

Product Recall Manual



Intended for intermediate compliance programs

Preparation Is Essential

A recall happens nearly every day, but it is easy to think that it can't happen to you. The reality is that we are all at risk of becoming involved in a recall and once you are involved in it you have an **obligation to respond immediately—that is, within 24 hours** you must take some action. And that makes prior preparation essential.

- **Anticipate Problem Products.** You have an obligation to continuously survey the market to learn about consumer products that have been or could be recalled.
- **Preparation Mitigates Consequences.** Delays in taking action or reporting product defects can result in hefty fines and penalties. You must be prepared to react quickly and effectively to protect your company, your customers and the industry.
- **Set A Process In Place.** Develop a solid and detailed recall plan.
- **Communicate.** Make sure your entire team understands their respective roles and responsibilities, procedures and important regulatory information and is prepared to move promptly.

Monitor The Market

You have an obligation to continuously survey the market — monitoring www.saferproducts.gov, news media, and social media—to learn about consumer products that have been or could be recalled. The Consumer Product Safety Commission (CPSC) expects you to do this for all of your products—even if they are not subject to any specific rules or testing requirements.

A manufacturer, importer, distributor and/or retailer of consumer products must notify the CPSC immediately if it obtains information which reasonably supports the conclusion that a product distributed in commerce poses a substantial product hazard to consumers.

You should develop a system for maintaining and reviewing information about your products that might suggest the product has a defect or poses an unreasonable risk of serious injury or death. Such information includes, but is not limited to, consumer complaints, warranty returns, insurance claims or payments, product liability lawsuits, reports of production problems, product testing or other critical analyses of products.

NOTE: Be sure to communicate this obligation with all of your employees, particularly customer service representatives who are often on the front line in receiving customer complaints. Provide training so they recognize complaints and know to report them to the product recall coordinator.

Reporting

Firms must report “immediately.” This means that a firm should notify the CPSC within 24 hours of obtaining reportable information (16 CFR 1115.12 or section 12 of the CPSC Recall Handbook). The CPSC considers a company to have product safety related information when that information is received by an employee who may reasonably be expected to understand the significance of that information. Once that occurs, the company has five working days for that information to reach the CEO (or other official assigned responsibility for complying with reporting requirements).

The CPSC encourages companies to report **potential** substantial hazards even while their own internal investigations are continuing. If a company is uncertain whether information is reportable, the firm may spend no more than 10 working days investigating the matter.

Reporting a product to the Commission does not automatically trigger a recall. The CPSC will evaluate the report and work with the reporting firm to determine if corrective action is appropriate. Many reports received require no corrective action because the CPSC staff concludes that the reported product defect does not create a substantial product hazard.*

**Consumer Product Safety Commission, Recall Handbook, March 2012*

Roles And Responsibilities

In order to respond to reports of product defects quickly and responsibly, it is important to put a recall team in place. A product recall team could be composed of these players:

- Senior Management
- Customer Service
- Information Technology
- Finance
- Recall Coordinator
- Sales
- Marketing

The recall team will be assembled at the discretion of the recall coordinator.

Recall Coordinator

Role/Authority. The recall coordinator is granted full authority to take the steps necessary to initiate and implement all recalls with the approval and support of the CEO. The recall coordinator should be familiar with the statutory authority and recall procedures of the CPSC.

Responsibilities- The recall coordinator responsibilities include:

Collecting Data- Organizing and collecting the documentation of all recall decisions and actions in a master recall database

Leading Recall Team- Assembling the recall committee or team.

Assembling Resources- Authority to involve appropriate departments and access necessary company resources to assist the process.

Overseeing Recall Process- Managing the implementation of the company's product recall, including making necessary recall decisions.

Communicating With Management. Keeping management informed at every stage of the recall. Liaison With Authorities. Serving as the company's primary liaison with the CPSC, FDA, or other authorities.

Review Product Line. Review the product line to determine how products will perform and fail under conditions of proper use and reasonably foreseeable misuse or abuse. Work with the development team to incorporate safety features into product design.

Institute Product Identification System. Model designations and date-of-manufacture codes should be used on all products to facilitate a recall should one become necessary. For children's products, the mandatory tracking code provides date and place of manufacture information.

