

See the <u>Regulated Handbook</u> or <u>Regulatory Robot</u> for guidance on specific regulations.

This handbook was prepared by the CPSC staff, and has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

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Foreword

The U.S. Consumer Product Safety Commission's (CPSC's) Office of Compliance and Field Operations prepared this Recall Handbook to help you understand your obligations and responsibilities under the Consumer Product Safety Act (<u>CPSA</u>) and other statutes administered by the CPSC. The guidance in this Handbook applies to anyone who manufactures, imports, distributes, or retails consumer products.

No one likes to conduct a recall, but when a safety problem makes a product recall necessary to prevent injuries and save lives, it benefits everyone to move quickly and effectively.

CPSC constantly strives to improve not only the timeliness of recalls, but also the effectiveness of the recall programs we negotiate. The <u>Fast-Track Product Recall Program ("Fast-Track"</u>) is designed especially for companies that are willing and able to move quickly with a voluntary recall. Fast-Track, described in detail in Section V of this Handbook, is intended to expedite the recall process by eliminating some of the steps in the traditional recall process, including a preliminary substantial product hazard determination.

If you are seeking information on a specific product regulation, you should begin with the CPSC's <u>Regulatory Robot</u>. You can also consult our Business Education pages on the CPSC <u>website</u>; or, if you are a small business, you can contact our Small Business Ombudsman's Office. Visit the SBO's <u>Contact Us</u> page, or call toll-free at: (888) 531-9070. If you are seeking guidance on how to address a regulatory violation, refer to the CPSC's <u>Regulated Products Handbook</u>.

CPSC's Office of Compliance and Field Operations Compliance@cpsc.gov

Note: This handbook does not replace the agency's authorizing statutes or interpretative regulations set out in 16 CFR parts 1115, 1116, and 1117. If there is any discrepancy, the statutes and regulations supersede this Handbook. This material is available on the CPSC's website at: <u>http://www.cpsc.gov</u>.

Background

The CPSC is an independent regulatory agency responsible for protecting the public from unreasonable risks of injury and death associated with consumer products. Established by Congress in the Consumer Product Safety Act (<u>CPSA</u>), 15 U.S.C. §§ 2051-2089, the CPSC has jurisdiction over approximately 15,000 different types of consumer products used in and around the home, in schools, in recreation, and otherwise.¹

This Recall Handbook provides information on the obligations and responsibilities applicable to anyone who manufactures, imports, distributes, retails, or otherwise sells consumer products. The Handbook has three purposes: (1) to explain the reporting requirements under sections 15(b) and 37 of the CPSA, 15 U.S.C. § 2064(b) and § 2084, and Section 102 of the Child Safety Protection Act, Pub. L. No. 103-267, 108 Stat. 722, 6/16/94; (2) to educate stakeholders about how to recognize potentially hazardous consumer products at an early stage; and (3) to assist firms in developing and implementing corrective action plans. The term "corrective action plan" (CAP) generally includes any type of remedial action taken by a company. A CAP, for example, could provide for the return of a product to the manufacturer

¹ The CPSC does not have jurisdiction over foods, drugs, cosmetics, medical devices, firearms and ammunition, boats, motor vehicles, aircraft, or tobacco. Specific questions about the agency's jurisdiction over particular products should be directed to CPSC's Office of the General Counsel.

or retailer for a cash refund or a replacement product; for the repair of a product; and/or for public notice of the hazard. A CAP may include multiple measures that are necessary to protect consumers. When a corrective action requires public announcement and a remedy offered to affected consumers, it is referred to as a "recall."

This Handbook is not an all-inclusive reference source for developing a CAP. The goal of a CAP should be to remove or correct as many hazardous products as possible from the distribution chain and consumers and to do so in the most efficient manner. Reaching this goal often requires creative planning and technology. Companies developing specific CAPs to address unsafe or potentially unsafe products should work closely with CPSC to take advantage of staff's expertise in designing and carrying out such plans. This results in greater protection for consumers against injury or death to consumers, and a more efficient and productive process for companies.

Plan Ahead: Compliance Programs and Designating Responsibility for Product Safety Issues

The first moments after a company becomes aware of a potential product safety issue are critical. However, it is essential to have a plan in place *beforehand*, a plan that details actions to take after obtaining information that a consumer product is noncompliant, contains a defect, or poses an unreasonable risk of serious injury or death.

Part of that plan should include a compliance program establishing policies and procedures for identifying and responding to consumer product safety issues as they arise. CPSC recommends that firms develop and implement a compliance program because a compliance program will help the firm to be prepared if a product recall, or similar action, becomes necessary. A comprehensive compliance program should focus on the prevention of product safety problems and stress early detection, in addition to prompt reporting.

A. Establish a Compliance Program

A compliance program will help a firm protect consumers from potential hazards through various prevention and mitigation efforts. A compliance program should begin at the design and manufacturing stage and carry through to a recall, establishing, and ensuring implementation of policies and procedures that address prevention, investigation and reporting procedures, crisis management, mock recalls, and standard reverse logistics protocols during product recalls.

A company with a comprehensive and proactive compliance program is best equipped to prevent product safety issues and is better prepared to handle those issues, if and when they arise.

For details see Appendix A: "Developing a Compliance Program."

B. Designate Personnel Responsible for Product Safety Issues

Designating a company official/employee or team responsible for product safety is essential for a firm to ensure product safety and meet statutory reporting requirements. Ideally, this individual (or team) would have full authority to take the steps necessary (including reporting to the CPSC) to initiate and implement all recalls, with the approval and support of the company's chief executive officer, or other appropriate senior management official.

The individual or team responsible should have knowledge of the CPSC statutes, regulations, and guidance for reporting and implementing CAPs, and should be delegated the following authorities and responsibilities:

- Authority to function as the central coordinator for receiving and processing all information regarding the safety of the company's products. Such information includes, but is not limited to: quality control records, engineering analyses, test results, consumer complaints, warranty returns or claims, lawsuits, and insurance claims.
- Responsibility for fully reviewing the company's product line to determine how each product will perform or fail under conditions of proper use and reasonably foreseeable misuse or abuse.
- Authority to involve appropriate staff and functional areas of the firm, and external resources, as appropriate, to implement a product recall, designate another to serve as the sole primary liaison with CPSC, and to designate a single person as the "Recall Coordinator,"² if a recall is warranted;
- Responsibility for making decisions to report and initiate a product recall, and for designating a central point of contact (*e.g.,* <u>recalls@xyzstores.com</u>) for communications to and from manufacturers, importers, and distributors, which is updated regularly. An identified point person can ensure that important notices are sent to the correct department or person; and
- Accountability to the company's chief executive officer, or other appropriate senior official, with the
 responsibility to keep the CEO informed about reporting requirements and potential safety concerns that could
 lead to product recalls.

Through research and analysis, product safety engineers can identify the safety features that could be incorporated into products that present safety risks, to reduce the product's potential to cause injury.

C. Create a Product Identification System

Part of effective planning for a potential corrective action in the future includes the creation of a product identification system. Model designations and date-of-manufacture codes should be used on all products, whether they carry the company's name or brand, or are privately labeled for other companies. Manufacturer designations also should be on all products, if there are multiple manufacturers of the same model. If a product recall is necessary, this practice allows the company to identify easily all affected products, without undertaking a costly recall of the entire line. Similarly, once a specific product has been recalled and corrected, a new model number, or other means of identification used on new and/or corrected products, allows distributors, retailers, and consumers to distinguish products subject to the recall from the new items. Until a production change can be made to incorporate a new model number or date code, some companies have used labels or bar codes to differentiate products that have been inspected and corrected from recalled products.

² If a CAP includes a recall, designating a Recall Coordinator is essential to effective implementation. The company's Recall Coordinator should be responsible for: (1) Working directly with CPSC to gain approval of all aspects of the proposed CAP, including notices; (2) Keeping the firm's senior management informed about pending product recalls; (3) Involving the appropriate internal and external staff and resources to implement a product recall; and (4) Submitting monthly progress reports to CPSC after the recall announcement.

I. Reporting Requirements.

A. Section 15 Reports

Section 15(b) of the CPSA establishes reporting requirements for manufacturers, importers, distributors, and retailers of consumer products distributed in commerce over which the agency has jurisdiction.

In enacting Section 15(b), Congress intended to encourage widespread reporting of timely, accurate, and complete information that is necessary to protect public health and safety. In addition to assisting the CPSC in uncovering substantial product hazards, reporting helps to identify risks of injury that could be addressed through voluntary or mandatory standards or information and education. It is important to recognize that a reporting obligation arises even if a firm cannot identify a defect and/or root cause; if the information reasonably supports the conclusion that a product could create an unreasonable risk of serious injury or death, a company must report.

Although CPSC uses sources other than Section 15 reports to identify potentially hazardous products, reporting by companies under Section 15 can provide the most timely and effective source of information about such products. This is because companies often learn of potential product safety problems at an early stage. Accordingly, companies involved in the manufacture, importation, distribution, or sale of consumer products should develop a system for maintaining and reviewing information about their products that might suggest that their 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.

Reporting a product to the CPSC under Section 15 does not automatically mean that the agency will conclude that the product creates a substantial product hazard or determine that corrective action is necessary. CPSC staff will evaluate the report and work with the reporting company to determine whether corrective action is necessary. Many of the reports received require no corrective action because staff concludes that the reported product defect does not create a substantial product hazard.

1. What to Report

Manufacturers, importers, distributors, and retailers must notify the CPSC immediately if they obtain information that reasonably supports the conclusion that a product distributed in commerce: (1) fails to comply with an applicable consumer product safety rule or with a voluntary consumer product safety standard upon which the Commission has relied under Section 9³; (2) fails to comply with any other rule, regulation, standard or ban under the <u>CPSA</u> or any other Act enforced by the Commission, including the <u>Flammable Fabrics Act</u>, 15 U.S.C. § 1193-1204; the <u>Federal Hazardous Substances Act</u>, 15 U.S.C. § 1261-1278; the <u>Children's Gasoline Burn Prevention Act</u>, 110 Pub. Law No. 278 (July 17, 2008); the <u>Virginia Graeme Baker Pool and Spa Safety Act</u>, 110 Pub. Law No. 140 (with amendments); the <u>Poison Prevention Packaging Act</u>, 15 U.S.C. § 1471-1476; the <u>Refrigerator Safety Act</u>, 15 U.S.C. § 1211-1214; the <u>Drywall Safety Act of 2012</u>; the <u>Child Nicotine Poisoning Prevention Act of 2015</u>; (3) contains a defect which could create a substantial product hazard; or (4) creates an unreasonable risk of serious injury or death. The Commission has issued an interpretive regulation at <u>16 CFR § 1115</u> that explains the reporting obligations. A more detailed discussion of what constitutes a defect or unreasonable risk for purposes of section 15 is contained in <u>section II</u>, (page 11).

³ As of January 2018, there were two such standards that would require reporting if failure of the voluntary standard occurred—the voluntary standard for chain saws (ANSI B175.1), and the voluntary standard for unvented gas space heaters (ANSI Z21.11.2); See <u>Appendix to § 1115</u> for more information.

Although reporting companies should be prepared to provide the information described below, a report should not be delayed because some of this information is not yet available. The following information should be transmitted as a written initial report, <u>16 CFR § 1115.13(c)</u>:

- Identification and description of the product;
- Name and address of the manufacturer and/or importer of the product, if known. If not known, the names and addresses of all known distributors and retailers of the product;
- Nature and extent of the possible defect, the failure to comply, or the risk;
- Nature and extent of injury or risk of injury associated with the product;
- Name and address of the person informing the Commission;
- If reasonably available, the other information specified in <u>16 CFR § 1115.13(d)</u> of the Commission's regulations; and
- A timetable for providing information not immediately available.

