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Product Safety
Expanding the Safety Professional Role

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Introduction

Safety professionals are continually called upon to demonstrate their value to their organization; hence, safety professionals are required to look outside their traditional roles to provide value to their company. The expansion of the Safety Professional/Practitioner role into "Products Safety" and their associated risk mitigation plans and liability prevention programs represents a significant opportunity for reducing product liability exposures, injuries to the public and a reduction in risk retention and transfer costs. The ability of the safety professional to present a business case to management to implement a "Product Safety and Liability Prevention" program represents a significant business opportunity to improve the safety professional value.

History and Background

In contemporary history, the safety and health movement has been impacted by legislation and the need to reduce injuries, save lives and reduce operational costs. In the following safety, health and environmental chronology; food products, consumers' goods and environmental legislative actions have been enacted. Key selected legislative actions are set forth to illustrate the theme that the safety professional has been a significant part of those preventive experiences.

In 1970, President Richard Nixon signed into law the Occupational Safety and Health Act (OSHA), thus creating the OSHA administration and the National Institute for Occupational Safety and Health (NIOSH) and on May 29, 1971, the first OSHA standards were adopted to provide a baseline for safety and health protection in American workplaces.

In 1970, on January 1, the National Environmental Policy Act, (NEPA) was signed. This provided a national charter for protecting and improving the environment and created the Environmental Protection Agency (EPA).

In 1972, the Consumers Product Safety Act (CPSA) was signed into law.

On the other hand, in 1930, the Bureau of Chemistry became the Food and Drug Administration (FDA). In 1933, the new FDA recommended a complete revision of the obsolete

1906 act. A five-year legislative battle ensued. But it wasn't until a drug-related tragedy occurred that a new food and drug law was passed. After 107 people died from a poisonous ingredient in a product called Elixir Sulfanilamide, Congress passed the Food, Drug, and Cosmetic (FD&C) Act with new provisions in 1938, which was amended on January 1, 2011 under the Food Safety Modernization Act (FSMA).

Emerging Role of the Safety Professional

Safety is the state of being "safe" (from French *sauf*), the condition of being protected against physical, social, spiritual, financial, political, emotional, occupational, psychological, educational or other types or consequences of failure, damage, error, accidents, harm or any other event which could be considered non-desirable. Safety can also be defined to be the control of recognized hazards to achieve an acceptable level of risk. This can take the form of being protected from the event or from exposure to something that causes health or economical losses. It can include protection of people or of possessions and assets.

While many organizations have learned that investing in safety, health and environmental (SH&E) practices is one of the best ways to protect workers *and* improve bottom line results, others have yet to realize SH&E's full potential by reducing product defects and/or failures; which in turn would help increasing productivity, market share and profits. However, for an SH&E program to be truly effective, it takes strong and visible commitment from senior management as well as an SH&E department that knows how to demonstrate the value of SH&E in terms management will understand and able to quantify and measure. Senior management will only invest in SH&E if they are well-convinced of its benefits.

It can be difficult for SH&E professionals to justify SH&E investment to senior management because the projected benefits and savings cannot always be quantified since it is difficult to prove a negative. However, SH&E professionals can use several models and methods to make their case.

Over the years, the SH&E professional has been successful in identifying and in certain cases quantifying the direct and indirect costs of injuries and illnesses by examined the following components of a loss or an accident:

- Direct Costs - Loss of life; Medical; Insurance and Case Management costs; Higher insurance premiums; Legal fees; OSHA penalties and fines as well as Rehabilitation and fraud investigation costs.
- Indirect Costs- Decreased profits and production; Time spent to repair damaged equipment and to investigate accidents; Costs to train and compensate replacement employees; Increased wages to attract and retain new employees; Dependence on workers' compensation, social security, welfare or other insurance programs to cover the costs of occupational injuries or illnesses; Increased absenteeism and turnover rates; Low employee morale and Administrative costs.