Team Member Responsibilities

Individual recall activities should be assigned to each prior to a recall event to prevent loss of time and confusion during a recall. A detailed checklist of specific responsibilities can be found in Appendix E.

Recall Procedures

The recall procedure outlines the steps needed to manage the recall of product(s) deemed to be defective, unsafe, and/or subject to regulatory action.

Four-step Process. There are four steps to a recall process:

- Product evaluation
- Notification of affected parties
- Location of products
- Product removal

1) Product Evaluation

Collect and Catalog Information. Gather and store all product defect complaints the company receives. Follow up with source for additional information as necessary.

- **The Problem-** What happened to trigger the complaint or concern? How likely is the defect to result in an injury to consumers? Was anyone hurt? How seriously?
- **Contact Info-** Record contact information for person reporting the hazard; the injured party; doctors or other professionals who were involved; etc.
- **The Product-** Record the product name, ID, batch, and any other identification. Obtain one or more samples of the product from the shipment.
- **Order Information-** Record all order information, including supplier, date shipped, ship-to person/address(es).
As the process continues keep records of all contacts/communications with regulators, supplier, buyer, authorities and end users.

Initial Evaluation- The Recall Coordinator makes an initial evaluation.

If the assessment indicates a recall may be necessary, the Recall Coordinator assembles the Recall Committee for a full evaluation. In general, but not always, three complaints indicate a situation that might initiate a recall.

Full Evaluation For Potential Recall- Where warranted, the Recall Team evaluates all necessary criteria and determines if a recall is necessary. Issues that should be discussed during the meeting should be as follows:

- **The Product-** What is the product? What is it supposed to do?
- **The Defect-** What is the defect that causes the product hazard? What was the cause of the product defect?
- **The Risk-** Is the risk obvious to the consumer? Are there adequate warnings and instructions to mitigate the risk? Is the risk of injury the result of consumer misuse and is that misuse foreseeable?
- **Location and Quantity-** Where are the unsafe products and how many are there?
- **Product Compliance-** Did the product fail to comply with government safety regulations? How?

Communication- Ensure all stakeholders are notified and appropriate actions taken.

- **Regulators-** What agency might need to be notified? Has any notification taken place and by whom?
- **Supplier/Manufacturer/Importer-** Has there been contact with the supplier, manufacturer and/or importer and by whom? What is the evaluation? Has and action been taken, including initiating a recall?
- **Internal-** Who in your company must know? What must they do?

Potential Recall- Determine if the recall is required and begin assessing financial impact.

- **Role/Scope-** Is reporting necessary? Is a recall necessary?
- **Cost-** Estimate recall elements and cost.

Prevention

- **Continuous Improvement-** What must you do—QC, risk analysis, screening—to prevent this from happening again?

Recall Needed- If a recall is deemed necessary:

- **Removal Strategy-** Determine the product removal strategy appropriate to the threat and location in commerce.
- **Record Keeping-** Maintain a log of the events of the recall including information such as dates, actions, communications, and decisions.

Communication

- **Regulators-** Contact the appropriate regulatory authorities.
- **External Advisors-** Alert legal counsel, insurance, etc. as appropriate.

A flowchart of the evaluation process can be found in Appendix A.

2) Identify Implicated Products

Identification. Identify the products and quantities of products implicated in the recall.

Gathering Detail. Information about the product, including how it has been distributed and to whom, should be prepared and documented.

- **Product-** The product should be identified through description, item number, style, color, lot/batch number, date of manufacture, date of import, etc. Gather photos of the product showing the defect or issue.
- **Distribution-** Determine how many products are in the stream of products and identify the recipients.

Recipients- Document the names, addresses and other contact information for the persons who received the recalled product(s).

Quantity- Amount of product shipped and distributed to users. Was any product undistributed and being held by customers? Was any product returned?

Dates- When was the product shipped from factory? When was it received? When was it given out? When was the first complaint received?

3) CPSC Notification And Recall Agreement*

Notifications- Recall notifications must be done in a timely manner. These should be delivered to the appropriate regulatory agencies, our customers, and consumers when necessary. According to the CPSC, firms must report “immediately.” This means that a firm should notify the CPSC within 24 hours of obtaining reportable information (16 CFR 1115.12 or section 12 of the CPSC Recall Handbook). The CPSC considers a company to have product safety-related information when that information is received by an employee who may reasonably be expected to understand the significance of that information. Once that occurs, the company has five working days for that information to reach the CEO (or official assigned responsibility for complying with reporting requirements).