Retailers and distributors can satisfy their initial reporting obligations by reporting the information described above to the Office of Compliance and Field Operations through the <u>Section 15 mailbox</u>.⁴ Alternatively, a retailer or distributor can send a written communication to the manufacturer or importer of a product, describing the failure to comply with an applicable regulation, a potential defect, or the risk of injury or death associated with the product; but they must also provide a copy of that communication to the Office of Compliance and Field Operations. A distributor or retailer may also satisfy a reporting obligation by forwarding reportable information received from another company to the Office of Compliance and Field Operations. Section 15(b) requires that a manufacturer, retailer, or distributor must immediately inform the CPSC of a failure to comply, a defect, or risk because, for example, the manufacturer provided the retailer of distributor a copy of the full report filed with staff. The Commission is "adequately informed" if staff has received the information requested under <u>16 CFR §1115.12</u> and/or <u>§1115.13</u>, or if the staff has informed the company that staff is adequately informed.

CPSC staff may request additional information to ensure appropriate data are available to determine the level of hazard. In addition to the standard report elements in <u>16 CFR § 1115.13(d)</u>, staff may request additional information including, but not limited to:

- Underlying documentation on related reported incidents, complaints, and warranty claims;
- The countries, other than the United States, to which the company distributed the products;
- Premarket and post-market test reports;
- Marketing, advertising, and promotional documents;
- Technical documentation on product design and manufacture, including change orders;
- UPC codes for all models involved;
- Incident and exemplar samples of the product;
- Documentation regarding any deaths reported involving this product, regardless of defect or hazard;
- Information on the foreign manufacturer or component manufacturer; and
- Other relevant information to assess the hazard.

2. When to Report

⁴ Retailers and distributors must include all information required by a Section 15 report "insofar as it is known to the retailer or distributor."16 CFR §1115.13(b).

Section 15 requires companies to report "immediately." This means that a company must notify the CPSC within 24 hours of obtaining information described in section A.1 ("What to Report"). Guidelines for determining whether a product defect exists, whether a product creates an unreasonable risk of serious injury or death, and whether a report is necessary or appropriate, are provided in <u>16 CFR § 1115.4-15</u>.

Companies frequently contact staff for input to determine if their situation creates a Section 15 reporting requirement. Compliance staff's consistent response is: "When in doubt, report."

A company must report to the CPSC within 24 hours of obtaining reportable information. The CPSC encourages companies to report potential substantial product hazards, even while their own investigations are continuing. However, if a company is uncertain about whether information is reportable, the company can take a reasonable time to investigate the matter. That investigation should not exceed 10 working days, unless the company can demonstrate that a longer time is reasonable under the circumstances. Absent such circumstances, the CPSC will presume that, at the end of 10 working days, the company has received and considered all information that would have been available to it, had a reasonable, expeditious, and diligent investigation been undertaken.

The CPSC considers a company to have obtained knowledge of product safety-related information when that information is received by an employee or official of the company, who may reasonably be expected to appreciate the significance of that information. Once that occurs, under ordinary circumstances, 5 working days is the maximum reasonable time for that information to reach the chief executive officer, or the official assigned responsibility for complying with the reporting requirements. If a firm has information that noncompliance or a defect in a consumer product caused, may have caused, contributed to, or could contribute to, a death or grievous bodily injury, the firm must report, unless it has investigated and determined that the information is not reportable. <u>16 CFR §1115.12(d)</u>.

The CPSC evaluates whether a company complied with its statutory obligation to report a defect, unreasonable risk, or violation to the Commission. The CPSC can assess civil penalties against a firm for its knowing failure to file a timely report (a "timeliness case"), or for the commission of other prohibited acts set out in Section 19 of the CPSA and other Acts administered by the Commission. If a violation is not only knowing, but also willful, criminal penalties can result.⁵ An evaluation of a timeliness case will be based, in part, on what the company actually knew about the hazard posed by the product, or what a reasonable person, acting under the circumstances, should have known about the hazard while exercising due care, including knowledge obtainable upon the exercise of due care to ascertain the truth of representations. Thus, a company is deemed to know what it would have known had it exercised due care in analyzing reports of injury or consumer complaints, or in evaluating warranty returns, reports of experts, in-house engineering analyses, or any other information.

3. Where to Report

A company should file its Section 15 report with the CPSC's Office of Compliance and Field Operations. The report should be filed electronically through the agency's website (<u>SaferProducts.gov</u>). Alternatively, a company can file its report electronically by email (<u>Section15@cpsc.gov</u>), and include "Section 15" in the subject line. A company should assign the responsibility of reporting to someone with knowledge of the product and knowledge of the reporting requirements of Section 15. The designated individual should have the authority to report to CPSC or raise the issue quickly with an authorized Firm representative.

⁵ See CPSA Section 20-21 (15 USC § 2069-2070), Federal Hazardous Substances Act Section 5 (15 USC § 1264), Flammable Fabrics Act Section 7 (15 USC § 1196), and <u>16 CFR § 1115.22</u>.

3. Confidentiality of Reports

The CPSC often receives requests from the public for information reported under Section 15(b). Section 6(b)(5) of the CPSA, <u>15 U.S.C. § 2055(b)(5)</u>, prohibits the release of such information, unless one of the following circumstances exist: a remedial action plan has been accepted in writing; a complaint has been issued; the reporting company consents to the release; or the Commission publishes a finding that public health and safety require public disclosure with less than 15 days' notice. There are additional considerations that may permit the release of information regarding a product that violates of a mandatory standard.

In addition, a company may claim that information it has submitted is a trade secret or confidential commercial or financial information. To do so, at the time the company submits the information, the company should mark the information "confidential," in accordance with Section 6(a)(3) of the CPSA, <u>15 U.S.C. § 2055(a)(3)</u>.

If the CPSC receives a FOIA request for information submitted by a firm pursuant to Section 15(b), the CPSC's Freedom of Information Office will give the company an additional opportunity to claim that the information should not be disclosed to the public because it contains confidential information. In cases where the Section 6(b)(5) prohibition against release does not apply, and the information may therefore be released, CPSC staff will not treat information as exempt from disclosure to the public under Section 6(a) of the CPSA, 15 U.S.C. § 2055(a), and the Freedom of Information Act, absent a specific claim for confidential treatment.

B. Section 37 Reports

<u>Section 37</u> of the CPSA requires manufacturers of consumer products to report information about settled or adjudicated civil actions.⁶ Within 30 days of the third final settlement or court judgment, manufacturers must report if:

- a particular model of the product is the subject of at least three civil actions filed in federal or state court;
- each lawsuit alleges the involvement of that particular model in a death or in grievous bodily injury—mutilation
 or disfigurement, dismemberment or amputation, the loss of important bodily functions or debilitating internal
 disorder, injuries likely to require extended hospitalization, severe burns, severe electric shock, or other injuries
 of similar severity;
- during one of the 2-year periods specified in the law⁷, each of the three actions results in either a final settlement involving the manufacturer or in a court judgment in favor of the plaintiff:

January 1, 2019 – December 31, 2020, January 1, 2021 – December 31, 2022, January 1, 2023 – December 31, 2024, January 1, 2025 – December 31, 2026, and continuing for each 2-year period; and

⁶ The Commission has issued a rule at <u>16 CFR § 1116</u>, interpreting the requirements of Section 37. The Commission recommends that manufacturers considering whether they have Section 37 reporting obligations refer to that rule and the applicable regulations cited here.

⁷ The periods of time run from January 1 of year 1 to December 31 of the following year (year 2). The list set forth above is illustrative of periods going forward, and does not include prior 2-year periods for which reporting obligations apply.

• The manufacturer is a party to, or is involved in the defense of, or has notice of, each action, before entry of the final order, and is involved in discharging any obligation owed to the plaintiff as a result of the settlement or judgment.

1. What to Report

A report under Section 37 must contain:

- The name and address of the manufacturer of the product.
- The model and model number or designation of the product.
- A statement as to whether the civil action alleged death or grievous bodily injury; and in the case of the latter, the nature of the injury. For reporting purposes, the plaintiff's allegations about the nature of the injury are sufficient to require a report, even if the manufacturer disagrees with the allegations.
- A statement about whether the civil action resulted in a final settlement or a judgment in favor of the plaintiff. However, a manufacturer need not provide the amount of a settlement.
- In the case of a judgment in favor of the plaintiff, the name and number of the civil action, and the court in which it was filed.

A manufacturer can also provide additional information, if it chooses. Such information might include a statement about whether the manufacturer intends to appeal an adverse judgment, a specific denial that the information it submits reasonably supports the conclusion that its product caused death or grievous bodily injury, and an explanation regarding why the manufacturer has not previously reported under Section 15.

2. When and Where to Report

A manufacturer must report within 30 days after a judgment or final settlement in the last of the three civil actions. The same is true of any additional lawsuits involving the same model that are settled or adjudicated in favor of the plaintiff during the same 2-year period.

Companies can file Section 37 reports electronically, by emailing them to: <u>Section37@cpsc.gov</u>, and should include "Section 37" in the subject line.

3. Confidentiality of Reports

Under section 6(e) of the CPSA, the CPSC and its employees may not publicly disclose information reported under Section 37, except that such information may be furnished to the reporting manufacturer, or Congress, under certain circumstances. By law, reporting under Section 37 is not an admission of the existence of an unreasonable risk of injury, a defect, a substantial product hazard, an imminent hazard, or any other liability under any statute or common law. Information voluntarily provided that is in addition to information required to be reported under Section 37 is governed by the confidentiality provisions regarding Section 15 reports (see above section A.3).

C. Section 102 Reports

Section 102 of the <u>Child Safety Protection Act</u> requires that companies report certain choking incidents to the CPSC. Each manufacturer, distributor, retailer, and importer of a marble, a ball with a diameter of 1.75" or less ("small ball"), latex balloon or other small part, or a toy or game that contains such a marble, ball, balloon, or other small part, must report information that reasonably supports the conclusion that:

1) a child (regardless of age) choked on such a marble, small ball, balloon, or small part; and

2) due to the incident, the child died, suffered serious injury, ceased breathing for any length of time, or was treated by a medical professional.

1. What to Report

The company should report the name and address of the child who choked, and the person who notified the company of the incident; detailed identification of the product; a description of the incident and any resulting injuries or medical treatment; information about any changes made to the product involved, or changes to its labeling or warnings to address the risk of choking; and the details of any public notice, or other planned corrective action. Refer to <u>16 CFR §</u> <u>1117</u> for more detailed information about this reporting requirement.

2. When and Where to Report

Section 102 reports must be filed within 24 hours of obtaining the information.

A company must file a Section 102 report with the Office of Compliance and Field Operations electronically by email to: <u>Section102@cpsc.gov</u> and include "Section 102" in the subject line.

3. Confidentiality of Reports

Section 102 reports receive the same confidentiality treatment as information submitted under Section 15 of the CPSA (see section A.3).

II. Identifying a Defect⁸

The Commission's reporting requirements provide information that assists the CPSC in evaluating whether some form of remedial action is appropriate. However, in the absence of a regulation that addresses a specific risk of injury, the product in question must create a substantial product hazard. That is, the product must contain a defect which creates a substantial risk of injury to the public to warrant remedial action. Next, the Handbook discusses the considerations for determining whether a product defect exists and, if so, whether the risk presented by that defect presents a substantial risk of injury.

A defect could result from:

- a manufacturing or production error;
- the design of, or the materials used in, the product
- a product's contents, construction, finish; or
- a product's, packaging, warnings, and/or instructions.⁹

In addition to these factors, we will also consider whether the risk of injury associated with a product is the type of risk which will render the product defective. To make that determination, CPSC staff considers the following factors, as appropriate, and as referenced in <u>16 CFR § 1115.4</u>:

- 1) The utility of the product.
- 2) The nature of the risk of injury that the product presents.
- 3) The necessity of the product.
- 4) The population exposed to the product, and its risk of injury.

