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“The Year Of The Recall”: CPSC Lessons To Learn

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In its November 2007 *Performance and Accountability Report*, the U.S. Consumer Product Safety Commission (“CPSC”) or (“Commission”) noted completion of 472 voluntary product recalls involving nearly 110 million product units in 2007. Dubbed “The Year of the Recall,” the startling increase in consumer product recalls has guided sweeping CPSC reform legislation, which is in its final stages of approval. Consequently, companies are scrambling to improve compliance with product safety requirements and manage the financial effects of a recall or increased litigation. The Senate and House of Representatives have each passed bills that, if signed into law, would dramatically affect the CPSC’s authority. Even absent new legislation, companies should evaluate existing procedures to ensure compliance with consumer product safety requirements.

Pre-Sale Product Safety Compliance

Companies can minimize the likelihood of a product recall by designing and manufacturing products that comply with specific safety standards and by implementing quality assurance programs in factories making the products. Because many of the federal product safety requirements also apply to retailers and organizations that buy products from third parties for resale, those entities should coordinate closely with manufacturers.

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• Mandatory and Voluntary Standards

Certain products are banned from sale unless they comply with mandatory safety standards, and some companies have learned the hard way about CPSC’s restrictions regulating lead use in furniture coatings, toys, and children’s products. Mandatory federal requirements also apply to potential hazards such as small parts and chemicals, and products such as clothing, bicycles and bicycle helmets, and mattresses.

In addition, organizations such as ASTM International, Underwriters Laboratories (UL), ISO, and American National Standards Institute (ANSI) administer voluntary standards for consumer products such as toys, sports equipment, candles and coffee makers. Because the standards do not cover every product or potential risk, compliance with an applicable mandatory or voluntary standard may be the minimum threshold for avoiding a product recall. Moreover, CPSC staff carefully considers compliance with a voluntary standard when determining whether a product presents a safety issue that should be reported to the Commission. For example, in April 2008, the Commission announced civil penalties against several companies, including Kohl’s Department Stores, Inc., to settle allegations of failure to report in a timely manner that products did not meet CPSC Guidelines for Drawstrings on Children’s Upper Outerwear, which were incorporated into a voluntary ASTM standard.

• Safety Audit and Certification Programs

As companies strive to manage manufacturing facilities and improve product quality, many are creating or enhancing existing quality audit and certification programs.



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Grymes

These programs can increase the control of manufacturers, private labelers and retailers. For example, the Toy Industry Association, Inc. is working through ANSI to develop an audit and certification program that would require importing companies and domestic manufacturers to meet three basic requirements for toys: (1) hazard and risk assessment for design; (2) factory process control audits; and (3) production sample testing to validate that compliance with U.S. safety standards in toy production is met.

At the federal level, the pending legislation would require third-party certifications for certain products and would require CPSC to establish standards for certification.

• Government Intervention for Imports

With an increasingly global economy, the number of consumer products imported into the United States has more than doubled over the past decade. Although imports currently account for about 44 percent of all consumer products sold in the United States, they account for over 75 percent of CPSC product recalls. In response, CPSC has announced new import surveillance strategies, including creating permanent posts for CPSC staff at major ports of entry to increase the agency’s oversight. The Commission, along with Customs and Border Protection, will test more samples and conduct more frequent port-of-entry surveillance blitzes – thus increasing the incentive to build product safety into the design and manufacturing process and to comply with safety standards.

Post-Sale Product Safety Compliance

A company’s obligations do not end once it manufactures or sells a consumer product. Section 15(b) of the Consumer Product Safety Act (CPSA)¹ requires manufacturers, importers, distributors, and retailers to report certain safety issues to the Commission,² which has authority to impose significant civil penalties against companies that fail to comply.

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• *Products That Must Be Reported*

Pursuant to Section 15(b), a manufacturer, importer, distributor or retailer must notify the Commission if it obtains information that reasonably supports the conclusion that a product distributed in commerce:

(1) *Fails to meet a consumer product safety standard or banning regulation.* This includes products that: (1) fail to meet the lead paint ban; (2) do not bear required warning labels; or (3) contain small parts and are intended for children under 3 years old.

(2) *Contains a "defect" that could create a "substantial product hazard."* A "defect" is a fault, flaw, or irregularity that causes weakness, failure, or inadequacy in form or function. A defect may result from a design, manufacturing or production error, or in a product's contents, construction, finish, packaging, warnings, or instructions, that presents risk of consumer injury. To determine whether a substantial product hazard exists, companies should consider the pattern of defect, the number of defective products distributed in commerce, and the severity of the risk. Products that violate regulations issued under laws the Commission enforces may also trigger a reporting obligation if the violation constitutes a product defect that could create a substantial product hazard.

(3) *Creates an unreasonable risk of serious injury or death.* The company should examine the utility of the product, the risk to consumers, the nature and severity of the potential hazard, and the likelihood of resulting serious injury or death. "Serious injury" includes mutilation, dismemberment, debilitating internal disorders, severe burns or electrical shocks, injuries requiring medical or surgical treatment, and injuries necessitating more than one day of absence from school or work. Products that violate regulations issued under laws the Commission enforces may also trigger a reporting obligation if the violation may create an unreasonable risk of serious injury or death.

