

Turkey

Overview

The Government of Turkey's Undersecretariat for Foreign Trade announced the implementation of twenty-three European Union industrial directives, which would affect an estimated 70 percent of the manufactured products imported into Turkey.

The Undersecretariat for Foreign Trade has adopted the EU's Low Voltage Directive, the Simple Pressure Vessels Directive, the Gas Appliances Directive, the Hot Water Boilers Directive, the EMC, the Machinery Directive, the Civil Explosives Directive, the Weighing Instruments Directive, the Equipment and Protective Systems Intended in Explosive Atmospheres Directive, the Lifts Directive (elevators), the Household Refrigerator/Freezer Directive, the Pressure Equipment Directive, the Noise Emission Directive, the Energy Efficiency for Ballast for Fluorescent Lighting Directive, the Active Implantable Medical Device Directive, the Medical Device Directive, the In Vitro Diagnostics Device Directive, the Toy Directive, the Recreational Water Craft Directive, the Construction Equipment Directive, the Personal Protective Equipment Directive, the Radio and Telecommunications Terminal Equipment Directive and the Cableway Directive (ski lifts and gondolas).

Equipment meeting the directive definition of products needing to conform to EU technical regulations must have evidence of meeting the requirements either through verified laboratory testing conducted by an EU approved notified body or by manufacturer's self-declaration if the directive dictates. Companies selling to the Turkish market must submit evidence of conformity (CE Mark) either by providing a notarized/consularized conformity certificate from a notified body or a manufacturer's issued certificate of conformity, which declares compliance of all relevant directives.

The CE Mark was established by the European Union to ensure the free circulation of products in Europe.

The directives that were entered into effect under a system called the "New Approach," were established to ensure, health and safety, consumer and environmental protection. The "New Approach" identifies level of risk and hazard.

Annexes to the various EU directives will specify levels of risk and types of products that would need to be either certified by a notified body or if the product can be certified by the manufacturer as conforming to the particular directive(s). The EU's laws and regulations made it compulsory to comply with the directives when goods are sold in the territory of the European Union and the European Economic Area (EEA). Companies must show evidence of product compliance by maintaining or presenting a technical file that includes product specifications, technical drawings and standards applied per the appropriate directives and corresponding annexes.

U.S. companies have reported that products of U.S. origin bearing the EU certificate of conformity (CE mark), particularly medical devices, have been detained by Turkish customs authorities for inspection related to a variety of Turkish requirements. Both U.S. companies and Turkish Government officials have acknowledged that products of EU origin bearing the CE mark, regardless of their point of origin, are not subject to inspection and therefore Turkish customs authorities have been unfairly singling out U.S. products. In some cases, U.S. products

apparently have been subjected to additional tests, despite their CE marks. U.S. products which have previously entered the EU Customs Union, with all required documentation including A-TR certificates, are still subject to inspections and in certain cases, further testing if deemed necessary by Turkish customs officials. The Embassy raised this issue on several occasions with the Foreign Trade Undersecretariat and the Turkish Standards Institute. They have argued that the policy is necessary because Turkey does not have an aftermarket monitoring system in place to ensure consumer protection.

There have been incident where, without prior notice, the Turkish Government published communiqués in January and April 2009 (2009/9, 2009/10, 2009/11, 2009/15, 2009/16, among others) outlining the standard procedures to be followed by importers or manufacturers of toys, personal protective equipment, batteries and medical equipment. Products manufactured in the EU are exempt from these inspections.

Standards Organizations

NIST Notify U.S. Service

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 your access to international markets. Register online at Internet URL:<http://www.nist.gov/notifyus/>

Conformity Assessment

The European Commission does not have a list of products to which their directives apply. Thus the manufacturer is to determine the applicability of relevant directives to any given product.

Conformity Assessment is a mandatory step for the manufacturer in the process of complying with specific EU legislation. As the initial step to obtain the CE marking manufacturers need to identify all applicable EU directives and determine the essential requirements indicated in the directives. This is followed by the selection of the appropriate conformity assessment module, which determines the relevant procedures to demonstrate conformity. For low risk profile products the process is relatively simple as manufacturers are allowed to self certify without a third party involvement. The high-risk group products are certified via an accredited testing laboratory, which is referred to as a “Notified Body”. The risk level of the product determines the scope of the notified body involvement during the conformity assessment process. A notified body may be involved in the design, the production phase or both. CE marking shall be followed by the identification number of the notified body if it has any involvement in the production phase. It is also possible to have multiple notified bodies involved in the conformity assessment process for those products, which fall under more than one directive. There are competent notified bodies in the U.S. to perform tests on products and an updated list is maintained by the U.S. Department of Commerce. You can find conformity assessment bodies in individual member state country in this list by the European Commission <http://ec.europa.eu/old-address-ec.htm>. To promote market acceptance of the final product, there are a number of voluntary conformity assessment programs.

