Technical Paper

Food safety and compliance

Executive summary.

In recent years, a rash of product recalls has caused significant long-term damage to many brands. These recalls cover everything from serious health and safety risks to misrepresentation of a product's performance or composition. The causes of these recalls stem from a wide variety of issues, including material tampering, improper labeling, inaccurate food-preparation instructions, cross-contamination, inadequate plant health and safety, false marketing claims, and inadequate shelf life.

Food safety and compliance keep many food company executives awake at night—and for good reason: According to the Recall Execution Effectiveness joint study by the Food Marketing Institute (FMI), the Grocery Manufacturers Association (GMA), GS1 US, and Deloitte, "the average cost of a recall to participating food and consumer product companies is $10 million, in addition to brand damage and lost sales."[1]

Yet many companies are not willing to invest heavily in food safety and compliance, until they've had a problem. Food poisoning outbreaks are rare, for any given company; but once they occur, they harm the company for a long time. The study additionally reveals, "a company with poor recall execution processes could see declines of up to 22 percent [in their stock valuations] within two weeks after the recall announcement."[2]

For instance, entire farm stocks were slaughtered—many unnecessarily—during the mad cow[3] (bovine spongiform encephalopathy) disease scare in the UK in the mid-1980s, and again in the UK during the foot-and-mouth[4] outbreak in 2001. In both instances, the UK also suffered from a dramatic drop in its meat export trade. Had better traceability been used to track the stock, many of the animals wouldn't have had to be destroyed.

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1 Food Marketing Institute (FMI), the Grocery Manufacturers Association (GMA), GS1 US, and Deloitte; Recall Execution Effectiveness: Collaborative Approaches to Improving Consumer Safety and Confidence; 2010; p. 11.
2 FMI, GMA, GS1 US, and Deloitte; p. 11.
3 David Brown, "The 'recipe for disaster' that killed 80 and left a £5bn bill," The Telegraph (http://www.telegraph.co.uk/news/uknews/1371964/The-recipe-for-disaster-that-killed-80-and-left-a-5bn-bill.html), October 27, 2000.
4 "Foot-and-mouth crisis remembered, " BBC (http://www.bbc.co.uk/news/uk-england-12472230), February 17, 2011

In an apparent case of life lobbying for legislation, in 2010 the largest egg recall in US history occurred just as the US Senate began studying the Food Safety Modernization Act (FSMA)[5]. This act, which was signed into law in January 2011, gives the US Food and Drug Administration (FDA) the power to enforce tough, new requirements that address food safety issues through preventative controls, inspection, compliance, ensuring imported food meets US standards, mandatory recall authority, and strengthening partnerships between food safety agencies.[6]

Safety, however, is not the only reason for potential recalls. Consumers now demand more information on the composition, origin, and handling of the food they eat. While dietary restrictions (such as peanut allergies) can also be safety issues, other issues relate to more personal preferences (such as gluten free, zero trans fat, and genetically modified ingredients). The label and any claims it makes must match what is in the product. Failure to comply might not necessarily bring government action, but it can result in lawsuits and irrevocable, bad publicity—all of which can make consumers wary.

The increase in recalls and the wide range of causes behind those recalls highlight the need for more than just internal improvements at process manufacturing companies. They also point out the need for manufacturers to be more vigilant about anything that could result in a product safety issue or recall.

With stricter food legislation being enacted around the world, the pressure to maintain food safety and compliance effectiveness can only increase. In 2011 alone, new labeling laws were passed in a number of countries and jurisdictions, including the United States, Canada, European Union, and South Africa. And the potential food safety and compliance issues that can arise from today's speedy supply chains only exacerbate the problem.