(4) *Fails to comply with a voluntary standard upon which the Commission has relied.* The Commission has only formally relied upon two voluntary standards – chain saws and unvented gas space heaters. Even if compliant with an applicable voluntary safety standard, a product could still contain a defect that presents a substantial product hazard and requires a report.

• *Timing*

Firms must report under Section 15(b) "immediately," defined by the CPSC as within 24 hours of obtaining reportable information or, if an investigation is necessary, within 10 business days. The Commission considers a company to have obtained knowledge of safety-related information

when the information is received by an employee of the firm who may reasonably be expected to be capable of appreciating the significance of that information. The substantial product hazard category for reporting is the most broad, and companies struggle to apply its subjective criteria.

Companies should not wait to report until they have complete or accurate risk assessments. The Commission advises companies to report *potential* substantial product hazards even while investigations continue. A company's report does not automatically trigger a recall – what initially looks like a potential substantial product hazard may not actually be one. In FY 2007, the Commission received over 500 Section 15(b) Reports, and almost 200 of those resolved by February 2008 were closed without requiring corrective action.

• *Confidentiality of Information*

How the Commission will handle the confidentiality of information in a Section 15(b) Report depends on the disposition of the matter reported and the nature of the information in the Report. If the Commission has accepted a corrective action plan, the Section 15(b) Report will not be exempt from disclosure pursuant to a Freedom of Information Act request. Any trade secret or confidential commercial or financial information contained in the Report will be withheld if the company marks it as such.

Confidentiality of incident information could change with the pending legislation. The Senate version would require CPSC to establish a publicly available database of reported deaths, injuries, illness, and risk of such incidents, including incidents described in Section 15(b) Reports and those received from consumers, competitors, or elsewhere. The bill would not require review of the information to confirm its accuracy; rather, it would require CPSC to promptly remove any information determined to be inaccurate.

• *Civil Penalties for Failure to Report*

For each Section 15(b) Report filed, the Commission staff will evaluate whether and when a firm should have reported. If the CPSC believes a company failed to report in a timely manner, it may seek to impose civil penalties. The staff typically obtains penalties "voluntarily" – there is only one federal court decision, imposing reporting liability, *Mirama Enterprises, Inc.*³ In that decision, the court imposed a \$300,000 civil penalty and cited the Commission's instruction: "When in doubt, firms should report. Firms should clearly err on the side of over-reporting, rather than under-reporting."⁴

Civil penalty amounts are capped at \$8,000 for each violation and \$1.825 million for any related series of violations, although both the House and Senate versions of the pending legislation would increase the max-

imum to at least \$10 million. Since the *Mirama* decision, the Commission has announced several penalties in the \$1 million range paid by companies including Hamilton Beach/Proctor-Silex, Inc., Reebok International and Fisher-Price Inc.

The CPSC has already received additional federal funding and would receive more under the pending legislation. Funding is being used to increase the number of its employees, who will be able to help inspect products at ports and in stores, and to review the timeliness of Section 15(b) Reports.

Companies are encouraged to stay abreast of legislative developments to mitigate risk and ensure compliance as industry standards become increasingly stringent. The following practical pointers provide a framework for navigating regulatory compliance issues that may be helpful to manufacturers, importers, distributors and retailers of consumer products in the United States.⁵

Practical Pointers

- Identify applicable mandatory and voluntary standards prior to production or purchase of products from third-party manufacturers or distributors.

- Periodically train employees who purchase products for resale. Topics may include compliance with mandatory and voluntary standards, review of vendors, and procedures for notifying appropriate personnel of potential safety issues.

- Implement audit and certification programs for the manufacturing and design process. Take prompt action if deficiencies occur – the program has little value if it exists only on paper.

- Appoint a product safety committee of representatives from manufacturing and engineering, claims (including warranties), customer service, and legal departments to regularly review information to determine if it could reasonably support the conclusion that the product contains a defect that presents a substantial product hazard.

- Do not wait for a conclusive analysis before reporting to the CPSC.

¹ 15 U.S.C. § 2064(b).

² Additional statutory provisions trigger separate reporting requirements, such as those for manufacturers to report information about lawsuits and for manufacturers, distributors, retailers, and importers to report certain choking incidents.

³ *United States v. Mirama Enters.*, 185 F. Supp. 2d 1148 (S.D. Cal. 2002), aff'd, 387 F.3d 983 (9th Cir.).

⁴ Id. at 1158 (citing *Consumer Product Safety Commission's Statement of Enforcement Policy on Substantial Product Hazard Reports*, 49 Fed. Reg. 13820 (Apr. 6, 1984)).

⁵ A related article in this issue authored by Donna L. Wilson and Elissa O. Tomanda, also of Kelley Drye & Warren, LLP, discusses insurance aspects of product recalls.