

Manufacturers and all entities in the supply chain have an increased responsibility to monitor their products in use and take appropriate actions to correct safety issues.

Product Recalls:

Product safety and recalls have been hot topics in the press all around the world, and government regulators in the United States and abroad have implemented new requirements and new penalties for not complying with the laws associated with product safety. And plaintiffs' lawyers, in product liability lawsuits, are increasingly using a company's failure to recall — or to recall adequately — as a reason to argue for an award of high damages. Punitive damages have been awarded, fines and penalties have increased, people have been hurt and killed, and the good name and reputation of many companies have suffered from a failure to meet their postsale obligations. Some companies have even gone bankrupt.

But companies and their supply management executives can prepare to meet these obligations as they design, manufacture and sell their products. Being proactive and prepared before sale can save all companies in the supply chain significant amounts of money and effort, and make any necessary recalls or product withdrawals implemented after the product has been sold in the marketplace much more effective.

Preparing to Meet Your Postsale Duties — Presale

The supply management executive's most important task is to establish procedures *before* the product is sold so that each entity in the supply chain can easily and efficiently obtain information, analyze it, make decisions about any appropriate

postsale remedial programs and implement the necessary programs. Many of these procedures cannot be implemented after the sale of the product — it is too late.

Traceability. Some of the most significant elements to build into your product's design, manufacturing and distribution processes are traceability and marking procedures that are used before manufacture, during manufacture and during distribution. Products, and especially safety-critical components, should be marked or coded so that anyone, including customers, can identify the product or component to be returned. In addition, supply management should maintain a continuous log of all batches, materials, processes, components and design changes of parts so that the organization can identify the exact products that need to be



Be Prepared

By Kenneth Ross

recalled or the exact products that contain the component part that needs to be recalled. This is not easy to do, and many supply management professionals, especially those who have never had to recall their products, will wonder if the effort is worth it. Of course, in the

event of a recall, this tracking can allow the manufacturer of the finished product or component part to narrow the affected population and clearly identify the population to customers. In that case, everyone wins, from the manufacturer, to the retailer, to the consumer.

Databases. The next important consideration is for supply management, in cooperation with all entities in the distribution chain, to design and maintain an effective database so that different levels of entities, including product users if possible, can be identified. These databases must be updated periodically, especially after sale. In this era of electronic tracking through such technology as bar codes and RFID, there is no excuse for not being able to track the affected population through at least the retailer or product seller. GS1 (www.gs1.org), the organization that created bar codes, is working energetically to create standards that will improve traceability for various products including food, healthcare and consumer products.

Electronic tracking, such as RFID, might even eventually help to identify products in consumers' hands. Other techniques to enhance customer identification include Web site product registration and



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an increased return of warranty registration cards. Of course, there are privacy issues, and many customers object to such tracking. But, at least with online purchases, the retailer will know what product was purchased, where it was shipped and what the customer's e-mail address is. This allows instant transmission of recall notices or safety alerts.

Supply management professionals who don't attempt to enhance the traceability of the product through the distribution chain, and possibly to the consumer, will pay a price by having to recall many more products than necessary. And, if an accident occurs, the organization needs to defend itself against charges that it was negligent in not trying, before sale, to set up a system to better identify the product and its components in various stages of distribution.

Product usage information. Another important component of presale planning involves the receipt of product usage information, and what to do with it. Supply management must develop an information-gathering network before sale so that the appropriate information received after sale can be identified and analyzed. The supply management organization has a number of readily available sources of information. For example, notices of claims or accidents might provide information on the types of products that are failing, the mode of failure and possible misuse of the product. The supply management department should be trained to ensure that sufficient information is gathered concerning these claims and accidents so that potential problems can be identified.

Customer complaints and warranty returns provide fertile sources of information. A pattern of complaints and returns may indicate that a product is failing in a particular mode on a regular basis. Again, supply management professionals should be trained to identify and clarify the information so that it is accurate and substantiated. Supply management does not want to gather and maintain inaccurate and overstated complaints and claims that incorrectly make it appear that a problem exists.

An unusual number of sales of safety-critical component parts may indicate that

a part is failing prematurely. Of course, observations by sales and service personnel who are actually out in the field talking to customers are invaluable sources of information. And, postsale information can also come from competitors at trade shows or as part of membership in a trade association.

Postsale information, albeit some of it unsubstantiated or even incorrect, is now posted by consumers on the Web. In addition, the new Consumer Product Safety Commission (CPSC) reform legislation passed this year requires the CPSC to establish a new searchable database with product incident and complaint information.

Some companies monitor the Web, especially sites that customers might visit, to read comments about their products. Supply management executives will need to determine whether a follow-up investigation of safety issues raised by customers or product owners who post such information is warranted. Ignoring such information can be risky, but following up on all alleged safety issues could be time-consuming and fruitless.