The CPSC encourages companies to report potential substantial hazards even while their own investigations are continuing. If a company is uncertain whether information is reportable, **the firm may spend no more than 10 working days investigating the matter.**

Recall Agreement- A recall agreement is negotiated with the CPSC staff and should address all salient details of the recall. Consider working with a seasoned product safety attorney when negotiating this agreement. The final recall agreement should include:

- How consumers will be notified, how soon and by what method?
- Who distributed the product, how they will they be notified and by when?
- What you will offer to consumers who have a defective product, whether it be a replacement, a refund, a repair or something else?
- How you will collect, account for and dispose of the defective products in coordination with the CPSC?

Execute The Recall Agreement. The CPSC encourages companies to be creative in developing ways to reach consumers of recalled products and motivate them to respond. The specifics of the communication plan will have been spelled out in the recall agreement but typically include a number of elements, including but not limited to:

- **Recall Notices-** Suppliers and customer(s) must be notified by appropriate means, preferably by written notice to all consignees. A record of all communication should be maintained. An example of a poster/sign can be found at Appendix D.
- **News Release-** A joint news release from the CPSC and the company. Very specific news release guidance is available in the CPSC Recall Handbook. An example of press release can be found in Appendix C.
- **Video News Release-** A video news release to complement the written news release.
- **Toll-Free Number/URL/Email-** A dedicated toll-free number and fax number for consumers to contact to respond to the recall notice.

Website Postings- Information on the company external websites.

Social Media- Use of the firm's social media presence to notify consumers of the recall.

Additional regulatory information may be obtained as follows:

CPSC. (301) 504-7520, <http://www.cpsc.gov/en/Business--Manufacturing/Recall-Guidance/>

Contact information may be found at

<http://www.cpsc.gov/About-CPSC/Contact-Information/Contact-Specific-Offices-and-Public-Information/>

FDA. (301) 796-8200, <http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>

Contact information may be found at <http://www.fda.gov/AboutFDA/ContactFDA/default.html>

*Consumer Product Safety Commission, Recall Handbook, March 2012

4) Product Removal

The procedure for product removal can be divided into five components: removal, control and disposition of affected product, recall effectiveness, and recall termination.

Recall flow chart can be found in Appendix B.

Removal. All reasonable efforts must be made to remove affected products from commerce.

- **Distributed Products-** Products returned by recipients/users must be gathered, segregated and handled in a manner determined by the Recall Coordinator.

- **Undistributed Products-** Products that are still in customer(s)' control should be detained and segregated, and handled in a manner determined by the Recall Coordinator.
- **Documentation-** All quantities and identification codes shall be documented to assist in the reconciliation of product amounts.

Control Of Recalled Product. All affected products must be prevented from reentry into commerce.

Marking/Segregating. All returned products will be clearly marked not for sale or distribution and stored in an area that is separated from any other products.

Documentation. All quantities and identification codes shall be documented to assist in the reconciliation of product amounts.

Product Disposition. Final disposition of the recovered product must be determined, but that disposition plan must be reviewed with and approved by the regulatory agency.

- **Option-** Disposition options include:

Destruction- Products determined to be unsafe for human consumption may be destroyed or denatured, and disposed by appropriate means.

Recondition. Products may be reworked to remove the safety risk.

Redirection- Products may be redirected for uses other than human consumption.

- **Documentation-** All quantities, identification codes and disposition shall be documented.

Recall Effectiveness. A recall effectiveness check verifies that all consignees have been notified and have taken the appropriate action. Elements include:

- Verifying that all clients have received the notification.
- Verifying that clients have taken appropriate action.
- If the response from clients is less than 100%, then the recall strategy should be reassessed.
- All verifications shall be documented.

