

# Revised Safety Label Standards Create Opportunity and Risk

By  
Kenneth Ross\*\*

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## Introduction

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As product liability law has evolved over the years, three defects have been identified as the main components of a product liability lawsuit. These are manufacturing defects, design defects, and defects in warnings and instructions. The test for determining when there is a manufacturing defect is objective. However, the test for defects in design and warnings and instructions is very subjective and based on reasonableness factors to be decided by the jury.

Once a duty to warn exists, a manufacturer can refer to standards in the U.S. and Europe which are helpful in developing labels which arguably transmit sufficient information and, at least in the U.S., can withstand legal challenge.

However, these standards have been changing, in part, because of increased interest by manufacturers in using one safety label for worldwide use. These changes in the standards can make it easier to comply with standards around the world. However, they raise a question of whether these global safety labels will be defensible in the U.S.

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## Labeling Standard Changes

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Recently, there have been revisions to the main U.S. and European labeling standards in an attempt to harmonize them. The goal is that a manufacturer could comply with either the U.S. or European standard without violating the other standard. The result is that a U.S. manufacturer would be able to create labels that comply with the European standard and use them in the U.S.

Given the differences in the labeling systems, this is a significant change and one that has ramifications for potential liability in the U.S. and Europe. The article

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\* Kenneth Ross is Of Counsel to Bowman and Brooke LLP in Minneapolis. Mr. Ross has advised manufacturers on safety label and instruction manuals since 1976. He co-authored one of the main reference texts on safety labels in 1980 and has been very active in assisting individual manufacturers and groups of manufacturers on labeling and manual projects. He can be reached at [kenrossesq@comcast.net](mailto:kenrossesq@comcast.net). This article appeared in the January 2005 newsletter of DRI's Product Liability Committee.

will discuss the U.S. labeling standard as it exists and will be revised. Then the European labeling standard will be discussed.

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## **Basic Duty**

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A manufacturer has a duty to warn where: (1) the product is dangerous; (2) the danger is or should be known by the manufacturer; (3) the danger is present when the product is used in the usual and expected manner; and (4) the danger is not obvious or well known to the user. See *Billiar v. Minnesota Mining and Manufacturing Co.*, 623 F.2d 240, 243 (2d Cir. 1980).

To determine whether the manufacturer has a duty to warn, during the design phase, manufacturers should do some sort of a risk assessment. This assessment identifies possible hazards with using the product and quantifies the probability that this hazard will occur and the severity of the harm that will be suffered if it occurs.

When this is completed and the product's design has been established, it should be easy to identify residual risks that need to be warned about. If the risk is not sufficient, then maybe no warning is necessary. There are no rules to tell a manufacturer when the risk is too small to warn or if the risk is not reasonably foreseeable, and no warning is required.

If the risk is obvious, a warning may not be needed. But this must be done carefully because the risk, and the probability and severity of harm may not be obvious to some potential product users.

In that case, the manufacturer needs to make a rational judgment as to whether a warning is necessary. Unfortunately, there are very few clear guidelines in this area. This is one reason why many manufacturers warn about too many hazards including small ones and obvious ones.

Once a warning is created, however, the guidelines, standards, and law are a little clearer.

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## **Adequacy of Warnings – U.S. Law**

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Once the decision has been made to warn, the manufacturer needs to determine whether the warning is adequate. The law has said that a warning is legally adequate if:

- it is in a form that could reasonably be expected to catch the attention of a reasonably prudent person in the circumstances of the product's use;
- the content is of such a nature as to be comprehensible to the average user; and
- it conveys a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person.

*Bituminous Casualty Corp. v. Black and Decker Manufacturing Co.*, 518 S.W.2d 868 (Tex.App. 1974).

In *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992) the court similarly found that, for a warning to be adequate, it should: "1) clearly indicate the scope of the risk or danger posed; 2) reasonably communicate the extent or seriousness of harm that could result from the risk or danger; and 3) be conveyed in such a manner as to alert the reasonably prudent person."

A statute in Louisiana defines an adequate warning as follows:

"Adequate warning means a warning or instruction that would lead an ordinary reasonable user or handler of a product to contemplate the danger in using or handling the product; and either to decline to use or handle the product or, if possible, to use or handle the product in such a manner as to avoid the damage for which the claim is made."

Despite these nice definitions, terms such as "reasonable user", "fair indication" and "reasonably be expected to catch the attention of the user" make it clear that the jury gets to decide the adequacy of warnings. Also, the cases have not been particularly helpful because there are so many variables with the hazards, the avoidance procedures, and the readers of the warnings. Is the reader educated, uneducated, skilled, unskilled, and illiterate or do they have poor reading skills, etc?

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## **U.S. Labeling Standard**

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The most significant standard in the area of U.S. safety labels has been developed by an Accredited Standards Committee on Safety Signs and Colors, ANSI Z535.

This standard which was approved on June 6, 1991, and reapproved in 1998 and 2002, will be referred to as ANSI Z535.

There are five parts to the ANSI Z535 safety label standard. The first standard relates to safety color codes and is designated ANSI Z535.1. The second part is designated as the standard for environmental and facility safety signs and is designated ANSI Z535.2. The next part deals with criteria for safety symbols and is designated ANSI Z535.3. The next part is ANSI Z535.4 and provides a national standard for product safety signs and labels. The last part, ANSI Z535.5, deals with temporary accident prevention tags.

