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How to Prepare for Possible

Product Recalls



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RECALL

How to Prepare for Possible Product Recalls

BY KENNETH ROSS

In 2011, Australia and Canada adopted new product safety laws that require manufacturers and others in the supply chain to monitor their products in use, and to report safety issues and take appropriate corrective actions in certain situations. In addition, the U.S. Consumer Product Safety Commission has become more aggressive in levying civil penalties on companies who do not report safety problems in a timely fashion.

Therefore, it is more important than ever that companies be prepared to meet these obligations as they design, manufacture and sell their products. Being proactive and prepared before sale can save all companies in the supply chain significant amounts of money and effort, and make any recall or corrective action implemented after sale much more effective.

PRE-SALE PREPARATION

One of the most difficult things I've ever done is try and convince a manufacturer to prepare for a recall when they are first designing a product. This is not something that most manufacturers want to do. They are focused on trying to get a product into

production and sold. Unfortunately, after the product has been sold, it is too late to do many of the practices discussed below.

Various entities in the supply chain should try to establish procedures *before* the product is sold so that each entity can, after sale, easily and efficiently obtain information, analyze it, make decisions about appropriate post-sale remedial programs, and implement any necessary programs.

Some of the most significant elements to build into the product's design, manufacturing and distribution processes are traceability and marking procedures for use before and during manufacture and distribution.

To the extent possible, products and, especially, safety-critical components should be marked or coded so that anyone, including customers, can identify the product or component to be returned.

The Retail Industry Leaders Association and British Retail Consortium recently issued some safety guidelines for their suppliers. One of the requirements is that the supplier "shall have a system to identify and trace product lots including raw materials, components and packaging materials and follow this from the source of the incoming material through all stages of processing to supply of the product to the primary *customer* and vice versa in a timely manner."

Manufacturers should think about what they will need to do to recall their product or withdraw it from the market.

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 tracing will allow the manufacturer of the finished product or component part to narrow the affected population and clearly identify the population to customers. 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 if possible, can be identified. These databases must be updated periodically.

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 their product is sold. Personnel should be trained to ensure that sufficient information is gathered concerning warranty claims, injury or damage claims, accidents, and near misses so that potential problems can be identified.

Personnel should also be trained to identify and clarify the information received so that it is accurate and substantiated. The manufacturer does not want to gather and maintain inaccurate and overstated complaints and claims that incorrectly make it appear that a problem exists.

Post-sale information, some of it unsubstantiated or even incorrect, can be posted by consumers on the

Internet. This information needs to be monitored and followed up where necessary. Ignoring such information is risky, but following up on all alleged safety issues can be time-consuming and fruitless.

Manufacturers should think about what they will need to do to recall their product or withdraw it from the market. While the manufacturer will not know what the problem is before it occurs, it can at least think about the ways in which a recall or withdrawal would be communicated and be prepared to get the information out quickly.

For example, how will press releases, customer alerts, distributor bulletins, Web site postings, and questions and answers be used and how will the manufacturer be able to communicate this information quickly and efficiently to the appropriate people or entities. Another example of monitoring the communication stream is deciding whether the information in returned warranty cards is entered periodically or the company waits until a recall occurs.

As discussed below, the manufacturer must understand all legal reporting requirements for each country in which its product is being sold. The requirements have grown recently and are different from country to country. The result is that there may be a reporting responsibility in one country and not another. This may result in a recall in one country and not another.

Canada has a new reporting law that requires reports, in part, for an

The manufacturer must understand all legal reporting requirements for each country in which its product is being sold.



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occurrence in Canada or anywhere in the world that resulted or may reasonably have been expected to result in an individual's death or serious injury. Australia's new reporting law is likewise based mostly on an occurrence anywhere in the world for a product that is sold in Australia. One difference though is that "near misses" can trigger a report in Canada but not in Australia. In both Australia and Canada, there is an interesting question as to when a foreign manufacturer has a duty to provide occurrence information to Canadian or Australian entities to trigger a report.

In December 2009, the EU issued a new post-sale risk assessment process (see http://ec.europa.eu/consumers/safety/rapex/guidelines_states_en.htm) that should be used to determine if a report to the EU is appropriate and whether any corrective action is necessary. This process could also be useful in analyzing post-sale risks elsewhere in the world.

