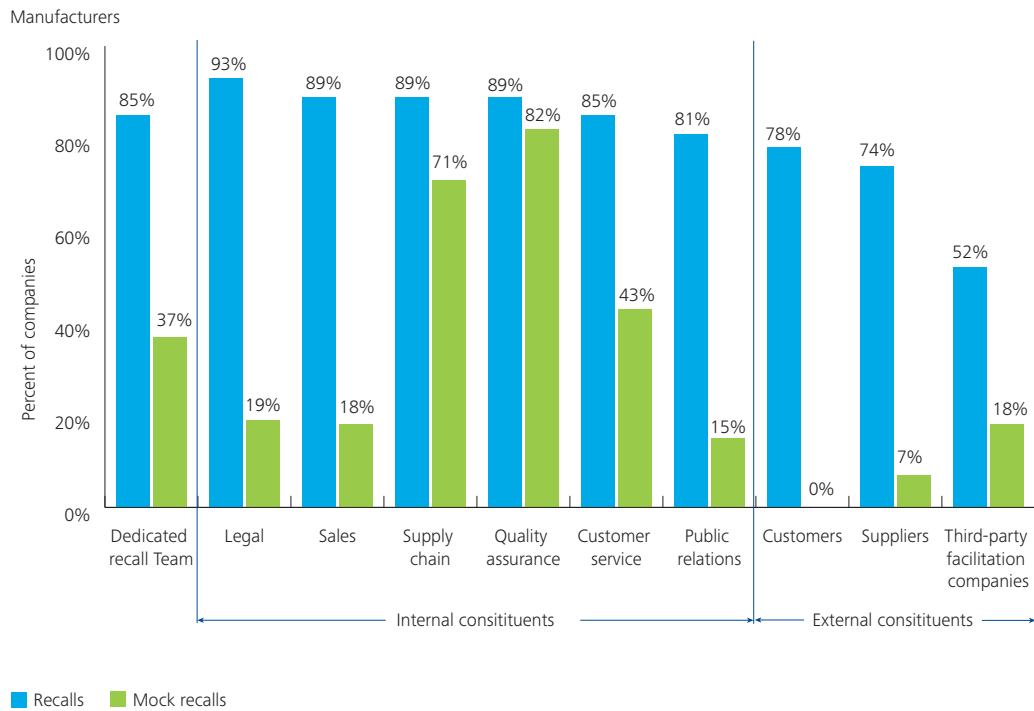
Exhibit 11. Capabilities of existing technology

Manufacturers



Q. Which of the following capabilities does your existing technology have?
N=27

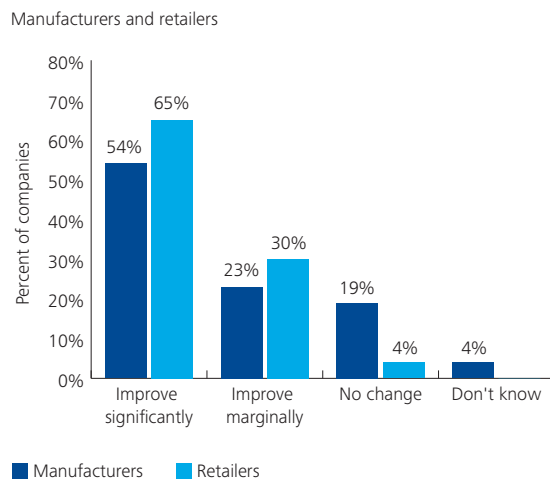
Exhibit 12. Constituents included in recalls / mock recalls



Q. Which constituents do you include in recalls and mock recalls?
N=27

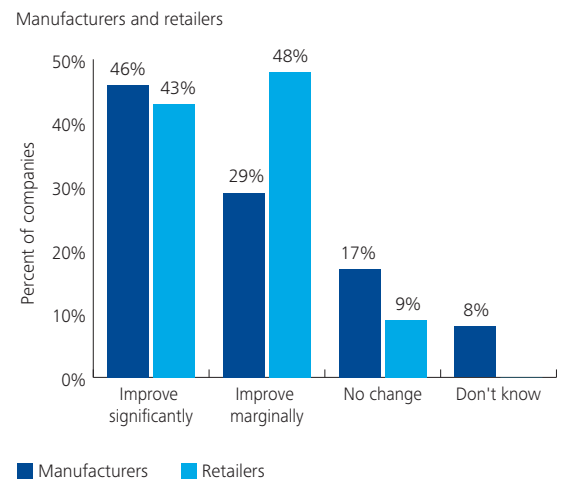
Notification

Exhibit 13. Improvement in notification procedures since three years ago



Q. To what extent have your notification procedures and policies evolved over the past three years.
Manufacturers: N=26, Retailers: N=23

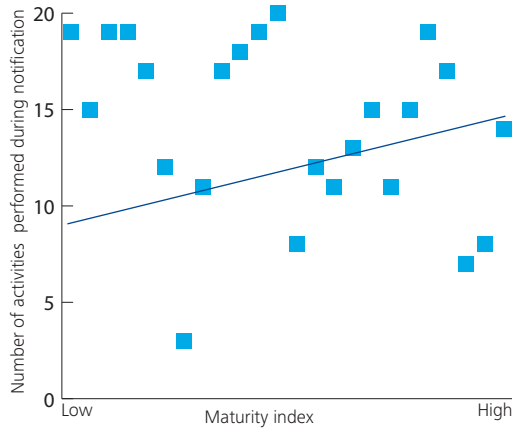
Exhibit 14. Anticipated improvements in notification procedures over next three years



