

REPORTING AND RECALL REQUIREMENTS FOR CONSUMER PRODUCTS SOLD IN THE UNITED STATES

What Every Manufacturer, Seller and Importer of Consumer Goods to Be Sold in the United States Needs to Know About Self-Reporting and Recalls for Substantial Product Hazards

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The United States Consumer Product Safety Commission (“CPSC”) was established in 1972 through the Consumer Product Safety Act (“CPSA”)¹, and is an independent federal agency that regulates the manufacture, importation, distribution and sale of consumer products in the United States. Generally, the CPSA defines the CPSC’s basic authority,² and provides the CPSC with the authority to ban products deemed unsafe, to pursue recalls for products that present a substantial product hazard, to require manufacturers, importers, distributors and retailers to self-report product hazards, and to fine entities that fail to properly self-report actual or potential product hazards. The focus of this presentation is the CPSC’s recall process and the associated self-reporting requirement, which requires a manufacturer or other responsible party to report to the CPSC when it becomes aware, through lawsuits, reports of injury or other sources, of actual or potential defects in a product it has placed in the stream of commerce.

¹ 15 U.S.C. §§ 2051–2089

² The CPSC’s additional regulations can be found at 16 CFR parts 1101 through 1406.

The CPSC has broad powers to investigate and penalize entities which have violated the CPSA by failing to report actual or potential defects. Penalties for responsible entities can include the seizure of products deemed imminently hazardous, mandatory product recalls and steep fines up to \$15,000,000. Therefore, manufacturers, distributors, private labelers, importers and retailers of consumer products that are sold in the United States should educate themselves as to when and under what circumstances self-reporting is required for consumer products and what the recall process will entail from start to finish.

I. DEFINING CONSUMER PRODUCTS

The CPSA and its regulations apply only to “consumer products.” Generally items such as food, drugs, cosmetics, medical devices, tobacco products, firearms and ammunition, motor vehicles, pesticides, aircraft, boats and fixed site amusement rides are excluded from the CPSC’s jurisdiction. The CPSA defines a “consumer product” as “any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation, or otherwise.”³ This definition encompasses approximately 15,000 different types of products ranging from children’s toys to household appliances to power tools.

II. WHO MUST REPORT

There are two types of reporting required under the CPSA for all consumer products. They can both be found at 15 U.S.C. § 2064(b) and § 2084, and are generally referred to as Section 15 reporting and Section 37 reporting, respectively. Manufacturers, distributors and retailers are all equally liable under the CPSA, and are all equally responsible for Section 15 and

³ 15 U.S.C. § 2052

Section 37 reporting.⁴ A manufacturer is defined by the CPSA as “any person who manufactures or imports a consumer product.”⁵ This means that importers are directly responsible for products they import to the United States from foreign manufacturers, even if they are not themselves a “manufacturer” under the traditional definition of the word. A “distributor” is defined as “a person to whom a consumer product is delivered or sold for purposes of distribution in commerce, except that such term does not include a manufacturer or retailer of such product.”⁶ This definition of “distributor” is broad and covers any entity that has passed a consumer good down the stream of commerce and is not a manufacturer or retailer. Finally, a “retailer” is defined as “a person to whom a consumer product is delivered or sold for purposes of sale or distribution by such person to a consumer.”⁷

III. SECTION 15 REPORTING

Section 15(b) of the CPSA, further defined by the CPSC in 16 C.F.R. § 1115.1 et. seq., contains two broad categories of circumstances that require self-reporting of substantial product hazards present in consumer goods. A “substantial product hazard” is defined as “(1) A failure to comply with an applicable consumer product safety rule, which failure creates a substantial risk of injury to the public, or (2) A product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public.”⁸

A self-reporting requirement is triggered when a company first receives information “reasonably supporting the conclusion” that (1) a product fails to comply with a consumer product safety rule or a voluntary consumer product safety standard upon which the CPSC has

⁴ 15 U.S.C. § 2064(b)

⁵ 15 U.S.C. § 2052(a)(11)

⁶ 15 U.S.C. § 2052(a)(7)

⁷ 15 U.S.C. § 2052(a)(13)

⁸ 16 C.F.R. § 1115.2(a)

relied, such as the voluntary standards for chain saws, (2) a product fails to comply with the CPSA or another Act, such as the Flammable Fabrics Act⁹, (3) a product contains a defect that could create a substantial product hazard, or (4) a product creates an unreasonable risk of serious injury or death.¹⁰ As each type of product will have different rules and standards that may apply for the first two categories, this presentation focuses on the third and fourth categories.

