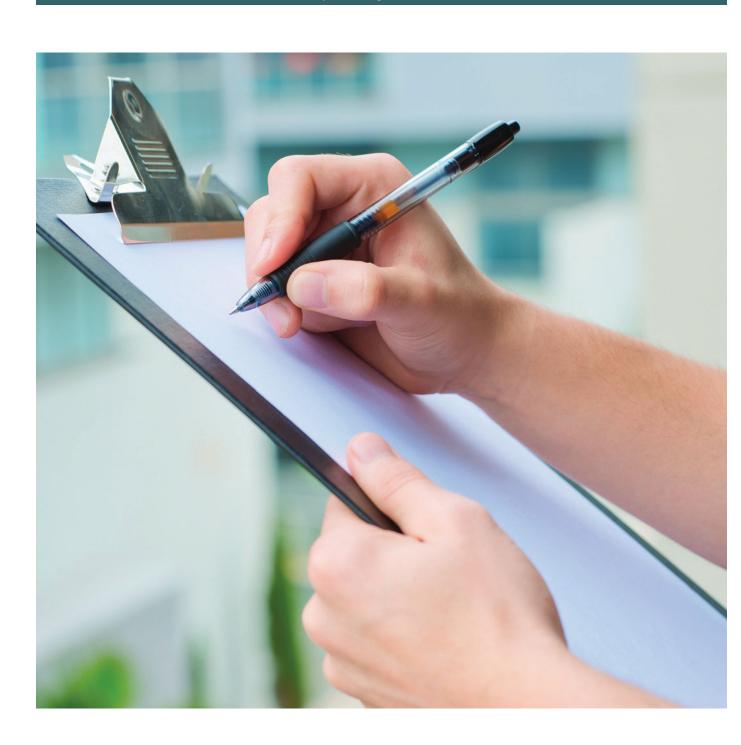
## **SAFETY PROGRAMS AND CPSC MANDATES**

Some Best Practices for Product Safety Management



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### By Kenneth Ross

ince its inception in the early 1970s, the U.S. Consumer Product Safety Commission (CPSC) has encouraged companies to implement active product safety management programs. This article will examine the CPSC's previous guidances on safety programs, describe the requirements imposed on companies, and discuss what they might mean.

These guidances and mandates are important since they can help a company determine if its safety program would be deemed sufficient by the CPSC or even by a jury in a product liability case and help identify areas where its program could be improved.

### PRIOR GUIDANCE ON SAFETY PROGRAMS

The CPSC first published the *Handbook for Manufacturing Safer Consumer Products* in the 1970s, shortly after the CPSC was created. The last edition of this Handbook came out in 2006 and discusses product safety policies, organization, and training as well as all aspects of design, manufacturing, quality, corrective actions, etc. In other words, it discusses safety procedures that it believes are appropriate for any company making consumer products in all aspects of design, production, sales, and post-sale.

The text of the Handbook begins by stating:

"Manufacturers must assure the safety of consumer products. This is achieved through the design, production, and distribution of the products they manufacture. It is best accomplished by a comprehensive systems approach to product safety, which includes every step from the creation of a product design to the ultimate use of the product by the consumer. The basic concepts for a comprehensive systems approach for the design, production, and distribution of consumer products are discussed in this Handbook."

In addition, the CPSC's Recall Handbook, in existence for many years but last updated in March 2012, includes sections on the appointment of a Recall Coordinator, development of a company recall policy and plan, and extensive suggestions for the creation and retention of records to support a recall.

The safety processes advocated in these handbooks are just suggestions and not legal requirements. In addition, they are similar to those procedures employed by companies that have a well-functioning safety effort. So, there is nothing particularly onerous here that a company shouldn't already be doing.

More recently, the CPSC's Small Business
Ombudsman posted a list of recommendations and
links to safety-related resources on how to make safe
products.¹ It is a concise yet informative list with links
to CPSC and other documents that can be helpful to
small business owners who don't have the resources for
full-time safety and compliance personnel.

And, in November of 2018, the CPSC hosted a Compliance Program Seminar featuring four separate panel discussions. There was a good discussion of the CPSC's list of ten steps to developing an effective compliance program. Slides from the Seminar are available at https://www.slideshare.net/USCPSC/compliance-program-seminar-panel-1-develop-a-compliance-program.