Recently passed food safety and labeling laws	
United States	Food Safety Modernization Act (FSMA)
Canada	Amendments to the Food Allergen Labelling Regulations
European Union	European Parliament and Council Regulation 1169/2011
South Africa	R146

No longer can you rely on purely reactive strategies to product safety. You need to incorporate strategies that assess risks and ensure the integrity and safety of your products. You need to adopt a master plan that makes the move toward a complete, proactive, product safety strategy as painless as possible—while you reduce risk, protect your products, reduce non-value costs, and boost profits. You need to focus on your greatest areas of risk, minimize the time it takes you to close those risks, and continually build on your existing capabilities.

Processes for improving food safety and recall effectiveness.

The FDA defines recalls as "actions taken by a firm to remove a product from the market. Recalls may be conducted on a firm's own initiative, by FDA request, or by FDA order under statutory authority." Furthermore, the FDA breaks out recalls into the following classifications:

5 "Egg Contamination and Recalls," The New York Times (http://topics.nytimes.com/top/reference/timestopics/subjects/e/eggs/contamination_and_recalls/index.html), September 23, 2010.
6 Food Safety Modernization Act (FSMA), Frequently Asked Questions, US Food and Drug Administration (www.fda.gov/Food/FoodSafety/FSMA/ucm247559.htm), March 15, 2012.

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Class I recall: A case in which there is a reasonable probability that the use will cause serious adverse health consequences or death. An example would be E. coli contamination of meat.

Class II recall: A situation in which the consumption of a product may cause temporary adverse health consequences or where the probability of serious health consequences is highly unlikely. One example might be an undisclosed food dye that is known to cause mild allergic reaction in some individuals.

Class III recall: A case where there is an error, but consumption of a product is not likely to cause adverse health consequences. An example would be an underweight product.[7]

Five processes that impact recall readiness.

To be prepared for a recall, you need to have a framework in place that is built around these five processes.

Regardless of which classification a recall is designated, there are well-defined processes for dealing with it that include prevention, identification, notification, removal and replenishment. If you're unable to prevent a recall, the first and most critical step is to identify the affected products. You next need to notify everyone who's affected; make sure the affected products are removed from the shelves; and then get replacement products onto the shelves as soon as possible.

After prevention, timely, factual identification of affected products is the most critical of these processes. The faster you can identify and isolate contaminants, the less potential for consumer harm you face, and the lower the possible costs to your supply chain stakeholders. This challenge is made even more acute in today's fast-paced and efficient supply chains, which can see ingredients distributed across multiple products, retailer channels, and geographies in a matter of hours.

7 Recalls, Market Withdrawals, & Safety Alerts; Background and Definitions; US Food and Drug Administration (www.fda.gov/Safety/Recalls/ucm165546.htm); June 24, 2009.

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Risk management is only part of the equation. You need to take a proactive approach as well. Detailed documentation of all your products' ingredients and processes are the foundation of public trust. When you can show your customers online exactly what went into the product they are buying, or give an auditor direct access to your system to review your quality controls, you powerfully enhance customer trust and your reputation.

In addition, to differentiate yourself and to break out of the commodity pricing game, you may decide to follow the path that many manufacturers and food processors have taken—adding value through what the US Department of Agriculture (USDA) refers to as "credence attributes," such as organic certification, kosher processing, and the labeling of "dolphin-safe tuna" and "fair trade coffee." Credence attributes derive their premium value from the credence—the trust—that they invoke. They are content or process characteristics whose existence or absence can only be established by documentation. Consumers cannot taste the difference between oil made from genetically modified and non-genetically modified (GMO) corn. That's why you have to be able to prove it.

Building a technology framework for improved recall effectiveness.

To ensure that your organization is effectively prepared for a recall, you need to assemble a framework around the five key processes:

1. Prevention.

The idiom, "an ounce of prevention is worth a pound of cure," is one that food manufacturers and distributors should heed. Implementing ample preventative measures can go a long way toward avoiding many contaminants, such as:

- Agrochemicals
- Allergens
- Carcinogens
- Environmental contaminants
- Human contamination
- Parasites
- Pathogens
- Pesticides
- Processing contaminants

Contaminants can come from many sources, including:

- High humidity
- Improper pH
- Labeling errors
- Manufacturing errors
- Plant safety problems

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- Tampering
- Temperature fluctuations
- Unapproved ingredients

Some of the processes and systems that you can put in place to minimize contamination include:

Supplier compliance—Your suppliers present a high area of potential risk. You can improve product safety by integrating more supplier data and interacting with your suppliers more often. Based on the supplier, commodity, item quality, and compliance/risk rating, you can enforce the appropriate level of material disclosure, supplier in-line or in-process quality testing and certification, and internal testing and certification.