Turkish Standards Institute, Turkish Cement Manufacturers Association and Turk Loydu Vakfi Iktisadi Isletmesi have been recognized as notified bodies in Turkey responsible for carrying out the conformity assessment procedures referred to in the applicable New Approach directives indicated below:

Turkish Standards Institute (Notified Body Number: 1783)

-89/106/EEC Construction Products
-90/396/EEC Appliances Burning Gaseous Fuels
-95/16/EC Lifts
-97/23/EC Pressure Equipment
Turkish Cement Manufacturers Association (Notified Body Number: 1784)
-89/106/EEC Construction Products
Turk Loydu Vakfi Iktisadi Isletmesi (Notified Body Number: 1785)
-90/396/EEC Appliances Burning Gaseous Fuels
-97/23/EC Pressure Equipment

Products that fall under the Active Implantable Medical Device Directive, the Medical Device Directive, the Low Voltage Directive, the EMC Directive and the Machinery Directive are inspected by the Turkish Standards Institution, in terms of CE compliance.

The inspection procedure in TSE, for CE compliance, starts with the examination of the declaration of conformity. The declaration of conformity must mention the applicable directive(s), the name of the manufacturer or his authorized representative, the name of the notified body (if involved), product information and reference to harmonized standards. If the notified body is also involved in the process, the type examination certificate should also be submitted.

Following the initial phase, the products are examined in terms of the way CE Mark is affixed. The examination process is conducted by a committee set up by the Turkish Standards Institute. CE Mark must be affixed to the data plate or to the product. If not, it should be placed on packaging and accompanying documents. It must be affixed visibly, legibly and indelibly. It must be in compliance with the predetermined proportions. If the committee decides that CE mark is affixed properly to the product, TSE issues another declaration of conformity.

For products falling outside of the scope of the European Union New Approach Directives and where the Government of Turkey has established a directive or standard, then that standard or directive would apply. At this point, certification of compliance with TSE standards would be required. Turkish Standards Institute contact information is provided below in the website portion of this chapter.

The manufacturers are required to submit a declaration of conformity for each applicable directive and prepare a technical file. Following this step the CE mark can be affixed to the product in accordance with the Directive 93/68/EEC.

Product Certification

To sell their product to Turkey, the EU 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 EU-wide harmonized standards.

In the 1980s, the New Approach was launched to overcome the lengthy adoption process of "old approach" type legislation. The goal of the European Union's harmonization program under the New Approach is to streamline technical harmonization and the development of standards for certain product groups, including, among others, machinery, toys, construction products, electromagnetic compatibility, personal protective equipment, non-automatic weighing instruments, medical devices, gas appliances, hot water boilers, and radio and telecommunications terminal equipment (RTTE). Under the New Approach, Directives cover

essential safety, health and environmental requirements. The three regional European standards organizations, CEN, CENELEC and ETSI, are mandated by the Commission to develop technical standards that are consistent with the essential requirements of EU Directives.

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 EU Directives. The manufacturer then applies the CE Mark and issues a declaration of conformity. With these, the product will be allowed to circulate freely within the European Union. A manufacturer can choose not to use the harmonized EU standards, but must then 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 mark 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 EU Member State inspectors, the consumer may well perceive it as a quality mark.

The CE mark 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 EU. This detailed information should not appear next to the CE mark, but rather on the declaration of conformity, the certificate 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 have been officially accredited by competent authorities to test and certify to EU requirements. However, under the U.S. /EU Mutual Recognition Agreements (MRAs), notified bodies based in the United States and referred to as conformity assessment bodies, will be allowed to test in the United States to EU specifications, and vice versa. The costs will be significantly lower and U.S. products will, as a result, become more competitive. At this time, the U.S. /EU MRAs cover the following sectors: EMC (in force), RTTE (in force), medical devices (in transition), pharmaceutical (in transition), and recreational craft (in force). This link lists to American and European Conformity Assessment bodies operating under a mutual recognition agreement.

<http://ts.nist.gov/ts/htdocs/210/gsig/mra.htm>

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.