### REQUIREMENTS FOR SAFETY COMPLIANCE PROGRAMS

Since the publication of the Recall Handbook, requirements for safety compliance programs have been inserted by the CPSC into various documents.

First, on March 31, 2010, the CPSC published in the *Federal Register* a final rule laying out the factors that



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the CPSC staff will consider when deciding whether the CPSC should seek civil penalties. The rule (16 CFR §1119.4(b)(1)) clearly states that product safety programs are one of the factors to be considered by the staff in assessing civil penalties:

"The Commission may consider, when a safety/ compliance program and/or system as established is relevant to a violation, whether a person had at the time of the violation a reasonable and effective program or system for collecting and analyzing information related to safety issues. Examples of such information would include incident reports, lawsuits, warranty claims, and safety-related issues related to repairs or returns. The Commission may also consider whether a person conducted adequate and relevant premarket and production testing of the product at issue; had a program in place for continued compliance with all relevant mandatory and voluntary safety standards; and other factors as the Commission deems appropriate. The burden to present clear, reliable, relevant, and sufficient evidence of such program, system, or testing rests on the person seeking consideration of this factor."

In addition, the Commission released a statement dated March 10, 2010, concerning these new factors, which said in part:

"The safety/compliance program factor takes into account the extent to which a person (including an importer of goods) has sound, effective programs/systems in place to ensure that the products he makes, sells, or distributes are safe. Having effective safety programs dramatically lessens the likelihood that a person will have to worry about the application of this civil penalty rule. Any good program will make sure that there is continuing compliance with all relevant mandatory and voluntary safety standards. This is not the same as saying if one's product meets all mandatory and voluntary standards that the Commission will not seek a civil penalty in

appropriate cases. The Commission expects companies to follow all mandatory and voluntary safety standards as a matter of course."

Then, in September 2015, the CPSC issued a Staff Guidance on enforcement of civil penalties. This guidance states that:

"If a violation appears to have occurred, staff will evaluate potential civil penalty enforcement, including the need for remedial action, such as the implementation of internal controls and a compliance program. Depending on the facts and circumstances as well as other considerations, OGC may take a variety of approaches. Staff may decide to seek a civil penalty, determine that other actions are appropriate, or conclude that the matter should not be pursued at that time. In some situations, calling for remedial action where applicable factors may not compel civil penalties, staff may consider closing the matter without any civil penalty if the potential defendant formally agrees to implement appropriate remedial action."

Therefore, the CPSC has made it clear that a compliance program is important and will be considered in determining whether civil penalties are appropriate. This is very important since the CPSC has great discretion over whether to levy civil penalties and, if so, how much. In addition, if there is product liability litigation, the existence of a comprehensive product safety program can help to lessen the chances that the plaintiff's attorney might seek punitive damages.

### THE DAISO CONSENT DECREE

Around the same time that the new civil penalty factors were being finalized, the establishment of a product safety management program was included for the first time in a consent decree that levied civil penalties. In a March 4, 2010 agreement, Daiso Holding, a U.S. subsidiary of a Japanese company, agreed to pay a little more than \$2 million in fines for

violating various laws and regulations concerning the sale of toys and children's products.

The consent decree required Daiso to hire a product safety coordinator, who would then be charged with taking the following actions:

- Create a comprehensive product safety program;
- Conduct a product audit to determine which of Defendants' merchandise requires testing and certification of compliance with the FHSA, the CPSA, and any other Act enforced by the CPSC;
- Establish and implement an effective and reasonable product safety testing program in compliance with the FHSA, the CPSA, and any other Act enforced by the CPSC;
- Create guidance manuals for managers and employees on how to comply with product safety requirements;

- · Establish procedures to conduct product recalls; and
- Establish systems to investigate all reports of consumer incidents, property damage, injuries, warranty claims, insurance claims, and court complaints regarding products under the jurisdiction of the CPSC that the Defendants imported into the United States.

Daiso retained an independent consultant to certify compliance and the CPSC sent its staff to Daiso facilities to audit compliance. Daiso passed the audit and the monitoring was ultimately discontinued.