⁸ The reporting requirement in the CPSA requires a firm notify staff, if the information reasonably supports the conclusion that a product contains a defect that could create a substantial product hazard **or** creates an unreasonable risk of serious injury or death. CPSA Section 15(b). (Emphasis added).

⁹ See <u>16 CFR § 1115.4.</u>

- 5) The obviousness of such risk
- 6) The adequacy of warnings and instructions to mitigate the risk
- 7) The role of consumer misuse of the product, and the foreseeability of such misuse
- 8) The Commission's experience and expertise
- 9) The case law interpreting federal and state public health and safety statutes
- 10) The case law in the area of products liability
- 11) Other information relevant to the determination.

We note, however, that not all products that present a risk of injury are defective. A typical kitchen knife is one example. A knife blade must be sharp for a consumer to cut or slice food. The knife's sharpness is not always a product defect, even though some consumers may cut themselves while using the knife. On the other hand, if the handle or blade of a particular knife is prone to breaking that may constitute a defect.

Because a product may be defective even when it is designed, manufactured, and marketed exactly as intended, a company in doubt about whether a defect exists should still report. However, even If the information available to a company does not reasonably support the conclusion that a defect exists, a company must still report if it has information indicating that the product creates an unreasonable risk of serious injury or death. See <u>15 U.S.C. §2064(b)(4)</u> and <u>16 CFR § 1115.6.</u> Note that a product may be found to be defective even if it complies with a voluntary or mandatory standard. <u>16 CFR § 1115.8</u>.

Appendix B of this Handbook depicts the processing flow of a standard defect investigation and the Fast-Track Program.

III. Evaluating Substantial Risk of Injury

When a company reports to the CPSC, the Office of Compliance and Field Operations will evaluate whether the product presents a substantial product hazard by considering whether the product contains a defect and whether any alleged defect creates a substantial risk of injury to the public. If staff concludes that the product in question creates a substantial product hazard, staff applies hazard priority standards to classify the severity of the problem.

Section 15(a)(2)¹⁰ lists criteria for determining when a product defect creates a substantial risk of injury. Any one of the following factors could indicate the existence of a substantial risk of injury:

- **Pattern of defect.** The defect may stem from the design, composition, content, construction, finish, or packaging of a product, or from warnings and/or instructions accompanying the product. The conditions under which the defect manifests must also be considered in determining whether the pattern creates a substantial risk of injury.
- Number of defective products distributed in commerce. A single defective product could be the basis for a substantial product hazard determination if an injury is likely or could be serious. By contrast, defective products posing no risk of serious injury, and having little chance of causing even minor injury, ordinarily would not be considered to present a substantial risk of injury. The number of products remaining with consumers is also a relevant consideration.

¹⁰ <u>15 U.S.C. §2064(a)(2)</u>.

• Severity of risk. A risk is considered severe if the injuries that have occurred, or that could occur, are serious or likely to occur. ¹¹ The definition of a serious injury is set forth in 16 CFR 1115.5(c) and includes grievous bodily injuries or injuries requiring hospitalization, medical treatment, or missing work or school for more than one day. The likelihood of an injury is determined by considering the number of injuries that have occurred, or that could occur, the intended or reasonably foreseeable use or misuse of the product, and the population or group (e.g., children, the elderly, or the disabled) exposed to the product.

A substantial product hazard also exists when failure to comply with an applicable consumer product safety rule creates a substantial risk of injury to the public.

IV. Hazard Classifications

The hazard priority system allows CPSC staff to rank defective products uniformly. If staff makes a preliminary determination¹² that a product creates a substantial product hazard, the hazard priority system also provides guidance on determining the appropriate corrective action.

Class A Hazards

A Class A hazard exists when a risk of death or grievous injury or illness is likely or very likely, or serious injury or illness is very likely.

Class A hazards warrant the highest level of attention. A company should take immediate, comprehensive, and expansive corrective action measures to identify and notify consumers, retailers, and distributors who have the defective product. In addition, the company must act expeditiously to remedy the defect through repair or replacement of the product, refunds, or other measures. A Class A hazard may require additional actions by the company to notify the public; and the associated corrective action plan requires approval by the Commission. In addition, CAPs for products associated with a death, even if unrelated, also require Commission approval.

Class B Hazards

A Class B hazard exists when a risk of death or grievous injury or illness is not likely to occur, but is possible, or when serious injury or illness is likely, or moderate injury or illness is very likely.

Class C Hazards

A Class C hazard exists when a risk of serious injury or illness is not likely, but is possible, or when moderate injury or illness is not necessarily likely, but is possible.

Regardless of whether a product defect is classified as a Class A, B, or C priority hazard, the common element is that each of these defects creates a substantial product hazard that requires corrective action to reduce that risk of injury.

¹¹ Generally, a product could create a substantial hazard when consumers are exposed to a significant number of units, or if the possible injury is serious or is likely to occur. Because a company may not know the extent of public exposure, or appreciate the likelihood or severity of potential injury when a product defect first comes to its attention, it should report to the CPSC, even if it is in doubt about whether a substantial product hazard exists.

¹² The decision is preliminary because only the Commission, after a hearing, can make a formal determination that a product is defective and creates a substantial product hazard.

The priority given to a specific product defect provides a guideline for determining the best way to communicate with owners and users of the defective product and to get them to respond appropriately. Although some companies have exemplary track records in communicating with consumers independently, it is still to a company's advantage to work with CPSC staff, using both the company's and CPSC's skills and resources to conduct an effective product recall.

V. Fast-Track Product Recall Program (No Preliminary Determination of Hazard)

A company that files a Section 15(b) report may wish to make use of an alternative procedure the Commission has established to expedite recalls.¹³ The program is called the "<u>Fast-Track Product Recall Program</u>." If a company reports a potential product defect, and otherwise meets requirements for timely recall of the product, staff will not make a preliminary determination (PD) that the product creates a substantial product hazard.

The Fast-Track Program allows staff and the company to work together on a CAP immediately, rather than spend the time and other resources necessary to investigate the reported defect to determine whether it rises to the level of a substantial product hazard.

To participate in this program, companies must:

- Stop sale¹⁴ of the product immediately;
- Request to participate in the program;
- Agree to publicly announce the recall;
- Provide all of the information required for a Full Report (<u>16 CFR § 1115.13(d)</u>); and
- Submit a proposed CAP that adequately addresses the reported issue, with sufficient time for CPSC staff to analyze any proposed repair, replacement, or refund offer and evaluate all notice material before the implementation (announcement) of the CAP.

Companies that are unable to move quickly may be removed from the program at the discretion of CPSC Compliance staff.

Appendix B of this Handbook depicts the processing flow of a standard substantial product hazard investigation and the Fast-Track Program.

¹³ This program is described in more detail in the *Federal Register* of July 24, 1997, 62 Fed. Reg. 39,827-39,828. http://www.gpo.gov/fdsys/pkg/FR-1997-07-24/pdf/97-19554.pdf.

¹⁴ Term "stop sale" is intended to convey a message sent throughout the distribution chain (all distributors <u>and</u> retailers), instructing them to stop sale and quarantine products for a pending safety action.

VI. Corrective Action Plans (CAPs)

An effective CAP will mitigate the hazard to consumers and correct or prevent the problem in any future production or similar product. A common component of a CAP is a recall. A recall is the component of a CAP that provides for public notice and a remedy for consumers. Other components of a CAP might include any actions taken to mitigate the potential hazard, as well as changes to design, manufacturing, materials, quality control, warnings, marketing, discontinuing the product, and other actions.

Note: Any product that is associated with a death requires Commission approval of the CAP.

A. Preparing for a CAP

Rarely will any two recall programs be identical. Therefore, companies should be prepared to address issues that invariably arise, such as:

Product, Defect, Scope, and Remedy:

- Consider the defect or failure to comply that causes the product hazard.
- Consider what caused the product defect or failure to comply to occur in the first place.
- Identify the location of the potentially unsafe products, and determine how many are at each level of distribution.
- Notify appropriate regulatory bodies (including CPSC), about the defect or potential safety issue.
- Discontinue production and shipment of the products.
- Review and improve quality control or risk analysis procedures to prevent a similar occurrence in the future.

Company Readiness for a CAP:

- Notify retailers to stop selling the product, and ask them to help identify consumers who own the product.
- Review existing databases to identify potential product owners, *e.g.*, product registration and customer service records.
- Determine the cost to deploy manpower and/or fund an effort to provide replacement parts for defective products, or to exchange them for new products that do not have the problem.
- Develop a plan to ship replacement parts or new units to distributors participating in the product recall or otherwise repair units in their inventory.
- Develop a plan to quarantine and correct returned products. Consider how the product will be reworked, broken down for reclamation of critical components, or destroyed. Develop and implement procedures to ensure proper control and tracking of all defective materials returned in the recall and to ensure they do not reenter the stream of commerce.
- Prepare to monitor the product recall, and provide timely progress reports to the CPSC.

Public Notice:

- Companies should prepare, for CPSC approval, a comprehensive communications plan, including a media plan utilizing direct notice, for communicating the recall. Additional detail on the elements of this comprehensive plan are provided in the following pages. A satisfactory plan will include:
 - A draft news release for CPSC review that announces the recall.

- A plan for other forms of public notice, including social and digital media. This plan will include, for example, outlets such as: news media, paid advertising, mobile notification, and outreach to affinity groups.
- Modifications of the company's website to aid in communicating the recall.
- Drafts of other notice documents, as appropriate, to reach all relevant consumers (*e.g.*, in-store notification/retail poster, print, radio, email, social media, other digital recall marketing).
- Arrange for a toll-free telephone hotline to be used for the recall. Plan for the hotline to handle the number of calls expected after the recall announcement.

The CPSC strongly recommends *a change in model number and UPC* for any new production or repaired products distributed in commerce following a product recall.

See our online guides: <u>Recall Planning</u>, <u>Recall Checklist</u>, and <u>Guidelines for Retailers and Logistics Providers</u> for more information.

B. Elements of a Recall

A company that undertakes a recall should develop a comprehensive plan that reaches the entire distribution chain and consumers who have the product. The company must design each communication to reach affected parties and consumers, motivate people to respond to the recall, and take the action requested by the company. The company should submit this communication plan (described above under Public Notice) to CPSC staff for approval as part of the CAP. CPSC staff is available to provide additional guidance throughout this process.

Once CPSC staff and a company agree on a remedy to correct a product defect, staff works with the company to finetune an effective plan for public notification and implementation of the recall. The information that should be included in a signed CAP is set forth at: <u>16 CFR § 1115.20(a)</u>.

The objectives of a recall are:

- 1) To prevent injury or death from defective or violative products;
- 2) To locate all such products as quickly as possible;
- 3) To remove such products from the distribution chain and from the possession of consumers; and
- 4) To communicate to the public in a timely manner accurate and understandable information about the product defect or violation, the hazard, and the corrective action. Companies should design all informational materials to motivate retailers and the media to get the word out and to spur consumers to act on the recall.

In determining what forms of notice to use, the company should consider how the product was marketed, its user population, the estimated useful life of the product, and how the product is most likely to be maintained and repaired. For targeted notice campaigns, it is most effective to use the same platforms and market segmentation as the company used during sales efforts to announce the recall.

CPSC will consider the level of hazard presented by the recalled product when reviewing the proposed CAP, and may request additional or different actions, if appropriate.

Recall outreach should be comprehensive to get the word out to as many consumers as possible. The outreach often will include a variety of elements, such as emails, letters, advertisements, social media, and other technological means.

See our online list of <u>Recall Notification Types</u> for more information.

