WARNING:
Conflicting Issues Regarding Warning Labels
May Be Hazardous To Your Company’s Health
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Until recently, a properly crafted safety warning seldom interfered with the salability of a product. The 2006 European Union Machinery Directive (“the EUMD”), ratified by the European Union’s member countries at the end of 2009, will likely create a great deal of interference.

Many U.S. manufacturers sell products in the United States and the European Union. In almost every case, such products are festooned with warning labels 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. Care must be taken to ensure they are properly affixed and properly placed on the product.

Manufacturers have been able to design harmonized product warnings on products bound for the United States and the European Union. The EUMD threatens that ability. If the EUMD is followed to the letter, every warning on every product destined for a European Union state must consist of a pictogram, and any written warnings must be translated into the official language of the country of the product’s destination. Manufacturers have four choices: ignore United States warning standards and risk liability for insufficient warnings; ignore the EUMD and risk product rejection in the European Union; draft multiple translations of all words and message panels and apply them on a case by case basis or; maintain one set of American National Standards Institute (“ANSI”) style warnings for the United States 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. ANSI and the International Organization for Standardization (“ISO”) designed the different warning schemes to promote and enhance the safety of the products produced. The warnings are based on an expectation that uniformity in format will enhance readability and compliance. Instituting a new set of requirements may interfere with that overarching goal.

A Brief History of the Standardized, Pictorial Warning Label

The story of modern, standardized, 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 1980’s, NEMA’s members set out to develop a warning label. Although their electrical equipment was generally locked, tampering by vandals gave rise to a number of serious injuries when children explored the interior of such equipment and were electrocuted. In order to combat the failure to warn claims, the manufacturers needed to develop a warning label effective for young children who either could not read, or who could not grasp the severity of danger in the language. NEMA members developed the now-famous pictorial of “Mr. Ouch” and engaged in extensive testing of children of several ethnicities aged 2.5-6.5 years. The Mr. Ouch pictorial ranked the highest in “every major category relative to depicting a threat and inducing a safe response.”

The beauty of Mr. Ouch was that it worked. The testing demonstrated that people, including children, recognized the symbol and were given the information necessary to avoid the risk of harm. From a products liability standpoint, manufacturers could prove that they had used an effective warning. This not only improved safety, it also improved a manufacturer’s ability to defend its products. Mr. Ouch was the first standardized warning adopted by an industry.
Manufacturers typically rely on compliance with consensus standards promulgated by bodies such as ANSI that oversee the creation, promulgation and use of thousands of norms and guidelines that directly impact businesses in nearly every sector of the U.S. economy.\(^5\)

In the case of warnings, the relevant standards have been promulgated under the ANSI Z535 committee since 1991. The Z535 standards were designed to create something that was as effective as Mr. Ouch. The mantra of the ANSI warning system is threefold: alert a user to the danger; inform the user of the severity of the danger; and instruct the user how to avoid the danger. A combination of symbols, colors, and mandatory warning language accomplish all three.

The stated purposes of ANSI Z535 are: to establish a uniform and consistent visual layout for safety signs and labels applied to a wide variety of products; to minimize the proliferation of designs for product safety signs and labels; and to establish a national uniform system for the recognition of potential personal injury hazards for those persons using products.\(^7\)

There are four levels of severity denoted by the following four “signal words” (with corresponding colors): “DANGER” (white letters, red background); “WARNING” (black letters, orange background); “CAUTION” (black letters, yellow background); or “NOTICE” (white letters, blue background). A safety symbol displayed as an equilateral triangle surrounding an exclamation point, accompanies all signal words.

A product safety sign or label consists of a signal word panel and a mandatory message panel that communicates the type of hazard, the consequence of not avoiding the hazard, and how to avoid the hazard.\(^8\) There are a number of specific instructions regarding the font, alignment, and other physical characteristics of the language used on the message panel. Grammatical instructions such as the avoidance of passive voice and prepositional phrases are also included.\(^9\)

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 more than a generation teaching users and consumers to recognize and interpret ANSI-style warnings.

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

ISO

While the ANSI committees were honing the Z535 standards, ISO, was developing its own standard, using a different concept. While the ANSI standard was based on a combination of safety symbols, signal words, and message panels, ISO created a symbol-based system.