As the role of the safety professional is emerging into business sustainability, it is becoming more and more imperative to expand the safety practitioner role into product safety, quality and liability prevention were the cost of product defect, product failure and/or

contamination can be usually quantified into direct cost of quality (COQ), product recall, product withdrawal and product contamination costs as well as cost of suppliers' disruption; while the indirect costs involve two key elements for business sustainability; namely, loss of customers/consumers, loss of community confidence, loss of market share and damage to brand reputation.

Understanding the Regulatory Environment

As stated earlier, The CPSC (Consumer Product Safety Commission) was established in 1972 and has the authority to regulate the sale and manufacture of consumer products, from cribs to all-terrain vehicles to barbecue grills and swimming pools. Products not under jurisdiction of the CPSC include those specifically named by law under the jurisdiction of other federal agencies; such as food, drugs and cosmetics that are regulated by the Food and Drug Administration (FDA).

CPSC fulfills its mission by banning dangerous consumer products, issuing recalls of products already on the market, and researching potential hazards associated with consumer products. The year 2007 was called the "Year of the Recall" in the United States, and the CPSC imposed 473 recalls, including many involving lead in toys and other children's products. These increased recalls led to the Consumer Product Safety Improvement Act (CPSIA) of 2008.

The Consumer Product Safety Improvement Act of 2008 imposed new testing and documentation requirements, and set new acceptable levels of several substances, including lead. It imposes new requirements on manufacturers of apparel, shoes, personal care products, accessories and jewelry, home furnishings, bedding, toys, electronics and video games, books, school supplies, educational materials and science kits. The Act also increases fines and specifies jail time for some violations. Other Nations have established similar product safety laws, including the European Union (2004 General Product Safety Device Directive), Asia Pacific (requiring governmental reporting of product safety problems), and China (new and expanding recall procedures).

Furthermore, on January 4, 2011 President Obama signed the Food Safety Modernization Act (FSMA), aimed at strengthening the security and safety of the U.S. food supply. The U.S. Center for Disease Control estimated about 48 million people or one out of six Americans get sick; 128,000 are hospitalized and 3,000 die each year from food borne diseases. Among additional changes, the new law grants the Department of Health and Human Services and the Food and Drug Administration regulatory authority to increase the frequency of inspections, establishes mandatory recall authority, strengthens the food import-tracing capabilities, and creates open access to records and documentation.

This regulation translates into new requirements for all food and beverage businesses regulated by the FDA in the food industry; including manufacturers, processors, packers, distributors, receivers, holders and food product importers. The FDA has regulatory authority over approximately 80 percent of the food supply.

The new law requires foreign suppliers to abide by the same rules and standards of a U.S. supplier. Verification of activities from a foreign supplier may include: monitoring shipping records, lot-by-lot certification of compliance, annual onsite inspections, checking the hazard analysis and risk-based control plan of the foreign supplier and periodic testing and sampling of

shipments. Records of a foreign supplier must be maintained for no less than two years and made readily available upon request.

Such an evolution in globalization is happening at an awe-inspiring pace and it creates significant risks that must be aggressively controlled. Hence, it becomes important for companies to develop a comprehensive product safety and liability prevention program that extends beyond quality management by developing strategies for managing imported products; which would enhance their competitive advantage as they become able to minimize and mitigate recalls' costs and litigation fees as well as potentially permanent brand and reputational damage.

Assessing Product Safety & Liability Prevention

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, processed or supplied products.

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 management 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.

For instance, first time since 1936, FDA will have a legislative mandate to require comprehensive, science-based preventive controls across the food supply. This mandate includes:

- Mandatory preventive controls for food facilities: Food facilities are required to implement a written preventive controls plan. This involves: (1) evaluating the hazards that could affect food safety, (2) specifying what preventive steps, or controls, will be put in place to significantly minimize or prevent the hazards, (3) specifying how the facility will monitor these controls to ensure they are working, (4) maintaining routine records of the monitoring, and (5) specifying what actions the facility will take to correct problems that arise. (FDA is currently in the process of developing rulemaking for the implementation of the enacted legislation).
- Mandatory produce safety standards: FDA must establish science-based, minimum standards for the safe production and harvesting of fruits and vegetables. Those standards must consider naturally occurring hazards, as well as those that may be introduced either intentionally or non-intentionally. (Final regulation due to be finalized in 2013).

