

## **Product Risk Management (PRM™) For Safety Professionals**

**George Nassif, CSP  
Director  
Aon Global Risk Consulting  
New York, NY**

### **Introduction**

Global Supply Chain operations have always been proactive in identifying and implementing opportunities that have usually resulted in cost reductions and / or productivity increases. However, each and every opportunity that was identified and / or implemented could potentially have important if not significant implications for safety professionals from either a risk mitigation or risk management viewpoint.

One of the Safety Professionals' functions that Global Supply Chain would directly impact is **“Product Safety/ Products' Risks”** with all the related liabilities to customers, shareholders, government agencies, employees and end users. In other words, decision made to changing suppliers, sourcing of raw materials or finished products, substituting manufacturing sources and materials, determining vendors' insurance coverage, concluding contractual arrangements, outsourcing packaging, transportation and logistics, etc.; all have a direct impact on products' integrity, quality, distribution and / or recall plans just to name a few.

All parties involved in the supply chain stream of commerce; such as suppliers/vendors, manufacturers, retailers, traders, etc. are becoming increasingly aware of the complex risks of product liability derived from both first party product exposures as well as liability resulting from failure of manufactured, assembled or supplied products.

There are primarily four major causes of product failures:

1. Unintentional breakdown of design
2. Vulnerability in manufacturing
3. Intentional tampering
4. Failure to warn

Failure to remove a “hazardous” product from the market can have serious consequences comparable to any catastrophe; including injury or death to end-users, lost revenue and market share to manufacturers and retailers, decrease in stock value, and adverse publicity resulting in injury to brand reputation as well as an increased probability of civil or criminal legal action or involvement of regulatory authorities.

The need to develop a plan for risk mitigation, control mechanisms and liability transfer mechanisms in advance of product failure is extremely important to control the cost of an adverse event and in some situations can be critical to the survival of the organization responsible for the product failure. Given this situation, one would assume that all manufacturers and suppliers would prepare for product failure; however, many companies lack the understanding of the level of exposure and its impact; or the strategy and resources necessary to respond to product crisis; leaving investors and directors with tremendous liability.

## **How the PRM™ Approach for Safety Professionals Works**

An innovative product risk management approach has been developed that enables organizations, such as manufacturers, distributors, suppliers and/or vendors to manage their product risks by deploying a ‘Product Risk Management’ (PRM™) process. The developed process focuses on evaluating, identifying, ranking and prioritizing the management systems that are already in place and provides safety professionals with the ability to directly communicate with different functions within their organizations to assist them in managing operational exposures that could result in product liability risks.

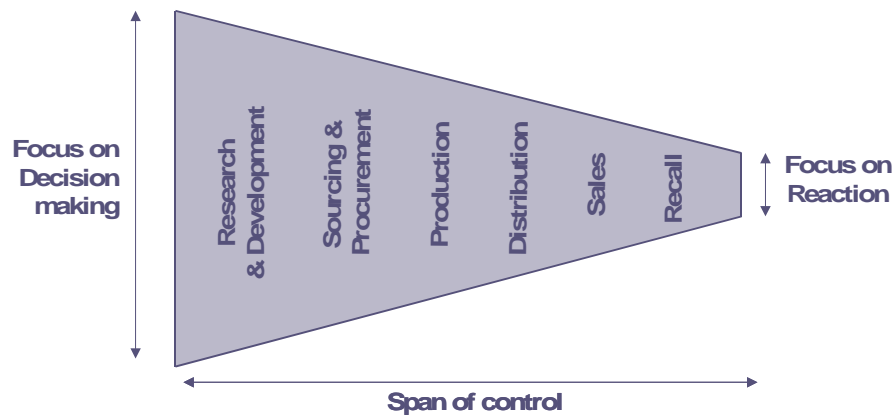
Over the years, numerous firms have allocated resources and funds to support and manage their product liability risks; however, they have struggled in their ability to demonstrate how the allocated resources have helped mitigate their product risks. Hence, the needs for a tool to help organizations not only finance but effectively manage their product liability risks emerged. Firms’ reputational risks and crisis management aspects of managing such product liability incidents have grown significantly; as evidenced by recent product recalls from Asia as well as other parts of the world.

