

Heading Translation Issues Off at the Pass: Legal Issues and Other Considerations

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Introduction – The Basics

Companies producing marketing collateral, instruction manuals, material safety data sheets (MSDS), specification sheets, user guides, etc., intended to be read by a foreign audience – at the very least – should be written in order to facilitate translation and be well received overseas. For example – especially for marketing collateral – colors evoke various cultural meanings and represent different emotions.

Technical writers know that even for native English-speaking audiences, sentences should be short and to-the-point. This not only allows translators to best convey important concepts, but it also helps keep translated text from over expanding (i.e., English text “grows” as much as 30% when translated into French or German).

When creating content intended for translation, writers need to be cognizant of other factors, such as abbreviations should be explained and U.S.-centric terminology and expressions be avoided, when possible. An advertising slogan like “T.G.I. Black Friday” is practically an all-encompassing example of what NOT to have translated into most languages. Even if in English for Australian or British markets, for instance, it references a holiday not celebrated in those countries. In addition, not only is the concept of “Black Friday” being the busiest shopping day to kick off the Christmas season completely foreign, but it could even sound morbid to those audiences. To translate the phrase into foreign languages would be difficult, if not impossible, without providing a full explanation of the significance of the American holiday and what the acronym “T.G.I.F.” stands for.

In addition to how to prepare for translation itself, other issues concerning the use of symbols and icons, warning label requirements, country laws, CE markings, as well as overall translation processes, must be considered.

Symbol and Icon Use

When used appropriately, symbols and icons are a great way to represent instructions and procedures. Icons containing words, that are gender specific and depict specific cultural references and even gestures, should be modified to be more generic. Instead, use universally understood symbols and pictures, and androgynous human figures, to avoid confusing (or

offending) foreign readers. An additional advantage of proper symbol and icon use is that word counts are reduced – saving time, effort, and money.

Warning Labels, Marketing Material, Instruction Manuals, and the European Union

Although symbols and icons effectively and universally attract attention, it is important to note that in the European Union, directives for compliance can be found in the “L-Series” of the Official Journal of the European Journal – the official legal gazette of record.

According to EU directive 1.7.1:

“Information and warnings on the machinery should preferably be provided in the form of readily understandable symbols or pictograms. 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 official Community language or languages understood by the operators.”

Per EU directive 1.7.4, instruction manuals must also be translated:

“All machinery must be accompanied by instructions in the official Community language or languages of the Member State in which it is placed on the market and/or put into service.”

To further comply with translation directives in the European Union, user manuals and related marketing materials must contain consistent information, as in EU directive 1.7.4.3:

“Sales literature describing the machinery must not contradict the instructions as regards health and safety aspects. Sales literature describing the performance characteristics of machinery must contain the same information on emission as is contained in the instructions.”

To meet these requirements, it is a best practice to have technical writing departments collaborate with marketing departments to ensure that there is no discrepant text going into respective documents. Computer Assisted Translation (CAT) tools can catch discrepancies as well; their use will be discussed in more detail.

To review other translation related directives, please visit:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:157:0024:0086:EN:PDF>

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF>

Other countries, other laws

As in the European Union, many other countries have laws and regulations governing translation requirements in many industries. Another best practice is to research and chart country laws governing translation requirements.

The ideal way to do this is by means of an Excel spreadsheet or Word document. The following sample illustrates how a medical device company tracks translation regulations – organized by country, official languages, the types of documentation they produce, and the applicable rules.

<u>Country</u>	<u>Official Languages</u>	<u>Labels</u>	<u>User Manual</u>	<u>Safety Related Info</u>	<u>Home Use</u>	<u>Clinical Investigation Docs</u>	<u>Secondary Languages or known flexibility</u>	<u>Language Requirements</u>
Austria	German	German	German	German	German	German	None	Medizinproduktegesetz (Medical Device Act)
Belgium	Flemish and French	Flemish, French and German	Flemish, French and German	Flemish, French and German	Flemish, French and German	Patient Info/ Consent forms must be in the national language of the patient. English or one of the national languages may be used for other investigation documents.	Belgian law (Royal Decree of 18 March 1999); for patients and professionals the national languages must be used; Exceptions are possible under special conditions.	Royal Order on Medical Devices, 18 March 1999; Also, competent authority Website (http://www.fagg-afmps.be/en/), accessed 02-Mar-2010
Bulgaria	Bulgarian	Bulgarian – or English if info for safe use explained in Bulgarian manuals	Bulgarian	Bulgarian – or English if info for safe use explained in Bulgarian manuals	Bulgarian	English	Only English GUI	Bulgarian instructions for use confirmed by research database, 20-Nov-2009
Cyprus	Greek and Turkish	English	English	Greek	Greek	English	English	Law 29(I)/2003, Law 30(I)/2004
Czech Republic	Czech	Czech	Czech	Czech	Czech	Consult Region Regulatory Affairs before clinical trial	None	Government Regulation No. 25/2004

Figure 1. Sample Translation Regulation Tracking Chart.

