

Recall Implementation and Effectiveness: New Guides and Standards

By Kenneth Ross*

Introduction

In the last issue of *Strictly Speaking*, I wrote on recall preparedness. In that article, I briefly mentioned, but didn't describe, various guides on how to undertake recalls. In addition, since I submitted that article, there have been a number of new guides and standards issued on implementing recalls. As a result, I thought it would be timely to bring you up to date on this important topic.

As I have previously discussed, recalls are the most costly and potentially damaging event in any manufacturer's experience. No matter what a manufacturer does, the success rate will be significantly less than 100%. Any resultant accident caused by a recalled product will have to be defended. And, as someone who serves as an expert witness on recall adequacy, I can attest to how difficult that can be.

Recall adequacy is based on negligence. The question is could you have done more? Of course, the answer to that question is always yes. But should you have done more? And does the fact that you didn't do more make you negligent and did that negligence cause the accident? That's the big unknown – it's up to the jury. Would doing more have prevented the accident? This is unlikely, but it is hard to know how a jury will react to the testimony and thus many of these cases settle.

Therefore, a manufacturer and product seller must be prepared to defend the adequacy of its remedial program. One way to do that is to consider and adopt "best practices" as set forth by government agencies and standards groups. One difficulty with doing so is that these best practices are being published and enacted all around the world. So there is no one guide or regulation to look at. Plus, these are just guides and do not offer a "safe harbor" if you do what is set forth in any of these documents.

However, if you ignore these best practices or aren't prepared to defend your decision not to employ such tactics, it could make the case harder to defend and possibly result in a higher settlement value.

So, let's see what is on the horizon.

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CPSC

In March of 2012, the CPSC issued a new recall handbook that brings up to date the original version that was issued in 1999. I described the CPSC's original Recall Handbook in my Fall 2009 article for *Strictly Speaking* entitled "Recall Effectiveness: A Hot Topic."

In September of 2009, the CPSC launched "CPSC 2.0," an effort by the CPSC to make safety information more accessible to consumers by utilizing a variety of technologies and social media sites. The new Recall Handbook basically incorporates these new social media technologies as techniques to be considered by manufacturers and product sellers. It also incorporates the new requirements authorized by the Consumer Product Safety Improvement Act.

The new CPSC handbook restates that the core element of a recall is as follows:

A company that undertakes a recall should develop a comprehensive plan that reaches throughout the entire distribution chain to consumers who have the product. The company must design each communication to motivate people to respond to the recall and take the action requested by the company.

And, it goes on to say that the objective of any recall is:

- to locate all defective products as quickly as possible;
- to remove defective products from the distribution chain and from the possession of consumers; and
- to communicate accurate and understandable information in a timely manner to the public about the product defect, the hazard, and the corrective action.

While it lists many ways to communicate the message, the manufacturer and/or retailer, with approval from the Commission staff, must decide which techniques to use. This determination is based, in part, on the level of hazard and the way the product was marketed and distributed.

In the new handbook, the CPSC added a section on social media which states in part:

Firms should notify its customers using all available social media and mobile platforms including firm [sic] Facebook, Google+ pages, Twitter accounts, You Tube accounts, Pinterest, Flickr blogs and company blogging networks in an effort to get as broad a notice as possible.

- Facebook, Twitter, Flickr, Pinterest or other social media notification must link to website location that includes recall information available in the news release.

And in connection with posters that go in retail stores, the handbook says "Use a QR code or other mobile scanning code to let consumers act on the recall immediately."

In the section where the Commission provides factors that they consider for identifying whether a product has a defect, they added three new factors. They are as follows:

3. Is the risk obvious to the consumer?
6. Are there adequate warnings and instructions that mitigate the risk?
8. Is the risk of injury the result of consumer misuse, and is that misuse foreseeable?

Of course, these additional factors should be considered, along with the original factors, by the manufacturer in deciding whether to report to the Commission.

The handbook also adds a new section called “Monitoring Recalled Products.” It talks about the new CPSIA requirements, monthly reports, inspections, retailer visits, and requests to the CPSC to dispose of or destroy recalled products.

