An Engineering Perspective

Consumer Product Recalls

by Jason L. Hertzberg, Ph.D., P.E.

The decision to notify the Consumer Product Safety Commission (CPSC) and investigate the need for a recall of a consumer product is a very difficult one for any company. In 2003 alone, 280 consumer product recalls were issued. *The Trouble with Recalls*, Consumer Reports, August 2004, pp.12–17. According to the CPSC, incidents involving consumer products account for over $700 billion dollars annually. *See* http://www.cpsc.gov/CPSCPUB/PUBS/REPORTS/2005Plan.pdf.

In November of 2004, the U.S. Court of Appeals affirmed the CPSC reporting requirement and the ability of the commission to impose civil penalties for not reporting in a timely manner. The court agreed that the CPSC must be notified about potentially dangerous products even before they are found to be defective and that separate offenses exist for every product not reported. In addition, it was determined that proof of a defect is not required before a civil penalty can be imposed. In March of 2005, a record civil penalty of $4 million was levied against a large children's product manufacturer for failing to inform the government in a timely manner about products that allegedly posed a danger to young children. *See* http://www.cpsc.gov/cpscpub/prerel/prhtml05/05138.html.

Given the trend outlined above and the fact that only general CPSC reporting requirements exist, it is beneficial to review both the existing requirements and factors to consider when deciding whether to report to the commission and when it is necessary to initiate a consumer product recall.

While there are different requirements for reporting depending upon the circumstances, this article will address only those pertaining to Section 15b of the Consumer Product Safety Act (CPSA). The CPSA states that manufacturers, importers, distributors and retailers (MIDRs) must notify the CPSC within 24 hours of obtaining information that reasonably supports the conclusion that the product exhibits one or more of the following conditions:

- Fails to meet a consumer product safety standard or banning regulation;
- Contains a defect which could create a substantial product hazard to consumers;
- Creates an unreasonable risk of serious injury or death; or
- Fails to comply with a voluntary standard upon which the CPSC has relied under the CPSA.

See 15 U.S.C. 2064.

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A product defect, a condition listed above, could be the result of a manufacturing or production error. A defect could occur in a product's materials, design, contents, construction, finish, packaging, warnings and/or instructions. It is important to note that not all products that present a risk of injury are defective. For example, the cutting ability of a kitchen knife is not a product defect for two reasons: 1) a dull blade inherently lacks utility, and 2) the risk associated with a sharp blade is considered reasonable and obvious.

In determining whether a risk of injury makes a product defective, the CPSC considers the following questions:

- What is the utility of product (*i.e.*, what is it supposed to do)?
- What is the nature of the injury that might occur?
- What is the need for the product?
- What is the exposed population and potential risk of injury?
- What is the CSPC experience with the product?
- What other information sheds light on the product and the patterns of use?

See http://www.cpsc.gov/BUSINFO/8002.html.

In determining if a substantial product hazard exists, the commission considers the following factors:

- Pattern of Defect—Is there a product defect that could or has directly resulted in a "pattern" of failures?
- Number of Defective Products in Commerce—One defective product can be the basis of a recall if an injury is likely or could be serious.
- Severity of Risk—Is there a risk of a serious injury?
- Likelihood of Injury—Consider the number of injuries that have occurred or could occur given the intended or reasonably foreseeable use or misuse of the product as well as the population group that is exposed. It is important to note that it is not necessary for any product failures or injuries to have occurred for a product to be recalled.

Id.

The remainder of this article outlines a basic engineering approach that can help to determine, from a technical perspective, when and if to report to the CPSC and whether it is necessary to initiate a product recall. Reporting merely signals the beginning of an investigation period and does not

necessarily result in a product recall. It must be mentioned that reporting is encouraged by the CPSC, even if it is unclear if a real danger or hazard exists. It is imperative that the company seeks legal counsel to assist in this decision.

