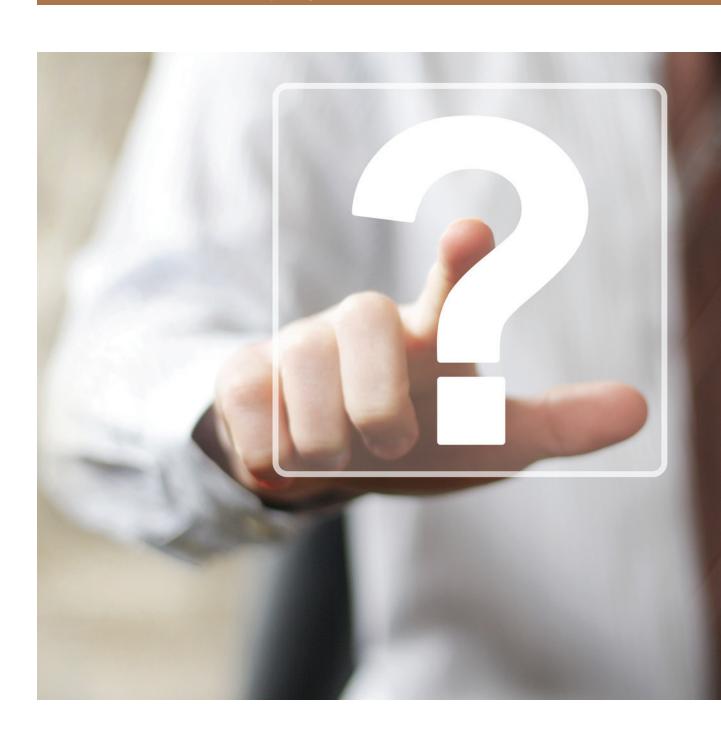
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PRODUCT SAFETY INSTRUCTIONS AND WARNINGS

Some Answers to the Most Frequently Asked Questions



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By Kenneth Ross

Readers of *In Compliance Magazine* have benefited from being able to read Geoff Peckham's excellent articles on product safety warnings for a long time. As a lawyer who has spent over 30 years providing advice on warnings and instructions to manufacturers, I wanted to provide my legal and practical perspective in this important area.

The intent of this article is not to discuss in detail the legal analysis that might apply to answering certain questions, but to provide short practical answers to questions that I have received and answered over the years. For more detail on the subjects covered in this article, see articles I have written on my website, www.productliabilityprevention.com.

Does the law require that my warnings comply with ANSI Z535?

The ANSI Z535 standards are voluntary consensus standards that have no official legal acceptance, either in the common law or in statutes or regulations. However, there are product specific laws and standards that governments have enacted over the years that pertain to warnings such as the CPSC's Federal Hazard Substances Act for chemicals in consumer products. These product specific laws would take precedence and therefore need to be identified and considered.

In addition, there are other ANSI or ISO standards that are product specific and would also take precedence over ANSI Z535. And the European Union has issued directives on products such as machinery that contain warnings requirements. Lastly, if the product has a third party certification, such as UL or CSA, the manufacturer's labels and instructions need to comply with the requirements of their standards.

For some products, there may be multiple laws, regulations, standards and guides that need to be considered when developing warnings and instructions. That is one reason why personnel involved in developing such information need to be familiar with all of the applicable documents that need to be considered. Some need to be complied with, while others might just provide helpful guidance. The goal is to use all of the relevant resources available and be prepared to defend the adequacy of your process and your warnings.

Do you always need to state the hazard, consequences and avoidance procedures even if they are obvious?

The ANSI Z535.4 standard says in Annex B:

"The word message on a hazard alerting sign typically communicates information to a viewer on the type of hazard, the consequence of not avoiding the hazard, and how to avoid the hazard. Many factors must be considered when determining whether to omit consequence, avoidance, or type of hazard information in the word message. Factors to consider include whether the message can be inferred from a symbol, other text messages, user training, or the context in which the safety sign is used."

Certainly, it is clear that many hazards and avoidance procedures can be readily inferred when the label is on the product and near the hazard. Studies also support this view.

But, you need to be careful about deleting some of these statements just to save a little space. If you think that the message is "obvious" from viewing the product, you could test out that assumption by asking a small focus group or even by just asking people at your company.

For example, you might delete the avoidance procedure where the product gets extremely hot during operation and you say that there is a burn hazard. To avoid the burn, you don't touch the product when it is in operation. That is pretty obvious. The problem is that the product may stay hot for a while after it is turned off and that will not be obvious, particularly for a bystander who didn't even know the product had been in operation.

In addition, you might not warn about a particular hazard because it is obvious (e.g., a crush hazard in a conveyor belt). However, the severity and probability also have to be obvious before I would omit the warning. If the user's hand can be cut off or crushed, this may not be obvious and the user might just think that his hand could be pinched.

