Product Safety Management – Its Time Has Come
By Kenneth Ross[*]

An effective product safety management program can help to reduce accidents, reduce recalls, reduce insurance premiums, increase the safety and quality of products, provide a more defensible product and company in the event of litigation, and minimize the chance of punitive damages. And the techniques have been well-developed for decades.

With that said, why are so many manufacturers being sued and fined by government safety agencies? Why are so many products being recalled, many times by well-known and respected manufacturers? Why are legislative bodies here and around the world enacting sometimes oppressive legislation to force manufacturers to do a better job of providing a safe product? And, why are retailers creating a global safety standard that will be imposed on those who sell to them?

Obviously, companies must not be devoting enough resources to these efforts. Why is that?

As someone who has counseled manufacturers on product safety, regulatory compliance, and product liability prevention for over 30 years, I have seen many answers and excuses: We haven't had too many problems yet; it's the cost of doing business; everyone's job is product safety; that's why I have insurance; my foreign supplier will take care of the problem if anything happens; it costs too much and I can't cover the cost in my prices; my competitor's aren't doing these things, so how can I justify the effort and expense?

I have written previously about the elements and benefits of such programs. See *PLP: Even More Important in Tough Economic Times* in the January 2009 issue of *Strictly Speaking* and *Establishing an Effective Product Safety Management Program* in the January 2003 issue of For the Defense. (These articles are available on www.productliabilityprevention.com.)

While I won't repeat what is in these articles, I wanted to report to you on some recent developments concerning consumer products and industrial products which help solidify my earlier thinking and recommendations concerning the necessity of such a program and its important elements.

RILA/BRC Global Standard for Consumer Products

In 2003, the British Retail Consortium (BRC) published a standard for consumer product manufacturers who were selling private label products to British retailers. Since then, this standard has been extensively revised and updated to reflect the latest thinking in the

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production of safe and legal consumer products. Its third edition has been released and BRC is now working with members of the Retail Industry Leaders Association (RILA) to finalize and implement the standard.

RILA members include Wal Mart, Costco, Lowe's, Home Depot, Target, Sears, Walgreens, and Best Buy. BRC members are the leading British retailers.

In the current draft, the standard is described as follows:

> The text of the Standard specifies the safety, quality and operational criteria required to be in place within a manufacturing organisation to fulfil obligations with regard to legal compliance and protection of the consumer. It forms a core to the Global Standard for Consumer Products scheme which encompasses a network of approved and accredited certification bodies, employing qualified auditors who audit companies and provide a detailed report assessing the company's compliance with the requirements of the Standard. If successful, the audited company becomes certificated to the Standard and is listed on the BRC Directory of suppliers.

The final draft will be published in April of 2010 with implementation to take place through 2011.

The standard applies to both private labeled products (branded with the name of the retailer or the retailers' brand name) and branded products (branded with the name of the manufacturer). Each retailer will have to decide which of its suppliers will be subject to the requirements of the new standard. I suspect that most will concentrate first on smaller manufacturers of private label products whose manufacturing facilities are in foreign countries.

Of course, this standard, to the extent it exemplifies the best current thinking on product safety procedures, can be used by anyone, including component part and raw material suppliers to consumer product manufacturers, as well as manufacturers of non-consumer products.

Some of the key elements of the standard are as follows:

- Supplier's senior management shall develop and implement a product safety policy that is communicated to personnel.

- The supplier shall perform a systematic, comprehensive, and thorough risk assessment that is fully implemented and maintained. This will include reference to legislation, product standards, codes of practice, and developments in science and technology.

- All documents, records and data critical to the management of product safety, legal compliance and quality must be in place and effectively controlled.

- The supplier shall have a clearly defined and documented organizational structure with responsibility for product safety, legal compliance, product quality, and management systems. This organization shall have a named individual with relevant experience and qualifications to be responsible for its management. In addition, the company shall audit the management system to ensure that it is being complied with and is appropriate under the circumstances.

- The supplier shall control all purchasing processes which are critical to product safety, legal compliance and quality. This includes an ongoing assessment which monitors performance of suppliers such as subcontractors and component part suppliers.

- Procedures must be in place to record, investigate, analyze and correct the causes of nonconforming products or the failure to meet standards, specifications and procedures which are critical to product safety, legal compliance and product quality.

- The standard requires an extensive traceability system starting with the identification of components and raw materials and ending with finished products and materials. The company must test the traceability system to ensure that products can be traced. This test must be done at least annually. It is also required that subcontractors and component part suppliers must be able to trace their products to a level appropriate for the risk.

- The supplier must have a plan in place to effectively manage product withdrawal and product recall procedures. These procedures shall be regularly tested, at least annually, and results of the tests retained.

