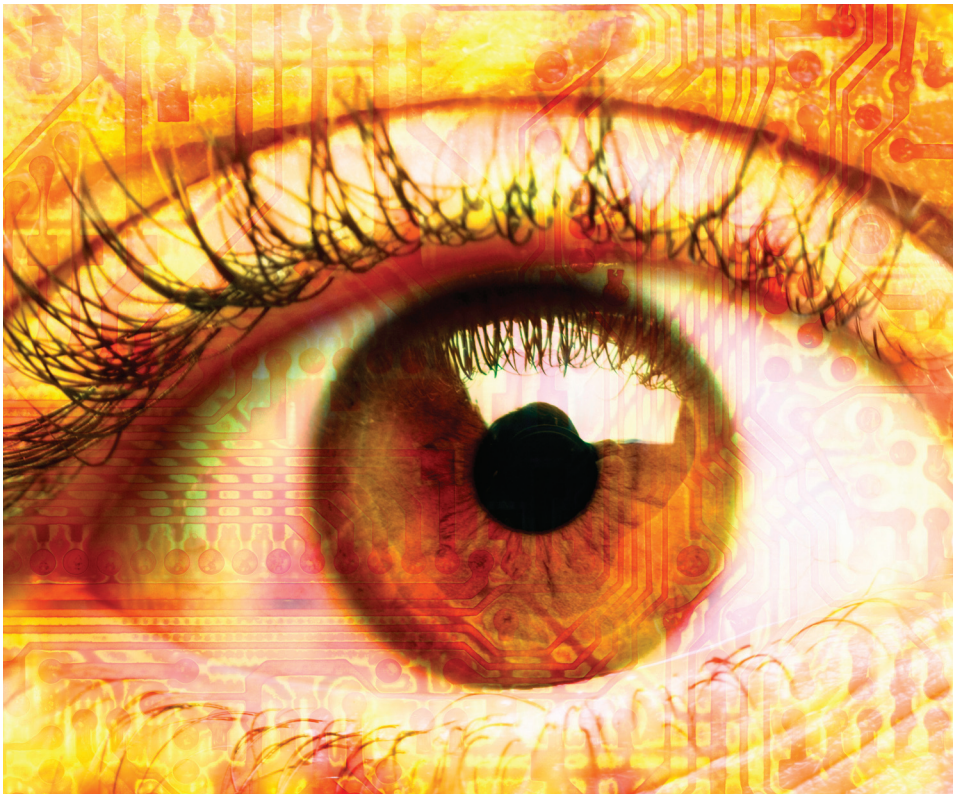
Risk Assessment

Analyzing Safety Before and After Sale

By Kenneth Ross



Originally developed in the 1950s in connection with the U.S. missile program, risk assessment and related engineering evaluations have, since that time, been a standard part of the design and manufacturing process. But, for many manufacturers, the risk assessment aspect was informal, with little documentation.

Recently, however, risk assessment has become a topic of discussion in legal and manufacturing circles. Industries and standards groups in the United States and Europe have turned their attention to risk assessment and developed a specific methodology for their industries or specific products.

In addition, risk assessment is now being used by manufacturers and government entities to assist in making decisions about post-sale responsibilities, including whether a product risk should be reported to a government agency or recall.

This article will discuss risk assessment techniques before and after sale and some of the potential consequences arising from their use.

Why the Increased Interest in Risk Assessment?

Although risk assessment methods have existed in various forms for many years, interest has increased over the last ten years for several reasons, including:

- **Costs.** Significant opportunities exist for productivity gains and cost efficiencies.
- **International influences.** The CE mark is an identifying symbol and certification that a product meets the applicable European standards and is in fact safe. The

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first step in obtaining the CE mark is to complete a risk assessment. The assessment must be documented. In most instances, the mark is obtained through a self-certification process undertaken by the product manufacturer. The CE mark is required for most products sold in the European Union (EU).

- **Capturing knowledge.** A completed risk assessment can be used to capture much of the knowledge pertinent to the design being considered, which can, in turn, be applied to similar designs.
- **Product liability.** Risk assessments help to reduce exposure to hazards and can assist in building a successful defense against a product liability claim.
- **Lack of standards.** When standards do not exist or have not kept pace with technological change, risk assessments provide a basis for making credible design decisions.
- **Customer requirements.** Some customers request that their manufacturers/suppliers conduct risk assessments.

Use of Risk Assessment in Determining Pre-Sale Responsibilities

Risk assessment has been at the core of negligence, the first legal concept used as a basis for the development of product liability.