Such country regulations can be organized by continent or region. It is also a good idea to keep hard copies of the regulations or directives themselves, or store them on a server accessible to relevant employees.

CE Marking Requirements

Another consideration that goes hand-in-hand with translation directives is CE Marking requirements. As testing standards vary worldwide, it is a best practice to provide explanations of these standards for source text intended to be translated for specific target markets, particularly for marketing collateral.

An example of this is for a marketing piece translated for safety gloves, which explains the Level 5 CE Marking rating for blade cut protection standards.

Europe uses the EN388 standard for glove performance. Regulated by the European Standardization Committee, tests include a cut (“coup”) test, involving a consistently weighted circular blade, moving in a back and forth motion. However, materials such as fiberglass and steel can dull the blade and not adequately protect hands in uncontrolled conditions.

In the U.S., evaluations are based on the American Society for Testing and Materials (ASTM) F1790 standard, which uses testing similar to those in ISO13997. Varyingly weighted flat-edge/razor type blades moving in a back and forth motion at a constant speed are used in this method and the distance the blade travels is measured before cutting through the material.

The EN388 standard does not require an alternate ISO test, which could cause confusion in global markets as the definition of CE Level 5 glove specifications can vary in different jurisdictions. To this end, testing standards, with explanatory text, should be used for all target audiences.

When cut- and puncture- resistant gloves are marketed to Japan, it is important to note Japanese Industrial Standards in user guides and advertising. Thus, text intended for release on a global scale should be modified to reference testing methods applicable to country-specific standards.

In regard to the CE Marking Requirements, it is important that companies marketing and selling their products into the EU have the product tested in-country, as well as have a law firm handle the CE compliance issues. Failure to follow EU directives will result in penalties, which is beyond the scope of this presentation.

In-Country Reviewers (ICRs)

In addition to being able to provide information on country laws and regulations, be it in an overseas branch, subsidiary or a distributor’s office, overseas staff, if carefully selected, can serve as excellent ICRs, or In-Country Reviewers.

The advantages that these native speakers bring is that, being familiar with a specific industry or field, they can assist with glossary creation before translations begin. ICRs should get involved early in the translation process so as to ensure vocabulary is agreed upon – usually after a representative portion is done and before desktop publishing begins. It is important to make sure that ICRs have the time to dedicate to such tasks; otherwise, delays can arise to time-sensitive projects.

Computer Assisted Translation (CAT) Tools

Computer Assisted Translation (CAT) tools, otherwise known as translation software, should not be confused with Machine Translation (MT) or online translation websites or otherwise. Used in conjunction with human translators, CAT tools are used to store translated segments and glossaries in the form of translation memories.

There are many benefits to using CAT tools. They help clients save money and allow translators to use time more effectively and maintain consistency. Updates to revised instruction manuals, for example, are facilitated through utilization of stored content – and translation memories belong to the client and can be shared with multiple translation vendors.

Even though CAT tools have key functions that assist translators – stored glossaries, analysis and search capabilities—the fundamental function of using stored content is what makes translation software so beneficial.

For example, there are phrases in automobile manuals that remain consistent, such as “Turn the engine on.” or “Call your dealer for assistance.” These are 100% matches in many cases – meaning that these are stored sentences in the translation memory - thus, if a manual for a newer model needs to be updated the following year, these previously translated words, do not need to be translated again. Duplicated efforts are eliminated, money is saved, and improved consistency is achieved.

“Fuzzy” or partial matches occur when a new phrase similar to one that has already been translated (and is in the translation memory) appears and needs to only be modified slightly. Let’s translate the sentence “The house has a red roof.” using translation software. In a subsequent document, the sentence “The house has a green roof.” the translation software flags this “fuzzy” match so that the translator only has to change one word as opposed to translating the sentence in its entirety. At the same time, the translator has the ability to use the software to find previously translated words to use in subsequent translations, which also assists in maintaining consistency.

CAT Tool Output for Reviews

Output from the CAT tools can also assist ICRs to perform quality assurance reviews. There are some varieties of translation software on the market, but the two most commonly used are Trados and SDL. For Trados based translations, your translation vendor can provide clients with bilingual Excel file from a Trados TMX export.

SDL is now the industry standard for applications and translation memories. For SDL based translations, your translation vendor can provide clients with files in the intermediate translation document (.itd) format or XLIFF for the newest release of SDLX Studio 09 and 11. In this method, files can be read and modified by SDLX Lite (used by translators themselves), which can be downloaded at no cost, or Microsoft Word for XLIFF. When reviewers work directly in tagged files, updates to translation memories are made automatically when revised .itd and XLIFF files are imported back into SDL.

Bibliography

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