The developed ‘Product Risk Management’ (PRM™) process offered a disciplined, structured and replicable framework reflecting widely recognized international product risks best practices. The developed ‘Product Risk Management’ (PRM™) process had the following objectives:

- Develop a credible methodology for managing product liability risks based on enterprise risk management principles
- Respond to existing operational risks in a timely manner
- Evaluate the effectiveness of product liability risk across all business units/product lines and identify best practices as well as areas for improvement
- Gain sufficient information on product liability risks and risk mitigation processes operating within the organization
- Evaluate product risks, contractual liability and future needs for risk management and risk financing
- Provide an internal risk management tool to benchmark different business units or operating facilities

It was recognized that risks are created at all stages in a product's lifecycle. Hence, any developed technique for quantifying and ranking product safety risks had to be structured and reproducible in a framework reflecting international best practices and built around the product life cycle that would focus on the decision making process and the span of control for the product from the point of inception till it reaches the end users (see Figure 1 below).

In many organizations the greatest scope to influence the liability profile of a product is at the research and development phase. The paradox, however, is that the threats may only become apparent once the product has been marketed and used for some period. Furthermore, a large number of organizations have not made the link between their investment in Quality Management Systems (such as ISO 9001, ISO, etc.) and/or good manufacturing practice (GMP) and their product liability insurance arrangements. This solution and approach force this linkage, delivering a resultant financial benefit.



**Figure 1. Illustration of a Product Life Cycle (Span of Control)**

The developed Product Risk Management (PRM<sup>TM</sup>) methodology following the product life cycle as shown is broken down into 15 distinct phases. Safety Professionals with experience from the electronics, chemical, pharmaceuticals, and aviation and automobile industries contributed to developing a methodology that resulted in the breaking down of the product lifecycle into 15 distinct phases.

For each phase, a series of factors are evaluated using a framework. Each risk factor is scored against a four-level Word model using a simple traffic-light methodology (blue-green-amber-red). Each phase is broken down to enable specific product risks' issues to be tested against a best practice framework. Typically, 150 best practices are evaluated in the process, which is adapted to each industry sector specific challenges and competitive environment (see Figure 2 below).

**Figure 2. PRM™ Evaluation Framework**

Product Risk Management		Client		
Phase	Life Cycle	Total Score	Maximum Score	Percentage
A	Management System	21	30	70
B	Research	30	40	75
C	Product Development	55	60	92
D	Sourcing & Procurement	40	70	57
E	Production	25	40	63
F	Quality Assurance & Labelling	55	100	55
G	Regulatory Compliance	35	50	70
H	Warehousing & Distribution	50	60	83
I	Sales & Marketing	64	80	80
J	Contract Risk Management	32	60	53
K	Service Delivery	50	80	63
L	Product Use & Recall	28	80	35
M	Event & Complaint Monitoring	44	50	88
N	Product Stewardship & Disposal	20	40	50
O	Documentation & Audit	35	80	44
<b>Total Score</b>		<b>584</b>	<b>920</b>	<b>63</b>

Largely optimised risk management programme	Blue - Over 80%
Structured programme still requiring some further enhancements	Green -65 - 80%
Programme requires improvement action plans	Yellow - 50 - 65%
Significant deficiencies - prioritised action to establish programme	Red - Less than 50%

**Note: These are not actual results, just illustrative of the process.**

The Product Risk Management (PRM™) protocol itself is highly visual and transparent, with scoring being based on structured interviews with management team from the different operational functions. The protocol is completed interactively scoring agreed upon based on evidence provided through discussions, observations and review of policies and procedures as well as specific documentations and internal/external auditing reports (see figure 3 below).

