Doing Business in Greece: 2010 Country Commercial Guide for U.S. Companies

Overview

Products tested and certified in the United States to American standards are likely to have to be retested and re-certified to E.U. requirements as a result of the E.U.'s different approach to the protection of the health and safety of consumers and the environment. Where products are not regulated by specific E.U. technical legislation, they are always subject to the E.U.'s General Product Safety Directive as well as to possible additional national requirements.
European Union standards created under the New Approach are harmonized across the 27 E.U. Member States and European Economic Area countries to allow for the free flow of goods. A feature of the New Approach is CE marking. For a list of new approach legislation, go to http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/index_en.htm

While harmonization of E.U. legislation can facilitate access to the E.U. Single Market, manufacturers should be aware that regulations and technical standards might also function as barriers to trade if U.S. standards are different from those of the European Union.
Agricultural Standards

The establishment of harmonized E.U. rules and standards in the food sector has been ongoing for several decades, but it took until January 2002 for the publication of a general food law establishing the general principles of E.U. food law. This Regulation introduced mandatory traceability throughout the feed and food chain as of Jan 1, 2005. For specific information on agricultural standards, please refer to the Foreign Agricultural Service's website at: http://www.fas.usda.gov/posthome/useu/

There are also export guides to import regulations and standards available on the Foreign Agricultural Service's website: http://www.fas.usda.gov/posthome/useu/

Standards Organizations

The Hellenic Organization for Standardization is ELOT, which elaborates the Hellenic National Standards, maintains a central point for testing of materials assesses management systems and certifies products and services. Offices and laboratories of ELOT are located in Athens and Thessaloniki.

The majority of imported products require the approval of ELOT, thus major end users request all certificates, such as UCL, and TUV, in addition to those for fire, environmental and health protection, from ELOT. ELOT also accepts appraisal certificates issued by one of the E.U. recognized agencies.

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E.U. standards setting is a process based on consensus initiated by industry or mandated by the European Commission and carried out by independent standards bodies, acting at the national, European or international level. There is strong encouragement for non-governmental organizations, such as environmental and consumer groups, to actively participate in European standardization.

Many standards in the E.U. are adopted from international standards bodies such as the International Standards Organization (ISO). The drafting of specific E.U. standards is handled by three European standards organizations:

- CENELEC, European Committee for Electrotechnical Standardization (http://www.cenelec.eu/Cenelec/Homepage.htm)
- TSI, European Telecommunications Standards Institute (http://www.etsi.org/)
- CEN, European Committee for Standardization, handling all other standards (http://www.cen.eu/cenorm/homepage.htm)

Standards are created or modified by experts in Technical Committees or Working Groups. The members of CEN and CENELEC are the national standards bodies of the Member States, which have "mirror committees" that monitor and participate in ongoing European standardization. CEN and CENELEC standards are sold by the individual Member States standards bodies. ETSI is different in that it allows direct participation in its technical committees from non-E.U. companies that have interests in Europe and gives away its individual standards at no charge on its website. In addition to the three standards developing organizations, the European Commission plays an important role in standardization through its funding of the participation in the standardization process of small- and medium-sized companies and non-governmental organizations, such as environmental and consumer groups. The Commission also provides money to the standards bodies when it mandates standards development to the European Standards Organization for harmonized standards that will be linked to E.U. technical legislation. Mandates can be checked on line at http://ec.europa.eu/enterprise/policies/european-standards/standardisation-requests/index_en.htm

Due to the E.U.'s vigorous promotion of its regulatory and standards system as well as its generous funding for its development, the E.U.'s standards regime is wide and deep - extending well beyond the E.U.'s political borders to include affiliate members (countries which are hopeful of becoming full members in the future) such as Albania, Croatia, FYR of Macedonia, and Turkey among others. Another category, called "partner standardization body" includes the standards organization of Australia, which is not likely to become a CEN member or affiliate for political or geographical reasons. Many other countries are targets of the E.U.'s extensive technical assistance program, which is aimed at exporting E.U. standards and technical Regulations to developing countries, especially in the Mediterranean and Balkan countries, Africa, as well as programs for China and Latin America.

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To know what CEN and CENELEC have in the pipeline for future standardization, it is best to visit their websites. CEN's "sectors" page provides an overview by sector and/or technical committee whereas CENELEC offers the possibility to search its database. ETSI's portal (http://portal.etsi.org/Portal_Common/home.asp) leads to ongoing activities.

With the need to adapt more quickly to market needs, European standards organizations have been looking for "new deliverables" which are standard-like products delivered in a shorter timeframe. While few of these "new deliverables" have been linked to E.U. Regulations, expectations are that they will eventually serve as the basis for E.U.-wide standards.

Key Link: http://www.cen.eu/cenorm/products/cwa/index.asp

Conformity Assessment

Conformity Assessment is a mandatory step for the manufacturer in the process of complying with specific E.U. legislation. The purpose of conformity assessment is to ensure consistency of compliance during all stages of the production process to facilitate acceptance of the final product. E.U. product legislation gives manufacturers some choice with regard to conformity assessment, depending on the level of risk involved in the use of their product. These range from self-certification, type examination and production quality control system, to full quality assurance system. You can find conformity assessment bodies in individual Member State country in this list by the European Commission.

Key Link: http://ec.europa.eu/enterprise/newapproach/nando/

To promote market acceptance of the final product, there are a number of voluntary conformity assessment programs. CEN's certification systems are the Keymark, the CENCER mark, and CEN workshop agreements (CWA) Certification Rules. CENELEC has its own initiative. ETSI does not offer conformity assessment services.