It also sets forth a new procedure to request that the CPSC close the file and cease monitoring the progress of the recall. The procedure provides in part:

At that time [when a request is made] the staff will review the number of notifications made to owners of the product and the number of products returned and/or corrected as well as whether there have been any post recall incidents/injuries or deaths involving the recalled product. As a result of the review of this information, recalling firms should maintain appropriate records to show steps taken to reach owners of the product, the distribution chain, and others. The Compliance staff will evaluate the effectiveness of the firm’s corrective action plan.

There are still no target effectiveness rates and it just says that the corrective action must be “implemented to the best of the firm’s ability and as many products as possible have been removed from the marketplace...” However, it also says that the staff could seek a broader corrective action if they believe that the plan was inadequate. There are many examples of reissued press releases, even years after the initiation of a recall, especially if consumers continue to be hurt.

There are other fairly minor differences between the handbooks but hopefully I caught the significant ones. In any event, it is suggested that everyone read through the new handbook and be prepared to deal with these procedures going forward.

One other document just issued by the CPSC on this issue is entitled “*Guidelines for Retailers and Reverse Logistic Providers.*” It reiterates current regulations applicable to retailers and companies who assist retailers in retrieving and disposing of recalled products.

Lastly, the CPSC still have a variety of checklists, brochures, and guidelines which need to be considered before implementing any corrective action.

European Union

One of the most useful guides on recalls was an excellent pamphlet published in 2004 by the EU and other safety organizations. It provides a comprehensive guidance on evaluating post-sale risk and communicating to product users about safety issues involving consumer products.

Last November, Prosafe, an organization of European product safety regulators, issued a new version of this guide called "*Corrective Action Guide: Guidelines for Businesses to manage Product Recalls & Other Corrective Actions.*" Stakeholders from the manufacturing community were able to contribute to and comment on this document.

Rod Freeman from Hogan Lovells LLP in London, Europe's leading product safety lawyer, who participated in the writing of this new guide, said "*These guidelines have been prepared to provide support to manufacturers and distributors of consumer products in carrying out their practical and legal obligations under EU product safety legislation. They are important because they will become the primary reference point for businesses when they are trying to undertake consumer product recalls and other actions to deal with dangerous products in the EU.*"

And, these guidelines may also serve as a "best practice" to consider for recalls anywhere in the world. So what do they cover?

The guide discusses product traceability, monitoring and communications inside and outside the company. It, importantly, discusses how to identify the post-sale hazard and how to estimate the level of risk. And then finally how to manage the corrective action.

One of the most important and controversial parts of the earlier guide was the post-sale risk assessment process. There was a feeling among the manufacturing community that following the analysis required by this process would always result in a product being recalled, even when the probability and severity are low.

According to those involved in rewriting the guide, it now provides a more useful and reliable basis for assessing the appropriate level of corrective action for a particular risk and recognizes that it will not always be necessary to undertake recalls. For example, in some situations, the new guide would support simply monitoring a post-sale problem rather than recalling the product at that stage.

It is difficult to compare this guide with the new CPSC Recall Handbook. Communicating with government agencies in 27 or more different countries is a bit different than issuing one press release through one government agency in the U.S.

However, anyone who sells products in Europe that could be subject to a recall should review this new guide to be sure they are prepared to analyze any post-sale issues in accordance with the new risk assessment process and are ready to implement a corrective action that is appropriate for Europe.

Even if a company does not sell into Europe, it should review this guide as it might have some “best practices” that would be helpful in risk assessment, traceability, or implementing a corrective action.

ISO Standard

There is a working group for a new ISO standard entitled “*Guidance standard on Consumer product recall and corrective action: Code of good practice.*” It is still in the ballot phase with an unknown completion date.

This standard deals with items such as training and recall simulation, assessing the need for a recall, investigation, assessing the risk, implementing the recall, evaluating effectiveness, and corrective actions to prevent reoccurrence.

It is unclear whether this group made any attempt to create procedures that are consistent with or at least not inconsistent with the CPSC and EU documents. There may be good ideas in this standard when it is finalized and companies should consider this document when establishing their own internal procedures for post-sale analysis and action.