U.S. Common Law Legal Principles

The common law negligence formulation of Judge Learned Hand in *U.S. v. Carroll Towing* 159 F.2d 169 (2d Cir. 1947), set forth three criteria for determining whether a person's conduct was negligent: (1) the probability that injury would result from the actor's conduct; (2) the gravity of the harm that could be expected to result should injury occur; and (3) the burden of taking adequate precautions to avoid or minimize injury.

Judge Hand went on to express this test in an algebraic equation: "If the probability be called P; the injury L [loss]; and the burden B [*i.e.*, the burden of precaution to avoid the risk of loss]; liability depends upon whether B is less than L multiplied by P; *i.e.*, whether B is less than PL." 159 F.2d at 173.

This negligence formulation was used as product liability was born and grew, first under negligence principles and then under the strict liability doctrine. Even under strict liability doctrine, which does not generally consider negligence, the concept of risk and the ability of the manufacturer to make a safer product is the key to deciding a case.

What Is Risk Assessment?

Risk assessment is a tool for manufacturers to use to identify possible hazards and provide a basis for considering alternative designs to mitigate or control risks. A risk assessment offers the opportunity to identify product hazards associated with intended uses and reasonably foreseeable misuses, and to take steps to eliminate or control hazards before an injury occurs. The risk assessment process can be a key factor in successfully reducing risks to an acceptable level.

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While it is difficult to imagine that a manufacturer may not use some kind of risk assessment when designing and manufacturing products, risk assessment itself poses some risks. Risk assessment techniques only provide a framework for an analysis of risk. The manufacturer must still decide what risk level is acceptable before making a decision on the product's final design, warnings, and instructions.

Risk assessment techniques are well-developed and documented. However, they can be difficult, time-consuming and costly to utilize. Therefore, while risk assessment has been mandated for use in the development of things like missiles and weapons systems, its use in analyzing safety when developing a typical product has not been as common.

Although many different approaches can be taken to performing a risk assessment, certain steps are common. Here is a brief summary of the risk assessment process, step-by-step.

The first step in the risk assessment process is to establish the parameters of the analysis. The scope will differ by industry or product.

The second step in risk assessment is to identify the hazards associated with the product, product design, or manufacturing process design. This step is absolutely critical to the assessment. Different methods have been developed for different industries. Once hazards have been identified, the third step of the risk assessment effort begins. Several different risk models are used. Some methods focus on assessing two risk factors (severity of injury and probability of occurrence). Other methods focus on assessing three or more factors by breaking probability into components (*e.g.*, frequency of exposure and avoidance).

Fourth, after the risk factors are assessed, a risk rating is derived from a risk matrix. The risk matrix combines risk factors, which have been mapped to various corresponding risk levels. Different industries use different risk matrices.

The risk assessment process yields a level of risk. If a risk level is unacceptable, protective measures can be implemented to reduce it. Determining which hazards or risk levels are and are not acceptable is, of course, company- and situation-specific. In some instances, individual industries have provided guidance on levels of acceptable risk. In other instances, original equipment manufacturers or retailers have dictated acceptable levels of risk. In many instances, the decision about acceptable risk level is left to the manufacturer, and its acceptability will vary depending on company culture or other individualized company considerations.

Unfortunately, the common law and, in most situations, federal regulatory law, are not helpful in determining how safe is safe enough. And, no matter what decision is made, no matter where the line is drawn, a plaintiff will argue that the product should have been made safer.

As mentioned above, risk reduction activities begin after the risk rating is derived. During the fifth step of risk assessment, product modifications are undertaken to reduce risks following a hazard hierarchy commonly accepted across several industries and authors. According to hazard hierarchy principles, the order in which actions

are best implemented is to (1) eliminate hazards through the design, (2) protect or guard against the hazard, (3) warn the user about the hazard, and (4) train the user to avoid the hazard, or require the use of personal protective equipment. This is not a rigid hierarchy and many additional factors need to be considered including cost, function and product usability.

Sixth, after the risk reduction strategies have been identified and implemented, most risk assessment protocols call for a second assessment of the risk factors. This second assessment helps to verify that the risks have been reduced to an acceptable level.

Seventh and finally, after the risks have been reduced to an acceptable level, the risk assessment activities should be documented. The documentation can be added to a technical file for future use.

Documenting Pre-Sale Risk Assessment

Any lawyer knowledgeable in product liability understands the dangers involved in evaluating risk with the exactitude required by risk assessment processes. However, the same can be said for any manufacturer's attempt to apply the Learned Hand analysis. No matter what actions a manufacturer may take, a plaintiff will likely argue that more could and should have been done. Or, a plaintiff will likely argue that a manufacturer intentionally quantified the risk level so low that "designing out" the hazard(s) would not be required.

