

Forget Chicken Little – The Sky is Falling: Current Enterprise Risk Management Strategies for Product Recalls and Corporate Compliance Matters

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Enterprise Risk Management: Agenda

- **Introduction to Enterprise Risk Management**
 - What is an ERM? Who is using ERM?
 - How and why do companies use ERM?
 - What is the role of counsel in ERM development and implementation?
 - What are the legal challenges?
- **Comments on ERM - product safety perspective**
- **Comments on ERM - food safety perspective**
- **ERM and Public Relations Considerations**
- **Hypothetical Case Studies**
 - Food recall example
 - Product recall example
 - Toy recall example
- **Product Liability Considerations**
- **Q&A**



What is Enterprise Risk Management?

Enterprise Risk Management is a process to identify and analyze risk from an integrated, company-wide perspective.

- **An organization-wide process**
- **Risk control at all points of the company**
- **Focus on the big picture**
- **A process to identify, understand and acknowledge risk (upside and downside) exposure to the company**
- **Create a plan to manage and mitigate those risks**



How Does ERM Define the Concept of Risk?

ERM broadly classified in the following 4 categories:

- **Hazards:** Compliance and liability actions; product recalls
 Personal injury and property damage
 Business interruption
- **Financial:** Cash flow, credit, ratings, disclosures, reporting
- **Strategic:** Markets and competition
 Technology
 Capital
 Regulatory trends
- **Operational:** Business operations
 Management structure
 Information technology
 Information reporting



Why Invest in ERM?

ERM helps a company:

- Identify and manage risks
- Align risk strategies
- Enhance risk response decisions
- Minimize surprises and losses
- Allow for proactive engagement and integrated response across the company
- Seize opportunities, redirect capital, deal effectively with future events that create uncertainty
- Respond to reduce adverse outcomes and increase upside potential



ERM by the Numbers

ERM is becoming more common, expanding from financial sector to other sectors.

In 2007, a survey over 60 large industrial manufacturers found:

- **65% agreed that ERM programs help their organization be more successful**
- **65% felt that a more efficient ERM program would help their organization remain competitive**
- **Higher-level management is often responsible for ERM program. 47% cited CFO as the primary executive in charge of ERM; 13% cited CEO; 13% cited General Counsel; 10% Chief Risk Officer.**
- **40% said ERM was transparent to their Board of Directors Audit Committee**
- **33% said ERM program was very effective; 42% mixed feelings; 13% said ineffective.**

Source: PwC, Manufacturing Barometer, 3Q, 2007



ERM Details

- **In May 2008, Standard & Poor's announced it will begin (starting in 2010) to include a review of ERM at non-financial companies in its ratings process.**
- **An S&P July 2009 Progress Report found that ERM programs vary widely across companies. Some preliminary conclusions:**
 - **Companies find it hard to ensure uniform behavior across the enterprise**
 - **Inability to provide clear examples of definitions for risk tolerance or risk appetite**
 - **“Silo-based” risk management, (focus only at the operational manager level) is prevalent.**
 - **Link between transparency, disclosure and company confidence about ERM**



Why is ERM important to your Company?

- **Sarbanes-Oxley**
- **Increased Transparency and Reporting**
- **Corporate Shareholder Actions**
- **Enhanced Enforcement and Penalties**
- **Potential for Criminal Enforcement**
- **Corporate Diligence and Board Responsibilities**
- **Bottom Line: Poor Risk Management has a Cost:**
 - **Poor governance**
 - **Market opinion**
 - **Negative impact on cost of capital**
 - **Share price**



What are the Long-Term Benefits of an ERM Program for your Company?

- **Reduces operational and compliance issues/surprises**
- **Early warning system to respond to corporate threats**
- **Allows for quick response to identify and correct deficiencies and improve performance**
- **Reduces fines and penalties in enforcement actions**
- **Improves decision-making processes**
- **Improves capital allocation and credit rating**
- **Reduces cost of insurance**
- **Responds to Board/Audit Committee needs**
- **Establishes a culture of risk management**



Some Questions to Ask To Get you Started

- **What are the top risks for your company?**
- **How big are the risks and how likely are they to occur?**
- **What is the company doing about these risks?**
- **Who within the organization is responsible for risk management?**
- **How do you measure the success of risk management?**
- **How would a loss from a top risk category affect the company?**
- **What discussions about ERM have taken place at the Board level?**
- **Can you think of an example of how your company recently responded to a risk in your industry? How did the risk affect your company as compared to others?**



