



Risktopics

Product Recall Program

Introduction

Despite a company's best efforts to design, manufacture and sell safe and reliable products, the possibility still exists that dangerously defective products may reach the customers. These products may cause accidents, leading to adverse verdicts in product liability litigations. Unfavorable publicity may result in loss of sales and damage to the company's reputation.

Unless appropriate action is taken promptly, these defective products may pose a severe financial threat to the company and can have a very serious financial impact on the company for years to come.

The very survival of a firm may depend on how well and how quickly it can respond to the first notice that a product recall may be necessary. Product recalls are certainly expensive, but attempting them without adequate planning can be much more costly.

Primary Reasons for a Product Recall

A product recall may be:

- Mandated by a regulatory agency as a result of a violation of a government act, standard or other mandatory regulations, such as toy recalls ordered by the Consumer Product Safety Commission.
- Required to avoid potentially serious additional product liability claims or losses.
- Indicated by the analysis of field monitoring reports and feedback that may point to product tampering, near-miss incidents, accidents or consumer complaints.
- Suggested by new information based on additional research and product testing.
- Needed when characteristics of the product don't measure up to the advertised claims for safety or effectiveness.

As indicated earlier, some product recalls come under federal regulations. For example, the Consumer Product Safety Act (CPSA), Section 15(b) requires that the Consumer Product Safety Commission be notified within 24 hours of the time it is discovered that a consumer product presents a "substantial" hazard. The Food, Drug & Cosmetics Act administered by the Food and Drug Administration (FDA) classifies recalls into three classes:

- Class I: Involves a life-threatening situation. FDA will mandate a consumer recall, a 100 percent effectiveness check and appropriate public announcements.
- Class II: Involves a potentially hazardous situation, but not a life-threatening condition. FDA will usually mandate a recall to the retail outlets and will not require a 100 percent effectiveness check. A press release may be required, depending on the reasons for the recall.
- Class III: Involves no serious hazard. It is usually limited to the wholesale level with no effectiveness checks and no press release requirements.

Depending on the seriousness of the situation, the company may have a choice whether to repair or modify the product (no cost or reduced cost retrofit by customer or the company), refund the purchase price, or initiate a total or partial recall (voluntary or mandatory).

In case of a mandatory recall, the company can contest the notice of recall from a regulatory agency. This should be done only after a thorough review of the situation and with appropriate legal counsel.

Need for a Standby Contingency Plan

If a product recall ever becomes necessary, speed in making decisions and initiating appropriate actions can help mitigate the unfavorable consequences. This requires a standby product recall plan, which must be established before the fact.

A standby recall plan will save response time through pre-planning for all foreseen contingencies, reduce costs by minimizing duplication of efforts, help in compliance with regulatory requirements, ensure the effectiveness of the recall plan which has been tested by use of a dry run or mock recall, and help in addressing potential problems of collection, storage, pickup, and/or disposal of recalled products.

Product Recall Standby Procedures

Product recalls can be complex and will always involve many departments within the company as well as dealers, distributors and customers. The plan should be reviewed periodically for its effectiveness, changing needs due to changes in product lines, geographic markets, and legal requirements.

The plan should spell out the responsibilities and procedures to be followed by various departments.

Recall Plan

Administration and Coordination: The recall plan must have the endorsement of top management, and it should assign responsibility and authority for the decision to recall or field modify a product to a specific executive officer of the company.

The standby recall should also outline the coordination of the program, for example, coordination may rest with the product safety/liability coordinator at the corporate, plant or division level.

Other elements of the recall plan should include:

- Analysis of the seriousness of the reported safety hazards and recommended appropriate action.
- Notification of recall to the appropriate regulatory agency, if required.
- Coordination of internal activities/procedures for all personnel who may be involved in the recall, including the Communication Department to acquaint them with the plan and to draft needed announcements. Training and duties and responsibilities in the event of a recall should also be outlined.
- Liaison (notification, cooperation, and assistance) with dealers, distributors, wholesalers, and retailers about prearranged procedures and fees for essential services, including collection, storage retrofit, and/or disposal of recalled items.
- Provision of publicity and damage control, through letters and telegrams to all traceable customers, and press releases to the media, to ensure that the situation is presented in a positive manner that will reduce negative perceptions.
- Notification of recall to the insurance company.
- Monitoring and appropriate corrective actions.
- Testing of recall plan by dry run or mock recall.

Traceability

Proper documentation is the single most important factor affecting the potential success or failure of a product recall. A document control system should be based on company policy, management analysis and appropriate legal counsel.

The success of a product recall will largely depend on how accurately the company's records can identify specific products (by model, serial numbers, batch or date codes) in question as well as tracing the customers who purchased these defective products. Such a system also enables the company to isolate specific causes of defects and thereby limit the number of products subject to recall.

Product traceability should start with raw material/component suppliers and progress through the production and distribution system to the end users. Shipping papers and invoices should contain the records of serial numbers of batch/date codes.

In the absence of adequate traceability, the company may actually end up recalling many more products through a blanket recall. Therefore, a practical and efficient lot or batch numbering, product or package identification, and shipment records system must be established before the fact.