Communication with Distributors and Retailers

A company conducting a recall must take particular care to coordinate the notice portion of the recall to ensure that all participating parties, including traditional and online retailers, have sufficient advance notice to be able to carry out the agreed-upon actions. In the recalling company's stop-sale notice to retailers, it should include the reason for the stop-sale, the potential hazard, an estimated date for follow-up correspondence or recall announcement, and any information necessary to identify the product, <u>including the product's UPC(s)</u>.

VII. Communicating Recall Information

Communication is a key element of a recall. The goal of recall communications, in almost every instance, is to both warn

consumers of a hazard and encourage them to take action to reduce the risk. Because consumers are flooded with messages about products all the time, recall communications are particularly important. Messages must be noticeable enough to break through the clutter, and recognizable enough that consumers know to pay attention and respond effectively. To help companies strike this important balance and to ensure some standardization for consumers' ease-of-understanding, CPSC has developed best practices and expectations for how companies engaged in a recall should notify consumers.

The CPSC strongly encourages companies to use all available communication channels to reach consumers, retailers, and distributors of recalled products and motivate them to respond. As new or innovative methods of notice and means of communication become available, CPSC staff encourages using these methods as well. As discussed above (A. Preparing for a CAP), companies will prepare a comprehensive recall communications plan including a media plan—for notifying the public (the general public and/or a specific audience) about the recall. The recall communications plan, as part of the CAP, must be approved by CPSC staff.¹⁵ A satisfactory recall communication plan will include specific information on how a company intends to market its recall, including identifying specific media outlets and other targets.

The Word "Recall"

CPSC expects that companies will use the word "recall" to refer to any voluntary action taken pursuant to a CAP that involves removing, repairing, inspecting, discarding, updating, or otherwise altering for safety a product once it has been purchased by a consumer. Although details and circumstances of CAPs and products may differ, the consistent use of the term "recall" is currently the best way to ensure consumers' attention to a safety notice. Should the vocabulary of risk communication evolve to include other words that carry a similar impact, CPSC staff will consider them.

CPSC's headline for recall announcements will include the word "recall." That headline is standard and not negotiable as part of a CAP agreement. When submitting an initial draft release to staff, companies should take care to write in clear and easy-to-understand language, avoiding technical jargon and other information that may make it difficult for consumers to understand the message. CPSC staff will not approve news releases that downplay the hazard or that use language that would make a consumer less likely to participate in the recall. In general, risks and injuries should be described with clarity and not euphemistically. CPSC staff can provide guidance and examples.

Companies should strive for high consumer participation, and they should draft news releases describing the recall in a manner that will motivate the consumer to take advantage of the remedy. For instance, if the subject product is associated with a risk of death, the word "death" should be used in the headline of the news release.

¹⁵ In the case of recalls where the product is associated with a death, the CAP and all accompanying documents are submitted to the Commission for a vote.

Review of Recall Notices and Timing of Publication: CPSC staff must review and approve all notices to be disseminated. These notices will be discussed in detail in the following pages. Companies must provide staff, in advance, drafts of all notices or other communications to media, customers, and consumers. CPSC should be the first to issue the approved public communication messages; and then, the recalling company should follow, by issuing its own CPSC-approved communication messages.

Checklist of CAP Communications CPSC must approve:

- Media Plan
- News release
- Digital/social media postings
- Recall webpage
- Notices to consumers, retailers, and distributors
- Video news release
- Scripts for recall customer service

As indicated below, CPSC has requirements as well as guidance for recalling companies. Some specific types of recall announcements and suggestions for communicating recall information are detailed below.

A. Direct and Targeted Notice

Direct Notice

Direct notice is the most effective method of engaging consumers for recalls.

Direct notice is notice to consumers who are known to have the product. Contact information for direct notice can be obtained from registration cards, sales records, catalog orders, retailer loyalty programs, contracting for service, or other means. Direct notice can also involve working with distributors, dealers, sales representatives, retailers (traditional brick and mortar and online), service personnel, installers, and other persons who may have the ability to contact consumers directly. Even when a company is using direct notice, CPSC may require additional notices to ensure that all affected consumers are notified of the recall.

The content of a direct notice must be approved by CPSC staff, and should follow the requirements and recommendations outlined below. Companies must provide sufficient customer contact information for CPSC to verify later that consumers received the recall communication. (See also subsection C, Recall Alerts, and Section VIII, Monitoring Recalled Products, for more information.)

Companies who can provide direct notice may also have to provide notice to the general public or to specific targeted audiences.

Targeted Notice

In some recall situations, companies may not have individual contact information for all consumers who bought a particular product, but may have contact information for a larger group of customers.¹⁶ For example, Company A cannot identify every purchaser of its product, but it does maintain a loyalty card database of customers who receive

¹⁶ Companies should consult counsel concerning any privacy laws that could impact the use of information for targeted notice.

periodic coupons or other marketing communications. Company A should discuss with CPSC using that targeted list of customers as part of a comprehensive recall strategy. In most instances, CPSC will urge companies to use their entire mailing list—even if the list cannot be narrowed to exact purchasers—on the theory that it is better to reach a wider audience of potentially impacted consumers. Any recall communications sent to consumers in this way must be approved by CPSC staff, and should follow the requirements and recommendations set out in the following pages.

Where targeted notice is by e-mail or postal mail, the notice should feature prominently, at the top of each e-mail, notice and/or cover letter, and on the front of any mailing envelope, the words: "Recall Notice," or "Safety Recall."

Examples of Targeted Notice:

- Loyalty customers of the brand, regardless of whether specific purchasing information is available;
- Regional targeted recall marketing, through local or regional media, for regions with higher sales;
- Notices in product catalogs, newsletters, and other marketing materials;
- Purchased lists or paid access to "Big Data" providers to generate leads;
- Posters on display at other locations where users are likely to visit, such as medical clinics, pediatricians' offices, child care centers, repair shops, equipment rental locations, and others;
- Notices to trade groups, utilities, and home/fire inspectors, as applicable;
- Notices to repair/parts shops;
- Service bulletins;
- Notices included with product replacement parts/accessories;
- Notices to child care centers;
- Notices to thrift stores and other secondhand retailers; and
- Engagement with bloggers or other relevant influencers to share information about relevant recalls.

See our online list of <u>Recall Notification Types</u> for more information.

See Section VIII, Monitoring Recalled Products for more information.

B. Recall News Releases

For a typical recall, CPSC issues a news release jointly with the company. Compliance staff, with the help of the CPSC's Office of Communications (OCM), works with the recalling company to draft the release. The agreed-upon language for the news release provides the foundation for preparing other notice documents.¹⁷ Companies should not independently issue news releases because they create confusion among the media and public, particularly if CPSC is also issuing a release on the same subject.

News releases from the CPSC can receive wide media attention and increase the response rate of consumers. OCM sends recall news releases to sources including, but not limited to, national wire services, major metropolitan daily newspapers, television and radio networks, periodicals, online news, and social media influencers. CPSC also sends recall news releases to its listserv of consumers and others who have signed up to receive direct notification of product recall news. In addition, CPSC posts recall news releases to its websites: www.cpsc.gov and www.saferProducts.gov;

¹⁷ Although the news release provides a foundation, the CPSC is not bound to its exact language, as long as any additional messaging meets the statutory requirements of Section 6 of the CPSA. *See box, next page.*

social media; and on CPSC's recalls app. CPSC reserves the right to publicize a recall—consistent with the agency's obligations under section 6(b)—to any outlet or in any format.

CPSC uses a template with a standardized format for most releases. This ensures that all critical information is easy to find for consumers, media, and other interested parties. CPSC staff will seek to maintain consistency between releases as appropriate. However, in recalls where a product has been associated with a death or in certain other circumstances, CPSC will often—at staff discretion—use a narrative format release, which must be approved as part of the CAP by majority vote of the Commission. Examples of news release templates are found in Appendix C.

The following page contains a checklist of all items that must appear in a recall news release.

Are there limits to what CPSC says—and where after a recall is announced?

CPSC staff will work with companies to effectively communicate recalls within the legal requirements of Section 6(b). This includes working collaboratively to draft and refine the joint news release announcing the recall.

CPSC is committed to fulfilling its obligations under 6(b). In addition, the agency may use words and phrases that do not appear in the four corners of the negotiated press release, so long as those words and phrases also comply with 6(b)'s requirements of fairness and accuracy.

CPSC may publicize a recall in any manner and at any time. For example, CPSC may grant interviews about the recall, issue social media, convene media calls or conferences, and work with publications to create accurate content about the recall. Decisions of where and how to communicate the recall are made exclusively by CPSC.

By law, CPSC is required to share requested information with certain members of Congress. When doing so, CPSC will communicate that the information being disclosed is confidential—but section 6(b) does not govern members of Congress. If information is inadvertently released despite the agency's best efforts, the agency may respond to media requests for comment on that information, to the extent necessary to protect or inform the public.

Checklist for Required Items in Recall News Release (per <u>16 CFR § 1115.27</u>)

The term "recall" in the headline (16 CFR §1115.27(a)).
The company's legal and commonly known trade name, and the city and state and/or
country of its headquarters.
A statement indicating whether the recalling company is the manufacturer (or importer),
distributor, or retailer of the product; if the company is not the manufacturer, the
statement must specify the name of the manufacturer, and the city and county of its
headquarters. In the case of a foreign manufacturer, the statement must specify the
identity of the U.S. importer, and its city and state.
A list of all significant retailers of the product using the commonly known trade name of the product. "Significant" is defined by <u>16 CFR § 1115.27</u> , and is determined in the sole discretion of CPSC staff.
The number of product units affected by the recall (not just those in the hands of
consumers), including the number of product units manufactured, imported and/or
distributed, and in inventory.
A description of the product, including product name, the intended consumer population
(<i>i.e.</i> , infants, children, or adults), the product's colors and sizes, model numbers, date codes,
SKUs, and tracking labels, and their exact location on the product.
High-resolution electronic or digital color photographs with clear and appropriate captions
(minimum 1MB size) that clearly show identifying features of the product.
A clear and concise description of the product's actual or potential hazards that give rise to
the recall, including product defect, and the type of hazard or risk (<i>i.e.</i> , laceration,
entrapment, burn).
The month and year that manufacture of the product began and ended, and when retail
sales began and ended, for each make and model of the product.
The approximate retail price or price range.
A concise summary of all incidents associated with circumstances giving rise to the recall, including number of incidents, property damage due to incidents, injuries and deaths, including age of persons injured and killed.
A clear description of the remedy available to the consumer, such as a refund, replacement,
or repair. Although per 16 CFR § 1115.27(n), a company may offer remedies including
refunds, product repairs, product replacements, rebates, coupons, gifts, premiums, and
other incentives, CPSC has determined that to avoid consumer confusion, such remedies
 should be referred to in the broad categories "refund," "repair," or "replacement."
 Complete and simple instructions for how to participate in the recall.
Contact information (telephone and email) for an appropriate recall hotline or customer
service department. If at any point, the contact information or web URL of the company's
recall webpage changes from the recall news release, the company must notify CPSC staff
immediately so the news release can be updated.

Timing of the recall news release: CPSC will work with companies to ensure that all requirements are met and all preparations are completed before announcing the recall. CPSC may request a particular date or time with the company, and may indicate a strong preference to send out the recall news release as a standalone or as part of a package. Typically, that decision will depend, in part, on the nature of the hazard, the popularity of the product, and other factors that CPSC will discuss with the company.

Notification to other companies named in the recall news release: When it is necessary to identify more than one company or product brand name in a recall release (*i.e.*, private labelers, distributors, and retailers), recalling companies are expected to provide adequate notification to the other companies identified before the official release. This notification is intended to announce the recall and to alert the other companies that their names or brands will be used. The recalling company should notify the Compliance Officer or Compliance Attorney once all named companies are notified and specify whether there are any objections from them. If naming a manufacturer, the recalling company must state affirmatively that the company has notified the manufacturer with the final news release and also state that the manufacturer did not object.