Q. How do you expect your notification procedures to change in the next three years
Manufacturers: N=24, Retailers: N=23

Exhibit 15. Importance of performing multiple activities within notification

Manufacturers

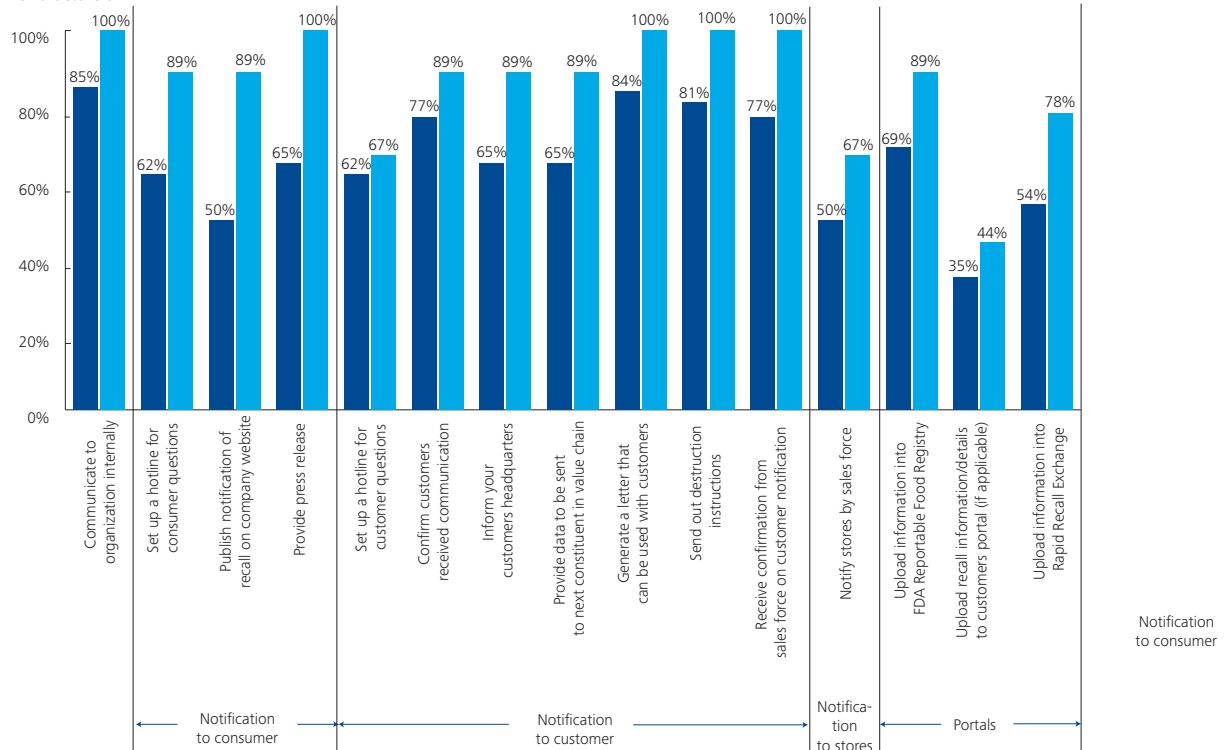


Maturity Index: Index developed based on individual company sophistication of recall practices during each recall stage

Q. What steps do you taken within the notification process?
N=26

Exhibit 16. Steps / activities performed during the notification process

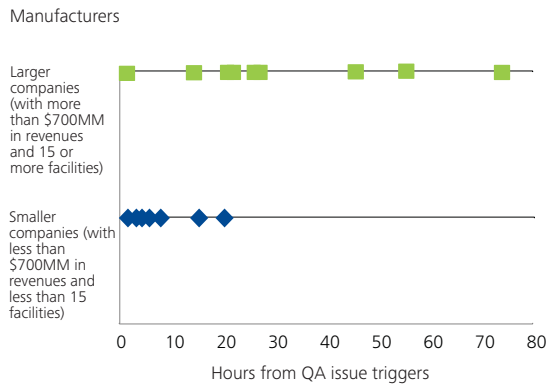
Manufacturers



■ All companies surveyed ■ Companies that have had a Class I recall

Q. What steps do you taken within the notification process?
All companies surveyed: N=26, Companies that have had a Class I recall: N=9

Exhibit 17. Time taken to complete Identification step of recall execution



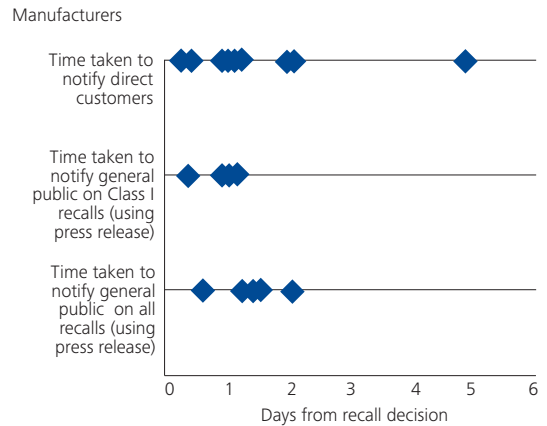
Overall
 Average: 21.5 hours
 Minimum: 0.5 hours
 Maximum: 72 hours

Larger companies
 Average: 32.1 hours

Smaller compaies
 Average: 6.4 hours

Q. How long does it take you to complete identification process?
 N=17

Exhibit 18. Time taken to notify public and direct customers

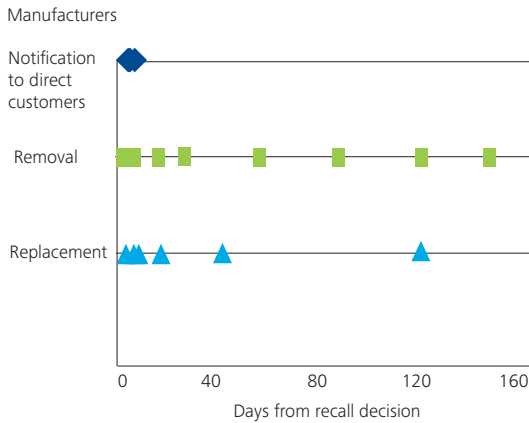


Averages:
 Notification to direct customers: 1.5 days
 Notification to public, all recalls: 1 day
 Notification to public, Class I recalls only: 0.7 days

Q. How long does it take you to inform general public and direct customers?

Time taken to notify direct customers: N=13
 Time taken to notify general public on class 1 recalls: N=5
 Time taken to notify general public on all recalls: N=10

Exhibit 19. Time taken to complete each recall stage



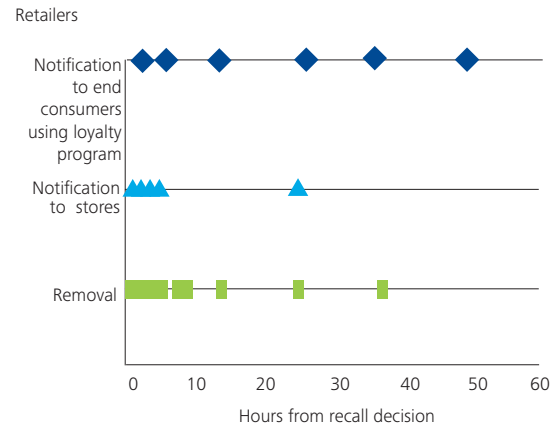
Averages:
 Notification - 15 days
 Removal - 44 days
 Replacement - 45.1 days

Minimums:
 Notification - 1 day
 Removal - 2 days
 Replacement - 5 days

Maximums:
 Notification - 5 days
 Removal - 150 days
 Replacement - 120 days

Q. How long does it take you to complete each recall step?
 Notification: N=13, Removal N=11, Replacement: N=7

Exhibit 20. Time taken to complete each recall stage



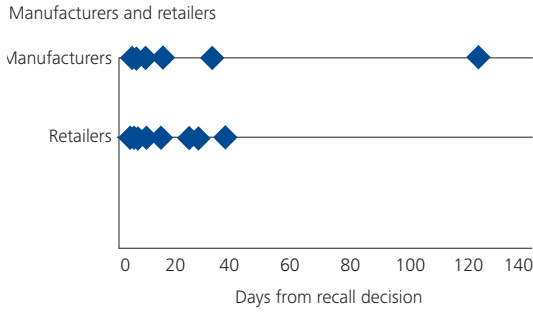
Averages:
 Notification to end cosumers - 21.4 hours
 Notification to stores - 2.4 hours
 Removal - 7.1 hours

