I'm From the Government and I'm Here to Help – CPSC Mandates Safety Programs for Manufacturers and Retailers

By Kenneth Ross[1]

Since its inception, the U.S. Consumer Product Safety Commission ("CPSC") has encouraged companies to implement active product safety management programs. Since 2010, however, the CPSC has made this a bit more official. Requirements for the establishment of safety compliance programs has appeared in a final rule of factors to be considered for civil penalties, in a number of consent decrees and settlement agreements for civil penalties, in letters from the CPSC where they decided not to seek civil penalties, and finally in a proposed interpretive rule.

This article will examine the CPSC's previous guidance on safety programs, describe the new requirements and proposed rules and discuss what they might mean.

Prior Guidance on Safety Programs

The CPSC first published the *Handbook for Manufacturing Safer Consumer Products* in the 1970s, shortly after it 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.

At the beginning of the handbook, it says:

> 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 updated in March 2012, has had 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 who have a well-functioning safety effort. So, there is nothing particularly onerous that a company shouldn't already be doing.

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New Requirements for Safety Compliance Programs

Recently, requirements for safety compliance programs have been inserted by the CPSC into various documents.

- Factors to Consider for Civil Penalties

First, on March 31, 2010, the CPSC published in the Federal Register a final rule of factors that the staff will consider to decide whether they will seek civil penalties. The rule 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.

16 CFR §1119.4(b)(1).

In addition, the Commissioners 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.

- Daiso Consent Decree

At the same time that the new civil penalty factors were being finalized, for the first time, the establishment of a product safety management program was included in a consent decree for 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 requires Daiso to hire a product safety coordinator that is approved by the CPSC to do, in part, the following:

- 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; and
- 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
- 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 Defendants imported into the United States

The consent decree contains many more specific requirements and includes the following monitoring requirements:

> At the end of the first year of the monitoring period and at the end of any 180-day extension of the monitoring period under this paragraph, the Coordinator shall provide a written report to the Office of Compliance. If the Coordinator certifies Defendants are in compliance as described in this paragraph, the monitoring period will end. If the Coordinator cannot certify that Defendants meet each of the compliance requirements listed below, the monitoring period shall continue for an additional 180 days, at the end of which the Coordinator shall provide an updated written report to the Office of Compliance.

Paul Rosenlund, counsel for Daiso, reports that Daiso retained an independent consultant to certify compliance, that the CPSC did send staff to Daiso facilities to audit compliance, that Daiso passed, and that the monitoring was ultimately discontinued.

- Safety Requirements in Civil Penalty Settlement Agreements

The CPSC did nothing further to impose safety requirements until they were inserted into three 2013 civil penalty settlement agreements and one 2014 settlement agreement.

In February 2013, Kolcraft agreed to pay a $400,000 civil penalty. In addition, they agreed to the following language:

> Kolcraft shall maintain and enforce a system of internal controls and procedures designed to ensure that: (i) information required to be disclosed by Kolcraft to the Commission is recorded, processed and reported in accordance with applicable law; (ii) all reporting made to the Commission is timely, truthful, complete and accurate; and (iii) prompt disclosure is made to Kolcraft's management of any

> significant deficiencies or material weaknesses in the design or operation of such internal controls that are reasonably likely to adversely affect in any material respect Kolcraft's ability to record, process and report to the Commission in accordance with applicable law.
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> Upon request of Staff, Kolcraft shall provide written documentation of such improvements, processes, and controls, including, but not limited to, the effective dates of such improvements, processes, and controls. Kolcraft shall cooperate fully and truthfully with Staff and shall make available all information, materials, and personnel deemed necessary by Staff to evaluate Kolcraft's compliance with the terms of the Agreement.
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> Kolcraft shall implement and maintain a compliance program designed to ensure compliance with the safety statutes and regulations enforced by the CPSC that, at a minimum, contains the following elements (i) written standards and policies; (ii) a mechanism for confidential employee reporting of compliance-related questions or concerns to either a compliance officer or to another senior manager with authority to act as necessary; (iii) effective communication of company compliance-related policies and procedures to all employees through training programs or otherwise; (iv) senior manager responsibility for compliance; (v) board oversight of compliance (if applicable); and (vi) retention of all compliance-related records for at least five (5) years and availability of such records to CPSC upon request.

Then Chairman Tenenbaum and Commissioner Adler issued a joint statement in connection with this agreement saying that they were concerned that Kolcraft had had a dozen recalls since 1989 and that some 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 2companies 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 get a company off the hook 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 report timely to the CPSC. The three paragraphs from the Kolcraft opinion quoted above were also inserted in the Williams-Sonoma agreement.