When can you use pictorials instead of text on labels and in the manual? And if you do, can you rely on pictorials without human factors testing?

This is a complex subject that is not readily susceptible to a short answer. But I will attempt to do so. There are some pictorials that can readily be used in labels in the U.S. in place of certain text. Most of them show the hazard and the consequences and have been used for decades. Some of them show the avoidance procedure (e.g., circle and slash). While many of these pictorials are very understandable, the general view among most lawyers is that, with some exceptions, it is risky to use no-text labels with only pictorials in the U.S.

Some messages are difficult, if not impossible, to transmit with just pictorials, and a label with many pictorials really needs to be studied for a while for a reader to possibly understand the entire message. That defeats the purpose of a label which should be understandable at a glance.

One way to use pictorials in lieu of text is to do human factors testing as described in ANSI Z535.3. However, such testing is expensive and the results may still be challenged by a plaintiff who says that they

didn't understand the pictorial. And the testing of multiple pictorials would have to be done to replicate what the plaintiff saw.

The use of no-text labels outside the U.S. is much more prevalent and certainly less of a legal risk. However, the company should consider the likelihood that products shipped outside the U.S. with no-text labels could end up being sold to consumers in the U.S.

Should labels and manuals in the U.S. be bilingual (English and Spanish)?

The quick answer is that the law does not generally require any language other than English. Despite that, some retailers do demand at least Spanish on warnings and instructions sold in their stores. Unless there is a customer request, the manufacturer should preferably add more pictorials rather than add a foreign language to try to communicate with non-English reading product users.

Once you add a foreign language, you have to decide which one to add and then you need to be sure that the instruction manual is also in that language. And, sometimes, Spanish is not the only language that needs to be considered. Lastly, adding other languages will sometimes diminish the conspicuity of the English message and thereby increase the potential liability for English reading users who have a hard time finding the English portion of the message.

When can safety messages be in the manual and not on the label? When on the label and not in the manual?

There is very little guidance in the law or the general warnings standards on this issue. Some product specific standards, including UL, specifically say whether the warning must be on the product or in the manual. Without that requirement, it is up to the manufacturer to decide.

My operating principle is based on an analysis of whether the reader needs to see the information each time they use the product or whether they can read the manual and then refer to that information later on an as-needed basis. Steve Hall from Applied Safety and Ergonomics said on this question:

"There is no hard and fast rule, but generally you want to try to provide messages in a way that gives people a reasonable chance to read them at an appropriate time. So, for tasks that are expected to involve referring to the manual (e.g., assembly, troubleshooting, maintenance, etc.), it is generally reasonable to provide safety messages in the relevant part of the manual, and not on a label. Conversely, for scenarios where the target audience is not reasonably expected to have access to a manual, a label may be more appropriate."

In addition, a product liability law professor said:

"Whether adequacy requires in any given case that warnings be placed directly on the product involves a balance of the significance of the hazard, the user's need for the information, the availability of a feasible means to place the warnings on the product, and other factors in the calculus of risk. If feasible, reason normally suggests that important warnings be placed on the product itself rather than in a pamphlet, booklet, or information sheet that can be damaged, lost, destroyed or stuffed in an office drawer... Depending on the circumstances, however, a warning may still be adequate even if it is provided off the product in a manual or other writing."

Do I always need to provide a hard copy of the manual, or can I put the manual on a CD that's included with the product, or have a reference (website link or QR code) to the manual on the label to the company's website?

The standards don't discuss whether a hard copy is required or whether the information can be provided in another way. The reason is probably that most manufacturers provide their instructions in a hard copy. However, there have been manufacturers of certain products that have recently asked about not providing a hard copy, but instead including the instructions as an electronic file in the product or in a CD or just provide on a label a link to the manual on a website. Examples of such products would be cell phones, computers, TVs, and certain machinery or equipment run by computers.

I have seen no law that discusses this issue and, as a result, a manufacturer could omit the hard copy and argue that what they provided was adequate under the circumstances.

At a minimum, if there is room, the on-product warnings should tell the user to read the manual before using the product and tell them how to obtain a replacement manual if one is missing. This can be done by providing an 800-number to call or website link to download a replacement manual.



When should new or improved warnings and instructions be offered to prior customers? When do you need to tell the government?

New and improved warnings and instructions might be considered safety improvements or they might be considered an admission that the earlier warnings and instructions were defective. The common law is clear that manufacturers are not required to offer safety improvements to prior customers if the earlier product was not defective. The problem is how do you decide whether the earlier product might be considered defective and the new safety information used as evidence to support the claim? It is a difficult decision and one that is fraught with potential problems no matter what you do.

Certainly if the earlier warnings and instructions are compliant with the standards and the law and the new versions are just updated and made a little better, then it is arguable that these are just improvements. However, if the earlier warnings and instructions did not comply with the standard or law or are significantly deficient or if there have been a number of lawsuits alleging a failure to warn or several jury verdicts ruling the warnings defective, then the new warnings and instructions might be more than just safety improvements.