As you process requests for information (RFIs), requests for proposal (RFPs), and plant certifications, integrated material disclosure can streamline processes for low-risk and high-quality suppliers, and provide additional scrutiny for higher-risk suppliers, materials, and plant certifications. Materials disclosure and screening processes can proactively identify issues, protect product safety, and reduce process lead times and costs.

Global recipes—Implementing global recipes can prevent the use of unapproved ingredients in your products. This doesn't mean, though, that the recipes are precisely the same from country to country—it means that you have global control over the recipes. Certain additives and ingredients that are permitted in one country, might not be allowed in others. Additionally, label and health claims that are valid for one country, could be forbidden in others. For example, claims such as "low fat," "high fiber," or "helps lower cholesterol" are all subject to country and regional laws. Failure to comply with these local laws can result in a recall.

Quality assurance integrated into production systems—You can proactively protect product safety and improve the value of your end product by integrating quality assurance all the way from advanced shipment notices through inventory, production, shipping, and logistics. By proactively monitoring to identify risks and issues, you can stop a suspect lot from being used or shipped. You can proactively monitor from initial shipment through inventory, production, and distribution. Not only do you ensure safety, you improve the value of your end product.

Asset maintenance practices—Improper changeover procedures, poor sanitation measures, leaky pipes or roofs, metal shavings that fall into packaging processes, and other asset maintenance issues have led to several high-profile recalls. These recalls could have been prevented. Preventive maintenance safeguards product quality, reduces safety risks, and boosts asset availability and longevity. Additionally, using alerting technologies that warn when conditions change that may compromise food safety (such as when the temperature is too low or the humidity is too high) can also significantly reduce the risks for contamination. By practicing preventive maintenance and refusing to operate under out-of-tolerance conditions, you proactively improve product safety, minimize write-offs, and improve fill rates.

Label compliance—Nearly 20% of recalls are due to labeling errors. There are two key areas where label compliance can be an issue. The first is ensuring that the listed ingredients match what is actually in the product, in regards to completeness and correct order. Failure to disclose all ingredients, especially if there is potential for allergic reactions, can result in a recall. Secondly, a product label's nutritional and health claims must be accurate and comply with government standards. Due to changes in formulas, as well as raw material fluctuations, food manufacturers must have a means to make sure that the product they produce matches the label they are using. Infor Optiva is designed specifically to address this—none of the customers who use it have ever had a labeling-related recall.

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Institutionalize practices—Don't wait for trouble; perform "fire drills" of recalls and assign employees well-defined roles. Push your concern for traceability back into your supply chain. Demand timely and accurate feedback from your suppliers as to the history of the raw materials, and keep their answers on record. Food safety and quality issues can be managed more readily if each partner in the supply chain can identify the direct source and direct recipient of traceable items. A healthful food supply depends upon a sound supply chain.

Supplier risk assessment—You can analyze performance to more accurately rate supplier, material, and production quality. By using supplier scorecards, which are generated from the data collected to create risk ratings, you can help drive purchase order volumes to more reliable suppliers—and also reduce safety risks. Since many suppliers are not staffed to implement advanced quality and compliance programs, you can move from just auditing to value-added education. You can use supply chain planning to perform what-if analysis if specific suppliers were to be affected. By improving supplier quality, you can help reduce your costs—and your suppliers' costs—while improving product quality and consistency.