Documentation of risk assessment can provide a roadmap from which a plaintiff and a plaintiff's expert can challenge each and every calculation and assumption made during the design process. Visions of a new version of the "Ford Pinto Memo" can scare risk assessment participants and counsel into inadequately analyzing and documenting risk.

Nonetheless, the reality is that risk assessment standards, requirements, and guidelines exist. If they might apply to a particular product, a manufacturer must decide whether to perform a risk assessment. Furthermore, if a risk assessment is performed, it must be documented. In some instances, a manufacturer's customer may require that a report be provided. Reports are particularly required of component part manufacturers selling to original equipment manufacturers who perform their own risk assessments.

Any type of risk assessment documentation will need to list the hazard(s), the probability and severity of harm, and the methods by which risk can be minimized and ultimately was minimized. The documentation will naturally show the residual risk in the final product as designed, as well as document the attempts to further minimize that risk through consumer warnings and instructions.

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Of course, risk assessment documentation, as with all company documents, should be subjected to guidelines established for the company's record retention program. In many instances, keeping a risk assessment is essential in showing a plaintiff and a jury that a manufacturer tried to design and sell a reasonably safe product. So, evidence that a risk assessment was done may become very helpful.

However, because, as mentioned above, details from risk analysis may allow a plaintiff's expert to criticize manufacturing decisions, manufacturers should strive to create and retain documents showing that a risk assessment was conducted but consider discarding the early analysis/documentation of risks that were subsequently viewed as low, "designed out" or minimized. The real goal of the assessment documentation is to show that the remaining risks in the product were reasonable and would be very difficult and costly to reduce further.

Risk Assessment and Post-Sale Responsibilities

One of the most important issues facing any manufacturer is how to determine whether it has post-sale safety responsibilities to report post-sale corrective actions to appropriate agencies, issue safety bulletins or undertake a recall or retrofit. Failure in any of these areas can result in big government fines and possible compensatory and punitive damages in product liability litigation.

U.S. courts first enunciated a manufacturer's post-sale safety duty under common law in 1959. Since that time, courts and commentators have generally concluded that some post-sale responsibility exists, but have differed greatly on when that duty arises and how far it goes.

Early courts that considered post-sale issues clearly utilized a negligence balancing test to decide whether a post-sale duty arose. The higher the level of risk of injury from the product in the hands of consumers and the lower the level of difficulty in getting a message to those consumers, the greater the duty to at least warn them. This post-sale duty test is very similar to the negligence formulation of Judge Hand in *U.S. v. Carroll Towing*, *supra*.

In the early 1990s, the American Law Institute (ALI) undertook to restate the law of product liability. One of the most difficult issues that ALI addressed dealt with post-sale duties. The key section is §10, which states:

§10. Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Warn

(a) One engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller's failure to provide a warning after the time of sale or distribution of a product if a reasonable person in the seller's position would provide such a warning.

(b) A reasonable person in the seller's position would provide a warning after the time of sale if:

(1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and

(2) those to whom a warning might be provided can be identified and can reasonably be assumed to be unaware of the risk of harm; and

(3) a warning can be effectively communicated to and acted on by those to whom a warning might be provided; and
(4) the risk of harm is sufficiently great to justify the burden of providing a warning.

This restatement of post-sale liability law clarified that negligence principles govern when a manufacturer has a post-sale duty to warn. Levels of risk are weighed against the difficulty of providing a post-sale warning to consumers. The post-sale negligence analysis is basically the same as the negligence analysis undertaken before the product is sold.

Therefore, risk assessment, which should be undertaken before sale, is also appropriate after sale when deciding whether there is a common law post-sale duty to warn. In addition, U.S. and foreign laws and regulations also encourage risk assessment after sale.

U.S. Post-Sale Regulatory Law

The U.S. Consumer Product Safety Commission (CPSC) is governed by the Consumer Product Safety Act (CPSA). Section 15(b) of the Act requires, in part, that a manufacturer report to the CPSC if a product has a defect that creates the possibility of a substantial product hazard.

The regulations outlined in the CPSA provide some guidance on how to determine the need to report. The first question to consider is whether there is a defect. Under this subsection, a product without a defect is not subject to the reporting requirements even if injuries occur. Many products are reasonably safe and not defective and people still get hurt.

However, if a defect exists, the next question to be answered is whether this defect could create a "substantial product hazard." The CPSC starts this analysis by saying:

> Generally, a product could create a substantial hazard when consumers are exposed to a significant number of units or if the possible injury is serious or is likely to occur. However, because a company ordinarily does not know the extent of public exposure or the likelihood or severity of potential injury when a product defect first comes to its attention, the company should report to the Commission even if it [sic] in doubt as to whether a substantial product hazard exists.