The key additional requirement is that suppliers must have their compliance with the standard confirmed by an accredited third party auditor. These auditors will most likely be the same third-party testing laboratories that currently are accredited to certify compliance with the standards issued pursuant to the Consumer Product Safety Improvement Act and with requirements of the EU Machinery Directive to justify a CE mark.

I have a few preliminary observations concerning this standard

- These requirements are an extensive and comprehensive interpretation of the product safety management procedures that have been around for decades.

- This is not an official consensus standard as you would have from ANSI or ASTM. And the number of retailers that are members of these groups is fairly limited. Therefore, it remains to be seen what effect this will have going forward.

- The inclusion of these requirements in such a document could enhance the acceptability of these procedures for manufacturers of all kinds of products. This could raise the state of the art in product safety as more and more companies

adopt these kinds of procedures and documentation controls. However, there are many different ways to improve product safety and many manufacturers do not have to do all of the things identified in this standard to achieve that goal.

- Those manufacturers who are not required by retailers to comply with this standard may still need to explain why they don't comply with the "state of the art" and may suffer the consequences of non-compliance. However, they still have that task today as these procedures have been well-known for decades.

- There will probably be much more documentation available that will be subject to discovery. The standard should increase documentation on safety and quality between the supplier, the retailer, and the third party auditor before and after sale as well as between the OEM and the OEM's suppliers. Some of these documents may prove challenging to explain if an incident occurs and litigation results. And manufacturers will have to worry about whether business confidential information will be disclosed to retailers and possibly competitors.

- A big question is whether such extensive procedures are necessary for the vast majority of manufacturers who already have product safety management programs of some sort in place. In addition, for those manufacturers who already spend lots of time and money on various certifications such as UL or CSA, do they really need to go through another audit process as required by this standard? Retailers who use this standard will need to make some important decisions as to which manufacturers need to comply and whether they really need to be audited.

This process will play itself out this year and next. RILA and BRC are preparing training programs for potential auditors, retailers and manufacturers to educate everyone about the new standard. At this point, it is safe to say that more organized and comprehensive product safety management procedures of some sort will be the norm in the future for many consumer product manufacturers.

U.S. Consumer Product Safety Commission (CPSC)

The CPSC has always encouraged companies to implement active product safety management programs. It has had available a *Handbook for Manufacturing Safer Consumer Products* for many years. For the current edition of this handbook, see http://www.cpsc.gov/businfo/intl/handbookenglishaug05.pdf.

However, recently, this has become a bit more official. On March 16, 2010, the CPSC Commissioners approved a final rule of factors that their staff will consider in connection with potential civil penalties. While the final rule has not yet been published in the Federal Register, the last draft (Interim final interpretative rule – Federal Register, September 1, 2009) stated clearly that product safety programs would be considered by the staff. The rule states:

> **Safety/Compliance Program and/or System**: The Commission may consider, for example, whether a violator had at the time of the violation, a reasonable program/or system for collecting and

analyzing information related to safety issues, including incident reports, lawsuits, warranty claims, and safety-related issues related to repairs or returns; and whether a violator conducted adequate and relevant premarket and production testing of the product(s) at issue.

In addition, the Chair of the Commission released a statement dated March 16, 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 approach is analogous to the 1992 Federal Corporate Sentencing Guidelines where the existence of comprehensive compliance programs can help mitigate criminal fines imposed by the government against corporations.

Lastly, the establishment of a product safety management program was included in a recent consent decree for civil penalties. In a March 2, 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 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

There are many more specific requirements in the consent decree which lead me to believe that this program was instituted at the request of the CPSC. Given the level of the fine and the description of the violations, it is apparent that the CPSC viewed this as egregious. In future penalty cases where the violation is not so significant and the manufacturer already has some safety program in place, it remains to be seen whether such a detailed program would be required.

Despite that, manufacturers and retailers should take these events as evidence that the CPSC will be less likely to impose heavy penalties if the company can show that they had a system in place which evidenced a real commitment to prevention and compliance.

<u>Machinery Safety</u>

There have been some developments in the machinery safety area which also expand requirements for some of the safety procedures we are seeing being mandated for consumer product manufacturers.

In 2006, the European Machinery Directive was modified and applies to all machines sold in Europe after December 29, 2009. The EU issued in December 2009 a 337 page guide to the new directive. While this directive does not specifically require many of the management procedures in the RILA/BRC standard, such as a product safety policy, it does include some of them. To see the December 2009 guide, go to http://ec.europa.eu/enterprise/sectors/mechanical/machinery/index_en.htm.

Risk assessment is a key requirement in this directive. It was not a requirement in the earlier version of the directive which came out in 1998. There are a number of new provisions where the manufacturer must make important design decisions based on a risk assessment. These can't be educated guesses. The procedures must comply with EN ISO 14121-1:2007 - *Safety of machinery — Risk assessment —*Part 1: *Principles*. And the risk assessment must be kept as part of the technical construction file.