## SAFETY REQUIREMENTS IN CIVIL PENALTY SETTLEMENT AGREEMENTS

The CPSC did nothing further to impose safety requirements on manufacturers until they were inserted into civil penalty settlement agreements starting in February 2013. In the first agreement,





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It is certainly possible for a company with a robust safety program to have information that the CPSC would expect to be reported but decides not to report that information because it does not believe that there is a defect or substantial product hazard.

Kolcraft agreed to pay a \$400,000 civil penalty and to adopt a variety of actions to enhance their safety program.

Then Chairman Tenenbaum and then Commissioner Adler issued a joint statement in connection with this agreement, stating that they were concerned that Kolcraft had had a dozen recalls since 1989 and that further action was required. They said:

"The failure of a company to have an effective means of detecting and addressing serious or continuous safety issues with its products is contrary to the expectations of consumers and is unacceptable to this Commission. While we certainly understand that even the most responsible companies can make mistakes, the failure of a company to have in place an effective compliance program and internal controls is irresponsible. Thus, going forward, we expect those companies that lack an effective compliance program and internal controls to voluntarily adopt them. If not, we will insist that they do so."

The commissioners also made it clear in their statement that having an adequate safety program does not exonerate a company for failing to timely report a safety problem.

Then, in May 2013, Williams-Sonoma agreed to pay \$987,500 in civil penalties for failing to file a timely report with the CPSC. The requirements in the Kolcraft opinion were inserted into the Williams-Sonoma agreement.

Since May 2013, every settlement agreement for civil penalties has included at least some compliance requirements. This includes the Gree civil penalty in 2016, the Polaris civil penalty in 2018, the Cybex civil penalty in 2021, and the Core Health & Fitness civil penalty in 2022. These compliance requirements include:

- Programs designed to ensure compliance with CPSC requirements including written standards, policies, and procedures; and
- A system of internal controls and procedures concerning documentation, reporting to the CPSC, and reporting to management.

Finally, in 2021, Gree Appliance agreed to a plea deal, thereby deferring prosecution for criminal charges. This agreement included requirements for establishing and maintaining written standards, policies, and procedures to ensure compliance with the CPSA, including UL certification or listing and whether testing to confirm compliance has been conducted. Under the plea deal, Gree also agreed to implement, maintain, and enforce an effective system of internal controls and procedures addressing the reporting of safety issues to the company's management.

The Gree plea agreement also included requirements in the areas of confidential employee reporting, training and enforcement, management responsibility and accountability, and record retention. And last, Gree was required to retain a compliance expert to help set up these programs and to report to the government concerning the company's progress in completing them.

Based on this history, it is virtually certain that future settlement agreements in civil penalty matters will contain some type of requirement for the establishment of more robust safety compliance programs. It is still an open question as to how compliance will be audited and monitored and when the CPSC will require that additional processes and procedures be established. In addition, it is unknown what the CPSC would do if a firm never fully complies with these requirements or complies with all of these requirements but still has a problem with safety and reporting to the CPSC.

#### CONCLUSION

It is certainly possible for a company with a robust safety program to have information that the CPSC would expect to be reported but decides not to report that information because it does not believe that there is a defect or substantial product hazard. So, reasonable minds may differ. At the same time, it's difficult to justify civil penalties and impose new procedures on a manufacturer who may already have sufficient programs in place.

It will be interesting to see in the future whether companies that have good safety programs are able to keep these provisions out of their settlement agreements and corrective action plans and whether these programs will enable them to escape all civil penalties or negotiate lower civil penalties.

In this context, manufacturers should consider all of these requirements and evaluate their own programs. They should also consider the best practices detailed in ISO 10377, "Consumer product safety – Guidelines for suppliers," which sets forth practical guidance in safety management, as well as other studies and reports on what constitutes an effective product safety management program. (See articles at http://www.productliabilityprevention.com discussing the ISO standard and other product safety management best practices.)

Most companies don't do a good enough job of safety management, especially as they begin to sell globally and have to monitor safety issues and incidents around the world. Therefore, it is prudent for every company to take a fresh look at its current safety program and evaluate what changes could be made to improve its effectiveness.

Being proactive about complying with these requirements before you have a safety problem is the prudent and responsible thing to do. Dealing with these issues after a problem arises increases the risk of it turning into a huge problem for your products and your company anywhere your products are sold. ©

### **ENDNOTE**

1. See https://www.cpsc.gov/business--manufacturing/business-education/business-guidance/BestPractices