CPSC Recall Handbook

The regulations also provide factors that a manufacturer must consider in determining if a substantial product hazard exists. Factors to consider include: pattern of defect, number of defective products in commerce, severity of risk, and likelihood of injury. The difference between the CPSC criteria and Judge Learned Hand's original negligence criteria is that the CPSC does not allow the burden on the manufacturer to locate and warn its consumers to outweigh a duty to report if the risk is substantial. As a result, there is a much lower threshold for reporting to the CPSC and undertaking post-sale actions than may be required under the common law.

In addition, the Food and Drug Administration (FDA) and the National Highway Traffic and Safety Administration, respectively, have thresholds for reporting that are much lower than under the common law.

Once a report is made, there is little guidance at the CPSC as to whether a post-sale corrective action is necessary and, if one is required, what elements constitute an adequate consumer notification program. The CPSC staff classifies the hazards as A, B or C based on an evaluation of the probability of future harm and the severity of that harm, which are the same factors used in pre-sale risk assessment.

The FDA also considers the probability and severity analysis; however, it designates a post-sale issue as a Class I, II or III hazard. The designation helps the FDA and the manufacturer to develop a recall strategy, including the rate of recall that should be achieved through consumer notification and the components of or need for compliance audits.

So, in the United States, it is perfectly acceptable and generally advisable for a manufacturer of any product to utilize risk assessment in evaluating post-sale issues.

Post-Sale European Union Regulatory Law

The 2004 General Product Safety Directive issued by the European Commission (GPSD) that is now being implemented in all European Union countries increases post-sale responsibilities for manufacturers and distributors of consumer products. Under the GPSD, distributors must monitor the safety of products placed on the market, especially by passing on information on product risks, keeping and providing documentation necessary for tracing the origin of products, and cooperating in actions taken by manufacturers and government agencies to avoid the risks.

Both manufacturers and distributors also will now have a duty to immediately notify the relevant government authorities when they know (or ought to know, in the case of distributors), that a product on the market poses risks to the consumer that are incompatible with the general safety requirements of the Directive.

The GPSD defines a "safe product" as one that "does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons…" The GPSD threshold for reporting appears to be much lower than under any U.S. statute or regulation, which usually requires a defect and substantial risk to be present, and under U.S. common law, which requires a substantial risk of harm to exist before a post-sale duty to warn arises.

However, the GPSD's low threshold will be tempered somewhat by the EU's adoption of risk assessment principles to assist a manufacturer in quantifying the level of risk to consumers from a product.

Risk Assessment and Its Use in Post-Sale Analysis

The European approach to risk assessment originally appeared in EN1050-1996, *Safety of machinery, risk assessment*. The EU countries explicitly require a pre-sale analysis of product hazards in accordance with the hazard hierarchy for manufacturers wishing to use the CE mark.

The first step in obtaining the CE mark for machinery is to conduct a hazard and risk assessment in accordance with EN1050; all machinery manufacturers selling their products in the EU must conduct hazard and risk assessments. The EN1050 standard "provides advice for decisions to be made on the safety of machinery and the type of documentation required to verify the risk assessment." It describes risk assessment as a procedure "by which the knowledge and experience of the design,

use, incidents, accidents and harm related to machinery is brought together in order to assess the risks during all phases of the life of the machinery."

For consumer products, in 2004, when the General Product Safety Directive was issued, the EU included typical risk assessment principles to be used by manufacturers to help them determine when a reporting responsibility arose. The guidelines were meant to supplement the definition of "safe product" and provide a consistent framework for analyzing post-sale problems.

However, the risk assessment principles were criticized because they were very subjective and thereby led to unpredictable and inconsistent reporting, and they tended to quantify some remote risks, rendering product safety risk reporting a necessity for low-level risks. *Lovells Product Safety Newsflash*, December 17, 2007.

As a result, the GPSD risk assessment process was recently revised, and a new, extensive draft has been issued by the EU Commission for member state comment in 2008. The new draft provides good analytical tools that can be used by manufacturers to decide whether to report to a government agency or to undertake a corrective action. See http://ec.europa.eu/consumers/safety/committees/index_en.htm.

While the risk assessment process outlined in the 2008 directive draft looks very similar to a pre-sale risk assessment of a product, because it will be issued by an official EU institution, it looks more official, and therefore, all manufacturers should consider implementing it wherever they sell their products in the world.

