

WARNING:

By Jonathan R. Cooper and Arun J. Kottha

Conflicting Issues Regarding Warning Labels May Be Hazardous to Your Company's Health

Until recently, a properly crafted safety warning seldom interfered with the salability of a product. The 2006 European

Union Machinery Directive (EUMD), which was ratified by the European Union's member countries last year, will likely greatly interfere with salability. Many U.S. manufacturers sell products in both the United States and the European Union. Most of those products are festooned with warning labels both to prevent accidents and to avoid liability. Warning labels are expensive. They must be designed, manufactured, and applied. They are made from special plastic that will withstand harsh environments. Manufacturers must take care to affix them to products properly and in the right places.

Manufacturers have been able to design product warnings for products bound for both the United States and the European Union that have harmoniously met US standards and EU standards. The EUMD threatens that ability. If the EUMD is followed to the letter, every warning on every product destined for an EU state must consist of a pictogram, or if a product contains written warnings, warnings translated into the official language of the country for which a product is bound. This leaves a manufacturer with four choices: ignore US warning standards and risk liability for insufficient warnings; ignore the EUMD and risk product rejection in the European Union; draft multiple translations of all sig-

nal words and message panels and apply them on a case-by-case basis; or maintain one set of American National Standards Institute-style warnings for the US market and another set of pictograms for the European market. None of these solutions is attractive. All are potentially costly.

But, this is not merely a financial decision. The different warning schemes put together by the American National Standards Institute on the one hand and the International Organization for Standardization on the other are both designed to promote and to enhance the safety of products. These schemes premise is that uniform formats will enhance readability, and hence, compliance. *See* ISO 3864-2:2004 & ANSI Z535.4-2007, §2.2. Instituting new requirements may interfere with that overarching goal.

A Brief History of the Standard Pictorial Warning Label

The story of standardizing modern pictorial warning labels begins with the National Electrical Manufacturers Association (NEMA). Confronted with rising levels of "failure to warn" allegations involving electrical equipment in the early 1980s, NEMA's members set out to develop a warning label. Kenneth Ross, *The Story of 'MR OUCH', Creation of a Warning Label, Product Liability Int'l*, October 1983 at 152-54. Although their electrical equipment was generally locked, tampering by vandals led to serious injuries when children explored the interior of equipment. *Id.* To combat failure to warn claims, manufacturers needed to develop warning labels effective for young children who either could not read or who could not grasp the severity of danger from language-

based labels alone. *See id.* NEMA members developed the now-famous pictorial image, "Mr. Ouch," and they extensively tested it with children of several ethnicities aged 2.5-6.5 years. The Mr. Ouch image ranked the highest in

"every major category relative to depicting a threat and inducing a safe response." *Id.*

The beauty of Mr. Ouch was that it worked. The testing demonstrated that people, including children, recognized the symbol and understood the information necessary to avoid harm. From a product liability standpoint, manufacturers could prove that they had used effective warnings. This not only improved safety, it also improved a manufacturer's ability to defend its products. Mr. Ouch was the first standard pictorial warning adopted by an industry.

ANSI

Short of a survey, manufacturers typically rely on compliance with "consensus" standards promulgated by bodies that draw their standards committees from more than one sector of society. In the United States that has often meant standards promulgated by the relevant committee of the American National Standards Institute (ANSI). ANSI oversees the creation, promulgation, and use of thousands of norms and guidelines that directly impact businesses in nearly every sector of the U.S. economy. American National Standards Institute, About ANSI Overview, http://www.ansi.org/about_ansi/overview/overview.aspx?menuid=1 (last visited Feb. 13, 2011).



■ Jonathan R. Cooper is a partner and Arun J. Kottha is an associate in the Cleveland office of Tucker Ellis & West LLP. Mr. Cooper is a trial lawyer whose practice focuses on the defense of product manufacturers including the national and regional defense of manufacturers of material handling, automation, and electrical products. Mr. Kottha focuses his practice on business litigation and mass tort and product liability. Prior to becoming an attorney, he was a licensed ISO auditor, and audited a variety of manufacturing facilities in the Midwest and Eastern Seaboard for compliance with the ISO 9001:2000 quality management standard.

In the case of warnings, the relevant standard since 1991 has been ANSI Z535. The ANSI Z535 standards were designed to create something that worked as Mr. Ouch had worked. The mantra of the ANSI warning system is threefold: (1) alert a user to the danger, (2) inform the user of the severity of the danger, and (3) instruct the user how to avoid the danger. This is accomplished by combining symbols, colors, and mandatory warning language.

