PREPARING FOR AND IMPLEMENTING PRODUCT RECALLS IN 2022

New Guides Provide Recall Assistance

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By Kenneth Ross

Recalls have received lots of attention recently by government agencies and industry as they try to determine how to help manufacturers be better prepared to undertake a recall and then how to implement the recall once one is started. Given the growing importance of this subject, there has been a recent proliferation of guides, standards, and best practices developed in the U. S. and elsewhere. Taken together, these can significantly help a manufacturer establish procedures and personnel necessary to meet its legal and practical obligations.

This article will discuss the ways in which a company can be organized and prepared to meet its post-sale duties and to undertake a field corrective action program or a recall.

GUIDES FOR PREPARING FOR AND IMPLEMENTING A RECALL

Many guides have been developed by government agencies and standards-setting organizations both in the U.S. and in foreign countries. The U.S. Consumer Product Safety Commission (CPSC) published a recently updated planning and recall handbook, while the Food and Drug Administration (FDA) issued, in March 2022, a guidance for industry and staff on the initiation of voluntary recalls. The U.S. Department of Agriculture has recall guidelines for food, and the National Highway Traffic Safety Administration has one for motor vehicles and accessories. Therefore, if you are selling regulated products in the United States, you should look at the relevant agency's recall guidelines for help. This article will focus on new guides that apply to consumer products.

The CPSC revised its 2012 Recall Handbook in September 2021 and now calls it the "Product Safety Planning, Reporting, & Recall Handbook" ("the CPSC Handbook").[1] The CPSC added a new section titled "Plan Ahead: Compliance Programs and Designating Responsibility for Product Safety Issues" and added an appendix on how to develop a compliance program. In addition, they added a number of templates of documents as appendices, including several for Health Canada and one for communicating recalls on social media. Some details of this new handbook will be discussed below.

The next new guide comes from the newly formed UK Office for Product Safety & Standards. The guide is entitled "Product recall and other corrective actions – Code of practice" (PAS 7100:2022) and was licensed and published by the British Standards Institution (BSI).[2]

A PAS is defined as follows:

> *"The PAS process enables a code of practice to be rapidly developed in order to fulfil an immediate need in industry. A PAS can be considered for further development as a British Standard or constitute part of the UK input into the development of a European or International Standard."*

This document makes it clear that it is not a British standard and that it supersedes an earlier version of PAS 7100, which was issued in 2018. This document also states that "this PAS is to be read in conjunction with PAS 7050:2022, which supports businesses and regulators in complying with their relevant legal duties relating to placing safe products on the market."[3]

The new PAS 7100 is a partial revision of the 2018 version and includes the following main changes:

- Incorporates changes regarding UK's exit from the European Union;
- Better aligns with the revised version of PAS 7050; and
- Adds new sections for online marketplaces and for repair and refurbishment.

As with the CPSC Handbook, PAS 7100 contains guidance and recommendations. Neither of these documents constitutes legal requirements, and therefore, compliance may not provide any legal immunity. However, the PAS says:

> *"Users may substitute any of the recommendations in this PAS with practices of equivalent or better outcome. Any user claiming compliance with this PAS is expected to be able to justify any course of action that deviates from its recommendations."*

In 2013, the International Organization for Standardization (ISO) issued a new standard, ISO 10393, providing guidelines for consumer product recalls. This standard does a good job of describing the types of personnel who should be involved in the establishment of a product recall team, as well as the procedures that should be in place so that the company is prepared to undertake consumer product recalls. It also talks about how to develop a recall strategy, recall objectives, and a recall process as well as how to develop a communication plan. All aspects of a comprehensive recall program are contained in this ISO standard.

Lastly, the European Union and the governments of Canada and Australia have developed various recall guides, especially for consumer products. Some of these guides may be useful in structuring your recall program in the U.S. There are great similarities between all of these guides, especially in the guidances on how to develop a compliance program. Therefore, the CPSC's Handbook, the new BSI PAS 7100, and ISO 10393 should provide sufficient guidance for recall programs established by companies selling consumer products in the U.S., Canada, and Europe.

DEVELOPING A COMPLIANCE PROGRAM

The CPSC Handbook contains detailed suggestions on setting up a compliance program. The focus should be on developing a culture of safety, communicating to employees that culture and the process of product safety and recall preparedness, and continuous improvement.

The CPSC Handbook gives an example of a sample compliance program:

1. Identify who in senior management is responsible for product safety issues at the company;
2. Research and create written policies and procedures to respond to product safety issues, including:
    a. Identify and centralize data for availability and review by the product safety team;
    b. Establish regular data reviews and, as appropriate, specific incident reviews;
    c. Establish or refine supplier qualifications and audits;
    d. Incorporate CPSC reporting requirements and recall execution plans into policies; and
    e. Establish a protocol for specific follow-up action;
3. Establish a records-retention policy. CPSC staff recommends retaining records for at least five years;
4. Train staff regularly; and
5. Routinely reevaluate and update compliance policies and training.