- Authority to prevent intentional contamination: FDA must issue regulations to protect against the intentional adulteration of food, including the establishment of science-based mitigation strategies to prepare and protect the food supply chain at specific vulnerable points. (FDA is currently in the process of developing rulemaking for the implementation of the enacted legislation).

Hence, it is in a company's best interest to develop and implement an effective product safety and liability program to prevent potential product failure or contamination events and to develop strategies to strengthen the defense position in case of product liability litigation.

Risk Management Strategies for Imported Products

Critical Product Safety and Liability Prevention Program elements primarily revolve around 'strategies for imported products'; specifically by establishing and implementing comprehensive and formal strategies for managing the imported product risk. Below are some key components of an effective imported product risk management:

Selection of qualified suppliers

The first step is the selection of qualified suppliers because of geographical distance as well as cultural, language, and regulatory difference you need to know who you are partnering with. Face-to-face meetings and foreign plant inspections are the best approaches to long-term success. If the foreign manufacturer is to be responsible for product design/formulation extra care must be taken to review formal specifications for compliance with industry and governmental standards, such as FDA and CPSC. Furthermore, any contractual agreements should be finalized with a written contract and reviewed by the competent attorney. In addition, any intellectual property and transfer risks may require additional contractual and legal consideration and protection. This serious risk exposes the firm to counterfeit imported products that may carry third party approval stamps.

Establishment of clear specifications and quality assurances

Best practice includes comprehensive product specifications, including evaluation of first pilot run, sample, etc. The sampling frequency should be consistent with the criticality and desired level of quality and safety assurance. Safety-critical product characteristics, such as lead in toys, flammability of fabrics, presence of contaminants, etc. require greater vigilance and appropriate testing levels for each shipment. A certificate of analysis (COA) can and should be requested for the desired level of assurance, but only with appropriate verification. Pre-release inspections of actual production run should be considered by your own staff or a reputable and qualified third party firm. Written contract should ideally include specifications, ingredient/material lists, including prohibited ingredients/materials, diagrams, and prototypes as well as a legal clause prohibiting any and all substitution of ingredients and materials without your expressed and formal permission. The contract should also include product recall requirements and business continuity plan.

Warnings, instructions, and labels

Importers must ensure their product labels/warnings are clear, commensurate with the degree of hazard, and comply with all applicable industry and government standards. A warning label is no substitute for a safer product design/formulation, but it should warn against risks that cannot be reduced by design/formulation. Key elements of an effective warning label include:

1. Appropriate signal word (Danger, Warning and Caution) with degree of risk
2. Statement of hazard
3. Avoidance instructions
4. Consequences and any special information

Additional considerations include color, pictograms, location, durability and readability.

Monitoring quality slippage
Another crucial step is to continually monitor product quality so no slippage in quality occurs. In addition to the initial selection and approval of a supplier, be sure to include Tier II suppliers in a supplier review process. Changes in process, materials, or sub-suppliers can alter product quality. The ongoing monitoring needs to cover two aspects: Supplier issues and how you approach subsequent vendor price negotiations. Failure to recognize such hidden cost of adverse impact on product quality can lead to very serious consequences, including expensive product recall and serious brand and reputational damage which could be permanent.

Having an effective Product Recall Program
Even with supplier "due diligence" and stringent inspection controls; defective products can slip through the screening process and reach customers. If these defects are safety-critical they can cause injuries, health related issues and in some cases death that can lead to product liability lawsuits and damage your firm. Being prepared for such an event is why you need an effective product recall program and crisis management plan that quickly removes the unsafe product from the hands of consumers and manages the frequently accompanying adverse publicity and media scrutiny. Critical to successfully recalling a product is traceability and tracking of products both upstream and downstream as well as a crisis communication portion of a recall plan that would include monitoring social media websites for false commentary and knowing who is speaking for the firm when the press starts calling. A successful recall program is not simply notifying consumers, but being able to assess how much product was sold and how much has been secured. Because food products are quickly consumed it may only be possible to evaluate success in terms of adequate notification and limited or no quarantine of the recalled product.

