Take the proper steps to manage product recalls.

Recall products
after the discovery
of defects.



To ensure consumer safety, manufacturers must design and produce products to meet a variety of required and voluntary safety standards. Besides safety, there are financial, moral, and legal obligations involved in quickly addressing product concerns. These obligations include addressing complaints and taking appropriate action to correct safety issues, including the recall of products. The Consumer Product Safety Commission reported 241 such recalls recently, ranging from unstable furniture to flammable clothing. The largest and most prominent reason for recall was the defective design of five million infant sleepers, which was tied to more than thirty deaths.

Plaintiff attorneys are increasingly using a company's failures to promptly and adequately recall as additional reasons to argue for large product settlements. Several large auto manufacturers have also been subject to large fines and penalties for their delays in recall efforts. Failure to properly plan for a recall scenario can expose the consumer to unnecessary harm, severely tarnish your brand reputation, increase financial liability, and potentially expose you to civil and even criminal penalties.



See the following pages for practical steps your business can take.

Product Recalls



Remove potentially dangerous products quickly and effectively.

Manufacturers need to react quickly and effectively, and be transparent about the type, source, and level of defect. The goal is to retain the trust of the marketplace, so a company can survive after a recall. The timely, well-communicated, and well-executed recall of a product can have a strong influence on consumers' attitudes about a business. To be successful, a company must prepare ahead of time to effectively deal with product issues. The following is a guide to some of the critical areas that need to be addressed when preparing a product recall plan.

Ownership Support

Recall pre-planning starts with garnering support and resources from the ownership/leadership team. Without the full support of leadership, recall planning may lack resources to be effective.

Nominate a Recall Coordinator

A recall coordinator must possess exemplary leadership and organizational qualities, have a thorough working knowledge of all facets of the business and understand legal and regulatory requirements. The coordinator must be given authority by management to execute activities of the recall and be trusted to make decisions on behalf of the company. Duties could include:

- Assembling a recall team
- Ensuring adequate tracking of recall activities
- Documenting and disposition of a recall
- Updating ownership/management of recall progress
- Making recall decisions
- Serving as a liaison between the company regulatory authorities
- Leading mock recalls
- Updating the recall plan

Assemble a Recall Team

An initial step in the development of a recall plan is to assemble your recall team. Your recall team will help draft the recall plan and play a role in the event of a recall. Ensure your team includes employees from all areas of the business to include but not limited to: sales/marketing, customer service, accounting, distribution, engineering, quality assurance and legal.

Draft a Written Recall Program

A company should have a comprehensive written recall program. Recall programs should contain, at a minimum:

- Identification. Definitions and an understanding of the types and levels of recalls for your industry (e.g. Class I, II, III recall, Class A, B, C Hazards, Market Withdrawal).
- Assignment roles and responsibilities during a recall event. Establishing roles and activities prior to the event will help to avoid confusion and/or duplication of activities during an actual recall. Back-ups of individual roles should also be identified to avoid gaps during vacation, illness, retirement, etc.
- A critical contact list. This list could include but does not have to be limited to: recall team members, recall coordinator, retail partners, distribution partners, component part manufactures, raw material suppliers, cross docks, third party warehouses, regulators, government agencies, testing labs, and approved disposal contractors. The contact list should be updated whenever changes are made or at least annually.
- Formal customer/product complaint handling channel. This could include a dedicated phone number, website, email address, marketing and sales feedback mechanisms, etc. Complaints should be tracked and monitored for early detection and product complaint trends. Training should be provided on how complaints are routed through and when to escalate for early review.
- Complaint/Condition evaluation. You should develop a flow chart to detail and provide clarity of the product complaint and evaluation process. The steps involved in the receipt and evaluation process could include:
 - Receipt of the complaint A file should be maintained containing any product complaints the company receives.
 Information that should be maintained in the product complaint file includes: Complainant contact information, reported problem with the product, product identification, product purchase date and location, extent of illness and or injury.
 - Provide the complaint to designated personnel for initial evaluation (e.g. QA, Engineering). If an initial assessment indicates a recall may be necessary, the Recall Coordinator assembles the Recall Committee for a full evaluation.
 - Determine the scope of the severity, likelihood of the hazard occurring and evaluate all foreseeable safety concerns with the product.
 - Determine the best possible removal strategy appropriate to the level of threat and location in commerce of the product.