C. Recall Alerts

Recall alerts follow the same format as a recall news release, but to make use of a recall alert, a company must have direct notice capability for all, or nearly all, consumers to whom the firm has sold the product (e.g., by phone, email, U.S. mail, or other means). If direct notice can be used, staff will consider various factors in assessing what additional actions may be necessary. In some circumstances, direct notice may lessen the need for notice to the news media, while in other cases notification to the media will augment the direct notice. As appropriate, even with a recall alert, CPSC may undertake its own efforts to publicize the recall and effectuate the mission of the agency, as required by law.

D. Joint Releases with Canada and Mexico

For recalled products also sold in Canada and/or Mexico, the CPSC recommends reporting to the appropriate governing agency in those countries to coordinate Joint News Releases or Recall Alerts. Consistent with agency policies and practices, CPSC may also notify or coordinate with other governments.

E. Digital Recall Marketing

The last several decades have seen significant changes and advancements to the way companies reach consumers for marketing and advertising products. Those same developments should be reflected in the way companies communicate with consumers about recalls and other important safety issues. It is important for companies to use equally effective digital channels and strategies to market the product and to perform recall notification. Tactics that a firm used successfully to *sell* their products will also be an effective means to reach consumers with notice of a recall. General expectations are discussed below; CPSC communications staff is available to advise companies as CAPs are developed.

Company Website

As a threshold matter, CPSC considers it a best practice for all firms to maintain a recall landing page on their primary website or U.S.-specific website so consumers can readily find information on multiple recalls at the same time. A recall

landing page lists all of the company's recalls. Such a page should be easily navigable from the main page or from a relevant secondary page, such as a Customer Service page.

When engaged with CPSC on a recall, companies must post recall announcements to all current websites. This announcement should link to a dedicated recall webpage (not to the general listing of all firm recalls). CPSC staff can provide additional guidance if a company would like to use a standalone website (*e.g.*, _____recall.com) in addition to or instead of the company website.

CPSC staff must review and approve all notices to be disseminated in connection with a recall or recall alert, including recall website/webpage content.

Website notifications are subject to the same requirements as the news release. Companies are also required to:

- Clearly link recall announcements to the company website's first-entry point, such as the consumer home page (not the corporate/shareholder site). The dedicated recall webpage link should appear within the top 1/3 of the company's consumer home page.
- Include the words "recall" and "safety" in the link to the recall information.
- Include all available recall information in the news release.
- Allow consumers to request the remedy directly from the website.
- Convey any additional instructions that consumers need to receive the remedy in plain language and include photos or videos to explain the remedy process clearly.
- Reflect recalls from mergers and acquisitions, ie. if the company is purchased or merges with another company, existing recalls must be included on the website of the new company or the acquiring company's website with the original brand names.

The CPSC strongly encourages companies to maintain their recall webpage(s) indefinitely. After 120 days, or when the case is closed, companies may remove the dedicated recall webpage link from the top of the company's homepage. If the URL for the recall posting changes, firms must notify the CPSC immediately. Companies should check their recall link quarterly and ensure it is active. Any changes to the URL will be made on CPSC's recall webpage.

See our <u>Website Notification Guide</u> for more information.

Social Media

Companies are expected to use any and all social media and mobile platforms on which the company maintains a presence¹⁸ including, but not limited to, Facebook, Twitter, YouTube, and Instagram, to notify consumers of the recall. Companies are encouraged to use paid advertising on social media. A <u>Guide to Best Practices for Communicating Recalls</u> on Social Media can be found in Appendix D.

Requirements for social media notifications:

- Use the terms "recall" and "safety" in the social media messaging about the recall.
- Keep it concise (#Recall hashtag, product name, hazard, remedy).
- Link directly to the dedicated recall webpage from Facebook, Twitter, Instagram Story or other social media notification.
- Use photos to increase priority on social media feeds and recall views.
- Use videos to give even greater priority on the various platforms, where possible.

¹⁸ "Maintaining a presence" means that the company has a profile or account on a given platform, even if the company rarely uses that platform.

- Make the recall a featured post, if possible.
- Use direct messaging to answer recall questions from consumers.

F. Video News Release (VNR)

CPSC encourages firms to produce video news releases for recalls. The video news release complements the written recall news release and gives media footage of the product to help tell the story.

G. National News Conference

CPSC may urge companies to join the agency in a national news conference to announce the recall. Whether to hold a national news conference depends on the recalled product's prominence, number of units, and the hazard. CPSC may request a company's participation in a news conference, or a company can initiate those discussions with the assigned Compliance Officer or Compliance Attorney. CPSC reserves the right to publicize recalls in any manner, consistent with Section 6(b), without company participation.

H. Retail Notifications/Posters

In certain circumstances, retail posters, or an appropriate alternative, can be an effective means of providing continuing notice of recalls to consumers at the locations where they shop, at the points of purchase, or at other locations where consumers will see them.

Guidelines for designing posters and counter cards:

- Keep them BRIEF and eye-catching; in general, a poster requires far fewer words than a news release.
- Describe the hazard, and tell consumers what to do.
- Use color to make the poster stand out.
- Use a print font, size, and color that provide a strong contrast to the background color of the poster.
- Include the terms "safety" and "recall" in the heading.
- Use a good-quality line drawing or photograph of the product, with call-outs identifying product information, such as model numbers and date codes.
- Include the company's toll-free recall telephone number in large-size type at the bottom of the poster.
- Include the phrase, "Post until [date at least 120 days from recall announcement]."
- Consider using posters with tear-off sheets that provide information on the recall for consumers to take home.
- Use a QR code or other mobile scanning code to allow consumers to act on the recall immediately.
- Use retailer's app to disseminate recall information or add reminders.
- Place posters at retail entrances, checkout counters, and at the location where regular or repeat purchase of the item is expected.

Before announcing a recall, the recalling company should contact the companies and individuals responsible for the locations where it wants to display recall posters and obtain permission to post from each company and responsible party. The company should explain the reason for the recall and the contribution to public safety that the posters provide. The company should also:

- Advise retailers and other companies to place the posters in several conspicuous locations in their stores or
 offices, where customers will see them, e.g., the area where the product was originally displayed for sale, store
 entrances, waiting rooms in pediatric clinics, and service counters at repair shops. It is not advisable to place
 recall notices in a separate area specifically designated for customer service because consumers may not visit
 these areas, unless they have a problem to address.
- Provide sufficient numbers of posters for retailers or others to display in more than one place in each store or location, and provide contact information for ordering additional posters.

See our online guide, "<u>Create a Recall Poster</u>," for more information. Other alternatives may be acceptable, such as the use of electronic retail "posters" projected on large screens.

I. Company Contact Information: Toll-Free Numbers/URL/Email

A company conducting a recall must provide an email address, a toll-free telephone number (800/888/877/866), and a website URL ("a response system") for consumers to respond to the recall announcement. Generally, this contact information should be dedicated solely to the recall. Historically, CPSC staff has found that most systems set up to handle typical customer relations, or to receive product orders or requests for repairs or accessories, are unable to also respond effectively to callers about recall announcements, particularly during the first few weeks after the initial announcement of the recall.

When establishing a response system to handle a recall, companies should assume a large consumer response, especially during the first several days/weeks. It is easier to scale-back the response system than it is to add more capacity once a recall is announced. If a response system is not effectively equipped, CPSC may contact a company for additional action to comply with its corrective action plan.

Whether an automated system or live operators are used to answer calls, companies should prepare scripts and instructions for responding to questions. Live operators or taped messages should begin by identifying the company and product, and explaining the reason for the recall. Most consumers who hear about a recall by radio, television, or word of mouth will not remember all the information they hear initially. Again, at its beginning, the message should reinforce the need for listeners to act, particularly if the message is lengthy. CPSC staff must approve all scripts before the recall is announced. All automated systems should provide a number for consumers to contact the company for special problems, *e.g.*, problems completing repairs or installing parts.

Reducing Call Volume: Required provision of a website and e-mail for consumers to register to participate in the recall will help reduce call volume and make the call volume more manageable. Companies should also consider offering a callback service to return calls within 24-48 hours.

See our online guide, "<u>Hotline Questions and Answers</u>," for additional information.

VIII. Monitoring Recalled Products

Every recall conducted in coordination with staff is monitored by both the recalling company and the CPSC. Among the reasons that recalling companies need to understand and prepare for this monitoring is that the Consumer Product Safety Improvement Act (CPSIA) makes it unlawful for any person to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any consumer product or substance that is subject to a voluntary corrective action taken by the manufacturer, in consultation with the CPSC (CPSA Section 19(a)(2)(B)-(C), 15 U.S.C. section 2068(a)(B)-(C). For more information, see section IX, Keeping Recalled Products Out of Commerce.

CPSC monitors product recalls by:

- Reviewing monthly progress reports submitted by companies to the Office of Compliance and Field Operations
 using the Monthly Progress Reporting portal. Submitting the information electronically using the required form
 found on the <u>Monthly Progress Report System¹⁹</u> allows CPSC to assess the effectiveness of the company's recall
 by evaluating the number of products remedied, the number of consumers notified of the recall, and any postrecall announcement incidents and injuries.
- Inspecting companies post-recall to verify and monitor implementation of the corrective actions undertaken.
- Assigning visits by CPSC field staff and state investigators to consumers to confirm receipt of recall notification and to ensure that recalled products are quarantined and no longer being sold.
- Visiting the Firm to follow-up on a company's corrective action.
- Verifying disposal or destruction of recalled products. Requests to verify should be submitted in writing and in
 advance of scheduling the disposal to <u>recalledproductdisposal@cpsc.gov</u>, so that a CPSC investigator can witness
 disposal or make arrangements for other means of verifying destruction.
- Assessing a company's request to cease monitoring. When a company determines that the CAP has been implemented to the best of its ability, and that as many products as possible have been removed from the marketplace, the company may submit an updated progress report and request that the CPSC cease monitoring the recall. Staff will review the effectiveness of the CAP, including the numbers and types of notifications made to consumers, the number of products returned and/or corrected, any post-recall incidents/injuries or deaths involving the recalled product, life expectancy of the product, and any other relevant factors, and advise the company whether monitoring may cease.

CPSC staff reserves the right to seek broader corrective action if the plan does not prove effective. Even after active monitoring has ceased, the company should continue to implement the recall plan until as many products as possible have been removed from the marketplace. The company's toll-free number should be maintained, as well as notice of the recall, on its website so consumers can continue to reach the company if they discover a recalled product. *If the company changes or discontinues its toll-free recall number or Web posting, the company must immediately notify the Office of Compliance and Field Operations, and provide a new recall contact number or URL.* If there are changes to the implementation of the CAP, the company should also immediately contact staff. The CPSC maintains the agreed-upon news release announcing the recall on the CPSC's website. Any change in the company's phone number or modification of the obligations under the CAP must be posted on the existing news release.

¹⁹ CPSC will publish information about a firm's progress on its website absent an objection from the firm.

IX. Keeping Recalled Products Out of Commerce

Removing hazardous consumer products from the marketplace is just one part of a CAP. Companies must also take steps to ensure that adequate measures are in place to prevent consumer products that are subject to a voluntary corrective action or recall (recalled products) from entering or re-entering the stream of commerce, after a recall is announced. Failure to do so violates the CPSA and can result in civil or criminal penalties. CPSA sections 20 and 21.

The CPSA provides:

It shall be unlawful for any person to sell, offer for sale, manufacture for sale, distribute in commerce, or import into the United States any consumer product, or other product or substance that is subject to voluntary corrective action taken by the manufacturer, in consultation with the Commission, of which action the Commission has notified the public, or if the seller, distributor, or manufacturer knew or should have known of such voluntary corrective action. <u>CPSA 19(a)(2)(B)</u>.