The stated purposes of ANSI Z535 are (1) to establish a uniform and consistent visual layout for safety signs and labels applied to a wide variety of products; (2) to minimize the proliferation of designs for product safety signs and labels; and (3) to establish a national uniform system for the recognition of potential personal injury hazards for those persons using products. ANSI Z535.4-2007, §2.2.

There are four levels of severity denoted by capitalized “signal words” that have corresponding colors: “DANGER,” in white letters with a red background; “WARNING,” in black letters with an orange background; “CAUTION,” in black letters with a yellow background; or “NOTICE,” in white letters with a blue background. *Id.* at §§5.1, 7.2. A “safety symbol,” an equilateral triangle surrounding an exclamation point, accompanies all of these signal words.

A product safety sign or label consists of a signal word panel, noted above, plus a mandatory “message panel,” which communicates the type of hazard, the consequence of failing to avoid the hazard, and how to avoid the hazard. *Id.* at Annex B. ANSI-style warning standards have a number of specific instructions regarding font, alignment, and other physical characteristics of the language used on a message panel, in addition to grammatical instructions, such as avoiding passive voice and prepositional phrases. *Id.*

The idea is that any person could, with a quick look, know what sort of trouble was ahead, what might happen, and how to avoid the trouble. Manufacturers in the United States have now spent a little over a generation teaching users and consumers to recognize and interpret ANSI-style warnings.

Complying with ANSI Z535 also offers a manufacturer an advantage in litigation. Complying with ANSI Z535 allows a manufacturer to argue that it fulfilled its duty to warn by following the relevant consensus standard.

ISO

While the ANSI committees were honing the ANSI Z535 standards, the International Organization for Standardization (ISO), based in Geneva, Switzerland, was developing its own standard, using different concepts. While the ANSI standards were based on safety symbols, signal words, and message panels, the ISO created a symbol-based system.

ISO is the world’s largest developer and publisher of International Standards. A non-governmental organization, ISO is a network of the national standards institutes of 161 countries, with a Central Secretariat in Geneva coordinating the system. International Organization for Standardization, Discover ISO, http://www.iso.org/iso/about/discover-iso_how-the-iso-system-is-managed.htm. A host of information about ISO can be found on its website, www.iso.org, and copies of all referenced ISO standards can be purchased online as well. ANSI is the official US representative to the ISO. American National Standards Institute, Introduction to ANSI, http://www.ansi.org/about_ansi/introduction/introduction.aspx?menuid=1. According to ISO 3864-2, which establishes principles for designing product safety labels, the purpose of a product safety label is to alert persons to a specific hazard and to identify how they can avoid the hazard. ISO 3864-2:2004, Graphical Symbols—Safety Colours and Safety Signs—Part 2: Design Principles for Product Safety Labels, http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=31020. In short, the ISO and the ANSI have similar goals—to establish uniform systems so that users and others have information about hazards, their severity, and how to avoid them. The major difference is the method that each system uses to attempt to achieve its goals.

To comply with the ISO regulations, businesses must use at least one of three types of “safety signs”: (1) an equilateral yellow triangle, which signals a warning;

(2) a red circle with slash, which signals a prohibition; or (3) a blue circle, which signals a mandatory action. ISO 3864-2:2004, §6.2.



Inside each type of sign a pictogram depicts a hazard, an action, or an instruction. The most familiar example is the no smoking “prohibition” sign. The ISO 3864-2 system uses three basic colors as signals for the severity of harm a person would encounter: red for high, orange for medium, and yellow for low. *Id.* at §4.3. So-called “signal words” can be associated with each level of severity: “danger,” “warning,” and “caution,” respectively. *Id.* at §5.3. Each of the three levels of severity has an equilateral triangle surrounding an exclamation

Table 1—Official European Union Languages

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|-----------------|---------------------------|
| Austria | — German |
| Belgium | — Dutch, French, German |
| Bulgaria | — Bulgarian |
| Cyprus | — English, Greek |
| Czech Republic | — Czech |
| Denmark | — Danish |
| Estonia | — Estonian |
| Finland | — Finnish, Swedish |
| France | — French |
| Germany | — German |
| Greece | — Greek |
| Hungary | — Hungarian |
| Iceland | — Icelandic |
| Ireland | — English, Irish |
| Italy | — Italian |
| Latvia | — Latvian |
| Liechtenstein | — German |
| Lithuania | — Lithuanian |
| Luxembourg | — French, German |
| Malta | — English, Maltese |
| The Netherlands | — Dutch |
| Norway | — Norwegian |
| Poland | — Polish |
| Portugal | — Portuguese |
| Romania | — Romanian |
| Slovakia | — Slovak |
| Slovenia | — Slovenian |
| Spain | — Spanish |
| Sweden | — Swedish |
| Switzerland | — French, German, Italian |
| Turkey | — Turkish |
| United Kingdom | — English |

point in the appropriate color, and together, they form a “hazard severity panel.” Using signal words or a hazard severity panel is not mandatory, however. *Id.* at §5.1 (“If the level of hazard severity is to be indicated...”). Stated differently, each label “shall be comprised of one or more safety signs,” and can be “accompanied by a hazard severity panel.” *Id.* at §6.1. Finally, a manufacturer has the option of adding “supplementary safety information text,” which can include warnings such as, “ELECTRICAL HAZARD—Contact with Water Can Cause Electrical Shock.” *Id.* at §§3.15, 6.1. Using these language-based warnings, as with signal words, is voluntary. *Id.* at §6.1.

