

Product Recall Risk Assessment
By Tony Munns

Product recall is a key area of risk for today's company. With greater focus on, and understanding of the impact of products and their raw materials on individuals, systems and the environment, the ability to manage the product throughout its lifecycles is essential. Those companies that have spent the time to understand the recall risk in advance, and have a defined and tested process in place, are far better prepared to cope with the unexpected when it does happen, and minimize the potentially negative consequences to the company's reputation. So, how does a company go about assessing the recall risk for its products?

Enterprise Risk Management¹ is now a standard tool for the management of an organization. Based on the landmark work of the Committee of Sponsoring Organizations of the Treadway Commission² (COSO) in the 1990s, their groundbreaking Enterprise Risk Management – Integrated Framework, published in 2004³, has become a key tool for organizational risk management. The enterprise risk assessment methodology has become an established approach to identifying and managing systemic risk for an organization. And, more and more,

this approach has been applied in such diverse fields as environmental Superfund⁴, health⁵, and corporate ratings⁶.

Utilizing the enterprise risk assessment approach to the product recall process not only helps ensure that an effective process is in place, but also educates the wider company on the full implications of potential recalls. Business process owners that look upon recall as a supply chain, safety or accounting issue, realize that they all have a stake in the process and its successful outcome.

Methodology

The risk assessment methodology analyzes the relationships between assets, threats, vulnerabilities and other elements. There are numerous methodologies, but in general they can be classified into two main types: quantitative and qualitative analysis. The methodology chosen should be able to produce a quantitative statement about the **impact** of the risk and the effect of the recall issues, together with some qualitative statements describing the significance and the appropriate measures for minimizing these risks. The second dimension to apply the quantitative and qualitative test to is the **likelihood** of the event occurring.

A risk assessment can only give a snapshot of the risks at a particular point in time. Recall risk assessment should be a frequent activity. A comprehensive risk assessment should be conducted at least once every two years to explore the risks associated with the organization's products. A key component of all risk assessments should be the relevant and constantly changing regulatory requirements. The progressive company is now including recall risk assessment contingency planning with all new and upgraded product rollouts.

Impact Assessment (also known as Impact Analysis or Consequence Assessment) estimates the degree of the overall harm or loss that could occur as a result of a recall. Quantifiable elements of impact are those on revenues, profits, cost, service levels, regulation and reputation. It is necessary to consider the level of risk that can be tolerated and how, what and when assets could be affected by such risks. The more severe the consequences of a threat, the higher the risk. An example of this would be: a recall on a product that is found to have an unacceptable breakage level where the consequent pieces are benign is a lot different to one where the pieces do not pass the infant choking hazard standard.

Likelihood Assessment estimates the probability of a threat occurring. In this type of assessment, it is necessary to determine the circumstances that will affect the likelihood of the risk occurring. The likelihood can be expressed in

terms of the frequency of occurrence, such as once in a day, once in a month or once in a year. The greater the likelihood of a threat occurring, the higher the risk. It can be difficult to reasonably quantify likelihood for many parameters; therefore, relative likelihood can be employed, as in a ranking. An illustration of this would be: the relative likelihood of a product piece to detach, or a catastrophic failure of a key control mechanism.

In conclusion, The Risk Assessment approach is particularly applicable when many disciplines of the company are directly involved in a process. It enables many voices and viewpoints to be heard, and a more inclusive and complete process results. For a product recall many constituencies are likely involved, including: safety, customer service, accounting, supply chain, public relations, etc. A well managed risk assessment will enable the definition of an encompassing process that if needed, will not only show the company as responsive, efficient, and prepared, but also may highlight corporate responsibility and good citizenship.

References

1. Enterprise Risk Management The COSO “Enterprise Risk Management-Integrated Framework” published in 2004 defines ERM as a “...process, effected by an entity’s board of directors, management, and other personnel, applied in strategy setting and across the enterprise, designed to identify potential events that may affect the entity, and manage risk to be within its risk appetite, to provide reasonable assurance regarding the achievement of entity objectives (PDF) *Enterprise Risk Management* —

Integrated Framework: Executive Summary. Committee of Sponsoring Organizations of the Treadway Commission. September 2004.

http://www.coso.org/Publications/ERM/COSO_ERM_ExecutiveSummary.pdf.

2. Committee of Sponsoring Organizations of the Treadway Commission: The Committee of Sponsoring Organizations of the Treadway Commission (COSO) is a voluntary private-sector organization, established in the U.S., dedicated to providing guidance to executive management and governance entities on critical aspects of organizational governance, business ethics, internal control, enterprise risk management, fraud, and financial reporting.
3. Enterprise Risk Management – Integrated Framework Executive Summary September 2004
4. <http://www.epa.gov/risk/basicinformation.htm#arisk>
5. <http://oehha.ca.gov/pdf/HRSguide2001.pdf>
6. Enterprise Risk Management: Standard & Poor’s To Apply Enterprise Risk Analysis To Corporate Ratings, www.standardandpoors.com/ratingsdirect May 7, 2008

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