PAS 7100 calls their compliance program a product safety incident plan ("PSIP") which should include the following, where appropriate:

1. Management commitment
2. Product and customer traceability plan
3. Product safety monitoring plan
4. Legal notification plan
5. Risk assessment plan
6. Corrective action decision plan
7. Communications plan
8. Training plan
9. Testing plan
10. Review plan

Both of these guides and the ISO standard have more detailed information on the development of a compliance program, and these should be consulted. However, in the next two sections of this article, I will discuss pre-sale preparation and post-sale implementation from my experience of helping manufacturers in these areas for over 40 years.

PRE-SALE PREPARATION

Some of the most significant elements to build into the product's design, manufacture, and distribution processes are product marking and traceability procedures that are used before manufacture, during manufacture, and during distribution. To the extent possible, products, especially safety-critical components, should be marked or coded so that anyone, including customers, can easily identify a recalled product and remove the component to be returned or repaired.

This is not easy to do and many manufacturers, especially those who have never had to recall their products, will wonder if the effort is worth it. Of course, in the event of a recall, this traceability will allow a manufacturer of the finished product or component part to narrow the affected population and allow customers to more easily identify whether their product is subject to the recall. A customer might even be able to return the affected part and replace it with a new one. In that case, everyone benefits, from the manufacturer to the retailer to the consumer.

The next important consideration is for the manufacturer, in cooperation with all entities in the distribution chain, to design and maintain an effective database so that different types of entities, including product users, can be identified. These databases must be updated periodically.

There are new and interesting ways in which this can be accomplished. In the past, manufacturers have relied on the customer sending in a warranty registration card. This hasn't worked well. Today, the customer's ability to quickly register their product online with the manufacturer has made it a lot easier. The enormous growth of retailer customer loyalty programs and membership retailers has also made it much easier to track products to specific customers. And QR codes can be programmed so that scanning the code with your smartphone will automatically send your contact information to the manufacturer.

One of the most important and difficult tasks is for the manufacturer to set up a communications network before sale, so that appropriate safety information is received. A manufacturer has a number of readily available sources of information anywhere its product is sold. Personnel should be trained to ensure that sufficient information is gathered concerning warranty claims, injury or damage claims, accidents, near misses, and customer complaints so that potential problems can be identified as early as possible.

Personnel should be trained to identify and clarify the information received so that it is accurate and substantiated. A manufacturer does not want to gather and maintain inaccurate and overstated complaints and claims that make it appear that a problem exists when, in fact, it doesn't. In addition, a company must decide which claims to follow up on and how to do so. Do they need to see and analyze the product? Do they need to interview the product user or claimant?

Post-sale information, some of it unsubstantiated or even incorrect, can be posted by consumers and others on the Internet. This information needs to be monitored and followed up where necessary. Ignoring such information can be risky, but following up on all alleged safety issues can be time-consuming, fruitless, and misleading. The goal is to separate the valid information from all the information that is available and received.

A manufacturer must understand all legal reporting and recall requirements applicable in each country in which its product is being sold. The requirements have increased recently and are different from country to country. The result is that there may be a reporting responsibility in one country and not another, with a recall being required in one place but not another. In addition, there may be differences in the ways in which different government agencies expect the manufacturer to announce and implement the recall. Coordinating reports and recalls in multiple jurisdictions is a significant challenge that can be very detailed and time-intensive.

Entities in the supply chain must consider contracts in anticipation of potential recalls or other corrective actions. Therefore, any company buying safety-critical products or services for inclusion in their product needs to consider which entity is financially and procedurally responsible in case that component part or service is defective. In addition, every entity within the distribution chain - dealer, distributor, and retailer - is potentially responsible for any accidents involving products that should have been recalled. Therefore, the contracts between these sellers and the manufacturer are critical in establishing the duties, obligations, and responsibilities of each of these parties in the event of safety problems in the field.

Unfortunately, most of the time, purchase and sales contracts deal with warranty matters, extra-contractual damages, and remedies, but rarely recalls. Marketing personnel from the manufacturer don't mind discussing warranties with their customers but discussing the possibility of the product being recalled and who is responsible for that is not something that is considered helpful during the sales process. In addition, buying component parts from a small company can be difficult if that company believes that it will be fully financially responsible for any defects in that component part. And many times, it is not clear what caused the problem - the component part itself, the selection of the part, the installation of the part, or the use of the part.

One other issue that should be considered before you start to sell products that could create a large financial risk if recalled is whether your company should consider purchasing recall insurance. The market for such insurance has grown significantly in the last ten years, and there are many options. Recall insurance is designed to cover first-party costs related to a recall that are excluded by most comprehensive general liability policies. Coverage is usually triggered by a voluntary safety recall or by government-ordered recall where the product has caused or is likely to cause bodily injury or property damage.

Some of the costs that might be reimbursed are those involving pre-recall and recall costs, business interruption and extra expenses, brand rehabilitation expenses, extortion costs, and consultant's costs. Limits, self-insured retentions, and coverage vary from company to company and are largely dependent on the underwriter's analysis of future risk. Any interested company must obtain an evaluation of their situation conducted by a broker experienced with recall insurance and get a recommendation on what type of policy might be best for them.