Minimums:
 Notification to end consumers - 2 hours
 Notification to stores - 0.15 hours
 Removal - 0.3 hours

Maximums:
 Notification to end consumers - 48 hours
 Notification to stores - 24 hours
 Removal - 36 hours

Q. How long does it take you to complete each recall step?
 Notification: N=6, Removal: N=24,

Exhibit 21. Time taken to replace 80 percent of product



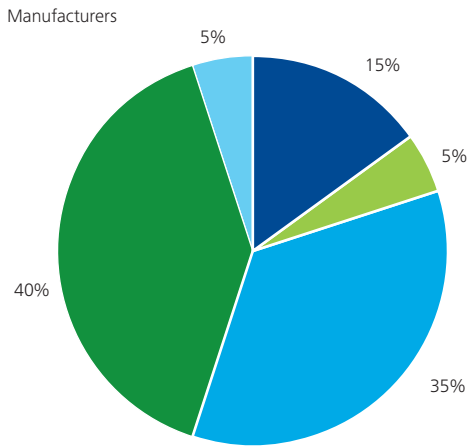
Averages:
 Retailers: 12 days
 Manufacturers: 45 days

Minimums:
 Retailers: 1 day
 Manufacturers: 5 days

Maximums:
 Retailers: 30 days
 Manufacturers: 120 days

Q. How long does it take you to replace 80% of products?
 Retailers: N=17, Manufacturers: N=7

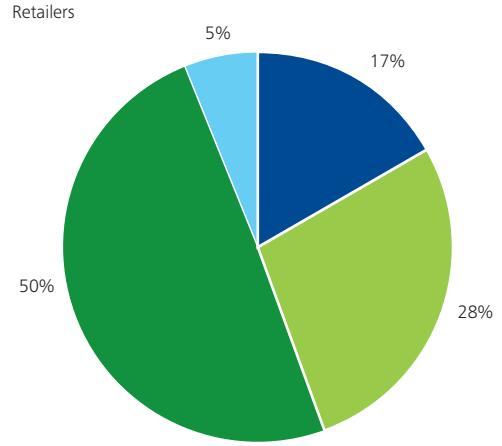
Exhibit 22. Frequency of customer recall team contact list updates



- As change occurs
- Update after each recall
- Update every six months
- Update each year or less frequently
- Do not have such contact list

Q. How often do you verify and update your contact list (for customer recall teams)?
 N=24

Exhibit 23. Frequency of vendor recall team contact list updates

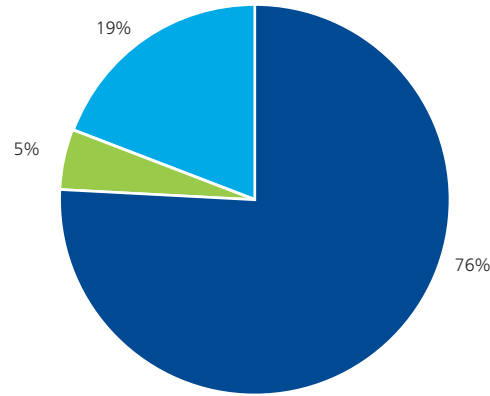


- As change occurs
- Update after each recall
- Update quarterly (or less)
- Update every six months or less frequently
- Do not store contact lists

Q. How often do you verify and update your contact list (for vendor recall teams)?
 N=18

Exhibit 24. Frequency of use of FDA Reportable Food Registry

Manufacturers

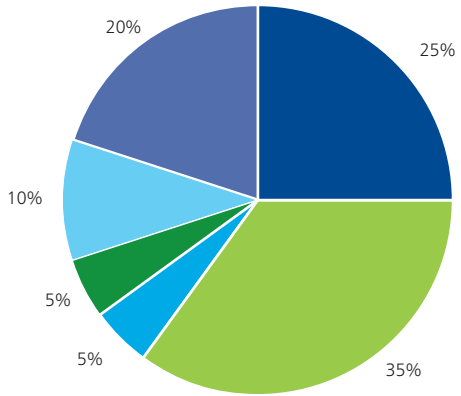


■ Never
■ 25 - 50%
■ Always

Q. How frequently do you use the FDA Recall Food Registry to distribute information concerning a recall?
N=21

Exhibit 25. Frequency of use of FDA Reportable Food Registry

Retailers



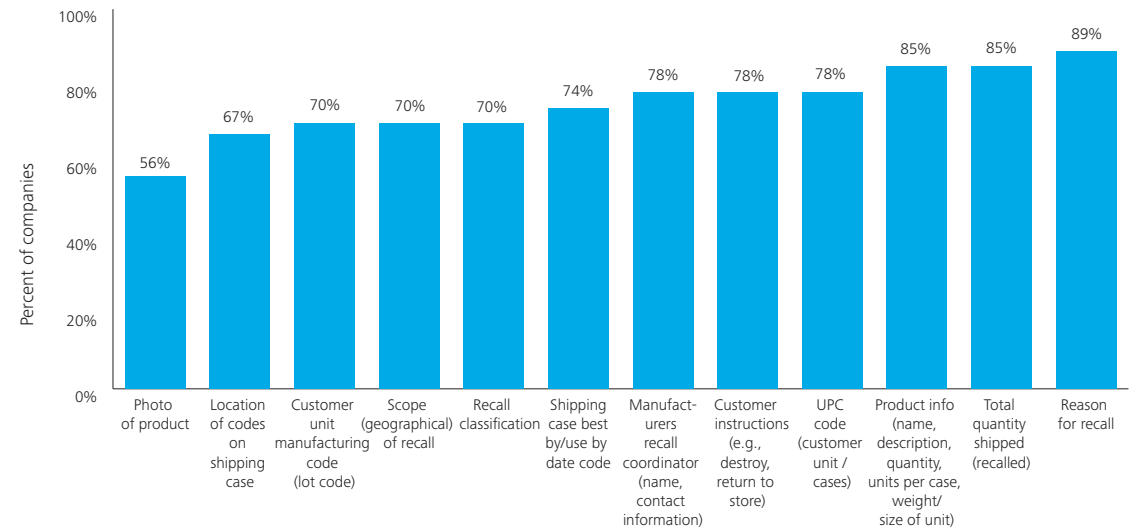
■ Never
■ 0 - 25%
■ 25 - 50%
■ 50 - 75%
■ 75 - 99%
■ Always

Q. How frequently do you use the FDA Recall Food Registry to distribute information concerning a recall?
N=20

Note: The FDA Reportable Food Registry was launched in September 2009.