Coordination with the CPSC. Firms involved in a recall must be prepared to:

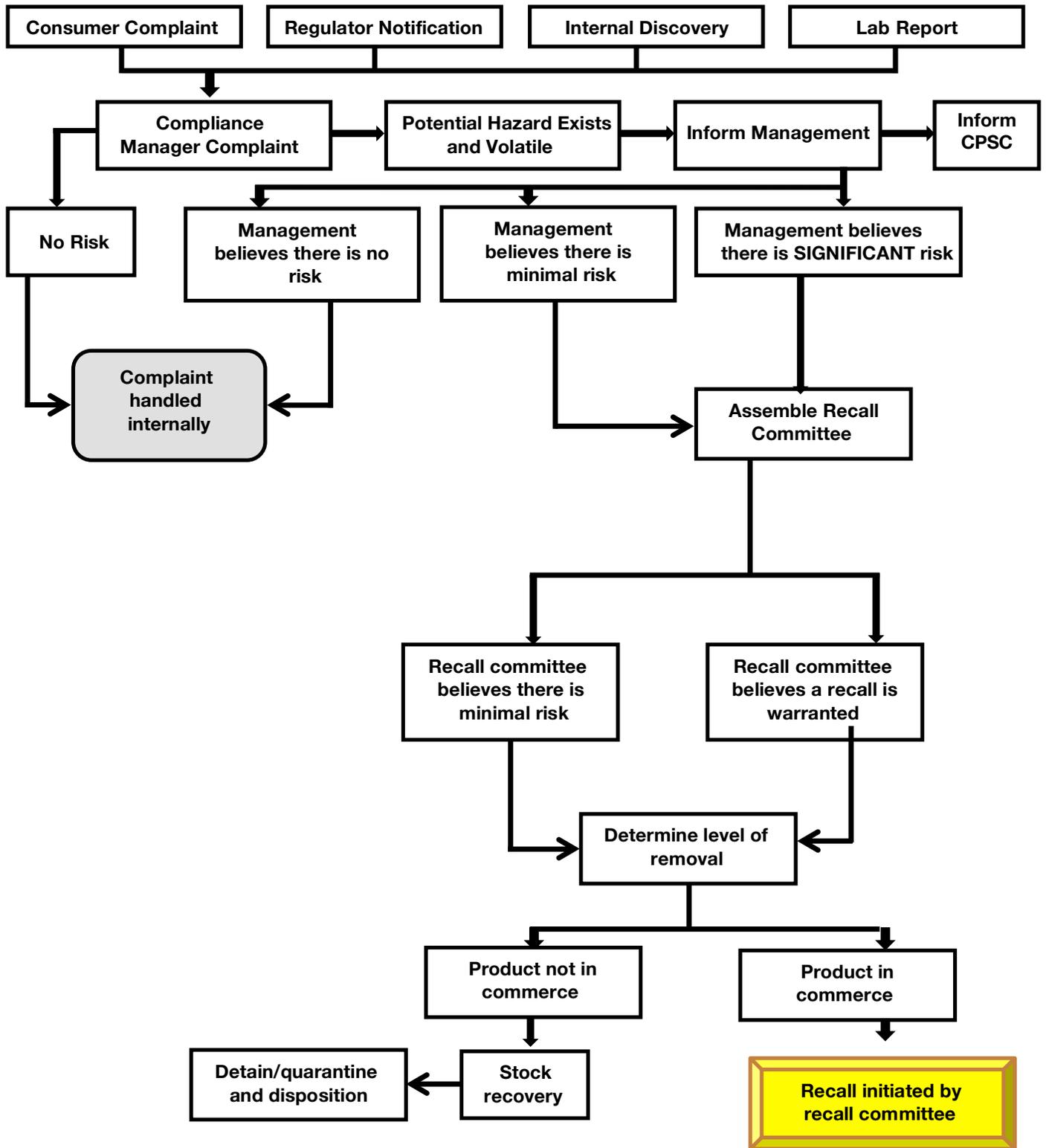
- Submit monthly progress reports to the CPSC.
- Perform recall verification inspections.
- Comply with CPSC field staff and state investigators.
- Submit all requests to dispose or destroy recalled products to the CPSC so they can either witness the disposal or other means of verification.