Companies are better equipped to prevent recalled products from entering the stream of commerce—and avoid penalties under the CPSA—if they have a comprehensive compliance program that contains mechanisms for identifying, quarantining, and removing recalled products from inventory. Recalled products enter commerce for a variety of reasons, all of which are preventable.

CPSC has found that recalled products typically enter the market because of poor communication throughout the supply chain and because compliance programs are not comprehensive, are out of date, or are not consistently followed. Companies can avoid these problems by:

1. Proactively Establishing a Recall Execution Plan

Some companies do not grasp the need for a recall execution plan until they are conducting a recall. It is a best practice to have a comprehensive recall execution plan in place before it is needed. This allows companies and their employees to identify, quarantine, and remove recalled products from all potential streams of commerce quickly and efficiently. The plan should include written policies and procedures that clearly identify the steps to be taken during and after a recall, and that explain the roles of each employee in the process.

2. Ensuring Adequate Communication

Recalled products are often found to have entered commerce due to gaps in communication to all affected entities during the recall process. Effective communication during a recall should include, but not be limited to:

- Early notice and frequent contact among the recalling company and suppliers, distributors and retailers to
 identify recalled products, and anticipate their quarantine and removal from inventory. This communication
 should include all subsidiaries, divisions, and third-party logistic providers, and it should be updated regularly to
 reflect changes in the supply chain;
- Regular management and employee training on what is a recalled product, how should recalled products be quarantined and/or removed from inventory so that the disposition of the recalled product can be accomplished smoothly—whether it is repair/replacement/destruction, per the CAP; and how to establish clear written parameters and expectations with reverse logistics/salvage/liquidation/destruction companies to ensure that recalled products do not reenter the stream of commerce.

3. Implementing Critical Inventory Controls

There are critical high-tech and low-tech inventory controls that can help prevent recalled products from entering or reentering commerce. Companies should ensure that their Recall Execution Plan includes:

- A robust electronic records system that informs manufacturers of the quantity of recalled products in inventory, in transit, and with retailers;
- Computer systems that communicate with each other, or are integrated;
- Procedures that allow stock keeping units (SKUs) for recalled products to be blocked permanently to prevent employees from overriding SKU blocks;
- Processes/SOPs to prevent quarantined and returned recalled products from being restocked;
- Designated physical space to store quarantined recalled products;
- A system to physically mark recalled products to identify them as such and store them in a quarantined area with clear notification that resale of the quarantined recalled product is illegal; and
- Communication to ensure that all employees know that donating recalled products is illegal.

Developing a Recall Execution Plan

Any entity that manufactures, imports, distributes, or sells consumer products should maintain a recall execution plan in the event of a product recall. This plan will help predetermine the steps to take to ensure recalled products are not in commerce.

Before a Recall:

- Send a stop-sale notice to all entities in the chain of commerce (e.g. importers, retailers, and distributors), notifying them of the pending recall. Companies should give notice to affected entities well in advance of the public announcement of the recall.
- Perform an audit or test current systems and processes (see section below).
- Review electronic inventory systems to ensure that the systems communicate.
- Identify improvements that would assist in tracking and appropriately blocking SKUs of recalled products. Assign
 a permanent location for quarantined recalled products. Ideally, access to the area is limited and signs are
 posted indicating the reason for quarantine. If a recalled product is to be re-worked or repaired, establish a
 marking and inventory system to distinguish easily recalled product from repaired product. Maintain a log for
 units moving in or out of quarantine.
- Provide refresher training to employees or develop recall-response training for employees. The training should set expectations, roles, responsibilities, obligations, and timelines for completing the company's recall execution plan. Training should emphasize that selling recalled products is illegal.
- Ensure that recalled products cannot enter any potential post-recall distribution channels, such as donation programs, third party reverse logistics providers, salvage sales, warehouse systems, and Internet sales.
- Assign one employee the responsibility of ensuring that all steps of the recall execution plan are being implemented before and after the recall announcement.
- Run regular (daily is best) reports of any changes to current SKU blocks, any sales of recalled SKUs, and inventory reports for each of the recalled SKUs, and plan what steps to take if there is an implementation issue.

After Issuance or Notice of a Stop-Sale and/or a Pending Recall, Manufacturers, Distributors and Retailers Should Work Together to:

- Remove recalled products from stores, on shelves, on display, in inventory, and at return desks. Physically mark the product as "recalled and illegal to sell, distribute, or donate," and place the items into quarantine.
- Identify any recalled products in transit, including recalled products marked for salvage or liquidation, and make
 arrangements for recalled products to be placed in quarantine. Make sure that all warehouse and transit
 facilities have procedures in place to stop the unauthorized shipment of recalled products, as well as procedures
 for how to handle recalled products.

- Report the number of recalled products in quarantine and in transit to the recalling company, and follow the disposal procedures set forth in the recalling company's corrective action plan.
- Block SKUs from registers. If scanned, the recalled product should not be available for sale. Optimally, you should notify cashiers with a message that the product is recalled and that it is illegal to sell. A generic "do not sell" message does not inform the cashier of the reason the product cannot be sold. The cashier should not have the ability to override the SKU lockout. Assign a new SKU for the repaired or similar new product in the future.
- Block online sales of the recalled product. Remove listing, if appropriate.
- Emphasize in employee training that recalled products should not be sold, and returned recalled products should be moved to the quarantine area. Ensure that the return desk knows not to put recalled products back on the shelves.
- Address any questions or feedback received from the distribution chain, and request that a company make sure that all recalled products have been removed from shelves and quarantined.

When the Recall Is Announced:

- Verify that the recalled product is off shelves, in quarantine, and labeled appropriately.
- Confirm the number of units in transit and the company's arrangements to move the recalled products to quarantine upon arrival.
- Physically segregate and/or mark recalled products: "Recalled: It is a violation of Federal Law to sell this item," or use similar wording.
- Work with the recalling company on a plan to return or destroy recalled products via methods approved by the CPSC.
- Train/retrain employees, as needed, on how to handle recalled product returns. Ensure knowledge of all recall announcements, by registering to the CPSC recall announcement listserv (https://www.cpsc.gov/Newsroom/Subscribe).

How to Handle Return or Destruction of Recalled Products:

- Communicate with the manufacturer to determine if the recalled product is to be returned or destroyed (destruction can occur only when approved by the CPSC, and CPSC may want to witness the destruction).
- For off-site destruction Set clear written instructions for the third party vendor. Communicate what is being sent, and indicate that the recalled products should not be comingled with other products, or sent to salvage. Clearly mark all boxes and pallets containing recalled products. Request a certification of destruction upon completion.
- For on-site destruction (at retailer or distributor) If approved by CPSC, and instructed by the recalling company, obtain a report certifying the destruction. An affidavit is preferred but, at a minimum, a signed statement, including the date, stating which recalled products were destroyed, the number of recalled products destroyed, and the name of the employee who performed the destruction, signed by the employee who performed the destruction and a witness. Inventory systems should be updated to reflect the destruction.
- If the recalled products are being returned to the recalling company, clearly mark all boxes and pallets containing recalled products.

Perform an Audit to Test the Recall Execution Plan:

• Perform an audit to test the effectiveness of a stop-sale and/or Recall Execution Plan at your facilities using a test SKU.

- Test communication systems between facilities by simulating a recall announcement to each facility, and ask each facility to verify receipt and follow-up instructions.
- Check to ensure the quarantine area is being used appropriately or is available at each location, and confirm that returned Recalled Products make it to the appropriate location in quarantine.
- Train employees at all facilities (including but not limited to retail locations) what to do when they receive a return of a Recalled Product.
- Confirm that computer systems are functioning as designed, and confirm that access to the appropriate information to identify current stock, lock out Recalled Products, and identify Recalled Products as quarantined.
- Run a report to identify all sales, donations, sales or transfers for salvage, Internet sales, and outlet store sales. Ensure that information can be accessed and that sales can be determined. Identify shortfalls or areas for improvement, and update the compliance program accordingly.

If Recalled Products Have Entered Commerce:

- Report to the CPSC immediately through the firm's assigned Compliance Officer or Compliance Attorney and <u>section15@cpsc.gov</u>.
- Reinforce the stop-sale notification and reverse logistics process to ensure they are properly in place.
- Change the reverse logistics program to address any shortcomings that allowed the Recalled Products to return to the market. Depending on the circumstances, understand that re-announcing the recall may be necessary.

X. Records Maintenance

The goal of any product recall is to retrieve, repair, or replace products already in consumers' hands, as well as those in the distribution chain. Maintaining accurate records about the design, production, distribution, and marketing of each product for the duration of its expected life is essential for a company to conduct an effective, economical product recall. Generally, the following records are important to identify product defects and conduct recalls:

- 1) **Records of complaints, warranty returns, insurance claims, and lawsuits.** These types of information often highlight or provide early notice of safety problems that may become widespread in the future.
- 2) **Production records.** Accurate data should be kept on all production runs—the lot numbers and product codes associated with each run, the volume of units manufactured, component parts or substitutes used, and other pertinent information that will help the company identify quickly defective products or components.
- 3) **Distribution records.** Data should be maintained about the location of each product by product line, production run, quantity shipped or sold, dates of delivery, and destinations.
- 4) **Quality control records.** Documenting the results of quality control testing and evaluation associated with each production run often helps companies identify possible flaws in the design or production of the product. It also aids the company in charting and more precisely defining the scope of a CAP.
- 5) **Product registration cards.** Product registration cards for purchasers of products to fill out and return are an effective tool to identify owners of recalled products. The easier it is for consumers to fill out and return these cards, the greater the likelihood the cards will be returned to the manufacturer. For example, some companies provide pre-addressed, postage-paid registration cards with pre-printed product identification information, *e.g.*, model number, style number, special features, on the card. Providing an incentive can also increase the return rate. Incentives can be coupons towards the purchase of other products sold by the company, free accessory

products, or entry into a periodic drawing for a product give away. The information from the cards should be maintained in a readily retrievable database for use if a recall becomes necessary.

XI. Conclusion

Proactive planning, reporting in a timely manner, taking effective steps to mitigate the hazard, appropriate announcement and dissemination of recall materials, and vigilant efforts to keep recalled products out of commerce are all essential to an effective corrective action. We hope that this guide provides useful information to help companies implement effective recalls.

For additional information on recall guidance, visit the CPSC's website at: <u>www.cpsc.gov</u> (click on "Menu" and then "Recall Guidance"). If you have additional comments or questions, please contact the Office of Compliance and Field Operations at: <u>compliance@cpsc.gov</u>.

Appendix A: Developing a Compliance Program

A compliance program should cover the life of a consumer product, from the design and manufacturing stage, through sales and distribution, and to a recall, if necessary. A compliance program may include policies and processes for addressing prevention of safety issues, crisis management, investigation and reporting procedures, mock recalls, and standard reverse logistics protocols during product recalls.

Every company should design a program based on its own structure, communicate that program to all employees, and assess the program regularly, to see if and how it can be improved or updated to reflect changes in the company's supply, distribution, and sales chains.

Why do you need a program?

There are many reasons to implement a compliance program:

- *Consumer protection:* By having the information available to identify and respond quickly to product safety issues, a compliance program helps prevent injury to your customers.
- *Product improvement:* A compliance program promotes robust design and testing of products during development and in the manufacturing/assembly process.
- *Early detection and correction of problems:* Compliance programs promote early detection of potentially unsafe product designs, manufacturing processes, and unsafe use conditions.
- *Efficiency in reporting and compliance:* Facilitates efficient and effective implementation of CPSC reporting obligations and CAPs, including recalls and reverse logistics.
- Avoidance of civil penalties: When seeking civil penalties, CPSC considers, among other factors, whether the company had a:
 - Reasonable and effective program or system for collecting and analyzing information related to safety issues, and
 - History of noncompliance.