Form a recall team and assign roles and responsibilities.

Loss Control Services 4

Product Recalls



Consequences for failing to recall products can be disastrous.

- Gather and maintain all appropriate records (complaint records, quality assurance records, production, distribution, warranty returns, etc.).
- Contact the appropriate regulatory authorities.
- Alert legal counsel, insurance, etc. as appropriate.
- Maintain a log of the events of the recall including information such as dates, actions, communications, and decisions.
- Suspension of production and distribution.
- Assessment of affected products. Types of quantities of product must be quickly identified. How many products are in the stream of commerce? How many in owned or non-owned distribution warehouses? Identify affected raw materials still in process or storage.
- Quarantine of product. All affected product and raw material that is in storage and has not been shipped or processed should be labeled and quarantined. Ensure there is adequate segregation between affected products and non-affected products.
- Development of recall communications and instructions. A well-rehearsed and planned communication strategy can help reduce the potential for customer injury and reduce your company's product liability exposure. The Recall Coordinator, Management and Legal Counsel must review and agree on communications and recall instructions. Be innovative with communication strategy to reach all affected parties (retailers, distributors, individual customers, repair shops, second hand/thrift shops). Communication avenues can include: company website, radio, television, social media, email, phone, posters, mailers, etc.
- Monitoring and documentation of the recall process. Create reports and logs that document dates, actions taken, communications, amount of product retrieved, disposition of product, etc.
- Disposal of or re-work of product. All product must be disposed of or re-worked in close conjunction and consultation with regulatory authorities. Maintain records of all product disposition.
- Monitor effectiveness of the recall. Review recall logs and reports, total injury/illness or property damage data, time involved to identify, amount of product returned/destroyed.

The written program should be reviewed at least annually and should be current and up-to-date at all times. The entire plan must be exercised and evaluated for effectiveness.

Traceability of Product

For a recall plan to work, products must have effective means of traceability in place. The manufacturer must be able to trace product from raw materials to wholesaler or retailer. Traceability methods could consist of:

- Component part and raw material lot numbers
- Retained raw materials samples
- Production records such as build sheets, identifying all component parts
- Finished product lot numbers
- Shipping and sales records
- Individual component and finished part labels and identification

Traceability can be accomplished through a pen-and-paper-type system or an automated computer-based system. Regardless of the system used, traceability must include all product throughout processing. It is critical that paper production/traceability records are maintained in fireproof cabinets and computer records are backed up off-site.

Mock Recalls

Mock recalls are also referred to as "Traceability Exercises". A mock recall is simply to verify your recall plan in place is adequate. Mock recalls also test the plant personnel to ensure everyone knows their responsibility and can react quickly and effectively.

- Your operation should perform at least one mock recall per year. Mock recall should include a "front-to-back" method, which is raw materials to finished product and a "back-to-front", which is finished product to raw material.
- Mock recalls should be timed to see how long it takes to identify and locate all product in question.
- The plant should practice each mock recall as if it were a real recall scenario.
- Results of each mock recall should be documented. Corrective actions on any issues found during the mock recall should be completed in a timely manner and documented. The plant should ensure that mistakes made are not repeated in future mock recalls.



Limit the impact of potential recalls with effective product traceability.

Conclusion

Of course, the most effective way to navigate a product safety issue is to avoid having one. However, in the event your company confronts a product safety reality, a well-planned and rehearsed recall strategy can help to remove affected product, restore consumer confidence and reduce the potential for customer injuries, civil penalties and product liability. Quick action, along with accountability and transparency, should help ensure a company will overcome a recall scenario and be able to continue to deliver products to consumers well into the future.

Resources:

<u>Consumer Product Safety Commission</u> <u>Recall Handbook</u>

<u>Consumer Product Safety Commission Regulated</u> Product Handbook

How to Develop a Meat and Poultry Recall Plan - USDA

Recall Procedures - FDA



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