Then Commissioner Nord submitted a statement on the Williams-Sonoma agreement that confirmed that while she is a strong advocate for corporate compliance programs, she questions the piecemeal creation of a mandate for such programs through enforcement. Commissioner Adler, who is now Acting Chairman, responded to Commissioner Nord’s concern and signaled how he views the future use of such safety requirements. He said, in part:

> Far from viewing this settlement as punishment, I view it as the Commission and the company mutually agreeing to a set of reasonable measures designed to lead to safer products and fewer recalls in the future. Indeed, I suspect that the reason that companies agree to such language is their sense that any conscientious, responsible firm should follow such procedures in their approach to compliance. And to the extent that their past practices might have fallen short of these goals, they are eager to demonstrate that their future approach will be one of strict adherence to such provisions.
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> The fact that the Commission has sought similar language in the two settlements says little at this point about whether there has been a shift in agency policy in the future. Even if it did, there is nothing improper about implementing the policy in individual case settlements. That said, I do not rule out asking for such clauses in future non-civil penalty settlement agreements nor do I rule out future expansions of the Commission's voluntary recall policies.

Next, in June 2013, an additional settlement agreement was finalized involving Ross Stores that included safety compliance requirements. In the settlement agreement press release, the CPSC stated:

> In addition to paying a monetary penalty, Ross has agreed to implement and maintain a compliance program designed to ensure compliance with the reporting requirements of Section 15(b) of the Consumer Product Safety Act and the Final Rule. Ross also agreed to enhance its existing compliance policies by ensuring that its ongoing program contains written standards and policies, a mechanism for confidential employee reporting of compliance related questions or concerns, and appropriate communication of company compliance policies to all employees through training programs. Ross has designed and implemented a system of internal controls and procedures to ensure that the firm's reporting to the Commission is timely, truthful, complete, accurate, and in accordance with applicable law. The company will also take steps to ensure that prompt disclosure is made to management of any significant deficiencies or material weaknesses in the design or operation of such internal controls.

On the question of the enforcement of this agreement, the agreement says:

> Upon reasonable request of staff, Ross shall provide written documentation of its procedures, including, but not limited to, the effective dates of its procedures and improvements thereto, and shall cooperate fully and truthfully with staff and shall, upon reasonable notice, make available all non-privileged information and materials, and personnel with direct involvement in such procedures, if reasonably requested by staff in relation to an investigation of noncompliance by Ross with the Final Rule and/or CPSA §15(b).

Then, lastly, the CPSC announced a fourth settlement of a civil penalty proceeding in April 2014 against Forman Mills. Forman Mills agreed to pay a civil penalty of $600,000 and to establish safety procedures described by the CPSC in their press release as follows:

> In addition to paying a monetary penalty, Forman Mills has agreed to implement and maintain a compliance program designed to ensure compliance with the statutes and regulations enforced by the Commission. Forman Mills also agreed to maintain and enforce a system of internal controls and procedures designed to ensure that information required to be disclosed to the Commission is recorded, processed and reported in accordance with applicable law and that all reporting made to the Commission is timely, truthful, complete and accurate. The firm will also take steps to ensure that prompt disclosure is made to Forman Mills' management of any significant deficiencies or material weaknesses in the design or operation of such internal controls.

Based on this history, it is virtually certain that future settlement agreements 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 the firm never fully complies with these requirements.

And, let's say the firm complies and then is charged again with late reporting? Will their new safety programs reduce the likelihood of penalties or reduce the amount of penalties? This is a concept that has already been adopted by the Department of Justice in connection with the Federal Sentencing Guidelines for Organizations. The establishment of a compliance program is taken into account when deciding whether to defer prosecution or what amount of penalties to seek.

<u>Safety Requirements in Other Agreements</u>

As signaled by Acting Chairman Adler in his statement above, even if the CPSC decides not to seek civil penalties, they might ask companies to set up more robust programs. In September 2013, I received a letter from the CPSC saying:

> Our decision not to proceed with a civil penalty is conditional upon the Firm agreeing to take the following corrective measures by establishing procedures for: (a) handling complaints and incidents; (b) corrective and preventive actions upon discovery of compliance deficiencies or violations; (c) appropriate internal controls to prevent future violations; (d) training and education of appropriate personnel on compliance procedures; (e) senior management-level responsibility for the compliance activities identified in this letter; and (f) periodic reporting to the Firm's board of directors (or equivalent governing body), including reporting of significant deficiencies or material weaknesses in the design or operation of compliance-related procedures described in this letter.

I have heard from other CPSC lawyers that they have also seen such requests in letters of this type. However, one recent letter used the word "encourage" rather than "required" concerning

such programs. And some of these letters make it clear that the manufacturer still has a duty to report new information and if they don't, they could again be subject to civil penalties for late reporting.