EU Market Surveillance Best Practices

Prosafe also embarked on a project to help regulators in each EU country to establish best practices for market surveillance of product safety issues. The project is entitled EMARS (‘Enhancing Market Surveillance through Best Practices in Europe’) and resulted in a large book that discusses many of the same things discussed by the other guides – risk assessment, risk communication, and surveillance.

The difference is that these are best practices for the regulators, not manufacturers and retailers. However, it is stated that the book may be used by businesses and consumers to enhance their understanding of the way in which market surveillance will be carried out by the regulators. This will help businesses anticipate safety issues and understand what regulators are looking for when analyzing post-sale risk and what to do about it.

Hopefully, this book is consistent with the EU Corrective Action Guide mentioned above, especially the risk assessment process that is contained in both documents. Since Prosafe drafted both of these documents, it can be safely assumed that there was some coordination in the preparation of both of these documents.

Other Guidelines and Laws

Australia issued Consumer Product Safety Recall Guidelines in July 2010 that describe how to implement a recall. Health Canada issued similar guidelines in April 2005 and is presumably

going to issue new guidelines now that they have enacted their new product safety law. New Zealand has also issued a guide for undertaking recalls and a recall checklist.

Manufacturers also need to keep track of states within the United States that may have established some legal requirements for recalls. For example, in 2008, New York passed the “Children’s Product Safety and Recall Effectiveness Act.” It is now considering rulemaking which would create regulations to implement this act. These regulations may supplement what is required by the CPSC for the affected products and would be required for selling products into New York.

GS1

GS1 is a not-for-profit organization dedicated to the adoption and implementation of standards-based, global supply chain solutions. It is made up of 200,000 businesses in 25 industries and they manage bar codes, RFID, and the United Nations Standard Products and Services Code®.

GS1 has done extensive work in the areas of product traceability and recall preparedness and implementation. They initially worked in the areas of food recalls, but have extended their efforts into consumer products.

They created a Business Requirements Analysis Document (BRAD) for Product Recall which will be finished and issued during 2012. Its intention is to develop a standard process for product recalls and to identify the data needed to support this process and to develop a standard message for product recalls.

The “immediate phase” is defined as follows:

The immediate phase documents and analyzes the business process and requirements to create the Product Recall Notifications, Product Removal Confirmations and Product Recall Closeouts. The scope of the standard is applicable across multiple industries and relevant to all segments of the supply chain from initial ingredients/inputs through to finished goods.

These requirements describe the business interactions between the traceability party that is issuing the Product Recall Notification and traceability parties that are directly impacted (i.e. they have traded the product through a commercial relationship).

This document contains sections on recall notification, managing the recall, and traceability. It has a case study and various considerations for implementing a recall.

As with these other guides, it is hard to know how they compare and what ideas might be contained in this document that are not contained in the other documents and that should be used

by a company in the future. At a minimum, this should be considered when developing a future recall procedure.

Conclusion

Recall implementation and recall effectiveness are very important to any business which has to recall its products. Not only are there legal ramifications in those countries that have product liability litigation, but there are ramifications for regulatory compliance. And what happens in one country can impact liability in another country.

At the recent meeting of the International Consumer Product Health and Safety Organization (ICPHSO), there was a panel discussion on how to improve recall effectiveness. There were interesting presentations by a baby products manufacturer, Bugaboo, who discussed how a more interesting interactive website is more likely to be frequently accessed by consumers who will, in turn, be more attentive to possible recalls or products or issuance of safety bulletins. In addition, Costco discussed their techniques for communicating to their members. Unlike most retailers, they know the identity of their customers and what each of them has purchased. As a result, it makes it fairly easy for them or the manufacturer to communicate the recall information.

The technology to easily and cheaply communicate to consumers is available to almost any manufacturer or retailer. The key is to be able to trace the product to be recalled to a specific consumer and to motivate that consumer to want to get safety information and to act on it accordingly. Manufacturers need to keep up on available technology and best practices established by these various documents and create their own procedures which make sense for their company and products.