In an engineering analysis of this kind, there are typically four basic questions that need to be answered:

- Why has the product(s) 'failed' or is likely to fail?
- How many products are affected?
- What is the risk and severity associated with the 'failure' of the product?
- What is the most appropriate Corrective Action Plan (CAP)?

Why Has the Product Failed or Is Likely to Fail?

In order to determine why a product has failed, a multidisciplinary approach is typically required. Many investigations of product failures require expertise in a variety of areas including materials science, corrosion engineering, mechanical engineering, electrical engineering, thermal sciences (*i.e.*, fire cause and origin), manufacturing processes and human factors (*e.g.*, man-machine interactions, evaluation of warnings, labeling, and instructions). In order to determine why a product has failed, it is necessary to determine the failure mechanism and, in some cases, the root cause.

It is important to distinguish between the failure mechanism and root cause. A failure mechanism is the mechanism by which the "failure" takes place while the root cause is the fundamental, underlying reason for the failure event. As an example, consider the hypothetical case of an electrical appliance that ignites, leading to a residential fire. In this case, one potential failure mechanism is overheating from within a thermostat, which causes the component housing to melt, thereby exposing the hot, electrical contacts of the thermostat to the flammable plastic cover of the consumer product. A possible root cause for this scenario would be corrosion of the silver electrical contacts within the thermostat that leads to a high-contact resistance and the intense, localized heating described in the failure mechanism above. While it is always desirable to determine the root cause of failure, in some cases identifying the failure mechanism is sufficient in order to implement an appropriate CAP.

There are many aspects of an engineering failure analysis investigation. Depending upon the situation, certain information may not be available to the analyst. As would be expected, the more information that is available for review, the more likely a complete understanding of the cause of a product failure can be achieved. Some of the information that can provide insight during an investigation is listed below:

- Incident information including what is known about the events leading up to the incident(s), the incident itself, post incident activities, eyewitness accounts, incident reports, and photographs.
- The "fingerprint" of the product including the manufacturing date of product, serial number, specific model and batch numbers, and the manufacturing facility where the product was assembled.
- Application specific information including how and where was the product used.
- Service/maintenance history of incident unit(s) and similar models, including any reports of previous problems.
- Available documentation including design, subassembly, and manufacturing assembly drawings, operation manuals, warnings and instructions.
- Timeline of product evolution including changes in materials of construction, product design, components, construction, finish, packaging, warnings, and/or instructions.
- Quality control procedures implemented from raw material vendors through manufacturing and assembly lines, including material certification sheets supplied by vendors as well as other certifications (*e.g.*, ISO certified).

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Aside from a review of the aforementioned information, the first step in determining the failure mechanism of a product is performing a non-destructive analysis of the incident unit. This typically consists of an overall visual examination and photo documentation of the product from various angles, as well as the surrounding environment, if at all possible. All available markings and labels on the product should be recorded, including serial number, model number, product name and brand, and batch information. This type of information can sometimes be useful in limiting the extent of affected product, as discussed in a later section. It is also prudent to perform a thorough examination of damage to the product. Mechanical damage (*e.g.*, impact, wear) can provide insight into the use or misuse of the product and the loads or stresses that the product was subjected to during its lifetime. Thermal damage patterns can provide insight into the origin of heat, smoke or open flame. In some cases, it is possible to narrow down the region or even the component responsible for a fire, depending upon the degree of damage to the product. It is important to note that thermal damage patterns can sometimes be easily marred or removed during normal handling or product removal from the incident site. Careful attention should be given to preserving both the product condition as well as the surrounding environment for subsequent analysis of thermal damage patterns. A powerful non-destructive method used to examine the internal damage to a product is x-ray imaging, a technique similar to that performed by medical doctors to look inside the human body without performing surgery. This method utilizes the fact that different materials of construction have different densities that show up as different shades of gray in an x-ray image. As most products are comprised of various materials, including different plastics, metals and ceramics, it is possible, in many cases, to look "inside" a product using x-rays and determine the extent of damage to the inner components without disturbing their condition or position.