2. Identification.

In 2007, USDA officials made the Topps Meat Company of Elizabeth, New Jersey, recall a year's worth (21.7 million pounds) of beef products because of potential E. coli contamination. That, combined with the company being served with a "notice of intended enforcement" by the USDA for "inadequate process controls," was enough to put the Topps Meat Company out of business.[8]

What put Topps Meat Company out of business was not the few hundred E. coli-tainted hamburger patties that made people sick; it was the company's inability to prove that its production was safe for the year leading up to the contamination. They didn't have the records. When they couldn't trace the problem to certain lots and dates, they were forced to recall and destroy everything. In addition, the problem went on too long. According to the Centers for Disease Control and Prevention (CDC), it typically takes two to three weeks from the time a person falls ill from food poisoning to confirm that the case is part of an E. coli outbreak.[9]

The more precise data you have, the more you can limit the consequences of a product recall or products withheld from market. Traceability solutions add so much visibility and transparency that you can execute a product recall within hours and with high precision. The alternative—manual or semi-manual trace-back—is a time-consuming, step-by-step process. Being unable to prove what lots were involved results in recalling more products than you need to, for a margin of safety.

Lot traceability is a core component in the food safety concept. Use the lot recall analysis capabilities of your own enterprise resource planning (ERP) system to manage what happens in your supply chain and processing operations. This should allow you to identify where the raw materials and packaging came from, how you have transformed them, how the raw materials were consumed, and where you shipped the finished product. Additionally, product lifecycle management (PLM) tools can help you identify other recipes that might contain the same contaminant.

8 Ken Belson and Kareem Fahim, "After Extensive Beef Recall, Topps Goes Out of Business," The New York Times (www.nytimes.com/2007/10/06/us/06topps.html?_r=2), October 6, 2007.
9 Timeline for Reporting of E. coli Cases, Center for Disease Control and Prevention (www.cdc.gov/ecoli/reportingtimeline.htm), September 19, 2006.

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Real-time transactional data collection is the foundation of traceability. It can be used proactively in the interests of efficiency, as well as reactively in the event of a product recall. Proactive use allows you to test and verify the traceability of supply chain input as a continuous part of operations. Increasingly, food safety regulations include standards for recall speed; organizations must prove that they can find and withdraw all potentially contaminated food from the supply chain within a specified time.

3. Notification.

As soon as you identify a bad lot, you need to notify your affected customers. They need to remove the products from their shelves (if they are retailers) or notify their customers (if they are distributors). It's not enough, however, to just communicate the problem down the supply chain; you also need to make sure all of your affected suppliers are notified as well, so they can identify and rectify the cause of contamination.

The Recall Execution Effectiveness study indicates that companies are effective at notifying regulatory agencies: "72% of manufacturers surveyed notify the FDA and/or USDA of a recall in eight hours or less."[10] That effectiveness, however, does not carry over to notifying affected customers: "This study indicates that surveyed manufacturers at times can take from one to five days to notify direct customers."[11] Often this delay is a result of companies not having ready access to their customer contact information, or the information is not current. Maintaining accurate customer contact information is essential for an effective recall. You also need a feedback system to confirm that your customers received the notification.

The longer it takes to make affected customers aware of the problem, the longer those bad lots will stay on the shelves. Not only does this create a potential increased health issue, but it can also damage your brand. By performing regular "fire drills," you can have recall notification templates already in place, based on potential issues. Using the collaborative capabilities of your ERP or customer relationship management (CRM) systems, you can quickly get notifications out to the right people.

Quickly notifying your customers is only part of the equation. What you communicate to your customers is equally important. The more information you provide, the more effective the customer can be at identifying the affected products and removing them from the shelves. This information should include all of the original order details, including:

- Product description
- Size or weight
- Recall reason
- When shipped
- Quantity shipped
- Lot codes
- UPC codes
- Plant number

10 FMI, GMA, GS1 US, and Deloitte; p. 20.
11 FMI, GMA, GS1 US, and Deloitte; p. 23.

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- Recall coordinator contact information
- Customer instructions
- Image of the product