Termination of a Recall

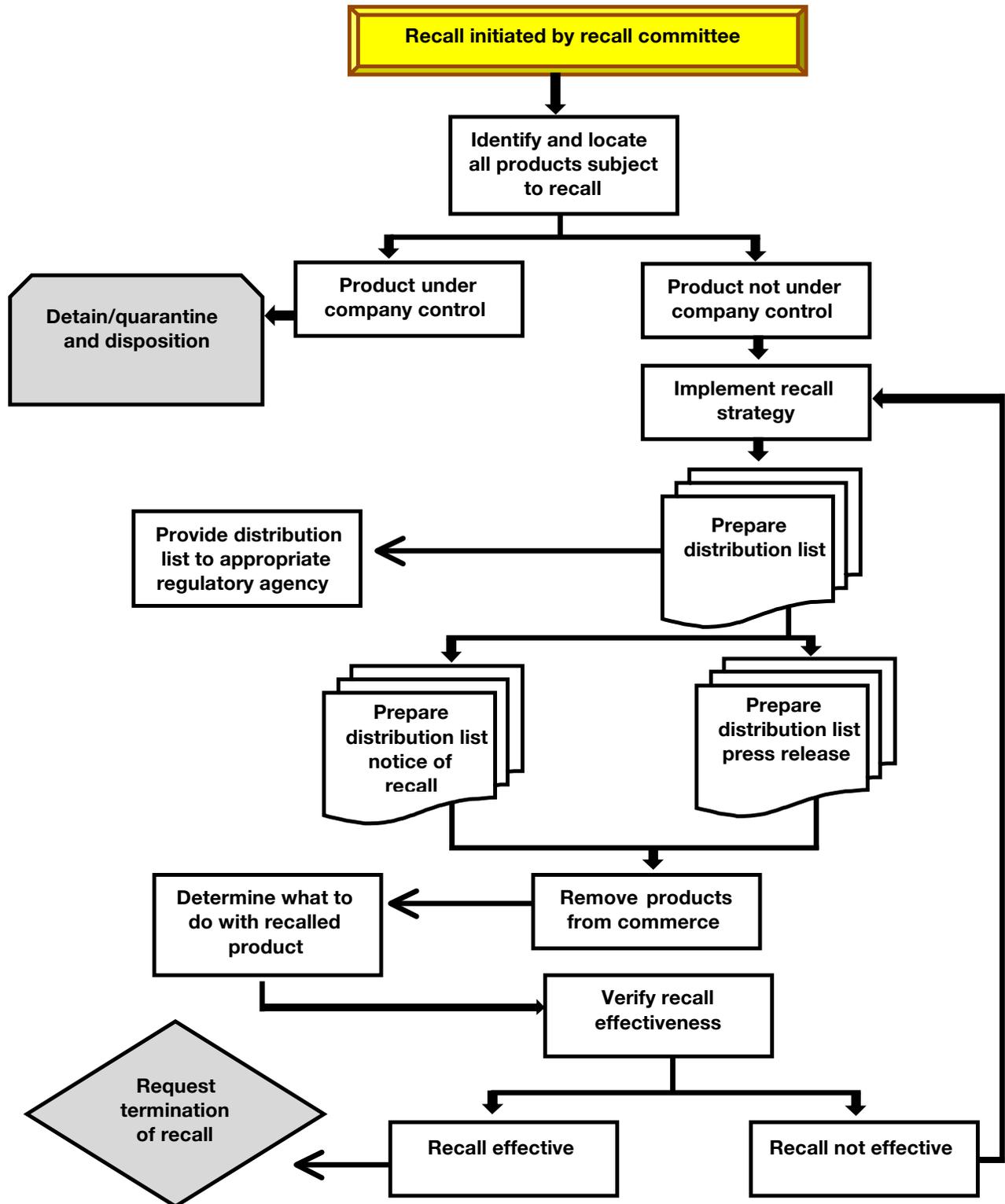
Determining Termination. A termination of the recall process may be considered after all reasonable efforts have been made to remove the affected products from commerce, including reconciliation, recall effectiveness, and disposition.

Collaborating With Regulator. A termination of the recall may be requested by submitting a written request to the regulatory authorities.

Appendix A. Recall Evaluation Flow Chart



Appendix B. Recall Evaluation Flow Chart



Appendix C. Joint Release Template

NEWS from CPSC

U.S. Consumer Product Safety Commission

Office of Communications

Washington, D.C.

