

Enterprise Risk Management: Ways to Prepare for and What to Do During a Recall

The creation and implementation of an enterprise risk management (“ERM”) plan at your company is integral to minimizing and preparing for possible risks your company might face with a product recall. Not only will it prepare your company for the unexpected, but the initial ERM investment will potentially save a company from the skyrocketing costs of litigation that might come with a recall. Furthermore, an ERM plan can be used as an opportunity for business growth since every product crisis is an opportunity to enhance your company’s reputation.

When creating and implementing an ERM plan, the following is food-for-thought when getting started or is a checklist if your company already has an ERM plan in place. It is not a comprehensive list, but should be used as a starting point that should be tailored to your company’s specific needs:

- 1) Be **PROACTIVE** and **PREPARED** before a recall occurs.
- 2) **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 inventory each other’s core applications, and how their respective data comes together to demonstrate 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.
- 3) **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. Isolating the problem and narrowing the amount of product that needs to be recalled can potentially save thousands of dollars.
- 4) **Get the Attorneys Involved at the Beginning to Lessen Potential Litigation Risks and Costs.** In-house or outside counsel should be involved in ERM creation and implementation. Every dollar spent on implementing an ERM plan is a proactive investment in lowering costs in potential litigation. ERM plans minimize the risks and costs of future litigation since they lessen or eliminate product liability claims, lessen the number of potential plaintiffs, lessen the total number of lawsuit participants, lessen the litigation costs since attorneys will already be familiar with what is involved and will spend less time ramping up for the case, and lessens the severity and cost of claims.

With an effective ERM plan in place, it will be harder for litigants to prove design and manufacturing defects, as well as harder to pose challenges to product warnings. In addition, it will be harder for plaintiffs to collect punitive damages

since it will be more difficult for them to prove willful disregard of the health and safety of consumers.

- 5) **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 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
- 6) **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 isolated and kept from contaminating any production lines and ending up in finished product. An effective quality assurance or quality control program can head off problems before they become significant impairments to your company.
- 7) **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.
- 8) **Test Finished Product.** In addition to following or ensuring good manufacturing practices, conduct random sampling to test finished product *before* it leaves the manufacturing facility.
- 9) **Practice.** After the Recall Task Force understands what information is needed in the event of a recall, the company should perform mock recalls to discover what critical information is missing, if any, such as the origin of ingredients or parts that integrated into finished goods and where in the manufacturing and 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 voids in the company's information.

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 become necessary? How long did the entire process take?

- 10) **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.
- 11) **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 only some of the costs associated with a recall, and indemnification clauses in supply agreements may not be adequate 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, the flow of its products to its customers could dwindle, could be interrupted, or even stop altogether, which can result in a huge financial burden on the business. A company will need to recover from both the 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 difficult situation and the company's ultimate 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.)

The first step is to identify your current insurance coverage. Compare a proper accounting of "loss exposure" of a potential claim or claims with the insurance 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 or outside counsel to determine where coverage exists. Also consider getting input from your broker and claims specialist.

When considering whether to obtain recall insurance, companies should keep in mind that insurance can be tailored to fit a company's specific needs. For example, insurance might cover basic recall costs, 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.

12) **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. Consider conveying an image of accepting responsibility and highlighting that safety is your company's highest priority. 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. Make sure the messaging about the recall is consistent to different audiences, including to company employees, and the public.
- 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 crisis. 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 post their complaints on the internet, only to be read by 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. Also, make sure to continue to communicate throughout the crisis.
- E. Include a media plan in your crisis communication plan that defines potential target groups for notices 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 & Powerful Imagery.** Utilize pictures that show the company protecting consumers, rather than allowing the first images people think of to be pictures of your products being pulled from shelves. 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. Make sure that you choose the right person to be the "face" of the recall. Ensure that they are available to answer media inquiries during the key phases of the recall. Do not choose your company receptionist for this job.
- H. A competitor's recall is also your recall. When another company in your industry issues a recall, prepare for the media to come to your company next. At a minimum, take the opportunity to differentiate your brand from those that are facing a recall and identify your company as a leader in safety.
- I. Do not 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. Again, keep communicating throughout the crisis. Also, it is important that your company target the appropriate audience in order to reach a majority of them. Just because a newspaper has nationwide distribution does not mean that it is read by your target audience. For liability purposes, your company must demonstrate a good-faith effort to interested parties that the notice disseminated was actually communicated to the right people.
- J. 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 factors, that take the lead on and control the story and from whom other media outlets take their cues. Focus your company's attention on these outlets. Also, commerce is now global, so consider the impact this recall is having around the world and use media in other countries, if applicable. 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 impacting their coverage and ensuring that they're telling your side of the story.

- K. When the crisis has been contained, don't stop the PR. This is not the time to stop your efforts, but rather an opportunity to begin branding again and redefine your company as a leader in preventing a similar crisis from recurring.
- 13) **Rehabilitation.** 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 for marketing and rebranding of their enterprise. This is, in many respects, the ultimate test of a company's enterprise risk management plan.