Remedial processes. The organization and supply management must develop criteria on the types of remedial programs that may need to be implemented, and then develop procedures and processes to implement each of these programs. Recall is not always necessary. Additionally, different levels of recall may be appropriate, depending on the level of risk and difficulty of locating the products.

General templates of acceptable press releases, customer alerts, distributor bulletins, Web site postings, and questions and answers to be used by management should be drafted before sale or, at least, not too long after sale. Of course, these will need to be customized for the product and the situation. But creating these templates will make the process go much faster when a problem arises. Processes to communicate this information quickly and efficiently to the appropriate people or entities should be developed at this time. For example, supply management should be able to almost instantly send (by broadcast fax or e-mail) a message to its distributors requesting that the distributors

and their customers embargo sales of a particular product. This will prevent sales of unsafe products and minimize the number of products recalled.

An organization and its supply management team need to be careful that this presale planning does not appear to be an admission that the company expects safety problems with a product and is just planning for the inevitable recall. The planning needs to be routine and consistent with the product safety policy. It can also be justified as necessary to comply with U.S. and foreign laws and regulations that require a manufacturer to be better prepared to recall its product.

Preparing to Meet and Meeting Your Postsale Duties — Postsale

Once supply management has obtained all relevant information about a possible problem, it must determine whether postsale action is necessary. Actions could include reporting to the relevant governmental agency and possibly undertaking some form of remedial plan.

Ideally, a corporate or divisional product safety committee will analyze the information. This committee should be made up of representatives from various areas of the company, including supply management, engineering, service, sales, marketing and legal. It is also very important that the lawyer advising the committee is experienced in product liability and regulatory law in the countries where the affected product was sold.

Risk analysis. Analyzing the information and deciding what it means is the most critical phase of this process. Many manufacturers use or should use risk assessment prior to selling their products. This process identifies the risk, probability of the risk occurring, consequences if it occurs and methods to minimize the risk. Before sale, supply management should make a best guess on the probability of the risk occurring. It is, of course, difficult to estimate the probability of an event occurring when it has never happened before.

After sale, the manufacturer is, in effect, plugging new numbers into its presale risk assessment. Postsale incidents may indicate

risks or consequences that were never imagined, or increase the estimated probability calculated before sale. Reworking the presale risk assessment is a good way to formally recalculate the numbers and assumptions. Unfortunately, using this approach doesn't necessarily tell you what type of action is necessary in the postsale situation.

For products regulated by a government agency, supply management needs to identify the threshold for taking action. For example, the CPSC provides criteria for determining the existence of a defect and substantial product hazard. If both exist, there is a legal duty to report. The criteria to be considered are the pattern of defect, the number of defective products distributed in commerce and the severity of risk to consumers. Using these criteria will provide guidance about what information to gather and how to analyze it. However, the CPSC provides little further guidance on this basic question and expects the manufacturer to report a substantial product hazard, or any suspicion that the product contains such a hazard.

After the manufacturer reports to a government agency, the agency will most likely, if not always, strongly encourage some type of remedial program. Thus, supply management must be prepared — if at all possible as part of the report — to describe the remedial program that it believes will minimize the risk.

For products that are not regulated, mostly industrial and commercial equipment and machinery, there is no government agency to report to and very little specific guidance in the law on when there is a duty to undertake a remedial program and what type of program is appropriate. It is based on negligence, which means that the jury gets to decide the issue. Would a reasonable manufacturer have undertaken a recall or retrofit knowing what future risk existed with its products? This is a very low-threshold, and every manufacturer and entity in the supply and distribution chain needs to seriously analyze its potential responsibility.

Expertise required. Every entity needs to have experienced technical and legal personnel who routinely evaluate

postsale data and information, and decide whether to report to the government and undertake a remedial program or to undertake a remedial program even if no agency is involved. If adequate presale planning has occurred, implementing the program will be less difficult and more organized than if no planning occurred. Everyone will know what to do and when to do it.

Recalls can be extremely difficult and expensive, and very ineffective, despite the best of efforts. There are no clear guidelines in the common law or even with government agencies about how effective a recall has to be. Recalls or retrofit programs with an effective rate of less than 10 percent have been deemed acceptable by the CPSC. And, the CPSC has said that the average response rate from consumers for most recalls is between 4 percent and 18 percent.

Virtually no recalls achieve 100-percent compliance. As a result, the manufacturer will have many products in the field that it has admitted or intimated are defective or at least pose a risk of injury. After an injury occurs and a lawsuit is filed, how will the manufacturer defend its product? This must be thought through as the program is implemented. How will the entity prove that its actions were reasonable and appropriate under the circumstances? Again, experienced personnel in this area can help and should be utilized.

In Summary

Preparing for a recall before it occurs can significantly increase its effectiveness and lessen the costs and disruption. Of course, before sale, the manufacturer and its supply management executives also need to try to prevent postsale problems that would necessitate a recall. Either way, it is the responsible and moral thing to do, and will reap significant benefits for the company, for all other entities in the supply and distribution chain, and for consumers and product users. **ISM**

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