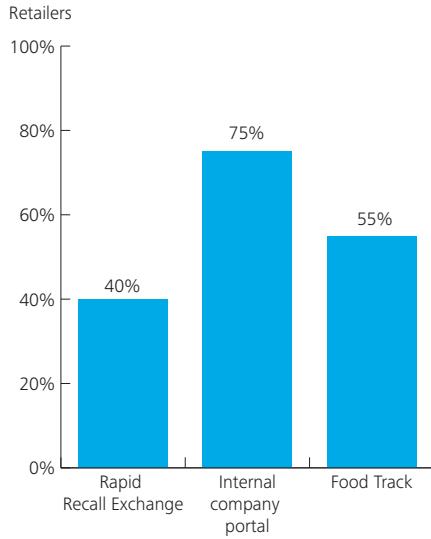
Exhibit 26. Informational elements provided during notification process

Manufacturers



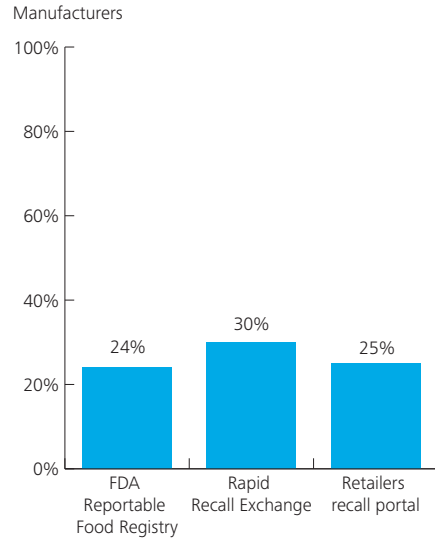
Q. Which of the following informational elements do you provide to FDA/USDA and to your customers?
N=27

Exhibit 27a. Usage of recall portals / informational sources



Q. Do you use recall portals or other online tools to capture/distribute information concerning a recall?
 Rapid Recall Exchange: N=20, Internal company portal: N=18; Food Track: N=16

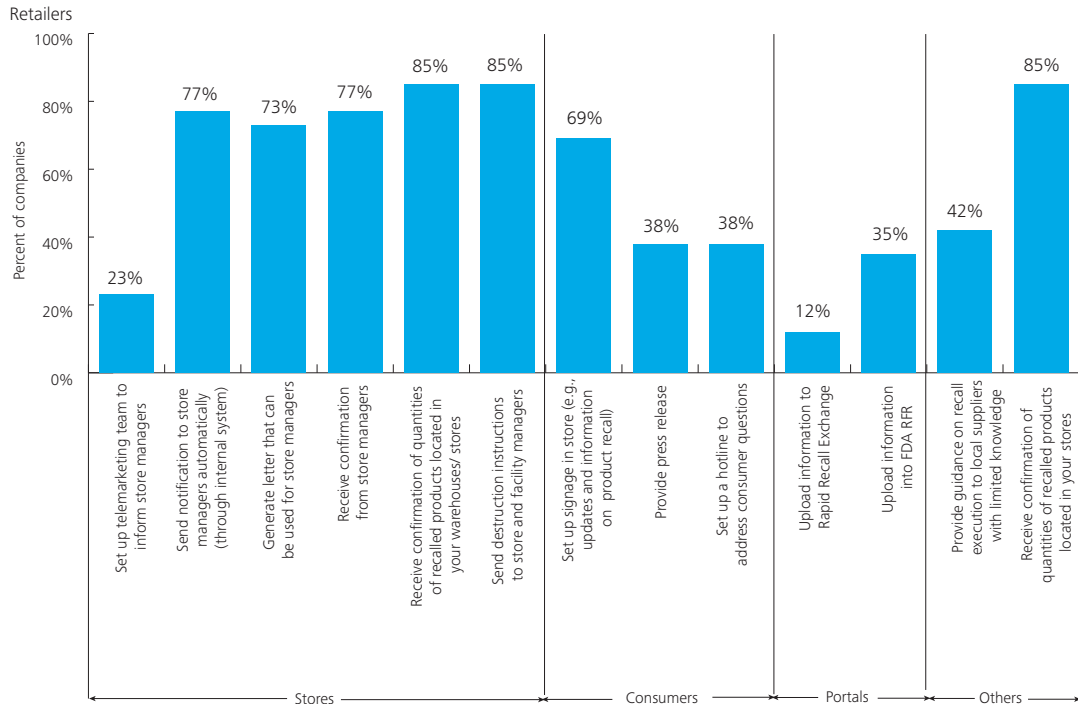
Exhibit 27b. Usage of recall portals



Q. Do you use recall portals or other online tools to capture/distribute information concerning a recall?
 FDA RFR: N=21; Rapid Recall Exchange: N=23; Retailers recall portal: N=21

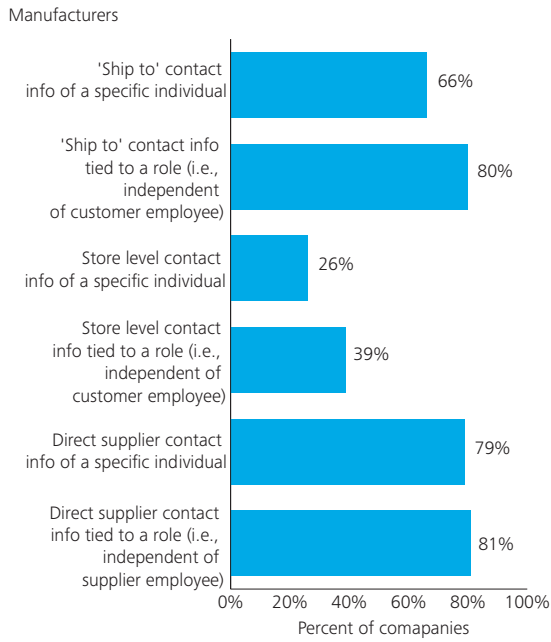
Note: The Rapid Recall Exchange was launched in September 2009. This survey was fielded Oct./Nov. 2009.

Exhibit 28. Steps / activities performed during the notification process



Q. What steps do you take within the notification process? N=26

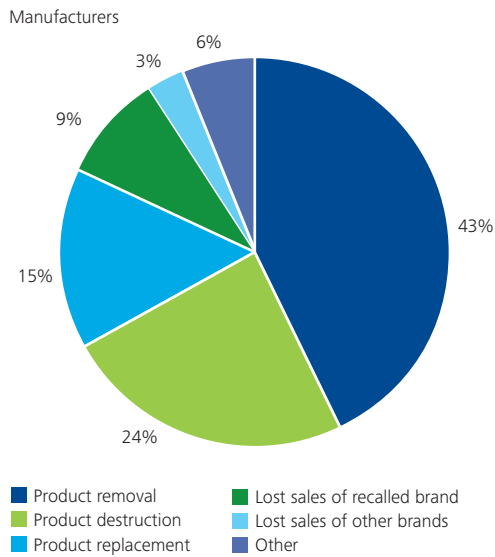
Exhibit 29. Contact information availability