In many cases, there is a limit to the amount of information that can be gained from a non-destructive evaluation. After all non-destructive methods have been exhausted, a destructive examination is typically in order. However, once a product is altered from its original condition, valuable information can be lost if proper procedures are not followed. Therefore, it is very important to carefully perform any disassembly of the product and photo document the individual steps of the destructive examination. In addition, if legal action has been taken or is pending as a consequence of the product

failure, it may be necessary to perform any destructive analysis in the presence of other parties in order to avoid problems related to evidence spoliation.

After the product is disassembled, it is useful to examine the components at high magnification using different types of microscopes in an effort to determine how a component performed or how it failed. By using different lighting conditions with an optical microscope, for example, it may be possible to determine the origin of the cracking, sequence of damage, or the nature of a failure (*e.g.*, single overload event, repetitive loading). In addition, it may be possible to determine the temperatures achieved during an overheating event. For example, in some cases, the color of a metal oxide is a sensitive function of the temperature at which it is formed. Once an optical examination has been done, it is sometimes helpful to examine the failed or damaged component or product using a Scanning Electron Microscope (SEM). This type of microscope allows for an examination at much higher magnifications than light microscopes since it is based on the use of electrons rather than light for imaging purposes. In some cases, it is possible to identify microscopic features at very high magnifications that indicate the nature of the failure or the existence of a material or manufacturing defect. In addition, it is also possible to determine the chemical composition of a component using Energy Dispersive X-ray Spectroscopy (EDS), a feature available on many SEMs. This can be helpful in determining the materials of construction, as well as the existence of contamination or corrosion products which may have led to failure.

Important insight into the foreseeable use and misuse of a product can also be gained by reviewing the warnings, labels and instruction manuals that accompany a product in the marketplace. As mentioned previously, a product defect can be the result of inappropriate product labels or product literature. Some of these problems include:

- Unclear or inaccurate description of required steps and/or precautions involved in assembly, operation, or maintenance of the product;
- Ineffective placement of warning labels on the product;
- Ineffective or inappropriate use of textual and pictorial components of the warning labels. For example, "Danger," "Warning," and "Caution" are terms used to convey different levels of hazard. *See* ANSI Z535.4-2002, American National Standard for Product Safety Signs and Labels, American National Standards Institute, Inc.;
- Ineffective usage of background color or foreground text font and/or color for warning labels;

Exemplar products (*i.e.*, new and identical products) are very useful as benchmarks with respect to construction and function. In addition, laboratory testing of exemplar products makes it possible to generate both normal use and abnormal use conditions. This can yield valuable information and help determine the cause of the product failure.

How Many Products Are Affected?

Once a failure mechanism, and possibly the root cause, has been established for a product, it is important to determine if this is an isolated incident involving a single product or whether there is evidence of a "pattern of defect." A strict definition of a "pattern of defect" is not provided by the CPSC. Therefore, the existence of a "pattern of defect" depends on the specific circumstances associated with a given product investigation. Review existing databases including listings of product returns, customer complaints and reported incidents should be conducted, preferably on an ongoing basis, in order to help determine the number of failures of a specific product and compare this information with historical data. Is this the first product to come back or is this the 12th product in the past three weeks to be reported? If there is a spike in the number of field returns, the next question is whether the failures are similar in nature. This requires a detailed examination of additional incident products. If additional incident products are not available to examine, it is beneficial to review all available photographs and reports associated with these incidents.