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POST-SALE PREPARATION

Every entity in the supply chain needs to expect that a recall may be necessary at some point. Importantly, they need to have experienced technical and legal personnel who routinely evaluate post-sale data and information and decide whether to report to the government and undertake a corrective action or to undertake a corrective action even if no government agency is involved. If adequate pre-sale planning has occurred, gathering and analyzing the information, and implementing the program will be less difficult and more organized than if no planning has occurred. Everyone will know what to do and when to do it.

Virtually every manufacturer should have a functioning product safety committee whose main job is to evaluate post-sale information and to make decisions concerning reporting to government agencies and undertaking corrective actions such as recalls. Decisions in this area are multi-functional and lend themselves to the kind of brainstorming that can be accomplished in a committee meeting. This is particularly true because information about post-sale issues comes into different parts of the company. Therefore several members of the committee might have information relevant to the post-sale analysis that will need to be discussed.

There should be well-defined procedures for the product safety committee as well as a list of the people who should always participate and those who will participate on an as-needed basis. It is important to decide what power the committee has in making decisions concerning corrective actions. For example, can they make the final decision, or are they merely making recommendations to upper management?

A company's legal counsel should be a member of this committee since most of the discussions will be sensitive and could become the basis of a product liability case and a governmental enforcement action. While it is not a good idea for legal counsel to try and make all of the writings of this committee legally privileged and confidential, counsel should provide some guidelines to committee members on what to write and what not to write and should review the minutes of the meetings and documents with recommendations.

Some manufacturers should consider running mock recalls. While these would not involve sending notices to consumers, they might include notices to the first tier of distribution or possibly even further. The purpose of sending notices like this is primarily to test the accuracy of the addresses – mail, e-mail, or social media – on file for each customer. You want to be able to immediately stop production, stop shipping, and stop sales of all products subject to the recall. Therefore, having the ability to quickly communicate to your immediate customers (i.e., distributors) and for your customers to be able to quickly communicate to their customers (i.e., retailers) is important.

While it is still important to be able to communicate with the end-use customer eventually, this should not be part of a mock recall. However, if end-use customers send registration cards to you, you might periodically send them a letter or an e-mail to test out the accuracy of their addresses. Then, when the time comes for you to communicate with them about a recall, most if not all of the addresses you have will be current and accurate.

Even if the company does not run mock recalls, training employees about all of these issues is very important. Product safety personnel cannot be everywhere. You want everyone involved in designing and making products and monitoring their performance in the field to understand what information they may receive that would be helpful in predicting potential safety issues and what to do about them. In addition, legal counsel should assist with the training so that employees understand what documents they need to create and keep that will help defend the adequacy of post-sale actions, including recalls.

One other task that should be undertaken is to develop templates for various types of communications that you will want to send out in the event of a recall. If you sell regulated products, you will want to look at the recall guides for those products to find the templates provided by the government agency. You can then use these as the basis for your template communications, recognizing that these are a minimum and you might want to exceed the requirements of that agency.

Also, you might want to consider testing the template communications with sample users or even personnel in the company. You want to know whether the communication makes it clear that this is a safety-

related matter, that it is important that they comply, and that it is clear what you want them to do. In addition, you might want to ask end-use consumers how they would like to receive such communications if any are necessary in the future.

The use of social media has significantly increased in the recent past. That is fine if the consumer is willing to receive information through these means and has signed up to do so. That is one reason why asking consumers how they would like to receive this information could be valuable. Some may be willing to receive it by letter, others prefer e-mail, and others prefer Facebook, Twitter, or text messages.

There are new companies being formed that are developing recall applications through social media that will help manufacturers get recall notices to those consumers who are interested in receiving this information. Manufacturers need to keep track of these developments and utilize those that make sense for their products. Ultimately, almost everyone will be willing to receive communications in some electronic form, thus making it quicker and less costly to send out recall notices or safety alerts.

Finally, in cases where a retailer has established a loyalty program for frequent customers, it makes it much easier to identify that customer and the products they purchased. One membership chain uses the data gathered through cards carried by its millions of members and calls them within 24 hours if they have purchased a recalled item. The company follows up with a letter. This results in the vast majority of recalled products (90% with some products) being returned to the store.

CONCLUSION

Compliance with the government's requirements and approval of your corrective action program may not be a defense in a product liability case brought in the U.S. or, most likely, anywhere else. Therefore, thinking about the defensibility of the program as it is being implemented will help a company anticipate challenges to the program's adequacy and help it respond to suggestions that it could have done more to prevent the accident that is the subject of the lawsuit.

There have been significant developments, procedurally and technologically, around the world that should help manufacturers do a better job in a more cost-effective way. But a manufacturer must plan for the possibility of a recall as soon as it begins designing a product. Doing so will reap huge benefits if the worst happens and a recall occurs. It will also help prevent the recall from turning into a corporate tragedy that hampers a company's activities or threatens to put it out of business.

ENDNOTES

1. https://www.cpsc.gov/Business--Manufacturing/Recall-Guidance
2. https://shop.bsigroup.com/products/product-recall-and-other-corrective-actions-code-of-practice/standard
3. https://shop.bsigroup.com/products/pas-7050-bringing-safe-products-to-the-market-code-of-practice/standard