How do you start a Compliance Program?

As a starting point, companies should emphasize the three "Cs" of a Compliance Program: Culture, Communication, and Continuous Improvement.

1. **Culture**. Establishing a culture of safety at a company requires a proactive approach that implements training and testing at the early stages of product development, and carries through the life of the product from manufacture, through distribution, and to any possible recall.

2. **Communication**: Ensure that safety expectations are effectively disseminated throughout the company, from entry level employee to top management. Develop a protocol for collecting information that could impact product safety and for elevating it to company individuals with authority to file reports to the CPSC.

3. **Continuous Improvement**: A compliance program should be dynamic; once established, it should be informed by experience. Identified shortcomings are an opportunity to improve the program.

One approach to developing a compliance program may look like this:

- 1. Identify who in senior management is responsible for product safety issues at the company.
- 2. Research and create written policies and procedures to respond to product safety issues.
 - a. Identify and centralize data for availability and review by the product safety team.
 - b. Establish regular data reviews, and as appropriate, specific incident reviews.
 - c. Establish or refine supplier qualifications and audits.
 - d. Incorporate CPSC reporting requirements and recall execution plans into policies.
 - e. Establish a protocol for specific follow-up action.
- 3. Establish a records-retention policy: CPSC staff recommends retaining records for at least 5 years.
- 4. Train staff regularly.
- 5. Routinely reevaluate and update compliance policies and training.

What Information Should a Compliance Program Capture and Analyze?

There are various sources of information that firm's should capture and analyze as part of a compliance program. In collecting information, think globally: If the product is sold outside the United States, information about its use, experience, performance, design, or manufacture should be considered. 16 CFR §1115.12.

These sources include:

- Engineering, quality control, or production data
- Information about safety-related production or design changes
- Product liability lawsuits and/or claims for personal injury and damage
- Information from an independent testing laboratory
- Incident complaints from consumers or consumer groups
- Information received from the CPSC (360 reports) or other governmental agencies
- Requests to return a product or for replacement or credit
- Warranty claims
- Product repairs or returns
- Premarket and production testing
- Compliance with applicable mandatory and voluntary safety standards.

16 CFR § 1115.12 and 16 CFR § 1119.4.

Other information that should be captured in a compliance program (and which impose reporting obligations) include the items set forth in Section I A-C, infra (pages 6 - 11):

What should the product safety team do with the information it collects?

A safety team should assess the information to determine whether the information requires a report to the CPSC under CPSA Section 15(b). A company is required to report immediately (within 24 hours) when it obtains information which reasonably supports the conclusion that a consumer product:

• Fails to comply with an applicable consumer product safety rule or a voluntary standard which is relied on under **Section 9** (of the CPSA),

- Fails to comply with any other **rule, regulation, standard or ban under the CPSA** or other acts enforced by the CPSC,²⁰
- Contains a defect which could create a substantial product hazard, or
- Creates an unreasonable risk of serious injury or death.

The Safety Team should assess:

Is there a defect?

A company should collect all available information and analyze it to determine whether the information reasonably suggests the existence of a defect (<u>16 CFR § 1115.4</u>). See <u>Sections II</u> infra.

Does the defect create a substantial risk of injury?

The safety committee should assess whether the defect or noncompliance creates a substantial risk of injury to the public. Refer to <u>Section III</u> infra (pages 12 to 13), for direction on how to conduct that assessment.

If you don't find a defect, are you done?

No, you still need to evaluate whether the information reasonably supports the conclusion that the product creates an unreasonable risk of serious injury²¹ or death. If an unreasonable risk of serious injury or death is possible, you should report. *Do not wait for a serious injury or death to occur before reporting*. <u>16 CFR §1115.6</u>.

What Information Should You Consider When Assessing an Unreasonable Risk?

- Reports from experts;
- Test reports;
- Product liability lawsuits or claims;
- Consumer or customer complaints;
- Quality control data;
- Scientific or epidemiological studies;
- Reports of injury;
- Information from other companies or governmental entities;
- Other relevant information;
- Judgment: "The CPSC will attach considerable significance if a company learns that a court or jury has determined that one of its products has caused a serious injury or death and a reasonable person could conclude . . . that the product creates an unreasonable risk of serious injury or death." <u>16 CFR §1115.6</u>.

- A grievous bodily injury <u>16 CFR §1115.12(d)</u>;
- Injury necessitating hospitalization requiring actual medical or surgical treatment;
- Fractures, lacerations requiring sutures, concussions, injuries to the eye/ ear/internal organs requiring medical treatment, and injuries necessitating absence from school or work of more than one day. <u>16 CFR §1115.6(c)</u>.

²⁰ A firm should always monitor to ensure compliance with standards. If you obtain information that your product violates a mandatory standard, you should immediately report. However, even if your product complies with a mandatory standard, you may still need to report, if the information reasonably suggests that the product contains a defect.

²¹ A "serious injury" is defined as:

Refining and Improving your Compliance Program²²

Step 1: Establish a culture of safety as the foundation

- a. Provide regular, recurring training on how to respond to product safety issues.
- b. Practice, audit, and improve your systems and processes to respond to product safety issues.

Step 2: Create written standards and policies

- a. Tailor the program to your company's specific needs.
- b. Increase staff awareness and training on these policies.
- c. Ensure that other relevant parties in the distribution chain (suppliers, distributors) are aware of the program and understand its requirements regarding their roles.
- d. Improve and refine your policies over time.
- e. Create a recall execution plan (see CPSC guidance, and ISO 10377, 10393, 19600, and 31000).

Step 3: Ensure Supplier qualifications and audits

- a. Make safety a priority at the design stage (See CPSC's "<u>Handbook for Manufacturing Safer Consumer</u> <u>Products</u>").
- b. Conduct adequate and relevant premarket and production testing to ensure products meet or exceed safety requirements of relevant mandatory and voluntary safety standards.
- c. Exercise due care when relying on a supplier, by taking affirmative steps, such as:
 - i. including contractual provisions requiring compliance with specifications and quality programs;
 - ii. visiting manufacturing locations;
 - iii. spot-checking products for ongoing compliance with safety requirements.

d. Conduct regular audits to confirm compliance within your company and among your suppliers.

Step 4: Establish an information-collection protocol

- a. Establish systematic procedures for collecting the information to be reviewed and evaluated for potential safety issues.
- b. Consider multiple sources of information.
- c. Types of incident information/samples to collect:
 - i. date of report;
 - ii. consumer contact information (name, address, email, and phone);
 - iii. product name, make, model, serial number, date code, and any other identifying information on the product or packaging;
 - iv. incident details, such as date of incident, surrounding circumstances, whether an injury was sustained, and if so, if medical attention was sought; and
 - v. incident samples, if available.

Step 5: Create a central database

- a. Establish a central database to track information:
 - i. Set up a system to capture all incidents, and route potential safety-related incidents to the compliance team.
 - ii. Make sure your databases speak to one another.
 - iii. Ensure that employees are trained to recognize safety-related issues so they are prepared to elevate these issues to management as soon as they see them.
 - iv. Have a system in place to analyze regularly what is contained in the database to ensure that issues are identified and addressed as soon as possible.

Step 6: Create a system for employee reporting

²² This section is based on information provided during the 2018 Compliance Seminar and the presentation, "10 Steps to an Effective Compliance Program."

- a. Make employees comfortable in reporting safety issues; create a confidential path for sensitive issues.
- b. Ensure that information gets to the right people in your organization, based on its structure and roles and responsibilities.

Step 7: Prioritize senior management responsibility for compliance

- a. It is essential to maintain a culture that emphasizes and values product safety, compliance with CPSC safety requirements and voluntary standards, and a comprehensive quality assurance program.
- b. Oversight of compliance by the company's responsible official will facilitate prompt disclosure to senior management of any deficiencies and foster consistent decision making.
- c. Develop a mechanism for elevating product safety reports to senior management.

Step 8: Incorporate CPSC reporting requirements

- a. Understand your legal responsibility to <u>report</u> information to the CPSC about the product, if it:
 - i. fails to comply with a CPSC rule, regulation, standard or ban;
 - ii. contains a defect which could create a substantial product hazard;
 - iii. creates an unreasonable risk of serious injury or death.
- b. Keep up with the CPSC's new and updated regulations through e-mail notification: <u>www.cpsc.gov/email.</u>

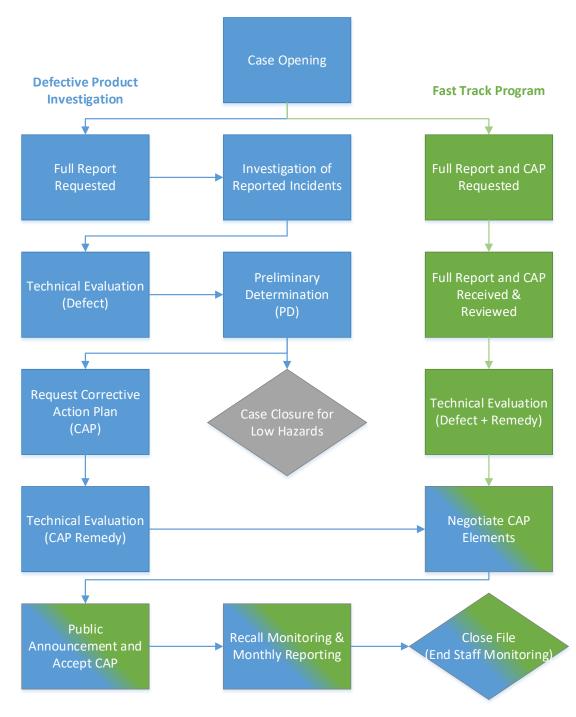
Step 9: Include reverse logistics in the recall execution plan

- a. Develop a standard recall execution and reverse logistics plan.
- b. Understand the system(s) of product distribution and the potential challenges in executing a recall, and develop an implementation plan accordingly.
- c. Regularly review the plan for effectiveness. Common reverse logistics mistakes include:
 - i. SKUs are reused;
 - ii. Computer systems do not communicate with each other;
 - iii. No single individual is identified as the point person for the recall;
 - iv. Inventory reports for recalled SKUs are not regularly conducted;
 - v. Sales reports for recalled SKUs are not regularly conducted; and
 - vi. Register prompts were unclear.

Step 10: Maintain Records

- a. Establish a records retention system:
 - i. CPSC staff recommends keeping all compliance-related records for at least 5 years.
 - ii. If you are upgrading systems, make sure you can access legacy data.
- b. Retention of documents can help identify actions to ensure future safety and compliance.
- c. In the event of a product recall, documentation helps CPSC understand the efforts you made to provide safe consumer goods, what went wrong, and how it has been corrected.

Appendix B: Substantial Product Hazard Investigations and Fast-Track Processes



Note: This chart reflects a typical process flow in defective product investigations handled by Compliance Enforcement and Litigation, and Fast Track Program recalls. These processes may be adapted to the circumstances of a case, as necessary, to respond to specific product safety issues.

Appendix C: News Release Templates

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Recall News Release Template



Release Date: MONTH DAY, YEAR Release Number: FY-DRAFT

FIRM NAME Recalls GENERIC PRODUCT NAME Due to XXX Hazard(s)

Recall Summary

Name of Product:

Hazard:

Remedy: Refund/Repair/Replace

Consumers should immediately stop using the recalled XXX, and contact the firm for a full refund/free repair/free replacement.

Consumer Contact: FIRM toll-free at XXX-XXX-XXXX from X a.m. to X p.m. ET/CT/PT Monday through Friday, or online at <u>www.XXX.com</u>, and click on XXX at the bottom of the page for more information.