A. Defect that Could Create a Substantial Product Hazard

With respect to the third category, the CPSC defines “defect” as, “a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function.”¹¹ Compliance with voluntary standards, such as those from the American National Standards Institute or ANSI, does not eliminate the possibility that a product contains a defect as defined by the CPSC, as the defect may be an inherent design defect which is present even if the product performs as designed. If a defect exists, the CPSC would then look to see whether that defect “could create a substantial product hazard.”

A “substantial product hazard” exists when a defect creates a “substantial risk of injury.” The focus is on the *risk* of injury, not on actual injury reports or the severity of injuries. The CPSC directs companies to certain factors to determine whether a “substantial product hazard” exists, including a determination of whether a pattern of defect exists, the number of products in the market, and the severity of the risk.¹² The CPSC requires that certain information be reported as a substantial product hazard including, “[i]nformation indicating that a noncompliance or a defect in a consumer product has caused, or may have caused, or contributed to the causing of a death or grievous bodily injury (e.g. mutilation, amputation/dismemberment,

⁹ 15 U.S.C. § 1193-1204

¹⁰ 15 U.S.C. § 2064(b)

¹¹ 16 C.F.R. § 1115.4

¹² 16 C.F.R. § 1115.12(g)

disfigurement, loss of important bodily functions ... and injuries likely to require extended hospitalization) ... unless the subject firm has investigated and determined that the information is not reportable.”¹³ Companies should pay careful attention to product testing results and should watch for warranty claims, consumer complaints, product liability lawsuits and other quality related complaints to watch for reportable defects and reportable injuries.

B. Product Creates an Unreasonable Risk of Serious Injury or Death

With respect to the fourth category, the requirement that a manufacturer report an “unreasonable risk of serious injury or death” is intended to ensure reporting of product hazards not yet associated with an identified “defect.” “Serious injuries” are defined by the CPSC as “injuries necessitating hospitalization which require actual medical or surgical treatment, fractures, lacerations requiring sutures, concussions, injuries to the eye, ear, or internal organs requiring medical treatment, and injuries necessitating absence from school or work of more than one day.”¹⁴ To qualify as a “serious injury,” an injury need only meet one of these qualifications, and the CPSC considers this a list of examples but not exhaustive of what it will consider a serious injury. For example, a laceration requiring sutures is considered a serious injury, even if it does not necessitate hospitalization or absence from work of more than one day. The factors that are used to decide whether a risk of serious injury is “unreasonable” are the utility of the product, the level of exposure to consumers, the nature and severity of the hazard, whether the product is state of the art, the availability of alternative designs, and the feasibility of eliminating the risk without compromising utility.¹⁵ Regardless of which category the report will come under, companies should pay careful attention to product testing results and should

¹³ 16 C.F.R. § 1115.12(d)

¹⁴ 16 C. F. R. § 1115.6

¹⁵ 16 C. F. R. § 1115.6(b)

watch for warranty claims, consumer complaints, product liability lawsuits and other quality related complaints for any indication that reportable defects or reportable injuries exist.

C. What and Where to Report

A company should file its report with the Division of Recalls and Compliance, either by mail, by telephone or electronically through the CPSC website. Reporting companies should be prepared to provide the following information, if available: a description of the product; the contact information of the reporting individual and company and the company's relationship to the product (manufacturer, distributor, importer, retailer); the nature and extent of the possible product defect or unreasonable risk of serious injury or death; the nature and extent of any injury or possible injury associated with the product; and a timeline for providing any additional information that the company does not currently have.

Manufacturers must follow the above procedure for Section 15 reporting. Retailers and distributors can satisfy their duty to report either by following the above procedure, or by sending a letter to the manufacturer of the product describing the defect, risk of injury or death, or failure to comply with a regulation, and forwarding a copy of the letter to the Division of Recalls and Compliance.

D. When to Report

The CPSC's reporting requirements are triggered based upon reasonableness, not upon certainty of defect. The requirement to self-report matures upon first receipt of information reasonably supporting a conclusion that one of the self-reporting circumstances exists. The statute states that reporting must be made "immediately," although the regulations allow ten business days for an internal investigation plus five business days for the report to reach the

responsible officials.¹⁶ Thus, reporting should be done as soon as a question of defect or serious injury is raised rather than waiting until the investigation and testing are complete. Certainly, once a defect is found, the reporting requirements are triggered. The consequences of failing to report in a timely way can be imposition of civil penalties and the concomitant publicity associated with such fines. The CPSC has sought and obtained significant civil penalties against companies who have filed late reports, and these penalties were recently raised in the Consumer Product Safety Improvement Act (“CPSIA”) of 2008 to \$100,000 for a single violation and \$15 million for a series of related violations. Each individual product containing a defect or a risk of serious injury is a separate violation.