FOR IMMEDIATE RELEASE
 May 1, 2017
 Release # ___ - _____

Firm's Recall Hotline: (800) 917-0213
 CPSC Recall Hotline: (800) 638-2772
 CPSC Media Contact: (301) 504-7908



_____ Recalls Stainless Steel Coffee Mug Due to Burn Hazard

WASHINGTON, D.C. - The U.S. Consumer Product Safety Commission, in cooperation with the firm named below, today announced a voluntary recall of the following consumer product. Consumers should stop using recalled products immediately unless otherwise instructed. It is illegal to resell or attempt to resell a recalled consumer product.

Name of Product: Double-wall 18/8 stainless steel mug with push-on lid; 14 oz. (Item # _____)

Units: About 1,200

Importer: _____

Manufacturer: _____

Hazard: The plastic lid of the coffee mug can come off unexpectedly, causing hot liquids to spill and posing a burn hazard.

Incidents/Injuries: The firm is aware of five incidents of sudden spilling. No injuries or property damage have been reported.

Description: The recalled product is a stainless steel coffee tumbler, with a black plastic inner liner, push-on lid and handle. The product was decorated with a company logo of _____ in red, orange, yellow, and tan ink colors. A batch code of _____ is printed on the bottom of the mug.

Sold/Distributed by: _____ as Distributor, and given away as a promotional product by _____.

Manufactured in: _____

Remedy: Consumers should immediately stop using the product and contact _____ for a replacement product.

Consumer Contact: _____ at (800) xxx-xxxx from 8 a.m. to 5 p.m. PDT, Monday through Friday, by email at recallinfo@company.com or online at www.company.com/recall and for more information.

Appendix D. Recall Notice/Poster Example

PRODUCT RECALL



The manufacturer of this bag is voluntarily recalling the basic blue backpack distributed at the _____.

This recall is being conducted in cooperation with the U.S. Consumer Product Safety Commission. The black metal zipper pull on this backpack may have failed to meet the standards set forth in the U.S. Consumer Product Safety Improvement Act of 2008 for lead in the surface coating applicable to products intended primarily for use by children 12 and under.

If you received one of these back packs, we ask you to call the distributor at _____ so that they can work with you directly to provide you with details regarding this recall, and provide you with a resolution.

Appendix E. Recall Checklist

(COMPANY) Recall Checklist

Rev. May 6, 2013, 2013

Product:	Assigned To:	Completed:	Comments:
Identify and document defect/safety issue			
Review all current and past purchase order files to determine which P.O.s are affected by the recall. An immediate inspection of all in-hand inventory units, wherever located, shall be conducted to stop or prevent production, printing or distribution of any affected products			
Determine what shipments, if any, of affected product are in production at the factory (foreign or domestic), "on the water" or are otherwise in-transit and attempt to stop production and shipment when possible. If any product is due for arrival in-port, have product stopped and held in a bonded warehouse for further determination and disposition as instructed by appropriate government regulatory body.			
Halt new/future orders			
Isolate inventory to be recalled; move product to secured quarantine area			
Determine appropriate remedy or response			
Test replacement/repair, if applicable			
Dispose units on hand and units returned under the recall; destruction must be a part of proper disposal			
Discuss all aspects with regulator's compliance staff			

Continued on next page

Client:	Assigned To:	Completed:	Comments:
Give clients notice of recall well before public announcement; contact clients that have purchased the recalled item(s)			
Give clients information to readily identify recalled products, e.g., item numbers, UPC codes, date codes, and any other critical identifying information			
Identify any in-transit shipments that may contain the recalled product; give clients information on such shipments			
Ask clients to stop sale or distribution of recalled product			
Ask clients to isolate inventory of recalled product and give them instructions on how to return and/or dispose of these products so they are not released for sale			
Provide retailers with recall posters to display in conspicuous locations; web pages of recall information to distributors			
Inform clients of remedy, e.g., recall/repair/replace/refund			
Work with clients on disposition of consumer returns, e.g. return to supplier, disposal, repair			
Ask clients to maintain accurate record of product inventory			
Ask clients to review customer records and identify likely purchasers using extended warranties, credit card customers, parts customers, catalog sales etc.			
Work with clients on how they will receive credit and/or refunds for recalled products			
Provide special "clients-only" phone number for clients' inquiries			

Continued on next page

Suppliers:	Assigned To:	Completed:	Comments:
Immediately notify all production partners of the affected product of the compliance issues			
Provide as much technical information as possible to have production partners assist in the investigation for root cause(s) for the defects/non-conformities			
Instruct production partners to cease all production of the product and shipments until further notice			
Communicate with production partners at all times during the investigatory and recall efforts and use each other as a "partner" in resolving the product problems and financial and legal issues relating to indemnity, payment (or refund) for the goods, and tracing other products that may be affected by the recall.			