ISO is the world’s largest developer and publisher of International Standards. ISO, a non-governmental organization, is a network of the national standards institutes of 161 countries, with its Central Secretariat in Geneva coordinating the system.\(^10\) ANSI is the official United States representative to ISO.\(^11\)

ISO 3864-2 establishes principles for the design of product safety labels. According to ISO 3864-2, the purpose of a product safety label is to alert persons to a specific hazard and to identify how the hazard can be avoided.\(^12\) In short, ISO and ANSI have similar goals – uniform systems to give users and others information about hazards, the severity of the hazards and how to avoid them. The major difference is the method each system uses to achieve its goals.

To comply with the ISO regulations, businesses must use at least one of three types of safety signs: an equilateral yellow triangle (warning)\(^13\), a red circle with slash (prohibition), or a blue circle (mandatory action).\(^14\) A pictogram describing a hazard, an action, or an instruction will be included on each type of sign. The most familiar example is the no smoking “prohibition” sign. The ISO 3864-2 system utilizes three basic colors as signals for the severity of harm to be encountered (red for high, orange for medium, and yellow for low).\(^15\) Signal words can be associated with each level of severity: danger, warning, and caution, respectively.\(^16\) Each of these three levels of severity has an equilateral triangle surrounding an exclamation point in the appropriate color. Together they form a hazard severity panel. Note, however, that the use of signal words or a hazard severity panel is not mandatory.\(^17\) Stated differently: each label “shall be comprised of one or more safety signs”, and may be “accompanied by a hazard severity panel.”\(^18\) Finally, there...
is the option of adding supplementary safety information text which can include warnings such as: “ELECTRICAL HAZARD - Contact with Water Can Cause Electrical Shock.” These language-based warnings, like the signal words, are permissive.

ISO V. ANSI

ISO places a heavier reliance on pictorial warnings than ANSI. In fact, the ISO warning can be exclusively pictorial, with no words at all. By contrast, the ANSI standard mandates a signal word and a message panel provide necessary information to the product user. Neither the ANSI nor the ISO warning schemes has the force of law. Their lack of uniformity can cause potential litigation problems and possible safety issues. If a manufacturer, adhering to the ISO standard, exports its products to the United States, it is at risk for liability based upon failure to warn. The liability stems from not producing warnings adhering to the relevant U.S. standards.

In addition, the goals of the two systems, while similar, are not exactly the same. ISO's goal is "to alert persons to a specific hazard and to identify how the hazard can be avoided," whereas ANSI’s goals are to: “establish a uniform and consistent visual layout for safety signs and labels applied to a wide variety of products; to minimize the proliferation of designs for product safety signs and labels; and to establish a national uniform system for the recognition of potential personal injury hazards for those persons using products.” The ISO system is less concerned with variation and more concerned with adapting safety labels to specific situations. By contrast, ANSI is more concerned with a standardized system. ANSI’s theory is essentially that although the warnings may not adapt to each unique situation, workers will be safer when conditioned to the same signal words and warning style year after year.

Using ISO warnings in the United States, or ANSI warnings in Europe may 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 is problematic.

It is possible to harmonize ISO and ANSI standards into a single hybrid warning label. For example, an ISO/ANSI hybrid warning label would be one with an ISO pictorial, accompanied by an ANSI-compliant message panel and signal word. This would ostensibly satisfy the ISO requirements and supply the required verbiage of the ANSI requirements. This solution is not perfect. The ISO system doesn’t require any language at all in either a hazard severity panel or supplementary safety information text. If one does exercise such an option, there is no guidance as to the language that must be used. The colors and color schemes are slightly different. For example, including an ANSI-compliant message panel for a given severity of risk would not be exactly congruent in color with ISO. However, the hybrid label is very close to full compliance with both standards.

Enter the New European Requirements

Much of the work harmonizing ISO and ANSI warnings may be for naught due to the EUMD. Unless the EUMD is modified, any manufacturer selling a product in Europe will now need to comply with this new law, which introduces a third set of requirements for approved warnings.

These new requirements are the law. The European Union Parliament has power to legislate directives and regulations. Both have the force and effect of law. Regulations are self-executing, and effective and binding on the member states automatically and immediately. There is no country-by-country ratification process for the individual member states, although they are sovereign nations. Directives, once approved by the Parliament, must still be enacted by each member state. Each member state may tailor a directive to its particular needs as long as its version remains aligned with the spirit of the directive. Directives generally set forth a series of goals and give a date by which each member state is to enact legislation to its effect.