IV. SECTION 37 REPORTING

In addition to the reporting requirements of Section 15, Section 37 of the CPSA, contained in 15 U.S.C. § 2084, requires a report to be filed when a company settles or loses three lawsuits within a set two year period involving the same product model. The current reporting cycle is 1/1/2009 to 12/31/2010. This Section 37 reporting of lawsuits and settlements is separate from and in addition to the requirements of Section 15. In order for reporting to be required under Section 37, four conditions must be met. First, a particular model of the consumer product in question must be the subject of at least three civil actions in either state or federal court. Second, each of those civil actions must allege death or grievous bodily injury, which includes severe injuries that are likely to require extensive medical care such as severe burns, amputation, mutilation, head injuries, or the loss of sight or hearing. Third, during the established two year period, each of the three actions must result in either a final settlement or a

¹⁶ 16 C. F. R. § 1115.14

judgment in favor of the plaintiff. Finally, the manufacturer must be involved in the action and in paying the settlement or judgment to the plaintiff.¹⁷

When reporting under Section 37, a company must provide the name and address of the manufacturer, the model and model number of the product, a statement regarding the nature of the injury, a statement as to the resolution of the case, whether as a settlement or a judgment in favor of the plaintiff, and if a judgment in favor of the plaintiff, the civil action number and court in which the action was filed. Although a company can provide additional information such as an intent to appeal or a denial that the information submitted supports a finding that the consumer product in question caused a death or grievous bodily injury.

Section 37 reports must be made within thirty days after a judgment or final settlement in the last of the three lawsuits, and a report must be made 30 days after any additional lawsuits involving the same product model are settled or adjudicated in favor of the plaintiff in that two year period. As with the Section 15(b) reports, the report is made to the Recalls and Compliance Division, but the report must be made in writing. Section 37 reports are confidential and are not an admission of the existence of any liability under either the CPSA or any other statute or law.

V. RECALLS

If, in response to a Section 15 report, the CPSC determines that a consumer product presents a substantial product hazard and that action must be taken in the public interest, the CPSC may order the manufacturer or any distributor or retailer to repair the product, replace the product, or refund the purchase price, which is generally accomplished through a product recall.¹⁸ There are two potential avenues for a voluntary recall following a Section 15 report, the

¹⁷ 15 U.S.C. § 2084

¹⁸ 15 U.S.C. § 2064(d)

standard track and the fast track recall program, and both recalls require what is known as a corrective action plan.

A. Fast Track Recall Program

In a standard Section 15 report, as discussed below, the CPSC will receive the report from a company and then make a determination as to whether the reported information shows that the product contains a defect which creates a “substantial product hazard,” using the same analysis that companies are directed to utilize in 16 C.F.R. § 1115.12(g). In order to avoid an official determination by the CPSC that a product creates a substantial product hazard, companies have the option of using an alternate reporting procedure called the “Fast Track Product Recall Program” that is intended to expedite product recalls. Under the Fast Track program, if a company reports a potential product defect and institutes a voluntary recall in conjunction with and with the approval of the CPSC within twenty business days of filing the report, the CPSC will not make any determination regarding whether the product contains a defect which creates a substantial product hazard. Instead, the CPSC will focus on a corrective action plan. To be eligible for the Fast Track program, a company must provide all of the information required for a full report under Section 15, request to participate in the Fast Track program, and submit a corrective action plan, discussed in detail below, that can be implemented within twenty working days.

B. Standard Recall

When a standard Section 15 report is filed with the CPSC, the Recalls and Compliance division of the CPSC will evaluate the information contained in the report using the same criteria that companies use in determining when a Section 15 report is required. The Division of Recalls and Compliance will evaluate whether a product contains a defect and if so, whether that defect

risks to the level of a substantial product hazard. If a product contains a defect that has the actual or potential risk to cause injury, the CPSC will initiate a recall, generally with the company's cooperation and input. The speed and specific requirements of the recall will be based upon the severity of the defect and the degree of the risk of injury. For example, a defect that has an imminent risk of death or serious harm will require immediate and comprehensive action to notify consumers, retailers and others who have the defective product so that the defective products can be identified and the defect mitigated through repair, replacement or refund. Regardless of whether a company chooses the Fast Track Recall Program or the standard recall, the company will need to develop a corrective action plan for the recall.