Question	Issue	Expectation	BLUE	GREEN	YELLOW	RED
Scoring			10	7	4	2
1	Recall Policy	The organisation have a clearly defined and communicated strategy for preventing and managing a product recall incident . The business has established a Policy for Product Recall, supported by appropriate guidance and procedures to ensure it is implemented consistently in all business operations. The Policy is endorsed by senior management and regularly reviewed to ensure it remains relevant.	In addition to 'Green', the policy is proactively communicated, with evident senior management support. Local procedures and documents support its practical implementation.	The Policy is well implemented and is effectively communicated and maintained. Local procedures support the Policy implementation.	Written policy exists but may be out of date, lack senior management endorsement or be poorly communicated.	No written policy in place.
2	Recall Accountabilities	There is someone in the organisation with overall accountability for the effectiveness of product recall processes. Clear responsibilities are assigned for the management of Recall within the business. Managers and staff responsible for the management of recall incidents have effective training to discharge their roles.	In addition to 'Green', Competency and resource levels are assured through effective training and ongoing reviews.	The responsibility for managing Recalls is clearly assigned within procedures and roles descriptions. Training is delivered to meet identified individual development needs.	Responsibilities are assigned within procedures, but insufficient resources assigned to deliver requirements. Some training delivered but not against a structured plan.	Responsibilities are not clearly defined. Recalls are managed in an ad-hoc manner with limited training of personnel involved.
3	Recall Risk Identification	The business has identified its primary exposures to Product Recall. The organisation has a clear perception of the major causes of product recall exposure (e.g. labelling error, expiry date, product defect, contamination, tamper, extortion, counterfeiting etc.) The organisation has a process for assessing the risk of recall when developing and launching new products.	In addition to 'Green', The organisation utilises loss history and industry data to evaluate trends. Management of recall is considered in the development and design of new products.	Risk Assessments are systematically and consistently completed identifying key product recall exposures.	Risk Assessments are generally completed although the quality of risk identification is inconsistent. No standard methodology is however adopted.	Poor identification and documentation of risks.
4	Recall Risk Assessment	The business has assessed its primary exposures to Product Recall. These have been quantified in a consistent manner and allow the business to understand the 'cost of risk' associated with Recall. Informed decisions can be made regarding the appropriateness of risk retention and risk financing solutions as a result. Recall incidents when they occur are evaluated in terms of severity to facilitate crisis management.	In addition to 'Green', the total cost of product risks is understood and quantified. Risk financing is an integrated part of the management of product recall exposures. Crisis Management processes evaluate recall incidents in terms of their consequences and potential to escalate.	Risk exposures are systematically and consistently quantified. Risk financing of recall exposures is founded on an evaluation of risk exposures.	Risk exposures are generally quantified in terms of likelihood and impact of occurrence. No standard methodology is however adopted.	Only limited risk assessments undertaken, that are not maintained and up to date. No understanding of overall cost of Recalls. No structured basis for Risk Financing decisions.

**Figure 3. Sample of the PRM™ Framework**

The process has delivered specific and unique benefits to clients in manufacturing industries where customers' audits are common, quality standards exacting, competition significant, and margins tight and the price of failures is high. The process has also led to the development and implementation of management strategies that mitigate key risks such as product recall, vendor assessment, contractual risk management, logistics management and delivery of after-sales services.

One of the direct financial benefits has included the reduction of risk transfer costs through the use of the PRM™ tool that articulated the quality of the product risk program with insurance markets.

Additional benefits include:

- **Strategic plans**
  - Provision of independent assurance to boards of the effectiveness of liability risk management
  - Ability to demonstrate strong governance and controls to customers, suppliers and business partners
  - Evaluation of the maturity of risk management processes against best practice.
- **Operational efficiencies**
  - Development of legal risk management frameworks and contract risk management

- Strengthening of 'gateway' decision-making in product development processes
- Implementation of product stewardship programs
- Ensuring best practices are communicated between business units

## Summary

This process offers significant opportunities for timely and thorough identification of potential risks and liabilities in an organization. Further, it has the capability to benchmark different business units within an organization and identifies systemic business issues. The addition of dash-board style reporting provides concise and clear summary results to senior management of key issues and the recommended solutions. The implementation of the PRM<sup>TM</sup> process has provided several organizations with the following benefits depending on the level of implementation that was selected:

- A prioritized action plans for risk mitigation
- A tangible action plan to address product vulnerabilities
- A reduction in claims frequency and severity
- A strong message to provide to liability insurance underwriters
- A cost saving on the operational and the risk transfer aspects
- Assurance provided to Senior Management and Board members
- An expanded internal communication between different product management departments
- An increased assurance for readiness in case a product crisis or recall
- A business tool that can be replicated at other business units or for due diligence prior to mergers and acquisitions