In addition, the new directive makes it clear that the machinery, especially safety devices, must be designed for reasonably foreseeable and intended use as well as abnormal or unintended uses. And, the requirements for instructions have been expanded. Last, this new directive contains market surveillance requirements mandating that member countries work together to locate non-complying machinery with a goal of taking them out of service or getting them fixed, and preventing their sale. The Guide makes it clear that manufacturers and government authorities are to use risk assessment to determine if machinery violates the essential health and safety requirements of the Directive and needs to be repaired or replaced. In addition, the authorities can take the machinery out of service by issuing a notice in RAPEX, the safety notification system used for consumer products.

Machinery sold in Europe will need to be redesigned in accordance with new risk assessment procedures and instruction manuals will need to be revised to comply. In addition, manufacturers will have to institute their own market surveillance programs where risk assessment is applied to adverse field experiences. These changes could also impact machines sold in the U.S. To the extent that manufacturers want to sell machinery in the U.S. that is the same as in Europe, they will need to consider this directive as well as U.S. based machinery standards.

Risk assessment is a concept that has been in U.S. machinery safety standards since 2000. However, these standards are being revised right now to make risk assessment mandatory for compliance. (see the ANSI B11 series of standards.)

Now you might think that requiring risk assessment is not a big deal. However, many manufacturers do not do a formal risk assessment. They design the product to comply with the standards in effect where the product is sold and that's it.   Their assumption is that the standards group did a risk assessment and they don't need to. But this guide to the new Machinery Directive raises lots of options in design that need to be resolved by the manufacturer. Therefore, doing a formal risk assessment becomes a necessity.

I have written before about risk assessment and the legal implications of creating those documents. See *"Risk Assessment and Product Liability,"* (with Bruce Main), For the Defense, April 2001 (also available at www.productliabilityprevention.com). The more risk assessments that are performed, the more explaining a manufacturer may have to do as to what they mean, how risk was evaluated, and how final decisions were made.

Product Safety Survey

In 2009, a product safety engineer who works in the plastics equipment industry was awarded a PhD in safety engineering. In connection with that effort, he published a dissertation which included a survey of over 30 product safety professionals in the plastics industry.

The engineer, Doug Sten, first reviewed the safety literature and identified the key elements of a safety program as described by those who have worked in the area for many years. He identified 40 key elements of any product safety program and asked these professionals to grade them as Critical, Very Important, and Important. Seventeen elements were described as critical. A review of these seventeen items (as well as all 40) shows that product safety management systems and procedures for consumer products and machinery are pretty similar. Below are the 17 elements viewed as critical:

- Ensure that there is a written corporate product safety policy

- Provide appropriate communications to all employees

- Perform design reviews, assessing intended use vs. misuse

- Perform formal risk assessment as part of design review

- Apply current, industry safety-related design standards

- Produce a prototype of a product before going into production

- Develop a manual that is easy to follow, apply and understand

- Test product for reliability, quality and safety prior to shipment

- Provide clear, emphatic warnings where there remains residual risks

- Design product safety labels that are in compliance with safety standards

- Provide labels and instructions in the language of users where the product is to be used

- Assess and communicate to engineering feedback from customers received from sales and technical service personnel regarding any product safety issue

- Send certified letters to customers whose machines were found not to be using safety guards as originally designed

- Sales and technical service personnel must report accidents they are aware of that occurred at a customer's site

- Perform on-site investigation once informed of an accident

- Develop a formalized product recall or retrofit program

The importance of the above list is that it is consistent with what has been done for decades and what is being included in standards and guidelines issued by various entities for all kinds of products. In addition, the respondents to this survey currently work in the product safety function and, when their individual levels of experience are added up, have many hundreds of years of experience. Therefore, their vote as to critical elements of a safety program should carry some weight.

Conclusion

No matter what a manufacturer does, it is always possible that its product safety program is lacking in some respect and could arguably constitute evidence of a disregard for safety. To combat that possibility, any program must be able to show a high regard for safety, both on paper and in actions. If this showing is made, even if the jury believes that the manufacturer could have done more, it should also believe that the manufacturer tried to do the right thing and may not be inclined to award punitive damages.

As companies better organize themselves for the world-wide challenges of providing safe products, the bar will be raised. Companies who do not follow the lead will be at great risk of further product safety, product liability, and regulatory problems, in the United States, in Europe, and in other foreign countries.

The techniques are well-known; the difficult part is to analyze what is appropriate for a particular company and then incorporate it into the company's organization, culture, and processes. Doing so should pay for itself, either by preventing future problems that could arise or giving the manufacturer a much better defense if accidents do occur.