How Do ISO and ANSI Standards Differ?

The ISO warning standards rely more heavily on images than the ANSI warning standards. In fact, an ISO warning can be exclusively visual, without words at all. In contrast, the ANSI standard mandates both a “signal word” and a “message panel” that provides necessary information to a user of a product. Neither the ANSI nor the ISO warning schemes has the force of law. The inconsistency between the two systems can create potential litigation problems and possible safety issues. If a manufacturer, adhering to the ISO standard, exports its products to the United States, it risks liability based upon failure to warn. The liability stems from failing to produce warnings adhering to the relevant US standards.

In addition, the goals of the two systems, while similar, are not exactly the same. The ISO’s goal is “to alert persons to a specific hazard and to identify how the hazard can be avoided.” ISO 3864-2:2004, http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=31020. The ANSI’s goals are “(1) to establish a uniform and consistent visual layout for safety signs and labels applied to a wide variety of products; (2) to minimize the proliferation of designs for product safety signs and labels; and (3) to establish a national uniform system for the recognition of potential personal injury hazards for those persons using products.” ANSI Z535.4-2007, §2.2.

The ISO system is less concerned with variation and more concerned with adapt-

ing safety labels to specific situations than the ANSI system. In contrast, the ANSI system is more concerned with standardization. ANSI’s theory is that although a manufacture may not adapt a warning may to each unique situation, workers will be safer because they become conditioned to respond to the same signal words and warn-

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ing style so that they heed warnings when they are exposed to them year after year. There is a great deal of debate in the scientific community about whether warnings are effective in changing behavior. That debate extends to whether the ANSI and the ISO formats increase user safety compliance. A recent study found that the ANSI and the ISO formats did not result in significantly greater safety compliance than messages that did not follow a particular format. Eric F. Shaver, *et al.*, *Comparison of ISO and ANSI Standard Formats on People’s Response to Product Warnings*, Proceedings of the Human Factors and Ergonomics Society at 2197–2201 (2006), <http://www.hfes.org/publications/ProductDetail.aspx?ProductId=79>, accessed 1/19/2011. Reading the study did show that US residents were more likely to comply with an ANSI-formatted warning than an ISO-formatted warning even though the ISO warnings contained a signal word and a message panel. *Id.* at 2199.

Using ISO-style warnings in the United States or ANSI-style warnings in Europe would probably have safety consequences. If the goal of each warning system is to provide a uniform system to provide readily understandable access to safety information, using a different system would seem contradictory.

It is possible to harmonize the ISO and the ANSI standards into a single “hybrid” label. An ISO-ANSI-hybrid warning label would have an ISO image accompanied by an ANSI-compliant message panel and signal word. This would ostensibly satisfy the visual ISO requirements and supply the required text of the ANSI requirements. This solution is not perfect. The ISO system doesn’t *require* language at all in either a “hazard severity panel” or “supplementary safety information text,” and if a manufacturer does choose to exercise such an option, the ISO standards do not offer guidance on the language a manufacturer should use. Moreover, the colors and color schemes of the ISO and the ANSI standards differ slightly. For example, including an ANSI-compliant message panel for a particular risk severity would not adhere to the ISO color standard. However, the “hybrid label” described above very nearly would comply with both standards.

Enter the New European Requirements

Harmonizing ISO and ANSI warnings may be for naught due to the European Union Machinery Directive (EUMD). A manufacturer selling a product in Europe will now need to comply with this new law, which introduces yet a third set of requirements for approved warnings, unless the EUMD is modified.

The EU Parliament has power to legislate “directives” and “regulations.” Both have the force and effect of law. Regulations are self-executing, and they are effective and binding on the member states automatically and immediately. Individual member states do not ratify them on a country-by-country basis although they are sovereign nations. Once the EU Parliament approves or “ratifies” a directive, each member state must still enact country-specific legislation. Each member state may tailor a directive to its particular needs as long as its version remains aligned with the spirit of the directive. And directives generally set forth a series of goals and assign a date by which each member state must enact legislation to its effect. For example, the EU Parliament enacted EUMD in 2006 and established that individual member states would enact country-specific legislation by June 29, 2008, which would take effect Decem-

ber 29, 2009, at the latest. 2006/42/EC, Art. 26, ¶1, http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_157/l_15720060609en00240086.pdf (last visited Jan. 18, 2011). Each European Union member state has now enacted EUMD country-specific legislation.