Q. For how many of your suppliers/customers do you have the following contact information in the event of a recall?
N=25

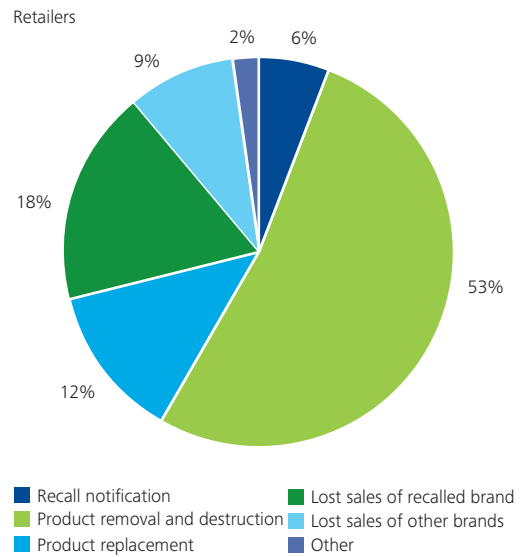
Removal

Exhibit 30. Cost of recalls



Q. How are your recalled costs allocated through the recall stages?
N=9

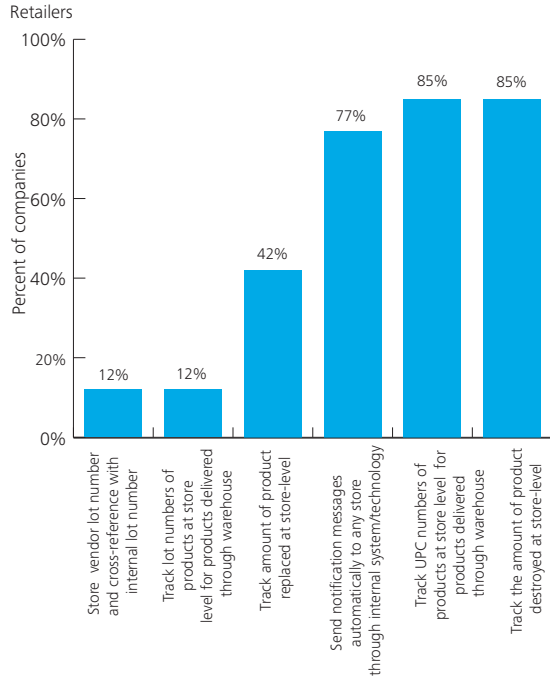
Exhibit 31. Cost of recalls



Q. How are your recalled costs allocated through the recall stages?
N=12

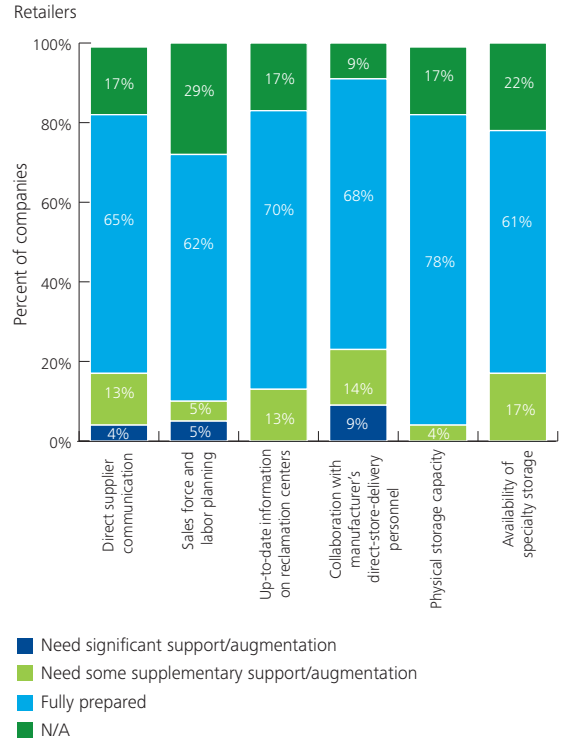
Other includes:
1. Product based costs 2. Costs incurred at warehouse

Exhibit 32. Capabilities of existing technology



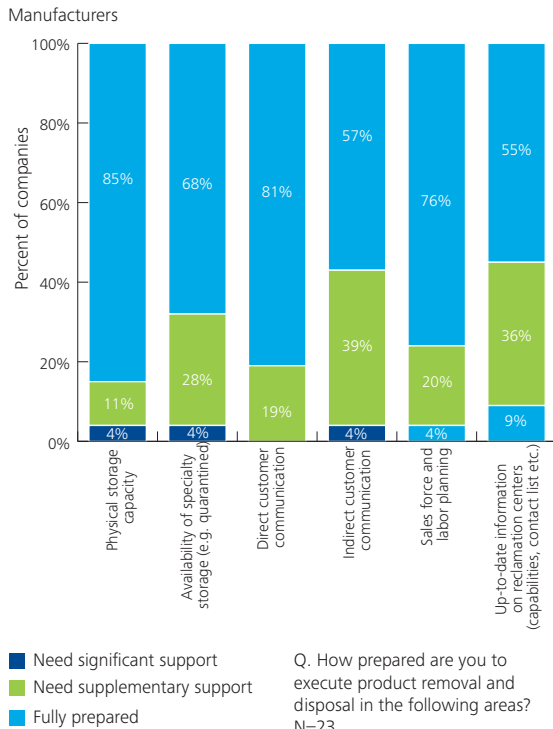
Q. Which of the following capabilities does your existing technology have?
N=26

Exhibit 33. Preparation for product removal and disposal



Q. How prepared are you to execute product removal and disposal in the following areas?
N=23

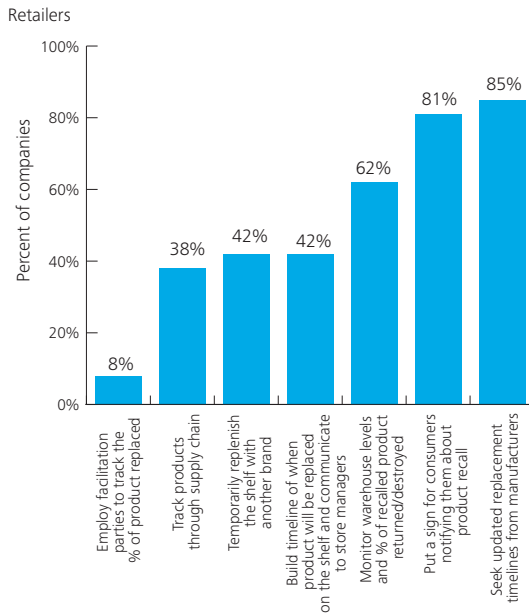
Exhibit 34. Preparation for product removal and disposal