This is an important analysis where competent safety and possibly trial counsel should be consulted. Since you don't know where any future case will be brought, it is hard to know what state's law to consider. The best approach is to consult with counsel you trust and who is familiar with your products and your litigation experience.

Then the question is, in the case of consumer products, do you need to inform agencies such as the U.S. Consumer Product Safety Commission or Health Canada about the new warnings and instructions? The reporting laws are different from country to country and you need to consider whether the issuance of new warnings and instructions to prior customers could arguably be considered a "recall" and create a reporting responsibility to any of these agencies.

Where on the product should the label be attached?

ANSI Z535.4 requires that safety signs be placed so that they will be readily visible to the intended viewer and will alert the viewer to the potential hazard in time to take appropriate action.

ANSI provides that, where feasible, the sign should be placed so that it is protected from foreseeable damage, fading or visual obstruction from things such as mud, dirt, ultraviolet light and abrasion. The standard says nothing else about placement. However, there are some practical guidelines to consider.

While safety signs should be placed near the hazard they are describing, it should not be so close so that the label will not be seen until the hazard is encountered. This requires the manufacturer to calculate the safe viewing distance described in Annex B to ANSI Z535.4. Also, the label should not be placed so far away that it will be forgotten by the time the user is near the hazard.

In some cases, it may be necessary to attach two labels – one in the immediate vicinity of the hazard and another one further away. For example, a safety label system created for hazardous electrical equipment could have a label using the signal word WARNING identifying the existence of hazardous voltage inside an electrical enclosure. On the inside of the enclosure, near the live electrical parts, could be another label using the signal word DANGER.

Another consideration in placement of the label is whether to place a label on a part of a product that can be removed. For example, placing a label on a removable door to a piece of machinery is not a good idea because when the door is removed, the label is also gone. If the label warns about operating the machine with the door removed, the current operator will not see this warning when someone else has removed the door. In that situation, the label should be placed next to the door on the frame of the machine.

Other things to consider in placement are the viewing angle, light conditions under foreseeable use and the relationship of label location to other labels or parts of the product. Also, if the product needs to be assembled, the manufacturer should state in the instruction manual, assembly instructions or elsewhere that the assembler must put the labels in the correct location and make sure they are clearly visible to the user.

Is there such a thing as overwarning?

One argument periodically made by plaintiffs and their experts is that there were too many warnings which resulted in a user not reading any of them. The concept has been called "sensory overload."

There are general statements in the law that overwarning is to be discouraged because it will detract from the more important warnings. But there is very little guidance about when that might occur. I have looked for but have been unable to find any court opinions ruling that the warnings were inadequate because there were too many of them.

Courts do talk about not overwarning, but it is up to the jury to say when that has occurred. For example, the Louisiana Court of Appeals said in response to a plaintiff's proposed new warning label with ten messages:

"As a practical matter, the effect of putting at least ten warnings on the drill would decrease the effectiveness of all of the warnings. A consumer would have a tendency to read none of the warnings if the surface of the drill became cluttered with the warnings. Unless we should elevate the one hazard of sparking to premier importance above all others, we fear that an effort to tell all about each hazard is not practical either from the point of view of availability of space or of effectiveness. We decline to say that one risk is more worthy of warning than another."



Considering the above language, I like to tell manufacturers that, to my knowledge, no company has been held liable for having too many warnings. While we do want to write warnings as succinctly as possible and not include clearly obvious hazards or remote risks, I tend to include all residual risks on the label or at least in the manual where we have unlimited space.

CONCLUSION

There are many other questions that I have been asked over the years and had to supply answers. There is very little law on these important, but narrow issues. And most of them are not answered by any of the standards. Despite that, the manufacturer must consider them and make a decision.

While designing a safe product is not an easy task, providing adequate warnings and instructions can be an even tougher job. It is so easy to add words, make the label bigger, provide more illustrations in the manual and do other things that some jury might believe would have prevented the accident. And a plaintiff will always say that they would not have been injured if the warnings had been better.

While the manufacturer shouldn't be paralyzed by the fear of not providing adequate warnings and instructions, they should not take this responsibility lightly. They should use competent legal and technical personnel to help, especially on the difficult kinds of questions discussed in this article.

In addition to hopefully providing information that will reduce the risk of harm, better warnings and instructions might also help make the product more marketable in that it will be perceived by customers to be easier to assemble, use and maintain. And that approach will also make it easier for defense counsel to defend if an incident occurs. •

ENDNOTES

- 1. Product Liability Law, 2d Edition, page 601 (Thomson West 2008).
- Broussard v. Continental Oil Co., 433 So. 2d 354
 (La. App), cert. denied, 440 So. 2d 726 (La. 1983).