In the 2008 draft guidelines, risk is defined as "the combination of the severity of the possible damage and the probability that this damage occurs." The 2008 draft also details three steps to determine risk: (1) identify the seriousness of the hazard intrinsic to the product; (2) determine the probability of injury to the consumer from the intrinsic product hazard; (3) combine the hazard (in terms of the severity of injury) with the probability (in terms of fraction numbers) to obtain the risk.

The 2008 draft also provides more guidance on how to implement the three steps to determine risk, and includes a number of examples of the methodology in use, and a table tool to chart the level of risk (serious, moderate, low or acceptable). A determination on the level or risk from an assessment tool will help a manufacturer to decide whether to report and how to report hazards.

This risk assessment process described in the 2008 draft presents an organized way for a manufacturer to analyze post-sale risk. It could be used by manufacturers to decide whether to report to a government agency, and even if a report is necessary, whether to undertake a corrective action. Predicting future risk is the key to deciding whether a recall or some other corrective action is necessary.

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Using the EU Commission risk assessment methodology could be equally helpful for products sold in the United States, as well as elsewhere outside of the EU, in that using the "best practices" presented by this EU Commission draft in analyzing post-sale risk would give a manufacturer the appearance of diligence. The use of the draft methodology might also be helpful in defending a future product liability case against allegations that the post-sale analysis was inadequate and/or a decision to forgo a product recall was wrong.

Using the same risk assessment analysis procedures and tools for products sold throughout the world will negate any argument that a manufacturer is discriminating against consumers in a particular country. There is a benefit in a consistent approach to post-sale risk in every location where the risk exists.

Documenting Post-Sale Risk Assessment

It is even more important to document post-sale than pre-sale risk assessment because a manufacturer may have to justify its decision not to report the risk to a government agency, or explain why a certain corrective action adequately addressed a hazard.

Again, however, as with pre-sale risk assessment documentation, post-sale documentation can be used against a manufacturer to support a plaintiff's claim. Despite that, documenting the rationale for post-sale decisions is imperative to justify your actions to a government agency or possibly defend against allegations calling for punitive damages.

Advantages of Risk Assessment

A plaintiff can still argue that products are defective even if a manufacturer performed a risk assessment. However, risk assessment can impact the nature of the argument considerably. Without evidence that a risk assessment was performed, a plaintiff can attack both the decision-making process and the decisions. With a documented risk assessment, the argument primarily involves issues of judgment about the decisions.

In the event of litigation, a risk assessment may be useful to frame the discussion before the court. Rather than isolating one hazard that the plaintiff encountered, the defense can present the risk assessment as evidence of (1) the many hazards evaluated, (2) how the risks interact (reducing the risk level of one hazard may increase risk level of another), and (3) the successful risk reduction efforts implemented for all of the risks.

In some cases, part of the legal argument involves whether the plaintiff's use of the product was reasonably foreseeable. After an incident, a manufacturer may have difficulty showing that any particular use or misuse was not foreseeable. However, a completed risk assessment can help, because an analysis would have identified and addressed uses and misuses that are reasonably foreseeable based on the information available. If the plaintiff's use or misuse was not identified during the risk assessment, the defense can argue that the action was not reasonably foreseeable. If it was identified, the defense can argue that the risk reduction measures employed reduced the risk to an acceptable level.

Defense counsel may raise concerns that risk assessments have not been thoroughly tested, that problems exist with documentation requirements, and that, if incorrectly conducted, risk assessments can be very damaging. These concerns are not unfounded. However, like it or not, requirements for documented risk assessments are here. Failing to conduct and document a risk assessment might result in a bigger problem than conducting one.

Conclusion

My best advice is to perform the appropriate assessment and be prepared to stand behind the process and conclusions. While a plaintiff and his or her expert may disagree with your analysis, you can argue that you employed state-of-the-art safety analyses to produce a reasonably safe product and analyze post-sale risks.

Risk assessment is a well-developed process that conforms to best practices in the engineering world as well as to the pre- and post-sale analysis that the common law and government agencies want manufacturers to engage in.

While some companies have been conducting and documenting risk assessments for ten years or longer, a great many manufacturers are just beginning to learn about the process. Corporate counsel can assist by making its introduction and integration smooth. Counsel should also be involved in evaluating the exposure that can arise from such analyses and educate employees on how to form judgments and create proper documentation.

Manufacturers must be aware of the available best practices and methodologies to design a reasonably safe product and to monitor and undertake legally required or appropriate post-sale activities. Failure to do so could expose a manufacturer to significant legal liability, whether determined by a government agency, a jury or a court. IDQ