C. Corrective Action Plan

A corrective action plan is a document signed by the submitting company that describes the remedial action that the company is voluntarily undertaking with the CPSC's approval to protect the public from an allegedly defective product.¹⁹ The CPSC can initiate an enforcement action if it cannot reach agreement with the company on the corrective action plan, or if it becomes aware of additional facts that were not disclosed by the company.

A corrective action plan may include a number of parts depending on what is appropriate for the particular action. The corrective action plan may include a description of the alleged hazard including the alleged defect and any associated potential injuries; details pertaining to the vehicle and method of public notification such as a letter, press release or advertising and who a notice will be sent to; the model number and description of the product; instructions for safe handling or use of the product pending the corrective action; an explanation of the cause of the hazard if known; the corrective action being taken to eliminate the hazard such as repair, replacement or refund, and if the products are to be returned a plan for their disposition; steps

¹⁹ 16 C.F.R. 1115.20(a).

taken to prevent reoccurrence of the hazard in the future; and action taken to correct products in the distribution chain. In addition to this information, a corrective action plan must be signed by company representatives, must acknowledge and agree that the CPSC has the power to monitor the action and publicize the terms of the corrective action plan, and may contain a statement that the submission of the corrective action plan does not constitute an admission by the company that either reportable information or a substantial product hazard exists.

After a company submits a corrective action plan, the CPSC staff decides whether to accept that plan. Some factors that are considered when the CPSC is determining whether to accept the corrective action plan are the promptness of the company's reporting, any remedial actions taken, and the likelihood that the company will fully comply with the plan based upon any prior corrective actions.²⁰ The CPSC can approve the plan, reject the plan and issue a complaint against the company which begins an administrative or judicial action, or take other action to ensure the plan is adequate, such as suggesting revisions to the plan.

D. Recall Notice

As part of its corrective action plan, a company must prepare a recall notice, which will inform the public about the details of the recall. Every recall notice must identify the specific product, allow consumers to understand the products actual or potential hazards, and allow consumers to understand all remedies available to consumers concerning the product.²¹ The purpose of the recall notice is not limited to information, as it is also supposed to motivate consumers to respond to the notice and take the action suggested.

The CPSC has a multitude of requirements for the form of recall notices. The notices must be written in language that can be easily understood by the targeted consumers, and should

²⁰ 16 C.F.R. 1115.20(a)(2).

²¹ 16 CFR 1115.23.

be as simple as possible. The notice should be targeted and tailored to the specific product and circumstances, and when determining the form and content of the recall notice a company should consider how the original product was advertised and marketed.²² The CPSC views a direct recall notice, or one that is sent directly to specifically identified consumers, as the most effective form of a recall notice. However, in any recall, at least two of the following forms of notice must be used: (1) letters, web site postings, e-mail, text message; (2) computer, radio or television transmission; (3) video news release, press release, recall alert or web stream; (4) newspaper, magazine, catalog or other publication; and (5) advertisement, newsletter or service bulletin.²³ If a recall notice is posted on a web site, a link to the relevant information must be placed prominently on the home page. The CPSC directs that a direct recall notice should be used for each consumer that a company has direct contact information for, such as information obtained from product registration, sales records, catalog orders, billing records, marketing, warranty information, loyalty purchasing clubs, or similar sources. The direct recall notice must be prominently labeled to show its importance with a term such as “Safety Recall” in large type on the front of the envelope or in the subject line of the email.

The recall notice must also contain certain information. The word “recall” must be included in the heading and text, and the notice must contain the date of its release or publication. The notice must include a clear and concise statement of the information that will enable consumers to identify the particular product and determine whether or not they have the product, through information such as the product’s formal and informal names, the intended users (such as children), colors and sizes, model numbers or serial numbers and their location on the product, product tags or labels and their location, photographs of the product and the number

²² 16 CFR 1115.26.

²³ 16 C.F.R. 1115.26.

of units recalled.²⁴ The recall notice must describe what action the company is taking, such as halting the sale and distribution of the product, and what actions are open to the consumer, such as returning the product to the distributor or retailer for repair or refund and what action the consumer needs to take to obtain that remedy. The recall notice must also include related information such as the identities of the recalling company, manufacturer and significant retailers, the region the product was sold in, the approximate dates of manufacture and sale and the price of the product.

