

FORGET CHICKEN LITTLE – THE SKY IS FALLING: CURRENT ENTERPRISE RISK MANAGEMENT STRATEGIES FOR PRODUCT RECALLS AND CORPORATE COMPLIANCE MATTERS

TAKE AWAYS FROM A PRODUCT RECALL EXPERIENCE

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Be PROACTIVE and PREPARED before a recall occurs.

Ways to Prepare for and What to Do During a Recall:

1. **Form a “Recall Task Force.”** This should include managers from manufacturing, IT, sales, and customer service. Also include people from supplier relations or transportation, if necessary. All task force members should be trained in how to query each other’s core applications, and how their respective data comes together to tell the story of how a product went bad, the scope of the problem and where it is located inside the supply chain. A recall requires a multi-disciplinary approach and a coordinated response.
2. **Study.** Read the investigative procedures of the CPSC, FDA and USDA to understand what data inspectors and compliance officers will request during a recall. Determine how quickly and completely you can provide necessary data and information. Consider implementing IT software that tracks products from manufacturing to point-of-sale, as a way to act quickly and effectively during a recall. This can potentially save thousands of dollars in pinpointing the problem and focusing the amount of product that needs to be recalled.
3. **Know Your Suppliers.** It is integral for any company to know their suppliers. Under the federal Bioterrorism Act, the FDA enacted a records maintenance rule that requires food manufacturers to maintain records that identify the immediate previous source, immediate subsequent recipient, and transporter(s) of a company’s products. A food processor’s ability to identify the ingredient source quickly is essential to identifying potentially contaminated product. This is especially true in situations in which companies source bulk ingredients from several suppliers—ingredients that are then commingled

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into a common bin. In the children's product arena, new CPSC regulations require the use of tracking labels and ongoing certificates of conformity for products. A similar chain of responsibility exists for medical device products.

4. **Audit Your Suppliers.** One common practice is to hire a third-party auditor to conduct periodic investigations and audits of a supplier's facility and operations. Another way to ensure product quality and safety is to sample and test incoming shipments. Ideally, the sampling and testing should occur on raw materials before the product is introduced into the manufacturing facility so that if testing reveals a problem, materials can be segregated and prevented from contaminating the production lines and finding its way into finished product. An effective QA/QC program can head off problems before they become significant impairments to your company.
5. **Audit Your Auditors.** Hiring a third-party auditor to conduct periodic investigations and audits of the supplier's facility and operations is one option. However, even this practice should not be the sole method for ensuring the safety of supplied product. A company might want to consider sending its own inspectors to inspect the supplier's operations. This additional step to ensure the safety of a supplier's operations and materials can be an important risk management tool. No one knows your business better than you do.
6. **Test Finished Product.** In addition to following or ensuring good manufacturing practices (GMPs) consider random sampling to test finished product before it leaves the manufacturing facility.
7. **Practice.** After the Recall Task Force understands what data is needed in the event of a recall, the company should perform mock recalls to discover gaps in the availability of critical data, such as the origin of ingredients or parts that went into the finished goods and where in the shipping pipeline the product's risk is identified. Retracing the steps of procurement, manufacturing and distribution to find out how a product went bad, where it is and how to get it back, highlights all of the company's information gaps.

For example, choose a batch number for a real group of products. Then using supplier, manufacturing, distribution and transportation systems, run reports to try and account for what was made, shipped and received. How accurate were those practice reports? Where and when did the collection of additional information, such as questioning the plant manager in person or calling the trucking company, become necessary? How long did the entire process take?



8. **Product Traceability.** It is often important to trace the pedigree of a finished product back to the component level. Evaluate whether you have practices and procedures to provide this level of information detail.
9. **Insurance.** Many companies rely on general liability insurance policies as well as supply agreements in which their suppliers agree to indemnify and cover all costs in the event that they supply defective product or a recall is necessary. Unfortunately, a general liability insurance policy will cover very few, if any, of the costs associated with a recall, and indemnification clauses in supply agreements may not be sufficient or enforceable. A recall costing hundreds of thousands or millions of dollars could easily force a company out of business. Companies should investigate whether recall insurance is a viable option and assess the costs in light of potential recall risks in the industry.

When a company is facing a potential product recall, its business is at risk of an interruption in the flow of product to its customers. This interruption can result in a huge financial burden on the business. A company will need to recover from both the out-of-pocket recall costs to physically remove and replace the product in the marketplace, as well as the potential downturn in sales if the company loses customers during the period of uncertainty.

If a recall occurs, insurance coverage can mean the difference between a challenging situation and a threat to survival. This may require buying a separate policy or policies from the general liability policy. A separate product recall or product liability policy may cover costs that are a substantial part of a product recall loss, which are not typically covered by the general policy (e.g., business interruption losses might be covered by “business interruption” or “lost profits” coverage.)