If a "pattern of defect" is established after a review of the failed products, it is necessary to determine how large of a population of product is affected. Some of the important questions to consider in this determination include:

- Is this an inherent design problem? For example, is the problem tied to the materials of construction? Is the problem with a defective component? Is this component single-sourced or multiple-sourced? If the problem is with only one component supplier, is there an easy way to separate out the unaffected population?
- Is this a batch problem tied to a manufacturing process deviation or temporary process change implemented based on other constraints?
- Is this a problem only with certain models of product? For example, are there differences in product construction that determine if the product is susceptible to a specific failure mode or unsafe condition? Can this be verified empirically?
- Are there geographical considerations that make it possible to rule out certain populations of product? For example, are products much more likely to overheat and cause fires in certain countries based on standard power outlet voltages (*e.g.*, United States 115 volts, Europe 230 volts)?

What Is the Risk and Severity Associated with Failure?

In addition to determining the size of the affected population, it is necessary to assess the risk of product failure in the field. Is the hazard impossible, possible, probable or virtually inevitable? In determining where the risk falls within this spectrum, it is necessary to determine the conditions under which a defect manifests itself. How many independent steps are required for the failure to occur? Is this a single-step criterion or are multiple steps required? If possible, it is advantageous to determine or approximate the probability associated with each respective step or event, either analytically or empirically. The probability of a failure can then be calculated by multiplying the probabilities of each event. For example, if there is a 50 percent probability of occurrence for each of the three separate events required to produce a failure, the probability of failure is calculated to be 12.5 percent. This can help to determine where the risk falls within the spectrum of occurrence.

It is insufficient to merely determine the risk of a product failure and ignore the severity of the hazard. For example, it is much more serious to have 1,000 products in the field that have a small chance of failure but would cause serious harm compared with one million products in the field

that will most likely fail but would cause little or no harm. In fact, in an extreme case such as that mentioned earlier, one defective product can be the basis of a recall if an injury is likely or could be serious. In order to assess the severity of a hazard, one approach is to perform targeted laboratory testing of "worst case" scenarios using a conservative approach to foreseeable conditions. This can be a very useful tool to determine the "end point" in the event of a failure. For example, this approach can be used in some instances to determine if the malfunction of an electrical product that is prone to overheating could lead to a fire, and if this fire would be contained within the product or could spread to its surroundings. This information can be a critical factor in deciding whether or not to recall a product. In addition to an empirical approach, analytical tools exist that can help evaluate the risk and severity associated with various failure scenarios. These tools include Failure Modes and Effects Analysis (FMEA), as well as Event Tree Analysis (*i.e.*, visual representation of all events which can occur in a system) and Fault Tree Analysis, whereby an "end point" (*i.e.*, fire) is specified and then followed by identification of all of the associated elements in the system that could cause this "end point" to occur.

What Corrective Action Plan (CAP) Is Most Appropriate?

If the decision to recall a product is made based upon the answers to the questions listed above, it is necessary to consider the most appropriate CAP. A CAP refers to any type of remedial action taken by a company in response to a safety issue with one of its products. Any CAP is called a "recall" for the purposes of public awareness. However, a CAP can be one of many different actions, including a customer fix using a repair kit sent from the manufacturer, complete removal of all products from the field, or an exchange for a new model. Even if the original hazard(s) will be sufficiently mitigated or eliminated by implementing the fix, it is possible that new hazards can be introduced as a result of the action. Therefore, it is prudent to evaluate a CAP using an FMEA or comparable approach, especially if a customer fix is the preferred solution, in order to both assess the ease of implementation and determine what can go wrong during the process. In the case of a field fix, providing detailed instructions and schematics to repair personnel or customers is important, and walking through these procedures with individuals unfamiliar with the product can be an insightful exercise during the development of these instructions. The bottom line with any CAP goes back to the KISS principle of basic design, Keep-It-Simple-Stupid.

Summary

Determining if a consumer product needs to be recalled from the field is a very difficult and important decision that involves both legal and engineering considerations. While general guidelines exist in order to aid in this determination, every product and corresponding set of circumstances is unique, which means that investigations typically need to be handled on an individual basis. Although all valuable information may not be available in all cases, a basic framework for conducting the technical portion of a product investigation can be built around the four basic questions outlined in this article. FD