Continued on next page

Customer (End-User):	Assigned To:	Completed:	Comments:
Set up toll-free number for consumers. Assure number is operational in all areas of the U.S.			
Maintain toll-free number during recall and afterwards for at least 120 days; forward calls to _____ main number after toll-free number is deactivated for recall.			
Ensure sufficient number of CSRs or operators are trained and available during business hours to handle calls			
Ensure sufficient number of phone lines			
Ensure reasonable hours of operation			
Ensure number has overload capability			
Ensure access for non-touch tone phones			
Determine need for non-English speaking operators or recorded information			
CPSC must review all scripts before implementation			
Select an automated or live operator system			
Ensure contingency plans for use of additional toll-free lines and operators in the event system is overloaded (especially during first week of public announcement)			
CPSC monitors use and responses - find out how consumer heard about recall			
Identify key company representative who can handle "special" consumer needs; all claims of injury/death, press and CPSC/governmental inquiries go to legal			

Continued on next page

Joint Press Release (all language must be worked out with CPSC compliance staff):	Assigned To:	Completed:	Comments:
Include all pertinent information in press release including the number of incidents and injuries and a description of each			
Provide a clear, unambiguous description of defects and hazards; provide toll-free number			
Describe recalled product and model number(s); include color photo or graphic of product/hazard			
Include incident information/injury information			
Describe how to obtain remedy, e.g., call manufacturer, return to retailer, etc.; include dates of production and sale			
Include _____ website address; identify where product was sold (list relevant clients or brands imprinted on product)			
Provide _____'s and CPSC's contact names and phone numbers for media inquiries			
Prepare questions and answers for media and consumer inquiries in consultation with CPSC			

Continued on next page

Website:	Assigned To:	Completed:	Comments:
Include reference to recall in prominent location on home page/first entry point			
Link to joint press release			
Include interactive registration of recalled product for remedy			
CPSC must review and approve text			
Be sure recall notice on website is operational at time of recall announcement			
Enlist all clients, as applicable, to post web page or link on their company websites too			
Maintain on-site during course of recall and thereafter			
Recall Posters:	Assigned To:	Completed:	Comments:
Make it big, bold and in color			
Include photo/graphic or picture of product hazard			
Include toll-free number/web site address			
CPSC must review and approve text			
Must be in stores before joint press release is issued			
Print on poster "display to date" (minimum 120 days) (for store clerks)			

Continued on next page

Direct mail (if applicable) (all language must be worked out with CPSC Compliance staff):	Assigned To:	Completed:	Comments:
Identify customers who have product in advance of public notice and mail them notice of recall			
Include all pertinent information related to recall			
Include picture from poster, press release, website			
Include as heading on notice and on outside of envelope "Important Safety Message" or "Safety Recall" (in red)			
Include toll-free number and website address			
Notify consumers through email			
Give consumers ability to obtain remedy through email notification			
Provide authorization for return shipping where applicable.			

Key Points to Remember

- Continuous market surveillance of risky consumer products will help prevent potential issues with consumer products in the future
- Remedy should be easy for consumer so as to encourage correction
- Submit timely monthly progress reports on the number of products corrected and notification measures implemented to CPSC and continually review for additional actions
- Support CPSC publicity efforts
- Be responsive to individual customer needs
- Designate a key company official to take care of special needs
- Stay on message (with language agreed to in joint press release)
- Consult frequently with CPSC Compliance staff working with you on the recall to avoid problems
- BE CREATIVE and ORIGINAL in an effort to reach as many consumer and other owners of the recalled product.

P R O D U C T[™]
R E S P O N S I B I L I T Y
 POWERED BY **PPAI**