Product Certification

To sell products on the E.U. market of 27 Member States as well as Norway, Liechtenstein and Iceland, U.S. exporters are required to apply CE marking whenever their product is covered by specific product legislation. CE marking product legislation offers manufacturers a number of choices and requires decisions to determine which safety/health concerns need to be addressed, which conformity assessment module is best suited to the manufacturing process, and whether or not to use E.U.-wide harmonized standards. There is no easy way for U.S. exporters to understand and go through the process of CE marking, but hopefully this section provides some background and clarification.

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Products manufactured to standards adopted by CEN, CENELEC and ETSI, and published in the Official Journal as harmonized standards, are presumed to conform to the requirements of E.U. Directives. The manufacturer then applies the CE marking and issues a declaration of conformity. With these, the product will be allowed to circulate freely within the E.U. A manufacturer can choose not to use the harmonized E.U. standards, but then must demonstrate that the product meets the essential safety and performance requirements. Trade barriers occur when design, rather than performance, standards are developed by the relevant European standardization organization, and when U.S. companies do not have access to the standardization process through a European presence.

The CE marking addresses itself primarily to the national control authorities of the Member States, and its use simplifies the task of essential market surveillance of regulated products. Although CE marking is intended primarily for inspection purposes by Member State inspectors, the consumer may well perceive it as a quality mark.

The CE marking is not intended to include detailed technical information on the product, but there must be enough information to enable the inspector to trace the product back to the manufacturer or the authorized representative established in the E.U. This detailed information should not appear next to the CE marking, but rather on the declaration of conformity (which the manufacturer or authorized agent must be able to provide at any time, together with the product's technical file), or the documents accompanying the product.

Accreditation

Independent certification bodies, known as notified bodies, have been officially accredited by competent national authorities to test and certify to E.U. requirements. However, under U.S.-E.U. Mutual Recognition Agreements (MRAs), notified bodies based in the United States and referred to as conformity assessment bodies, are allowed to test in the United States to E.U. specifications, and vice versa. The costs are significantly lower which results in U.S. products becoming more competitive. At this time, the U.S.-E.U. MRAs cover the following sectors: EMC (in force), RTTE (in force), medical devices (in transition), pharmaceutical (on hold), recreational craft (in force) and marine equipment (in force). The U.S. Department of Commerce, National Institute of Standards and Technology (NIST), has a link on its website to American and European Conformity Assessment bodies operating under a mutual recognition agreement.

Key Link: http://ts.nist.gov/Standards/Global/mra.cfm
Accreditation is handled at Member State level. "European Accreditation" (http://www.european-accreditation.org/content/home/home.htm) is an organization representing nationally recognized accreditation bodies. Membership is open to nationally recognized accreditation bodies in countries in the European geographical area that can demonstrate that they operate an accreditation system compatible with EN45003 or ISO/IEC Guide 58.

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Publication of Technical Regulations

The Official Journal is the official gazette of the European Union. It is published daily on the internet and consists of two series covering draft and adopted legislation as well as case law, studies by committees, and more (http://eur-lex.europa.eu/JOIndex.do). It lists the standards reference numbers linked to legislation (http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/index_en.htm). National technical Regulations are published on the Commission's website http://ec.europa.eu/enterprise/tris/index_en.htm to allow other countries and interested parties to comment.

Member countries of the World Trade Organization (WTO) are required under the Agreement on Technical Barriers to Trade (TBT) Agreement to report to the WTO all proposed technical regulations that could affect trade with other member countries. Notify U.S. is a free, web-based e-mail subscription service that offers an opportunity to review and comment on proposed foreign technical regulations that can affect access to international markets. Register online at Internet URL: http://tsapps.nist.gov/notifyus/data/index/index.cfm

Labeling and Marking

Manufacturers should be mindful that, in addition to the E.U.'s mandatory and voluntary schemes, national voluntary labeling schemes might still apply. These schemes may be highly appreciated by consumers, and thus, become unavoidable for marketing purposes. Manufacturers are advised to take note that all labels require metric units although dual labeling is also acceptable. The use of language on labels has been the subject of a Commission Communication, which encourages multilingual information, while preserving the right of Member States to require the use of language of the country of consumption.
The E.U. has mandated that certain products be sold in standardized quantities. Council Directive 2007/45/EC, harmonizes packaging of wine and spirits throughout the E.U. Existing national sizes will be abolished with a few exceptions for domestic producers.

Key Link: http://ec.europa.eu/enterprise/prepack/packsize/packsiz_en.htm

The Eco-label

The E.U. eco-label is a voluntary label which US exporters can display on products that meet high standards of environmental awareness. The eco-label is intended to be a marketing tool to encourage consumers to purchase environmentally-friendly products. The criteria for displaying the eco-label are strict, covering the entire lifespan of the product from manufacture, to use, to disposal. These criteria are reviewed every three to five years to take into account advances in manufacturing procedures. There are currently twenty-three different product groups, and approximately 250 licenses have been awarded for several hundred products.

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Applications to display the eco-label should be directed to the competency body of the member state in which the product is sold. The application fee will be somewhere between €300 and €1300 depending on the tests required to verify if the product is eligible. The eco-label also carries an annual fee equal to 0.15 percent of the annual volume of sales of the product range within the European community. However, the minimum annual fee is currently set at €500 and maximum €25,000.

There are plans to significantly reform the eco-label in the near future, reducing the application and annual fees and expanding the product ranges significantly. It is also possible that future eligibility criteria may take into account carbon emissions.

Key Links: Eco-label Home Page
Product Categories eligible for the Eco-label
Eco-Label Catalogue
List of Competent Bodies
Revision of the Eco-label
The Eco-label and Carbon Footprint

Contacts

http://buyusainfo.net/docs/x_4284752.pdf
http://ec.europa.eu/comm/environment/ecolabel/index_en.htm
http://www.eco-label.com/default.htm

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