These ANSI standards provide the basis for developing a safety label system. Unlike some other labeling standards, ANSI Z535.4 sets forth performance requirements for the design, application, use and placement of safety labels. The purpose of this standard is "to establish a uniform and consistent visual layout for safety signs and labels applied to a wide variety of products." It is also designed to create a "national uniform system for the recognition of potential personal injury hazards for those persons using products."

ANSI Z535 .4 provides for a specific format label containing a signal word panel, word message panel, and an optional pictorial or symbol panel. The message required by the standard, either with words or symbols, is (1) nature of the hazard, (2) seriousness of the hazard or probability that the user will encounter the hazard, (3) the consequences of encountering the hazard or the severity of the injury, and (4) how to avoid the hazard.

The ANSI standard defines a symbol or pictorial as a graphic representation intended to convey a message without the use of words. It goes on to say that the symbol or pictorial may represent a hazard, a hazardous situation, a precaution to avoid a hazard, a result of not avoiding a hazard, or any combination of these messages. The pictorial panel should have a black pictorial on a white background although other colors may be used for emphasis such as red for fire. Z535.4 also states that the pictorial should be readily understood and effectively communicates the message. It should also allow the viewer to immediately recognize an existing hazard.

The 2002 version of the ANSI standard allows the manufacturer to use symbols that have not been tested for comprehension if the meaning of the symbol is contained in the instruction manual.

While the ANSI standards allow for pictorials or symbols to take the place of words in the message panel, any manufacturer should be careful before they fully rely on a symbol or pictorial to fully communicate the message. Since symbols or pictorials may represent a hazard, a hazardous situation, a precaution to avoid a hazard, a result of not avoiding a hazard, or any combination of these messages, it would be unusual for a pictorial to be able to replace all word messages that are generally required by law.

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## **European Law and Standards**

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International laws and standards make the situation even more confusing. Given the number of languages around the world, any manufacturer who sells its products in more than a few foreign countries, must consider what the labels and instructions should look like and what attempt should be made to create labels and manuals that can be used for worldwide sales.

The Product Liability Directive in Europe, which adopted strict liability, has a definition of defect that includes the “presentation of the product.” In addition, the Directive says that a product is defective if the product does not provide the safety that a person is entitled to expect. One way this can happen is to have inadequate warnings and instructions.

In addition, the European Machinery Directive expressly creates a duty to warn and instruct. The Directive requires a manufacturer to “inform users of the residual risks due to any shortcomings of the protection measures adopted, indicate whether any particular training is required and specify any need to provide personal protection equipment.” Instructions are specifically required to accompany all machinery and they must include instructions for safe servicing, use, assembly, and maintenance of the machinery.

Warnings and instructions under the Machinery Directive “should preferably use readily understandable pictograms and/or be drawn up in one of the languages of the country in which the machinery is to be used, accompanied, on request, by the languages understood by the operators.”

The General Product Safety Directive, which applies mainly to consumer products, also requires adequate warnings and instructions.

It is easy to conclude that the duty to warn and instruct in the European Union is significant and, even more difficult than the U.S., given the number of languages

used in Europe. Some manufacturers in the U.S. have tried to get around this by using pictorial only labels in Europe. While this is allowed in some technical standards for sales in Europe, it is not allowed in the U.S. and, therefore, unless the manufacturer wants to take a significant legal risk, they cannot rely on pictorial only labels for worldwide sales of their products.

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## **ISO Labeling and Product Standards**

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The International Organization for Standardization (ISO) has a labeling standard that is very different than ANSI Z535. Symbols are the essential ingredient of this labeling system. ISO 3864 defines four basic formats for labels. Through the use of shape, colors, and symbols, ISO believes that each symbol can adequately communicate a safety message.

The hazard symbol is a picture of a hazard on a yellow background inside a triangle. The prohibited action is the familiar picture of a prohibited activity inside a red circle and slash. Last, the mandatory action for how to avoid the hazard is a white pictorial inside a blue circular shape.

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## **Conclusion**

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Complying with the duty to warn and instruct in the U.S. and in foreign countries is not easy. The manufacturer must seriously undertake an effort to do so, both for the safety of the product and to enhance your ability to sell your products both here and abroad. This article and the previous article touched on the most important aspects of this duty. But it only scratched the surface and was intended for people to understand how difficult this area can be. Using competent people to assist will pay off in the long run. Your products will hopefully be reasonably safe and, if there is an accident, will also be defensible.

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## **Conclusion**

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This area is dangerous because it is so easy for a plaintiff to argue that the manufacturer should have added a few more words and the accident would not have happened. The remedy is cheap – add a few more words – and it may be hard to defend given a serious injury and sympathetic plaintiff.

As a result, creating new warnings and instructions (or updating your current warnings and instructions) should not be done without first obtaining adequate assistance from legal counsel and engineers and label suppliers that know how to design and produce labels and manuals that comply with any applicable laws and standards. Once the labels and manuals have been developed correctly, it is easy to update or modify them in the future.