Q. How prepared are you to execute product removal and disposal in the following areas?
N=23

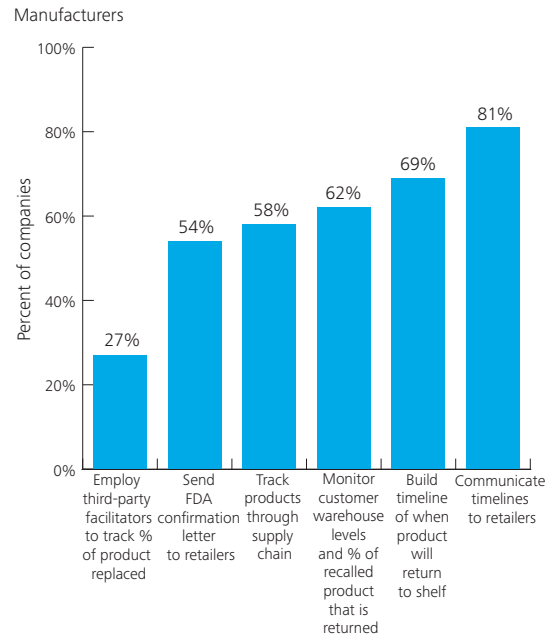
Replacement

Exhibit 35. Actions taken during Replacement



Q. What actions do you take as part of the replacement process?
N=26

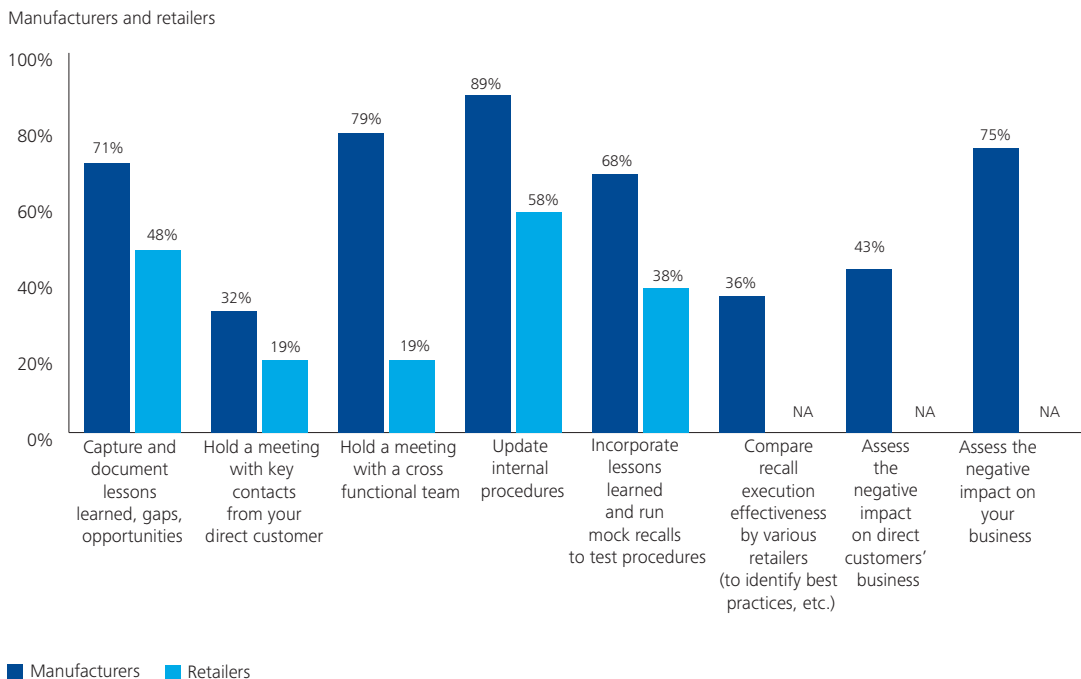
Exhibit 36. Actions taken during Replacement



Q. What actions do you take as part of the replacement process?
N=26

Feedback Loop

Exhibit 37. Activities performed during Feedback Loop



■ Manufacturers ■ Retailers

Q. Which of the following activities do you perform following a recall?
Manufacturer: N=28, Retailer: N=26

Appendix 2. Standard Data to Provide the FDA, USDA, State / Local Authorities, Customers and Consumers

Standardized data elements to be provided:	FDA	USDA	State / local authorities	Customer	Consumer
Manufacturer's name / recalling company	x	x	x	x	x
Manufacturing / producing location(s)	x	x	x	x	x
Address of manufacturing site	x	x	x		
Manufacturer's recall coordinator (name, contact information), regulatory contact	x	x	x		
Manufacturer's recall coordinator (name, contact information), customer contact				x	
Manufacturer's consumer contact information (toll free number, website, etc.)	x	x	x	x	x
USDA establishment number		x	x	x	x
Plant number (i.e., dairy) [Not BT food facility registration number]	x		x	x	x
Registration number under section 415(a)(3) [BT registration of food facilities]	x				
Product name / description	x	x	x	x	x
Total quantity (cases) produced	x	x	x	x	x
Number of units per case	x	x	x	x	
Weight (size) per unit	x	x	x	x	x
Total quantity under manufacturer's control	x	x	x		
Total quantity shipped (i.e., being recalled)	x	x	x	x	x
UPC code, consumer unit	x	x	x	x	x
UPC code, cases	x	x	x	x	
Consumer unit manufacturing code (lot code)	x	x	x	x	x
Explanation of how to interpret consumer unit manufacturing code	x	x	x		
Consumer unit best by / use by date code	x	x	x	x	x
Location of codes on consumer unit	x	x	x	x	x
Consumer unit label example	x	x	x	x	x
Shipping case manufacturing code	x	x	x	x	
Explanation of how to interpret shipping case manufacturing code	x	x	x		
Shipping case best by / use by date code	x	x	x		
Location of codes on shipping case	x	x	x	x	
Reason for recall (i.e. listeria / salmonella / allergens / foreign material)	x	x	x	x	x
Explanation for recall (i.e. consumer complaints received)	x	x	x	x	x
Consumer instructions (i.e. destroy, return to store)	x	x	x	x	x
Customer instructions (i.e. destroy, return to manufacturer)	x	x	x	x	
Scope (geographical) of recall	x	x	x	x	x
Consignee list (ship to name, address including zipcode, contact information)	x	x	x		
Individual customer consignee information (ship to name, address, contact information)				x	
Quantity shipped to consignee with identifier (e.g., date, delivery number)	x	x	x	x	
Sold to name (if different from ship to name)	x	x	x		
Has company press release been issued?	x	x	x	x	
Recall classification when known	x	x	x	x	
Photo of label/product	x	x	x	x	x

Appendix 3. Disposition Instructions, Select Guidelines

- 1.** Instruct your customers to remove the product and to dispose of it in one of three ways:
 - Correct/recondition the product (in a Class I and some Class II recalls, any correction/reconditioning of the product, such as affixing stickers to correct an expiration date or ingredients statement, must be done with the approval of FDA or FSIS).
 - Destroy the product at the store.
 - Return the product to a central location for destruction.
- 2.** If the product is to be destroyed, the instructions should describe the place and manner of destruction.
- 3.** The regulatory authorities should be notified of the plan prior to destroying product. The officials who are investigating the situation may request additional samples of the product or may ask to witness the destruction.
- 4.** If the product does not pose a health hazard, customers may usually dispose of the product as if it were other normal waste.
- 5.** If the product poses a health hazard, consider collecting all of it at a central location, so that destruction can be monitored and confirmed.
- 6.** In disposing of the product, comply with federal, state and local environmental regulations on landfills and disposal of toxic materials.
- 7.** Retain records or receipts substantiating the identification, removal and destruction of all recalled product.
- 8.** If instructions indicate that the product needs to be returned to the supplier, be sure to have specific instructions regarding how to handle the transport of the product. For example, the supplier may want the product shipped under seal.
- 9.** If the product is only misbranded and does not pose any health hazard (such as undeclared allergens), it may be donated.