Each of the European Union member states has now ratified the EUMD. The EUMD is applicable to machinery: interchangeable equipment; safety components; lifting accessories; chains, ropes and webbing; removable mechanical transmission devices; and partly completed machinery. A number of items are excepted from the EUMD.

At issue is section 1.7 to Annex I, entitled “information” which 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, any “…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.”

In short, any verbiage on a warning label must be
translated in the official language(s) of the destination
member state. If a product is sold to an entity near a
border, the language problem may multiply. So now, to
comply with the EUMD, ANSI and ISO, multiple translations
of the signal words and the message panels are required.

**European Union Enforcement**

With the EUMD in full force and effect in member states for
1.5 years, EU member states have taken multiple actions
to comply with the myriad of EUMD requirements. A brief
overview of the approval process for machinery may be
helpful: There are several ways a manufacturer can
establish conformity with the EUMD. For machinery listed
in Annex IV of the EUMD (e.g. circular saws, band-saws,
vehicle servicing lifts, etc.), the manufacturer can
construct a so-called technical file and ensure compliance
with the file through self-certification; contact a “notified
body” (an organization authorized by a member state to
assess whether the design and manufacture of a machine
meets the requirements of the EUMD) to certify that the
machine satisfies the EUMD’s requirements, or confirm
that the machine was manufactured using a full quality
assurance system by having a “notified body” assess and
approve the quality system and monitor its application. If
the machine is not listed in Annex IV, the only option for
the manufacturer is to self-certify compliance with the
Directive.

Once the manufacturer of a machine has established
conformity with the EUMD, it can prepare a Declaration of
Conformity. The Declaration of Conformity appears in the
machine’s operation manual, and declares that the
manufacturer guarantees each piece of equipment sold is
in conformity with the Directive.

An accompanying regulation – automatically binding on all
member states – notes that a machine presenting a
“serious risk”, must be recalled or withdrawn from the
market. If a member state takes action in accordance
with this provision, it must notify the European
Commission immediately.

The EUMD was implemented by the United Kingdom
through the Supply of Machinery (Safety) Regulations
2008 (“the Regulations”). The Regulations are enforced
by the Health and Safety Executive (comparable OSHA) for
machinery used in the workplace, and by the Trading
Standards Service for machinery used at home. When a
machine is suspected of being deficient, the authority
must serve the manufacturer in writing, stating that the
machine has failed to comply with the requirements of the
EUMD. The notice must include the reason the authority
finds the machine deficient and the actions the
manufacturer must take to bring the machine into EUMD
compliance (whether through a product recall, withdrawal
from the market, or the repair of a faulty product).

There are signs that the EUMD has some teeth. Although
there have been no apparent actions relating to the
warning language requirements specifically, there has
been activity in the months since the EUMD’s effective date.
For example, in the UK, a Chinese-made angle grinder was
voluntarily recalled because it failed to comply with the
EUMD for a safety concern (sticky power switch).

**Harmonizing the United States’
and Europe’s Requirements:
What Do We Do?**

Subsequent to the ratification of the EUMD, designing one
warning label that will pass muster in both the United
States and Europe may be impossible. The main problem
in this regulatory nightmare is the language requirement in
the EUMD. By itself, it provides for an almost unworkable
requirement of translating any text on warning labels into
over 20 languages. It appears the only clear way to comply
with the machinery directive’s language requirements is to
have no language at all. However, that warning would then
fail to comply with ANSI Z535.4. Failure to comply with
ANSI Z535 in the United States may make the product
less safe. It will almost certainly make it harder to defend in the
event of a failure to warn claim.

There are limited options to solve this issue and none is
ideal. The first option is to simply issue different warnings
for European products: use ANSI for the United States
bound products and a wordless ISO-based warning label
for products sold in Europe. This possibility precludes the
use of a universal warning label and increases costs, due
to the need to design and implement two warnings
regimes, engage workers to install these warnings, and
engage inspectors that insure that the proper warnings are
continuing
used. Another possibility is to utilize an ANSI compliant warning for the product for distribution across continents, and offer a method for obtaining a language translation to a subsequent European purchaser, such as an automated website which will send translated warnings to anyone who provides a serial number. This methodology, does not solve the problem of retaining one universal warning label, and in fact, requires maintaining warning labels in myriad languages, at increased cost. In addition, it underscores the main problem with the Machinery Directive: in order to comply with the strict letter of the EUMD, a manufacturer must keep on hand or affix to the product, a warning label in all of the community languages, which is extremely difficult. Moreover, the EUMD requires that the warning accompany the product.40 It is not clear that directing a buyer or user to a website will satisfy that requirement.