Managing supply chain risks
In addition to quality and safety related risks, firms have considerable supply chain risk. Managing this risk requires balancing the competing priorities of maintaining quality, controlling costs, and boosting profitability. Additional risks of geopolitical stability, trade restrictions, currency fluctuations, and emerging risks, such as unavailability of clean water sources; power disruption and logistics need to be carefully considered. Managing the supply chain risk requires balancing supply-side planning for long lead times and low costs with agile demand side response to rapidly changing consumer demands. Any unanticipated quality or safety issues, including product recalls can lead to further uncertainty, resulting in empty store shelves, loss of sales, and loss of customers.

As the role of the Safety Professional expands in the arena of suppliers'/vendors' assessment, it is important to ensure that the following tasks are instituted at the beginning of any discussions or involvement:

- Getting the buy-in from different stakeholders (Quality and Supply management, Risk Management, Finance and operational management)
- Reviewing internal documents (SOP's, written plans, records, contracts, etc.)

- Ensuring that all outcomes will help Identify gaps and areas for potential improvements
- Providing a tool to measure outcomes and facilitate continuous improvements through the utilization of a scoring dashboard

Therefore, a need exists now for the Safety Professional to integrate an assessment process for suppliers/vendors to provide management with tools for controlling both safety and liability risks. The figure below provides an example of a dashboard report to benchmark suppliers and address gaps or vulnerabilities within a manufacturing, processing, and warehousing and transportation environments.

Foreign Vendor Verification Program								
Section	Self Assessment	Supplier Input		Rating*				
		Description	Supporting Documents	1	2	3	4	5
Quality Management System	Quality Management System is fully documented							5
	Quality Management System requirements are communicated to and understood by all employees							5
	Quality audits are performed on a regular basis to ensure adequacy and effectiveness of quality system							5
	Calculated Score							15
Customer Interaction	Frequently in close contact with customers							5
	Customers often visit your plant							5
	Customers give feedback on quality and delivery performance							5
	Customers buy from you JIT to meet their needs							5
	Have a low incidence of customer complaints compared with your industry							5
	Customers' complaints are investigated and resolved in a timely manner							5
	Customers contracts and/or orders are reviewed prior to acceptance to determine capability and capacity to meet all specified requirements							5
	Participate in certification programs with the majority of your customers (Describe/specify)							5
	Calculated Score							40
ction	Strive to establish long term relationships with suppliers							5
	Suppliers are actively involved in your new product development process							5
	Quality is your #1 criterion in selecting suppliers							5

Impact of Product Safety and Liability Prevention Program

Historically, products were for the most part produced locally there were few quality miscommunications; and when errors were made they could be quickly corrected. Distributors purchased locally manufactured and grown products and resold them locally too. Relationships between growers, suppliers, distributors, and retailers were close and long-term. Globalization changed those relationships. The motivation for higher profits with the importation of goods once procured locally increased the risk for product defects/contamination.

According to the Consumer Product Safety Commission (CPSC), 66% of all recalls are for imported products. These recalls have included appliances, bicycles, children's clothing, food products (fresh produce and processed food), lamps, magnetic toys, medications, power strips, power tools, step stools, strollers, television mounts, and many, many other kinds of products.

According to the January 18, 2011 edition of Bloomberg.com jury verdicts for defective/contaminated products increased 77% between 2009 and 2010.