Source: The Food Institute, "Food Products Recall Manual," 2009; The Food Recall Manual, FS&HN, University of Florida, Association of Food and Drug Officials

Appendix 4. Key Guidelines for Conducting Effective Mock Recalls

- **Prepare:** Prior to conducting a mock recall exercise, establish a recall team and develop recall plans, processes and templates. Members of the recall team should have a clear understanding of their roles and responsibilities.
- **Duration:** Conduct a mock recall over a span of two or three days – not weeks or months. Assess progress every few hours.
- **Objective:** Have a clearly defined objective for the mock recall exercise. For example, validate that the company can trace their supply chain – from raw materials through receiving, packaging and storage – as well as determine to which locations the product has been shipped.
- **Support:** Go beyond gaining the passive support of senior managers’ team to generating their active participation in improving the recall process.
- **Unexpected:** Conduct unannounced mock recalls in order to replicate a closer-to-real-life experience. Conducting a mock recall at an inconvenient time helps validate communication capabilities, especially when the recall team is caught by surprise.
- **Realistic, but Comprehensive:** Be realistic in terms of scope, yet comprehensive enough to cover all aspects of the emergency plan. Include key participants.
- **Record and Critique:** Record results of the recall and use them as a baseline to track improvements in future recalls. Analyze results and identify gaps.
- **Follow Up:** Address gaps identified during mock recalls through changes in recall plans and processes, as well as in employee training.
- **Incentives:** Include key external constituents, such as brokers, distributors and retailers. To ensure participation, provide external constituents with incentives, such as a discount on their next order.
- **Debrief:** Validate that all objectives of the mock recall exercise have been met, as well as capture lessons learned from each of the participants.

Source: The Food Institute, “Food Products Recall Manual”, 2009; The Food Recall Manual, FS&HN, University of Florida, Association of Food and Drug Officials

Appendix 5. Recall Resources, FDA and FSIS

FDA Recalls

- **FDA recall regulations (codified at: 21 CFR 7)** <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=b6ab96150dda3573e74b8d3b5cb72906&rgn=div6&view=text&node=21:1.0.1.1.5.3&idno=21>

Subpart C — RECALLS (INCLUDING PRODUCT CORRECTIONS)—GUIDANCE ON POLICY, PROCEDURES, AND INDUSTRY RESPONSIBILITIES

- §7.40 Recall policy
- §7.41 Health hazard evaluation and recall classification
- §7.42 Recall strategy
- §7.45 Food and Drug Administration-requested recall
- §7.46 Firm-initiated recall
- §7.49 Recall communications
- §7.50 Public notification of recall
- §7.53 Recall status reports
- §7.55 Termination of a recall
- §7.59 General industry guidance

- **FDA mandatory recall requirements for infant formula**

21 CFR 107 Subpart E—Infant Formula Recalls

- § 107.200 Food and Drug Administration-required recall
- § 107.210 Firm-initiated product removals
- § 107.220 Scope and effect of infant formula recalls
- § 107.230 Elements of an infant formula recall
- § 107.240 Notification requirements
- § 107.250 Termination of an infant formula recall
- § 107.260 Revision of an infant formula recall
- § 107.270 Compliance with this subpart
- § 107.280 Records retention

- **FDA requirement for a recall plan for manufacturers of acidified canned foods** 21 CFR 108.25 (e) Acidified foods.
- **FDA requirement for a recall plan for manufacturers of low acid canned foods** 21 CFR 108.35 (f) Thermal processing of low-acid foods packaged in hermetically sealed containers.
- **FDA's Investigations Operations Manual (IOM)** — the primary guidance document on FDA inspection policy and procedures for field investigators and inspectors. Chapter 7 deals with FDA recall activities. It also includes examples of recall communications documents and the FDA form for recall audit check reporting. <http://www.fda.gov/ICECI/Inspections/IOM/ucm123363.htm>

- **FDA's Regulatory Procedures Manual** — reference manual for FDA personnel that provides information on internal procedures to be used in processing domestic and import regulatory and enforcement matters. Chapter 7 provides very detailed requirements that all Agency units are to follow during recalls whether initiated by the firm or requested by the Agency. It spells out the responsibilities of the various FDA offices and explains the Recall Enterprise System (RES) that is to be used by district and center recall personnel to submit, update, classify, publicize and terminate recalls.
<http://www.fda.gov/downloads/ICECI/ComplianceManuals/RegulatoryProceduresManual/UCM074312.pdf>
- **FDA Guidance for Industry: Product Recalls, Including Removals and Corrections** — an FDA-generated industry guidance document that provides guidance and instructions to FDA regulated industry for obtaining information to help fulfill the Agency's plans regarding product recalls and represents the Agency's current thinking on product recalls.
<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>

FSIS Recalls

- **FSIS Directive 8080.1, Revision 5 (11/17/08)** provides terminology, responsibilities and public notification procedures regarding the voluntary recall of FSIS-inspected meat and poultry products. This directive also includes three attachments:
 - Attachment 1 – Product Recall Guidelines for Firms
 - Attachment 2 – Factors That Are Considered by the FSIS Recall Committee in Evaluating the Public Health Significance of an Undeclared Ingredient in a Meat or Poultry Product
 - Attachment 3 – Effectiveness Checks
<http://www.fsis.usda.gov/OPPDE/rdad/FSISDirectives/8080.1Rev5.pdf>
- FSIS requirement for a recall procedure for canned product manufacturers
9 CFR 318.311 and 9 CFR 381.311 Recall procedure
<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=81245de1d850d51d1d5d7d4a6ad3b6c4&rgn=div8&view=text&node=9:2.0.2.1.19.3.22.12&idno=9>
- **FSIS regulatory provision for posting lists of retail consignees who received recalled product**
9 CFR 390.10 Availability of Lists of Retail Consignees during Meat or Poultry Product Recalls
<http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=81245de1d850d51d1d5d7d4a6ad3b6c4&rgn=div8&view=text&node=9:2.0.2.3.36.0.70.10&idno=9>