A third possibility is to utilize an entirely ISO pictorial warning in the United States and Europe. However, such a plan creates a risk when a party is injured by a product is sold in the United States. The argument will be that the manufacturer failed to effectively warn, because it failed to comply with the ANSI standard.

All of these options present a potential for eventually mastering the regulatory structure anomalies, but all have their drawbacks.

The overarching concern in all of this is worker safety. As counselors, we can advise our clients as to the best way to prevail in a lawsuit, but it is far better to avoid lawsuits in the first place and promote safety as a company policy. The premise of the ANSI warning systems and the one permitted by ISO is to give the user quick information: a worker sees the word “Danger,” in a certain recognizable format he has seen hundreds of times. That worker knows injury or death is a result of not following the instructions, whether warnings are effective in changing behavior. That debate shows neither is significantly better at changing user behavior than a non-standardized label41, adding a third varying scheme with no scientific basis will certainly not advance that cause of safety. If the EUMD precipitates a sudden deviation after 30 years of training workers what to look for, shouldn’t there be some effort to advance safety?

Endnotes
3. Id.
4. See id.
5. Id.
7. ANSI Z535.4-2007, § 2.2.
8. Id. at Annex B.
9. Id.
13. Note that the colors inside the ISO and ANSI triangles differ; with ISO, the color is always yellow and with ANSI, the color varies according to the level of hazard.
15. Id. at § 4.3.
16. Id. at § 5.3.
17. Id. at § 5.1 (“If the level of hazard severity is to be indicated...”).
18. Id. at § 6.1.
19. Id. at §§ 3.15, 6.1.
20. Id. at § 6.1.
22. ANSI Z535.4-2007, § 2.2.
23. 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 formats set forth by ANSI and ISO result in any increased compliance. A recent study found that the ANSI and ISO formats did not result in significantly greater compliance than messages that followed no 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, 50th Annual Meeting, 2006, pp. 2197-2201. A copy of the proceedings, including the article, can be purchased at the HFES website at http://www.hfes.org/publications/ProductDetail.aspx?ProductId=79, accessed 1/19/2011. Reading the study does show that the US residents were more likely to comply with the ANSI formatted warning than an ISO formatted warning, even though the ISO warning contained a signal word and a message panel. Id. at 2199.
25. 2006/42/EC, Art. 1, ¶ 1. 26. Id. at Annex I, ¶ 1.7. There are a number of exceptions to 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.
27. 2006/42/EC, Annex I, ¶ 1.7. 28. See id. 24, supra.
29. A machine’s technical file contains details of a hazard and risk assessment in which categories of risk are identified. 2006/42/EC, Annex VII. The file then details how the machine complies with the EUMD, using detailed drawings of the equipment and any calculations or test results. 2006/42/EC, Annex VII (A)(1)(a). For example, the file will detail each essential health and safety
requirement (and how the machine complies or actions that must be taken in order for it to comply), and then address numerous other requirements. 2006/42/EC, Annex VII (A)(1)(a). Because most machines that are CE marked are self-certified by the manufacturer, technical files are not typically examined until an incident occurs. In the case of an incident, the member state’s agency responsible for consumer safety will request the machine’s technical file. The EUMD requires manufacturers based outside of the EU appoint a person based in the EU to be responsible for providing the technical file to the national authorities if so requested. 2006/42/EC, Annex VII(2). Non-EU manufacturers who previously self-certified their machines, are now burdened with having to establish a link with a European company/individual before they are able to sell their machine in the EU.

31 2006/42/EC, Art. 12, ¶2.
34 Id. at Art 22.
36 Id. at part 6(21)(2)
37 Id. at part 6(21)(3).
38 Id.
The maximum penalty under the Regulations is two years imprisonment and/or a fine. Part 6(22)(a), (b). The Regulations also note that any incident that involves injury or damage to a consumer will also fall within the scope of other UK safety legislation, so further sanctions may be applied.
40 2006/42/EC, Annex I, § 1.74.
41 See n. 23, supra.

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