The CPSC also requires that information on the substantial product hazard, as well as descriptions of incidents or injuries, be included in the recall notice. Companies should be meticulous in their drafting of this information, as it is possible that the company will have the recall notice presented as an exhibit in a later product liability action. The recall notice must give a clear description of the hazards that result from the defect, failure, flaw or problem that gave rise to the recall, including the associated risks and potential injuries or deaths and the type of risk, such as burn, fall or choking. The recall notice must also contain a summary of all incidents, including property damage, injuries and deaths, associated with the product's defect, failure or flaw, as well as the number of these incidents, so that consumers understand the nature and extent of the incidents and injuries. Finally, the recall notice must state the range of dates during which the CPSC received information about injuries and deaths.

The CPSC makes the final determination as to the form and content of any recall notice related to Section 15 reporting and recalls, and the CPSC must review and agree in writing to the notice before a company can send out the recall notice.²⁵

E. Monthly Progress Reports

²⁴ 16 C.F.R. 1115.27.

²⁵ 15 C.F.R. 1115.29.

After a recall has been initiated, a company's reporting requirements are not complete. For a year after the recall has been initiated, the company must submit monthly progress reports, showing how many products have been corrected by the recall, how many additional accidents or injuries have occurred since the time the corrective action plan was implemented, what notification measures the company has taken each month and overall, and how many consumer contacts the company has received regarding the recall. The reports are submitted to the CPSC to ensure compliance with the terms of the corrective action plan and that the recall measures have been effective.

VI. PENALTIES

Engaging in proper reporting and recall procedures under the requirements of the CPSC is important not only from the perspective of ensuring customer safety, but also due to the heavy penalties the CPSC can levy against companies who are in violation of the Section 15 reporting and recall requirements. Prior to 2008, the CPSA provided for maximum penalties of up to \$8,000 per violation of the CPSA and up to a maximum of \$1.825 million for a series of violations. The CPSIA, which took effect on August 19, 2009, provides for increased civil penalties, namely up to \$100,000 for a single violation of the CPSA, and up to a maximum of \$15 million for a series of violations.²⁶

On March 31, 2010, the CPSC announced a Final Rule identifying and interpreting the factors that the CPSC will consider when determining the amount of a penalty against a company for a knowing violation of the CPSA, such as a failure to report under Section 15 or Section 37.²⁷ Once the CPSC has determined that a knowing violation of the CPSA took place and a civil penalty is appropriate, prior to March 31, 2010 the CPSC would consider the severity of the risk

²⁶ 15 U.S.C. § 2069

²⁷ 15 U.S.C. § 2068

of injury, the occurrence or absence of injury, and the number of defective products or the amount of substance distributed. As of March 31, 2010, in addition to those factors the CPSC must also consider the nature, circumstances, extent and gravity of the violation, including the nature of the product defect or the substance; the appropriateness of the penalty in relation to the size of the business or of the person charged, including how to mitigate undue adverse economic impacts on small businesses; and other factors as appropriate. The CPSC will also consider (1) whether a company had a reasonable safety and compliance program in effect at the time of the violation, including a system of collecting and analyzing information relating to safety issues such as incident reports and warranty claims; (2) whether a company has a history of noncompliance with the CPSC that is deserving of a higher penalty for repeated noncompliance; (3) whether a company has benefitted economically from a delay in complying with the requirements; and (4) whether a company has failed to respond to the CPSC in a timely and complete fashion in response to requests for information or for remedial action.²⁸

The range of penalties has steadily increased over the past several years, even prior to the enactment of the CPSIA. For example, in 2009 the CPSC collected nearly \$10 million in penalties, including a settlement with a power tool manufacturer for \$800,000 for failing to timely report a product hazard, a settlement with a small home appliance manufacturer for \$600,000 for failing to timely report defects and product hazards, and a settlement for \$2.3 million with an importer and seller of children's toys allegedly containing impermissible amounts of lead paint. In 2010, the CPSC's focus thus far has been on lead paint and children's toys, collecting nearly \$4 million so far this year. For example, the CPSC settled with an importer and distributor of children's toys for \$2.05 million and completely enjoined the company from importing children's products into the United States. In addition, the CPSC

²⁸ 16 C.F.R. 1119

settled with other companies for lead paint violations with fines for \$1.25 million, \$400,000, \$50,000 and \$25,000. Companies can expect that these fines will continue to increase.

VII. CONCLUSION

Regardless of how safety conscious a company tries to be, there are potential regulatory minefields that can have serious consequences for the unprepared. It is critical for every company manufacturing, importing or distributing products that will be sold in the United States to be aware of the CPSC regulations, reporting and recall requirements, and the penalties for non-compliance. Although reporting settlements and verdicts, potential defects or serious injuries to the CPSC can open a company up to a myriad of consequences, including increased product liability litigation, failing to report can create much worse financial and public relations difficulties for companies.