Source: Grocery Manufacturers Association

End Notes

- ¹ Poll conducted during the Deloitte debrief “Food Recall Prevention: Manage Risk to Protect Your Consumers and Your Brand,” November 12, 2009 (367 participants — manufacturers, retailers and service providers). See Exhibit 1, Appendix 1 for poll results.
- ² Progressive Grocer, “Ahead of What’s Next,” May 2009. <[www. progressivegrocer.com](http://www.progressivegrocer.com)>
- ³ Poll conducted during the Deloitte debrief “Food Recall Prevention: Manage Risk to Protect Your Consumers and Your Brand,” November 12, 2009 (367 participants — manufacturers, retailers and service providers). See Exhibit 1, Appendix 1 for poll results.
- ⁴ Exhibit 2, Appendix 1
- ⁵ U.S. Food and Drug Administration, <[http:// www.fda.gov/Safety/Recalls/ ucm165546.htm](http://www.fda.gov/Safety/Recalls/ucm165546.htm)>
- ⁶ U.S. Department of Agriculture Food Safety and Inspection Service, FSIS Directive, “Recall of Meat and Poultry Products,” November 17, 2008
- ⁷ The Food Institute, “Food Products Recall Manual,” 2009
- ⁸ U.S. Food and Drug Administration, <[http:// www.fda.gov/Safety/Recalls/ ucm165546.htm](http://www.fda.gov/Safety/Recalls/ucm165546.htm)>
- ⁹ Food Industry Report, April 15, 2009
- ¹⁰ The Food Institute, “Food Products Recall Manual,” 2009
- ¹¹ USA Today, “Peanut product recalls spread fast,” February 2, 2009
- ¹² National Institute of Allergy and Infectious Diseases, <[http://www3.niaid.nih.gov/ topics/foodborne/default. htm](http://www3.niaid.nih.gov/topics/foodborne/default.htm)>
- ¹³ Pat Conroy and Diane Kutyla, “What’s for Dinner? Consumers Seek Answers About the Food They Eat,” November 2008. <[www. deloitte.com](http://www.deloitte.com)>
- ¹⁴ USDA, “Outbreak linked to Spinach Forces Reassessment of Food Safety Practices,” June 2007
- ¹⁵ U.S. Department of Health & Human Services — Public Health Service, “Progress Review Food Safety”, December 20, 2007
- ¹⁶ President’s Food Safety, Working Group, <[http://www. foodsafetyworkinggroup.gov](http://www.foodsafetyworkinggroup.gov)>
- ¹⁷ <[http://www.consumerfed. org/a bout/def a ult. asp](http://www.consumerfed.org/about/default.asp)>
- ¹⁸ Exhibit 5, Appendix 1
- ¹⁹ Exhibit 6, Appendix 1
- ²⁰ Marian Burros, “More Testing of Seafood to Address Mercury Concerns,” The New York Times, January 30, 2008. <[http://www. nytimes.com/2008/01/30/ dining/30mercury.html](http://www.nytimes.com/2008/01/30/dining/30mercury.html)>
- ²¹ Poll conducted during the Deloitte debrief “Food Recall Prevention: Manage Risk to Protect Your Consumers and Your Brand,” November 12, 2009 (367 participants — manufacturers, retailers and service providers). See Exhibit 1, Appendix 1 for poll results.
- ^{22, 23} Exhibit 17, Appendix 1
- ²⁴ Exhibit 7, Appendix 1
- ²⁵ Exhibit 8, Appendix 1
- ²⁶ Exhibit 9, Appendix 1
- ²⁷ Exhibit 10, Appendix 1
- ²⁸ Exhibit 11, Appendix 1
- ^{29, 30} Exhibit 12, Appendix 1

- ³¹ Poll conducted during the Deloitte debrief “Food Recall Prevention: Manage Risk to Protect Your Consumers and Your Brand,” November 12, 2009 (367 participants — manufacturers, retailers and service providers). See Exhibit 1, Appendix 1 for poll results.
- ³² Assuming that each distributor or wholesaler takes approximately the same time as a manufacturer to inform the next constituent in the value chain
- ³³ Exhibit 13, Appendix 1
- ³⁴ Exhibit 14, Appendix 1
- ³⁵ Exhibit 15, Appendix 1
- ³⁶ GMA, “GMA Product Recall Manual,” June 2010
- ³⁷ Exhibit 18, Appendix 1
- ³⁸ Exhibit 16, Appendix 1
- ³⁹ Exhibit 20, Appendix 1
- ⁴⁰ FMI, “2009 Food Retail Industry Speaks”
- ⁴¹ Center for Science in the Public Interest Newsroom, “Supermarkets Urged to Use Loyalty Card Info to Notify Consumers Who Purchased Recalled Products,” February 3 2009.
- ⁴² Exhibit 18, Appendix 1
- ⁴³ Exhibit 22, Appendix 1
- ⁴⁴ Exhibit 16, Appendix 1
- ⁴⁵ Exhibit 16, Appendix 1
- ⁴⁷ Exhibit 26, Appendix 1
- ⁴⁸ Exhibit 26, Appendix 1
- ⁴⁶ Exhibit 27a and 27b, Appendix 1
- ⁴⁹ Exhibit 27, Appendix 1
- ⁵⁰ Exhibit 20, Appendix 1
- ⁵¹ Exhibit 28, Appendix 1
- ⁵² Exhibit 29, Appendix 1
- ⁵³ IBIS World Industry Report, August 2009
- ⁵⁴ Exhibit 30 in Appendix 1; Note: Total recall costs consist of costs for each step of the recall execution process and exclude other costs such as those associated with “brand impact”; Removal & Destruction costs typically consist of cost of goods sold, loss of sales, flat or variable fees to retailers for removal services, fees to third parties, and destruction and refurbishment costs”.
- ⁵⁵ Exhibit 31 in Appendix 1; Note: Total recall costs consist of costs for each step of the recall execution process and exclude other costs such as those associated with “brand impact”; Removal & Destruction costs typically consist of cost of goods sold, loss of sales, flat or variable fees to retailers for removal services, fees to third parties, and destruction and refurbishment costs”.
- ⁵⁶ FMI, Industry Overview 2008. <http://www.fmi.org/facts_figs/?fuseaction=superfact>
- ⁵⁷ Exhibit 26, Appendix 1
- ⁵⁸ Exhibit 32, Appendix 1
- ⁵⁹ Exhibit 32, Appendix 1
- ⁶⁰ Exhibit 33, Appendix 1

- ⁶¹ “The Benefits of Using Two-Dimensional Barcodes,” December 2, 2009.
<[http:// www.articlesbase.com/ industrial--articles/the-benefits-of-using-twodimensional-barcodes-1 531858. html](http://www.articlesbase.com/industrial-articles/the-benefits-of-using-twodimensional-barcodes-1531858.html)>
- ⁶² Amit Rawal, “RFID: The Next Generation Auto-ID Technology,” Microwave Journal, March 2009.
<[http:// www.mwjjournal.com/Journal/ article.asp?HH_ID=AR_7232](http://www.mwjjournal.com/Journal/article.asp?HH_ID=AR_7232)>.
- ⁶³ Exhibit 34, Appendix 1
- ⁶⁴ Exhibit 19 and Exhibit 20, Appendix 1
- ⁶⁵ Exhibit 30 and Exhibit 31, Appendix 1
- ⁶⁶ Exhibit 21, Appendix 1
- ⁶⁷ Exhibit 35, Appendix 1
- ⁶⁸ Exhibit 36, Appendix 1
- ⁶⁹ Exhibit 36, Appendix 1
- ⁷⁰ Exhibit 35, Appendix 1
- ⁷¹ Exhibit 35, Appendix 1
- ⁷² Exhibit 36, Appendix 1
- ⁷³ Exhibit 21, Appendix 1
- ⁷⁴ Exhibit 36, Appendix 1
- ⁷⁵ Exhibit 35, Appendix 1
- ⁷⁶ Exhibit 37, Appendix 1
- ⁷⁷ Exhibit 37, Appendix 1
- ⁷⁸ The Food Recall Manual, FS&HN, University of Florida, Association of Food & Drug Officials
- ⁷⁹ Exhibit 37, Appendix 1
- ⁸⁰ Exhibit 37, Appendix

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