Safety Requirements in Corrective Action Plans

The last CPSC action concerning compliance programs is contained in a notice of proposed rulemaking published in the November 21, 2013 Federal Register. This rule deals with voluntary recall notices, but also allows the CPSC to mandate compliance programs as part of corrective action plans ("CAP"). The staff description of the rule says:

> Negotiated corrective actions give Commission staff the opportunity to tailor remedies to a particular situation and the associated health and safety risks presented. The proposed rule would include language that would permit, in appropriate situations and at staff's discretion, staff to pursue compliance program requirements in the course of negotiating corrective action plans. The proposed rule contemplates that if appropriate, a corresponding reference to compliance program requirements may be included in the related voluntary recall notice. Inclusion of compliance program requirements as an element of voluntary corrective action plans would echo compliance program requirements incorporated as part of recent civil penalty settlement agreements.

This proposed interpretative rule also provides that the corrective action, including an agreement as to the establishment of a safety program, is legally binding. Therefore, if this rule is approved, the CPSC would be able to legally enforce the compliance program if the company does not comply.

The new proposed rule would allow the CPSC to include compliance programs in CAPs in the following situations:

- Multiple previous recalls and/or violations of Commission requirements over a relatively short period of time;
- Failure to timely report substantial product hazards on previous occasions; or
- Evidence of insufficient or ineffectual procedures and controls for preventing the manufacturing, importation, and/or distribution of dangerously defective or violative products.

As stated in the description, the requirements for safety programs are the same as those in the civil penalty settlement agreements described above.

As with the inclusion of compliance programs in settlement agreements, there are significant unknowns concerning the ability of the CPSC staff to become familiar with a company's compliance program, make suggestions for a future program and to audit compliance. Erika Jones stated in her comments to this proposed rule on behalf of the Bicycle Product Suppliers Association:

> Moreover, this proposal would significantly slow down the negotiation of corrective action plans. Rather than focusing solely on the product safety issue and the appropriate remedy, the negotiation process would now include such things as the adequacy of the structure of the firm's internal management, the firm's written policies and procedures for handling product issues, the training that is offered to firm employees involved in product safety and quality, among many other items. Before staff can even begin the negotiation process and create a proposed structure for an appropriate "compliance plan," they will have to first inquire into and fully understand the operations of a company and its current compliance plans and product safety programs. This is a far greater administrative undertaking than gathering and reviewing the information required to be submitted with a Section 15 Report.

And, since the compliance program requirements will be legally enforceable, it is even more important that they be achievable and that the manufacturer can accomplish them without slowing down the primary task of recalling the product.

It is unclear how the CPSC will be able to evaluate the procedures and controls of the manufacturer or product seller and determine whether they are insufficient or ineffectual. Who will do it? When will they have time to do it? What is the basis of their determination? Will the recall be postponed until this analysis is done?

The comment period was over in February 2014 and we are waiting to see what the staff and Commissioners decide to do. However, since February, the President nominated two new Commissioners, one being the new Chairman, and they are awaiting confirmation. Therefore, it is likely that there will be a delay in any decision on this interpretive rule.

Conclusion

It is certainly possible for a company to have a robust safety program, to have information that the CPSC believes should be reported, but it doesn't report because it does not believe that there is a defect or substantial product hazard. So, reasonable minds may differ. That doesn't justify imposing 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 agreements and whether these programs will enable them to escape all civil penalties or negotiate lower civil penalties.

Unfortunately companies can't just worry about the U.S. The European Union has just proposed revisions to its safety regulations. The new proposed General Product Safety Regulations have enhanced requirements for all companies in the supply chain in areas such as documentation, risk assessment, traceability, labeling, and market surveillance.

So, manufacturers should consider all of these requirements and evaluate their own programs. They should also consider the new ISO standard which sets forth some "best practices" in safety management as well as other studies and reports on what is an effective product safety management program. See Ross, "New International Standard on Consumer Product Safety," in

Strictly Speaking, August 2011and Ross, "Establishing an Effective Product Safety Management Program," in *For the Defense,* Defense Research Institute, Inc., January 2003.

Most, if not all, of these practices and requirements have been utilized for decades by many companies. None of this is particularly new. However, most companies don't do a good enough job, especially as they begin to sell globally and have to monitor safety issues and incidents around the world. Also, the reporting requirements in other countries make it more difficult to coordinate this monitoring and decide how to respond to incidents and comply with everyone's different reporting requirements.

Therefore, it would be prudent for any company to pull their safety program out of the file cabinet and take a look at it with a fresh eye. 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 the product is sold.