The EUMD is applicable to (1) machinery; (2) interchangeable equipment; (3) safety components; (4) lifting accessories; (5) chains, ropes, and webbing; (6) removable mechanical transmission devices; and (7) partly completed machinery. 2006/42/EC, Art. 1, ¶1. There are a number of items excepted from the EUMD: site hoists; weapons; devices for lifting personnel; consumer products; certain farm tractors; electrical equipment, including a variety of items from consumer electronics to high-voltage switchgear; certain safety devices; vehicles for transport of persons and cargo, land, sea, and air; machinery for “nuclear purposes”; military equipment; and a variety of highly specialized machines. *Id.* at Annex I, §1.7. Section 1.7 to annex I, entitled “information,” deals with warnings and accompanying instructions. The Machinery Directive explicitly states a preference for pictorial-based warnings, presumably due to the diversity of languages spoken in the European Community. In fact,

written or verbal information and warnings must be expressed in an official Community language or languages, which may be determined in accordance with the Treaty by the Member State in which the machinery is placed on the market and/or put into service and may be accompanied, on request, by versions in any other official Community language or languages understood by the operators.

2006/42/EC, Annex I, §1.7.

In short, a manufacturer must translate warning label text into the official language or languages, if more than one, of the member state in which a manufacturer places it. If a manufacturer sells a product to an entity near a border, the languages can multiply. Table 1, Official European Union Country Languages, on page 37, lists the official

community languages of each EU member state. So to comply with the EUMD and with the ANSI and ISO standards now requires translating signal words and the message panels into multiple languages.

Harmonizing US and European Requirements: What Do We Do?

After ratification of the EUMD, designing one warning label that would pass muster in both America and Europe may be impossible. The main problem is the language requirement of the EUMD, which requires translating all text in warning labels into over 20 languages. It appears that the only clear way to comply with the directive’s language requirements is to use no language at all! However, that warning would then fail to comply with ANSI Z535.4, and its effects on safety are unknown.

Manufacturers have limited options to solve this problem, and none is ideal. The first option is to simply issue different warnings: use ANSI standards for the US-bound products and wordless, ISO-based warning labels for products sold in Europe. This possibility precludes using a universal warning label and increases costs because a manufacturer will need to design and implement two warnings regimes, engage workers to install the warnings, and engage inspectors to ensure that labelers use the proper warnings. Another possibility is to use an ANSI-compliant warning for a product for distribution across continents and offer a subsequent European purchaser a way to obtain language translations, perhaps through an automated website that would send translated warnings to anyone who provides a serial number. This methodology, though, does not solve the problem by permitting a manufacturer to retain one universal warning label, and in fact, it requires maintaining warning labels in myriad languages at increased cost. In addition, it underscores the main problem with the Machinery Directive: to comply with the strict letter of the EUMD, a manufacturer must keep on hand, or affix to a

product, a warning label in all of the community languages, which is extremely difficult. Moreover, the EUMD requires that a warning “accompany” a product. 2006/42/EC, Annex I, §1.7.4. It is not clear that directing a buyer or user to a website would satisfy that requirement.

A third possibility is to use an entirely pictorial ISO warning in the United States and the European Union. However, such a plan creates risk if someone using a product in the United States is injured. If someone is injured, that person’s attorney will argue that the manufacturer failed to effectively warn because the manufacturer failed to comply with the ANSI standards’ text requirement. All of these options might potentially address the regulatory structure anomalies, but they all have drawbacks.

The overarching concern with these warning standards is worker safety. Attorneys can advise clients of the best way to prevail in a lawsuit, but it is far better to avoid lawsuits in the first place and to promote safety as a company policy. The premise of the ANSI and the ISO warning systems is to present information to a user quickly: a worker reads the word “Danger,” in a certain recognizable format that he or she has seen hundreds of times because the same scheme is used on every product. That worker knows that injury or death can result from failing to follow the label instructions. While the research on the effectiveness of ISO and ANSI warnings shows that neither truly effectively changes user behavior when compared to user behavior when they confront nonstandard labels, adding a third scheme without a scientific basis certainly will not advance the cause of safety. Shaver, n.23, *supra*. If the EUMD precipitously changes how workers comply with label warnings compared to how they complied with the labels that manufacturers have used for 30 years, labels that they have used to teach workers about safety for those past 30 years, shouldn’t the EUMD have included some effort to advance safety? 