4. Removal.

The natural response for retailers is to pull everything of yours off the shelves—not just the affected lots—in an attempt to protect consumers and their brands. This can make an already costly undertaking even more expensive. The Recall Execution Effectiveness study reports that removal and destruction of recalled products for manufacturers "accounts for 67 percent of the total cost of a product recall; for retailers, the cost is 53 percent of the total."[12]

The better the information you can provide on the actual lots affected, the more you can minimize the cost of the recall. This can help limit the extent to which retailers remove products outside of the scope of the affected lots from the shelves. During recall notification, 70% of manufacturers provide the affected lot numbers to their customers.[13]

But only 12% of retailers have access to technology that allows them to track lot numbers. The Recall Execution Effectiveness study states that "the moment a national brand product reaches a customer warehouse, manufacturer lot information is often lost and not cross-referenced with the retailer's/wholesaler's internal codes." This leaves UPC numbers as the primary means for retailers to track recalled products. "85% of the surveyed retailers have the technology to track UPC numbers of products at store level."[14]

5. Replenishment.

According to the Recall Execution Effectiveness study, replacing recalled products "takes anywhere from 1 to 30 days depending on whether they have unaffected product available at their stores or distribution centers." The longer it takes to replenish products on retailers shelves means more lost revenue—12% in lost sales for manufacturers, and 27% for retailers. And to make matters worse for manufacturers, 42% of retailers fill empty shelves with products from competitors.[15]

The key to minimizing the time it takes to refill stocks and shelves is effectively collaborating with your suppliers and customers using supply chain management (SCM) solutions, such as an advanced planning tool. This will allow you to assess exactly how to estimate resources and costs and make maximum use of your production capacity, while still meeting demand for your other products. You can even use the advanced planning tool's what-if analysis to model replenishment scenarios during "fire drills" and to help build contingency plans.

12 FMI, GMA, GS1 US, and Deloitte; p. 27.
13 FMI, GMA, GS1 US, and Deloitte; p. 27.
14 FMI, GMA, GS1 US, and Deloitte; p. 27.
15 FMI, GMA, GS1 US, and Deloitte; p. 32.

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Essential guidance.

To be properly prepared for effective and comprehensive food safety and recalls, make sure that collectively, your solutions allow you to:

- Collaborate with suppliers and customers.
- Integrate supplier data.
- Use supplier scorecards with risk ratings.
- Integrate quality assurance into production systems.
- Implement asset management alerting technologies.
- Conduct recall “fire drills.”
- Analyze what-if scenarios.
- Share data between product development and supply chain systems.
- Trace ingredients from suppliers through manufacturing.
- Track lot and UPC numbers at all levels.
- Collect transactional data in real time.
- Maintain accurate customer contact information.
- Send automated notifications.
- Receive notification feedback.
- Perform advanced planning to estimate resources and costs, and maximize production capacity.

Ask yourself these important question to asses your recall effectiveness:

- Do you integrate lot-specific supplier data into your manufacturing systems?
- Do you have tools in place to ensure against labeling errors?
- Do you have total lot-tracking capability, including raw materials used per batch, as well as location of finished products?
- Do you have an efficient and timely communication plan for both customers and regulators in the event of a recall?

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Conclusion.

Food safety and recall effectiveness is not a single-issue event. It covers multiple business processes and crosses many disciplines. Product recalls can do potentially irreparable damage to brands and can even put companies out of business for good. You can't wait for a problem to arise before you implement a food safety or recall plan. Your response will be too slow and ineffective. You'll lose customers, tarnish your reputation, and rack up significant costs.

You need to assess your effectiveness in terms of prevention, identification, notification, removal, and replenishment. You need to enlist proactive strategies designed to reduce risks, and the key to implementing these strategies is to build them into the technology you use to run your business. With robust ERP, CRM, enterprise asset management (EAM), PLM, and SCM solutions in place, you'll be much better positioned to quickly and effectively respond to problems when they arise, and do so while minimizing costs and maintaining customer trust and your reputation.

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