Recall Details

Units: About X

Description:

Incidents/Injuries:

Sold at: XXX stores nationwide and online at XXXX from MONTH YEAR through MONTH YEAR for about \$XX.

Importer:

Distributor:

Manufacturer:

Photos with captions

About U.S. CPSC

The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of injury or death associated with the use of thousands of types of consumer products under the agency's jurisdiction. Deaths, injuries, and property damage from consumer product incidents cost the nation more than \$1 trillion annually. CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical or mechanical hazard. CPSC's work to ensure the safety of consumer products - such as toys, cribs, power tools, cigarette lighters and household chemicals – contributed to a decline in the rate of deaths and injuries associated with consumer products over the past 40 years.

Federal law bars any person from selling products subject to a publicly announced voluntary recall by a manufacturer or a mandatory recall ordered by the Commission.

For more lifesaving information, follow us on <u>Facebook</u>, Instagram <u>@USCPSC</u> and Twitter <u>@USCPSC</u> or sign up to receive our <u>e-mail</u> alerts. To report a dangerous product or a product-related injury go online to <u>www.SaferProducts.gov</u> or call CPSC's Hotline at 800-638-2772 or teletypewriter at 301-595-7054 for the hearing impaired.

CPSC Consumer Information Hotline

Contact us at this toll-free number if you have questions about a recall: 800-638-2772 (TTY 301-595-7054) Times: 8 a.m. – 5:30 p.m. ET; Messages can be left anytime Call to get product safety and other agency information and to report unsafe products.

Media Contact

Recall News Release with Health Canada Template



Release Date: MONTH DAY, YEAR Release Number: FY-DRAFT

FIRM NAME Recalls GENERIC PRODUCT NAME Due to XXX Hazard(s)

Recall Summary

Name of Product:

Hazard:

Remedy: Refund/Repair/Replace

Consumers should immediately stop using the recalled XXX, and contact the firm for a full refund/free repair/free replacement.

Consumer Contact: FIRM toll-free at XXX-XXX-XXXX from X a.m. to X p.m. ET/CT/PT Monday through Friday, or online at <u>www.XXX.com</u>, and click on XXX at the bottom of the page for more information.

Recall Details

Units: About XX (In addition, X in Canada)

Description:

Incidents/Injuries:

Sold at: XXX stores nationwide and online at XXXX from MONTH YEAR through MONTH YEAR for about \$XX.

Importer:

Manufacturer:

Manufactured in:

Note: Health Canada's news release is available at:

Photos

About U.S. CPSC

The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of injury or death associated with the use of thousands of types of consumer products under the agency's jurisdiction. Deaths, injuries, and property damage from consumer product incidents cost the nation more than \$1 trillion annually. CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical or mechanical hazard. CPSC's work to ensure the safety of consumer products - such as toys, cribs, power tools, cigarette lighters and household chemicals – contributed to a decline in the rate of deaths and injuries associated with consumer products over the past 40 years.

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Media Contact

Fast-Track Recall Template



Release Date: MONTH DAY, YEAR Release Number: FY-DRAFT

FIRM NAME Recalls GENERIC PRODUCT NAME Due to XXX Hazard(s)

Recall Summary

Name of Product:

Hazard:

Remedy: Refund/Repair/Replace

Consumers should immediately stop using the recalled XXX, and contact the firm for a full refund/free repair/free replacement.

Consumer Contact: FIRM toll-free at XXX-XXX-XXXX from X a.m. to X p.m. ET/CT/PT Monday through Friday, or online at <u>www.XXX.com</u>, and click on XXX at the bottom of the page for more information.

Recall Details

Units: About XX

Description:

Incidents/Injuries:

Sold at: XXX stores nationwide and online at XXXX from MONTH YEAR through MONTH YEAR for about \$XX.

Importer:

Distributor:

Manufacturer:

Photos



This recall was conducted voluntarily by the company under CPSC's Fast-Track Recall process. Fast-Track recalls are initiated by firms that commit to work with CPSC to quickly announce the recall and remedy to protect consumers.

About U.S. CPSC

The U.S. Consumer Product Safety Commission is charged with protecting the public from unreasonable risks of injury or death associated with the use of thousands of types of consumer products under the agency's jurisdiction. Deaths, injuries, and property damage from consumer product incidents cost the nation more than \$1 trillion annually. CPSC is committed to protecting consumers and families from products that pose a fire, electrical, chemical or mechanical hazard. CPSC's work to ensure the safety of consumer products - such as toys, cribs, power tools, cigarette lighters and household chemicals – contributed to a decline in the rate of deaths and injuries associated with consumer products over the past 40 years.

Federal law bars any person from selling products subject to a publicly announced voluntary recall by a manufacturer or a mandatory recall ordered by the Commission.

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CPSC Consumer Information Hotline

Contact us at this toll-free number if you have questions about a recall: 800-638-2772 (TTY 301-595-7054) Times: 8 a.m. – 5:30 p.m. ET; Messages can be left anytime Call to get product safety and other agency information and to <u>report unsafe products</u>.

Media Contact

Fast-Track Recall with Health Canada and/or Profeco



Release Date: MONTH DAY, YEAR Release Number: FY-DRAFT

FIRM NAME Recalls GENERIC PRODUCT NAME Due to XXX Hazard(s) (Recall Alert)

Recall Summary

Name of Product:

Hazard:

Remedy: Refund/Repair/Replace

Consumers should immediately stop using the recalled XXX, and contact the firm for a full refund/free repair/free replacement. The firm is contacting all known purchasers directly.

Consumer Contact: FIRM toll-free at XXX-XXX-XXXX from X a.m. to X p.m. ET/CT/PT Monday through Friday, or online at <u>www.XXX.com</u>, and click on XXX at the bottom of the page for more information.

Recall Details

Units: About XXX (in addition, about XXX were sold in Canada, and about XXX were sold in Mexico)

Description: This recall involves . . .

Incidents/Injuries:

Sold at: XXX stores nationwide and online at XXXX from MONTH YEAR through MONTH YEAR for about \$XX.

Importer:

Distributor:

Manufacturer:

Manufactured in:

Note: Health Canada's news release is available at: Profeco's news release is available at:

Photos



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Media Contact

Recall Alert Template



Release Date: MONTH DAY, YEAR Release Number: FY-DRAFT

FIRM NAME Recalls GENERIC PRODUCT NAME Due to XXX Hazard(s) (Recall Alert)

Recall Summary

Name of Product:

Hazard:

Remedy: Refund/Repair/Replace

Consumers should immediately stop using the recalled XXX, and contact the firm for a full refund/free repair/free replacement. The firm is contacting all known purchasers directly.

Consumer Contact: FIRM toll-free at XXX-XXX-XXXX from X a.m. to X p.m. ET/CT/PT Monday through Friday, or online at <u>www.XXX.com</u>, and click on XXX at the bottom of the page for more information.

Recall Details

Units: About X

Description:

Incidents/Injuries:

Sold at: XXX stores nationwide and online at XXXX from MONTH YEAR through MONTH YEAR for about \$XX.

Importer:

Distributor:

Manufacturer:

Photos

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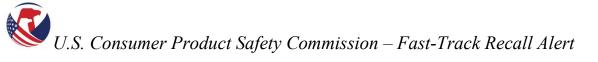
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Media Contact

Fast-Track Recall Alert Template



Release Date: MONTH DAY, YEAR Release Number: FY-DRAFT

FIRM NAME Recalls GENERIC PRODUCT NAME Due to XXX Hazard(s) (Recall Alert)

Recall Summary

Name of Product:

Hazard:

Remedy: Refund/Repair/Replace

Consumers should immediately stop using the recalled XXX and contact the firm for a full refund/free repair/free replacement. The firm is contacting all known purchasers directly.

Consumer Contact: FIRM toll-free at XXX-XXXX from X a.m. to X p.m. ET/CT/PT Monday through Friday, or online at <u>www.XXX.com</u> and click on XXX at the bottom of the page for more information.

Recall Details

Units: About XX

Description:

Incidents/Injuries:

Sold at: XXX stores nationwide and online at XXXX from MONTH YEAR through MONTH YEAR for about \$XX.

Importer:

Distributor:

Manufacturer:

Photos



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Media Contact

Fast-Track Recall Alert with Health Canada Template



Release Date: MONTH DAY, YEAR Release Number: FY-DRAFT

FIRM NAME Recalls GENERIC PRODUCT NAME Due to XXX Hazard(s) (Recall Alert)

Recall Summary

Name of Product:

Hazard:

Remedy: Refund/Repair/Replace

Consumers should immediately stop using the recalled XXX, and contact the firm for a full refund/free repair/free replacement. The firm is contacting all known purchasers directly.

Consumer Contact: FIRM toll-free at XXX-XXX-XXXX from X a.m. to X p.m. ET/CT/PT Monday through Friday, or online at <u>www.XXX.com</u>, and click on XXX at the bottom of the page for more information.

Recall Details

Units: About XXX (in addition, about XXX were sold in Canada and about XXX were sold in Mexico)

Description: This recall involves . . .

Incidents/Injuries:

Sold at: XXX stores nationwide and online at XXXX from MONTH YEAR through MONTH YEAR for about \$XX.

Importer:

Distributor:

Manufacturer:

Manufactured in:

Note: Health Canada's news release is available at: Profeco's news release is available at:

Photos



This recall was conducted voluntarily by the company under CPSC's Fast-Track Recall process. Fast-Track recalls are initiated by firms who commit to work with CPSC to quickly announce the recall and remedy to protect consumers.

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Media Contact

Appendix D: Best Practices for Communicating Recall Information on Social Media

Use of Organic vs. Paid Ads on Social Media

- Organic ads: posts get shared by users (free).
- Paid ads show up as a result of targeting the demographic that likely purchased the product (user demographic, interests, geographic location). The costs for engaging in social media advertising are typically much less than comparable radio, television, or print advertising.
 - Facebook allows segmentation targeting by relationship status, age location, interests, and more.
 - LinkedIn allows segmentation targeting by industry, company size, function, seniority, location, and language preference.
 - Twitter allows segmenting based on language, follower, device, behavior, tailored audiences, keyword, and geographic location.
 - Snapchat ads Select from pre-defined audiences, age, location, device type, and advanced demographics like household income and parental status.

Recalling companies should have their staff or a PR agency monitor activity to respond to questions and comments.

See CPSC's "Social Media Guide for Recalling Companies" for more information.

Other Digital Marketing Opportunities for Recalls

CPSC also encourages the use of common digital marketing techniques to improve dissemination of recall notices. These include paid search engine, display, and online video advertising.

- Search engine advertising and display ads will appear on Web searches before or beside the organic search results. These charges are typically assessed using a "cost-per-click" system.
- Display ads, such as banners, images, and videos, are the advertisements built into websites. Display ads allow:
 - "Retargeting" by reconnecting a recent visitor with your message;
 - Targeting by website placement (selecting the websites on which you place your ads);
 - Targeting by interests, using categories and labeling as in-market or affinity audiences. In-market users make a buying decision, and affinity users are more akin to enthusiasts.
 - Contextual targeting using keywords to identify relevant websites to show your ads.
- Online video advertising captures a different demographic of users
 - Develop video through YouTube or Vimeo, or place video ad at the beginning of others' video(s).
 - Video production essentials:
 - Camera, mobile device, laptop, among other devices
 - Microphones to capture sound
 - Additional lighting, as appropriate, to make visible or highlight the content
 - General video ad development process
 - Make decision on release schedule/date.
 - Draw storyboard showing scenes with content.
 - Decide on, and secure, location and props.
 - Engage with professional video crews, as appropriate, or desired.
 - Shoot and edit videos.
 - Post/release content.