Identify your current coverage. Match proper accounting of “loss exposure” of a potential claim or claims with the policy, especially to determine if there are areas where coverage is uncertain or does not exist. If you have a risk management department or risk manager, they should work with the legal department to map out where coverage exists. Also get input from your broker and claims specialist.

When considering whether to obtain recall insurance, companies should keep in mind that insurance may be tailored to fit specific needs. For example, a program of insurance might cover the lost value of the defective product or the cost of replacing that product, but insurance might also be available for the following risks:

- the lost value of downstream products;
- costs incurred in connection with consumer complaints or illness, including medical bills;



- expenses associated with lost productivity and loss of profits in the event of a plant shutdown;
- costs associated with storage, transportation, destruction, and disposal of defective product;
- media and public relations costs; and
- attorneys' fees.

10. **Public Relations.**

- A. Work with public relations professionals to identify and implement key actions and involve legal counsel in determining your key messages.

Use the Web to communicate with consumers, taking some of that burden off the retailers. Companies faced with a recall often use websites to communicate information about ongoing recalls, plus images and video to answer consumer questions.

- B. Work with public relations and legal counsel to make sure your communications balance the corporate and legal issues. You may want to relay an image of accepting responsibility because safety is the highest priority for your company. There will be appropriate ways to make public statements that respond to risks, perceptions and legal responsibilities for the company. It is often appropriate to get the "bad news" out, and have a management plan in place to respond.
- C. Be prepared to respond quickly to the media about the company's problems.
- D. Avoid the appearance of hiding information. Whatever your company decides to do, do NOT cover up the crises. If you try to cover it up or evade the truth you could be creating a huge backlash of negative response. Today, any unhappy customer can instantly broadcast their complaints to millions of people around the world. Provide quick access to truthful information so consumers can understand what you are doing to fix the immediate problem. And keep communicating throughout the crisis.
- E. **Media Plan.** Include a media plan in your crisis communication plan that defines potential target groups for notice about product recalls. This type of plan should be targeted (consumers, suppliers, and manufacturers), and should consider appropriate disclosure requirements to meet Consumer Product Safety Commission, Food and Drug Administration, or other regulatory programs (e.g., Internet site, toll-free 800 number, or mail-in program). Also, adequate product recall notification could potentially reduce a company's exposure to liability for



future harm caused since those individuals harmed after the recall should have known of the product's inherent dangers.

- F. **Effective Communication; Images are Powerful.** Utilize pictures that show the industry or company protecting consumers, rather than letting pictures of your products being pulled from shelves dominate the landscape. Consider running an ad campaign that reinforces your company's focus on safety. Issue press releases or post notices on your company website, as well as other quick and efficient communications in order to defend your company's reputation, strengthen consumer loyalty and restore consumer confidence.
- G. Treat a competitor's recall as your own. It used to be that a competitor's recall was good news, but that is no longer true today. When another company in your industry issues a recall, prepare for the media spotlight to shine on you next. At the very least, take the opportunity to differentiate your brand from those that are falling short and define yourself as a leader in safety efforts.
- H. Don't issue a one-time ad or press release and think you are done. Your company must demonstrate that a best practicable attempt was made to notify those who may be at risk. Just because a newspaper enjoys nationwide distribution does not mean that it is read by your target audience. You must demonstrate a good-faith effort to interested parties that the notice disseminated was actually communicated to the RIGHT people. Also, it is important that your company target the appropriate audience in order to reach a majority of them.
- I. Identify which media outlets the media is listening to. Whenever a big story breaks, there are always particular media outlets, depending on geography, subject matter or other considerations, that jump out in front and control the story from start to finish—and from whom other media outlets take their cues. Focus your company's attention on these outlets. Think in global terms. . Make these media outlets' inquiries a top priority and proactively offer them information as it became available. Knowing to whom the media is listening is imperative to managing their coverage and ensuring that they're telling your side of the story.
- J. Identify the tipping point. In every crisis situation there is a tipping point, a moment when the crisis has been contained and the public is ready to move forward. This is not the time to stop your efforts, but rather an opportunity to begin branding again and redefine a company or industry as a leader in preventing a similar crisis from recurring.



11. **After the recall, consider the cost of rehabilitation.** How badly was the company/brand impacted? Should you consider getting rid of the old brand and introducing a new one. The work on rehabilitation post recall is perhaps more important than the recall situation. There are hundreds of examples of companies that used an adverse event as a springboard to marketing and rebranding of their enterprise. This is, in many respects, the ultimate test of a company's enterprise risk management plan.

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