The financial and corporate costs of products recalls can be staggering! According to MarlerClark Law Firm the cost of an e-coli outbreak traced to contaminated hamburger cost a restaurant chain $126 million. According to the CPSC, one firm agreed to pay a civil penalty of $1.1 million for selling magnets that children could swallow. In the February 22, 2011 edition of PritzkerLaw 714 individuals in 40 States were sickened by salmonella contaminated peanut butter. The supplier of the peanuts is out of business. According to the October 16, 2009 edition of USA Today a leading toy company agreed to settle lead in toy claims for $50 million. In addition to these financial costs there is the added adverse media publicity and potential brand damage.

Different approaches have been developed for the management of product safety and liability risk that enabled organizations; such as manufacturers, distributors, suppliers and/or vendors to manage their consumers' product risks. However, to meet the new FDA regulatory requirements, a Food Safety Defense Assessment (FSDA) was developed based on the Food Safety Modernization Act (FSMA), SQF standard (Safety Quality Food), ISO Quality management and recognized risk management best practices. The developed assessment 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 food product safety and operational exposures that could result in product liability risks.

The developed 'Food Safety and Defense Assessment' (FSDA) process offered a disciplined, structured and replicable framework reflecting widely recognized international product risks best practice that was built around the product life cycle to support management decisions making process and enhance the span of control for the product from the point of inception till it reaches the consumers/end users. .

An illustration of the developed Food Safety and Defense Assessment (FSDA) methodology is shown below and is adapted to each industry sector specific challenges and competitive environment.

Food Safety & Defense Assessment (FSDA)		ABC CO - BU		
Phase	**Life Cycle**	**Total Score**	**Maximum Score**	**Percentage**
A	Management System	71	100	71
B	Research	88	100	88
C	Product Development	76	100	76
D	Sourcing & Procurement	54	100	54
E	Production	79	100	79
F	Quality Assurance	78	100	78
G	Regulatory Compliance & Labelling	84	100	84
H	Warehousing & Distribution	70	100	70
I	Sales & Marketing	60.5	100	61
J	Contract Risk Management	61	100	61
K	Security & Defense	58	100	58
L	Product Use & Recall	56	100	56
M	Event & Complaint Monitoring	82	100	82
N	Product Stewardship & Disposal	76	100	76
O	Documentation & Audit	66	100	66
Total Score		1059	1500	71

The Food Safety and Defense Assessment (FSDA) 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 as shown below.

Sample of the FSDA framework

Q	Issue	Expectation	Blue	Green	Yellow	Red
		Scoring	10	7	4	2
1	Recall policy	The organization has a clearly defined and communicated strategy for preventing and managing 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, lacks senior management endorsement or be poorly communicated	No written policy in place
2	Recall accountabilities	There is someone in the organization 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 reviews	The responsibility for managing recalls is clearly assigned within procedures and role 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 organization has a clear perception of the major causes of product recall exposure (eg. Labeling 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 organization 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 exposure	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

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.

Benefits from Risk Management Strategies for Managing the Product Risks

The degree of formality of the strategies for managing the imported product risks will vary for each organization, depending on all of the risks presented by the firm's products, markets served, user population, legal jurisdiction and other commerce factors. However, the goal of the strategies is to produce a reasonably safe product and to provide evidence of actions aimed at reducing the risk should an injury, damage, or other loss occur regardless of how or where a product or any of its components has been produced or sold. The company that does these well is probably the more competitive, profitable, and lasting whose brand(s) and reputation are not known for defect or contamination, but on the contrary are valued by consumers who will purchase future products from them too.

Conclusions

According to the 2012 FDA Global Insights Report "Growing access to the global marketplace and increased Internet commerce will expose consumers to increasingly sophisticated threats of fraud, product adulteration, and even terrorism-threats that likely will grow as resource scarcity renders fraud and adulteration more profitable." The globe will continue to get smaller and more complex rather than remain the same and become less complex. As increased emerging markets produce more goods; the risk of product recalls will likely increase too. Because 10 years (FDA Global Insights) is a short period of time, it is sound business sense for firms, including manufacturers, importers, distributors, and retailers to do everything possible to insure their products are safe and reliable now and in the future. Working together we can help insure the products all of us consume, require, and enjoy; do not harm our children, families, or ourselves.

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