There is a new draft ISO standard dealing with recalls that will be published in 2013. It is called ISO 10393 and is being developed by ISO/PC 240. It is a "guidance standard" that contains an "international model code of good practice for consumer product recalls and other corrective actions." This standard contains requirements for recall plans and policies that should be developed before sale.

Lastly, in 2004, the EU published a guide to corrective actions in Europe. This guide included suggestions for actions to take place before sale, many of them already discussed here. This guide is being updated and should be reissued in late 2011 or early 2012.

POST-SALE PREPARATION

As a manufacturer obtains and analyzes post-sale information, it must determine whether any post-sale action is necessary at any point in time. This includes reporting to the relevant governmental agency and possibly undertaking some form of recall.

Analyzing the information and deciding what it means is the most critical phase of this process. Many manufacturers use or should use risk assessment prior to selling their products. This process identifies the

risk, probability of the risk occurring, consequences if it occurs, and methods to minimize the risk. Before sale, the manufacturer should make a best guess on the probability of the risk occurring. It is, of course, difficult to estimate the probability of an event occurring when it has never happened before.

After sale, the manufacturer is, in effect, considering new information from field experience. Post-sale incidents may indicate risks or consequences that were never imagined, or change the estimated probability calculated before sale. Redoing the pre-sale



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risk assessment is a good way to formally recalculate the numbers and assumptions. Unfortunately, doing so doesn't really answer the question of whether and what type of corrective action is necessary.

For products regulated by a government agency, the manufacturer needs to identify the threshold for taking action. For example, the CPSC provides criteria for determining the existence of a defect and substantial product hazard. The criteria to be considered are the pattern of defect, the number of defective products distributed in commerce, and the severity of risk to consumers. Using these criteria will provide guidance

report to the government and whether to undertake a corrective action or to undertake a corrective action even if no government agency is involved. If adequate pre-sale planning has occurred, implementing the program will be less difficult and more organized than if no planning occurred. Everyone will know what to do and when to do it.

Again, there is guidance on how to undertake recalls. I mentioned the EU guide to corrective actions. ISO 10377 will also provide general suggestions on how to undertake a recall. The CPSC also has a recall handbook. All of these guidelines discuss "best practices" and it is up to the individual manufacturer or product seller to determine which of

response rate from consumers for most recalls is between 4 and 18 percent.

Virtually no recalls have 100 percent compliance. As a result, the manufacturer will have many products in the field that it has admitted or intimated are defective or at least pose a risk of injury. After an injury occurs and a lawsuit is filed, how will the manufacturer defend its product?

As the program is implemented, the manufacturer must think about how it will prove that its actions were reasonable and appropriate under the circumstances. Again, experienced personnel in this area can help and should be utilized.

Every entity needs to have experienced technical and legal personnel who routinely evaluate post-sale data and information

to the manufacturer about what information to gather and how to analyze it. However, the CPSC provides little further guidance on this basic question, and expects the manufacturer to report a substantial product hazard or any suspicion that the product contains such a hazard.


After the manufacturer reports to a government agency, the agency will most likely, if not always, strongly encourage some type of corrective action. So, the manufacturer must be prepared, if it can as part of its report, to describe the actions that it believes will minimize the risk. It is possible, however, to propose that no corrective action is necessary.

Every entity needs to have experienced technical and legal personnel who routinely evaluate post-sale data and information and decide whether to

these practices to utilize in a particular situation. Therefore, there is no such thing as an "off the shelf" recall plan that would make sense for sales of any product around the world.

Recalls can be extremely difficult and very ineffective, despite the best of efforts. There are no clear guidelines in the common law or even with government agencies about how effective a recall has to be. Recalls or retrofit programs with an effective rate of less than 10 percent have been deemed acceptable by the CPSC; the CPSC has said that the average

CONCLUSION

Preparing for a recall before it occurs can significantly increase its effectiveness and lessen the costs and disruption to the manufacturer, distributor and customer. The effort will be well worth it if something happens. These efforts will also generate post-sale information that can provide insights into how your products and maybe your competitor's products are being used. This will be helpful in making future product improvements. The end result will be safer products, less accidents, and more defensible products and actions if problems occur. 

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