Next Steps – How to Begin an ERM Program

- **Don't need to start from scratch - You already have some components**
- **Formalize the program – Establish context for the company and make the business case for implementing an ERM program**
- **Set ERM objectives – Articulate Strategic Goals**
- **Establish an ERM infrastructure - Assign Leadership**
- **Identify Risks – Assess Gaps and Vulnerabilities**
- **Analyze and Quantify Risks**
- **Assess and Prioritize**
- **Determine Risk Response Strategies**
- **Develop Effective Communications Across the Company**
- **Manage and Exploit Risks**
- **Monitor and Review**



Managing Emerging Risks: Case Studies on ERM as applied to Product Recalls and Product Liability

- **Comments on ERM - product safety perspective**
- **Comments on ERM - food safety perspective**
- **Hypothetical Case Studies**
 - Food recall example
 - Product recall example
 - Toy recall example



Case Study #1: Setton Pistachio and the Pistachio Industry

- **Case Study – The 2009 Pistachio Recall**
 - Salmonella
 - FDA
 - The pistachio industry’s response
- **What If . . .**
 - Initial contact was different?
 - Distribution was different?
 - All retailers needed to be reached?
 - Consumers had already bought the product?
 - Public relations had occurred at a later time?
- **What about . . .**
 - The attorneys?
 - Insurance?



Case Study #2: ACME Device Co.

- **Case Study – FDA’s Device Reclassification and Recall**
 - Class I device reclassified to a Class III device.
 - Recall required, otherwise a violation of Federal Food, Drug and Cosmetic Act (FDCA)
- **What If . . .**
 - Liability was higher?
 - Public statements were necessary?
 - ACME disagreed with the FDA’s reclassification?
 - The device remained in the patient post-surgery?
- **What about . . .**
 - Dissatisfied customers?



Case Study #3: XYZ Toy Company

- **Case Study - Leading Manufacturing and Importer of Toys**
- **Emerging Risks on the radar ...**
 - New product safety regulations and mandates
 - Product recalls
 - Access to safe raw materials and quality factories
 - Substantial increase in testing costs
 - Inflation and costs of production
- **What if...**
 - Product safety teams started at the design level
 - Product recall response team
 - Product reformulations and raw material quality
- **What about...**
 - Enhanced internal controls and risk management?



Communications Considerations

- **What is the issue?**
 - Is the impact to us primary or secondary?
- **Reaching each constituency**
 - Prioritizing the recipients
- **What's the message**
 - Is it different for different audiences?
 - Will that work in the age of social media?
- **Who does the talking to each?**
 - Who is your “face”?
- **Be prepared**
 - Plan, test, practice, plan some more



The importance of ERM in Product Recalls and Product Liability -- Direct and Indirect Costs

The Costs of Product Recalls and Product Liability Lawsuits...

- **Compensatory Damages**: The theory behind compensatory damages is to award the plaintiff an amount to make him or her whole.
- **Punitive Damages**: In addition, if the conduct was willful, the jury may award punitive damages to punish the defendant. The “bigger” the defendant the more it will take to send the message.
- **Litigation Costs**: The costs of litigation exist irrespective of the result. Costs include attorney fees, expert witnesses, forensic testing, etc.
- **Product Recall and Government Action**: A product liability case may trigger an obligation to recall the product since the manufacturer is now on notice.
- **“Pile On” Lawsuits**: Other plaintiffs may try to ride the coattails of the first plaintiff. The case may spawn a class action lawsuit on behalf of every consumer who has purchased the product. A recent innovation is shareholder lawsuits based on product failures.
- **Media/Industry Exposure**: Further damage may result from bad publicity.



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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CONCLUSION

The ERM Value Chart

Reduce Costs ↓↓

Decrease Liabilities ↓↓

Increase Revenues ↑

Capture Value ↑

ERM programs can help you to manage emerging risks and avoid or lessen the impact of risks at your company.

The objective is not simply a paper risk management exercise, but rather a springboard for ongoing discussion regarding the benefits of a risk management program for your company.