As previously stated, Turkish Standards Institute, Turkish Cement Manufacturers Association and Turk Loydu Vakfi Iktisadi Isletmesi have been recognized as notified bodies in Turkey responsible for carrying out the conformity assessment procedures referred to in the applicable New Approach directives The Turkish Standards Institute is

the accredited authority in the Republic of Turkey for all matters related to ISO, EN ISO and TSE standards and directives.

Publication of Technical Regulations

The Turkish Standards Institute publishes all Turkish standards and directives and documents are available for purchase.

Turk Standartlari Enstitusu (TSE)

Necatibey Caddesi 112

Standart Hazirlama Baskanligi

06100 Bakanliklar

Ankara, Turkey

Tel: [90] (312) 417-0020

Fax: [90] (312) 425-4399

Web site: <http://global.tse.org.tr/>

Labeling and Marking

All packages, cases, and bales must bear shipping marks, numbers, dimensions and the gross weight of the merchandise. Packages along with accompanying bills of lading for goods to be shipped through Turkey must be marked "In Transit." All goods entering Istanbul or any other entry port in Turkey (Ankara, Iskenderun, Izmir, Mersin, Sinop, Samsun, and Trabzon) will be cleared through customs, and full payment of duty will be required unless the packages and bills of lading are marked "In Transit." If so marked, the goods may be cleared for entry and reshipment.

Contacts

The Turkish Customs can be reached via

<http://www.gumruk.gov.tr/ENG/homepage/Pages/default.aspx>

Trade Agreements

Turkey has been in accession negotiations since December 17, 2004 and continues to reap the benefits of its 1996 customs union agreement with the EU, particularly in terms of improved economic efficiency. The customs union commits Turkey to adopt the EU's common external tariff and a commercial policy "substantially similar" to that of the EU, including adoption of the EU's preferential trade regime with third countries. Turkey has already signed Free Trade Agreements with the EFTA member countries and is in the process of finalizing agreements with the other EU applicant countries.

Turkey is a founding member of the Black Sea Economic Cooperation (BSEC) in which the governments of Albania, Armenia, Azerbaijan, Bulgaria, Georgia, Greece, Moldova, Romania, Russia, Turkey and the Ukraine are nurturing multilateral cooperation among the members on a number of issues including trade. Turkey, along with Pakistan and Iran, is a founding member of the Economic Cooperation Organization (ECO). ECO, whose membership beyond the founders includes Afghanistan, Azerbaijan, Turkmenistan, Uzbekistan, Kyrgyzstan, Tajikistan and Kazakhstan has had limited success in improving trade cooperation.

Turkey is a founding member of the Southern Europe Cooperative Initiative (SECI); a regional association aimed at encouraging cooperation among its member states on a variety of issues including customs, transportation and anti-crime efforts. SECI member states include Albania, Bosnia &

Herzegovina, Bulgaria, Croatia, Greece, Hungary, the Former Yugoslav Republic of Macedonia, Moldova, Romania, Slovenia and Turkey.

Turkey has free trade agreements (FTA's) with the following countries:

- Chile
- Serbia
- Montenegro
- EFTA countries (Norway, Switzerland, Iceland and Liechtenstein)
- Israel
- Macedonia
- Croatia
- Bosnia Herzegovina
- Morocco
- The Palestinian Authority
- Tunisia
- Syria
- Egypt
- Georgia
- Albania
- Jordan

Web Resources

The United States Embassy's Commercial Section has been assisting U.S. companies, which meet EU directives conformity, in having products clear Turkish Customs as expeditiously as possible. The Commercial Service is also working to have the Government of Turkey accept CE conformity certification from U.S. corporations or U.S.-based Notifying Bodies, without having U.S. companies face additional bureaucratic delays at customs and additional testing at the Turkish Standards Institute. For additional assistance in managing the new CE Mark regulations in Turkey, please contact Commercial Specialist Ozge Cirika at Ozge.Cirika@trade.gov. For additional information on the European Union Directives and European standards, please contact:

U.S. Mission to the E.U.
Foreign Commercial Service
Rue Zinner 13
B - 1000 Brussels, Belgium
Fax: 32 2 513 1228
<http://export.gov/europeanunion/>

CE Websites

<http://gsi.nist.gov/global/index.cfm/L1-3>
http://ec.europa.eu/index_en.htm
<http://www.newapproach.org/>

Standards Websites

<http://www.cen.eu/cen/pages/default.aspx>
<http://www.cenelec.eu/>
<http://www.etsi.org/WebSite/homepage.aspx>
<http://www.ansi.org/>

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