Hazard Analysis and the Decision to Recall

The hazard analysis should be an integrated part of the field monitoring activities, which deal with the prioritizing, investigation and analysis of the field feedback.

Sources of unsolicited feedback generally include product liability claims or losses, incidents of near misses, complaints from customers, dealers, distributors and field failure analyses.

Some companies may also solicit feedback to supplement their field monitoring activities. Solicited feedback may come from field personnel, warranty cards, comment cards returned by customers, user training, user surveys, government data, and industry and trade association data, including feedback from competitors.

The Product Safety Coordinator should be the focal point for all pertinent in-coming data and be responsible for the analysis to determine the seriousness of the safety hazard and then recommend appropriate action to top management. The Product Safety Coordinator should seek technical assistance from other departments in this effort.

Safety Analysis

Factors to be considered in this analysis include:

- Seriousness of the safety hazard in terms of severity of consequences (bodily injury, property damage, consequential damage, including business interruption and extra expenses).
- Validity of the information, data or results.
- Nature of defect or problem: design, manufacturing or packaging defect, a defect in suppliers' raw material or purchased component or possible product tampering.
- Estimates of the number of products involved in the potential recall, including those in the hands of customers, those in the distribution chain, including the company's own warehouses, and products possibly consumed or used up.
- Estimates of costs (provided by the Accounting Department) and possible prearranged method of financing these costs. Some of the costs would include communication and publicity related to the recall, disposition or recalled products, compensation for claims and replacement products, documentation and handling, management overheads, and long term intangible costs. Depending upon the case, the manufacturer may bear the full cost of recall/retrofit or the supplier of the defective component may be required to pay for the full or prorated expenses. Having the customer pay for them will adversely affect the success of a recall campaign.
- Impact on the company's image, customer confidence.

Internal Action Plan

Once the decision to retrofit or recall has been made at the executive level, internal procedures of the contingency plan go into effect. It may be helpful to develop a checklist of tasks or actions to be followed by various departments.

Key actions would include:

- Suspend production, distribution and sale of the affected product(s).
- Inform the appropriate regulatory agencies, if required, and seek legal counsel.
- Telephone the recall decision to sales executives and staff in the field operations, if they are involved, and customer service personnel.
- Follow up with written instructions to sales, service and plant personnel detailing the procedures they have to follow in handling the recall. Make sure to identify the products being recalled by model, serial or batch numbers and date codes. Alert personnel to prepare to receive, pick up, transport, repair and dispose of recalled products. Compile appropriate traceability records for use by the Recall Coordinator.
- Notify dealers, distributors, Original Equipment Manufacturers, and retailers about the recall and the procedures they are to follow. Once again, identify the products being recalled by model, batch, serial number and their location on the product. Instruct them to stop sales of affected products and to post notices of recall in the store and to prepare to receive recalled products. Dealers should be notified of retrofit replacement procedures if it is not a total recall. Ask them to prepare a list of the affected customers and provide the list to the company.
- Publicize the recall/retrofit campaign with the help of legal counsel and the Public Relations Department. Begin by sending letters and telegrams to all traceable customers. Make sure to explain the reasons for the recall, identify the product(s) in question (location of serial number and date code), identify the nature/seriousness of the hazard, instruct the customer to discontinue using the product immediately, and provide clear, specific instructions on how and where the product is to be returned or repaired.

Note: Letters should be sent by Registered or Certified Mail with return receipt.

Make appropriate use of the media. For a mandated recall, the regulatory agency may require appropriate publicity of the recall in magazines, newspaper, radio and/or TV and may also want to review the publicity release.

The publicity should cover the appropriate geographic area in which the product was sold or distributed. The selection of media will depend on the media effectiveness for the target audience, costs (for example a 30-second spot on primetime TV may cost about \$250,000) and response time requirements.

Even if the recall publicity is not mandated by any regulatory agency, the company management may still decide to use the media for damage control and to combat adverse publicity.

In publicizing the recall, the company is walking a fine line between the need to notify all their customers about the potential hazard due to the fear of subsequent product liability claims and reassuring the other users of the company's products. Johnson & Johnson's Tylenol recall is a good example of how a well-tuned recall program can help minimize the impact of a potentially devastating recall and actually help regain the consumers' confidence and market share.

Monitoring the Recall

In case of certain mandatory recall, the company is required to monitor the success of the recall. All recall campaigns (mandatory or voluntary) should be monitored for their effectiveness. Besides measuring the effectiveness of a recall, appropriate documentation of a recalled product can also help in defense of product liability litigations.

The Recall Coordinator should maintain a record of the number of products returned (retrofitted) and should compute percentages. If the initial recall response is low, this may indicate a need for additional action, like wider publicity or additional media coverage.

The success of the recall will depend on:

- Accurate records for estimating the population of defective products.
- Accurate traceability of customers.
- Success in informing the customers through proper selection and use of media (targeting).
- Cost of the product being recalled (the higher the price, the better the chance of customer action).
- Customer perception of seriousness of the hazard. It is strongly suggested that the recall plans be tested at least once a year by dry run or mock recall without physically recalling the product. It is relatively simple to match up code numbers of production records and shipping records.

The advice is to pay now for a well-tuned, debugged standby recall plan or pay more later in terms of confusion, tarnished image and loss of customer confidence.

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