

Romania

Overview

The Romanian Standards Association (ASRO) is the only National Standards Body in Romania recognized as such by the Governmental Decision no. 985/2004. ASRO is a specialized private body of public interest in the standardization area, a non-profit association authorized by the Government.

The principal responsibilities of ASRO are:

- to carry out standardization policy;
- to coordinate and guide standardization activity;
- to coordinate and approve standardization program;
- to approve and publish Romanian standards;
- to represent Romanian interests in international, European and regional standards organizations;
- to organize the database of standards and technical normative regulations;
- to certify conformities to Romanian standards and
- to promote standardization in the economy.

The National Standardization Program is issued annually and is available on internet at the following address: <http://www.asro.ro/> – at the Standardization section, together with free access for the standards users to all the standardization products and services.

The Romanian Standards Body is a full Member of the European standards organizations, CEN and CENELEC. All Romanian standards are voluntary. All products tested and certified in the U.S. to American standards are likely to have to be retested and re-certified to European Union requirements as a result of the EU's particular approach to the protection of health and safety of consumers and the environment. Where products are not regulated by specific EU technical legislation, they are always subject to the EU's General Product Safety Directive as well as to possible additional national requirements.

Key link: http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm#gpsd

European Union standards are harmonized across the 27 EU Member States, Croatia and European Economic Area countries to allow for the free circulation of goods. A feature of the New Approach is CE marking. While harmonization of EU legislation can facilitate access to the EU 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.

The European Union is currently undertaking a major revision that will enhance some aspects, especially in the areas of market surveillance. To follow the revision, please visit:

Key link:

http://ec.europa.eu/enterprise/regulation/internal_market_package/index_en.htm

Agricultural Standards

The establishment of harmonized EU 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 Act establishing the general principles of EU Food

legislation. This Regulation has 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/> .

Standards Organizations

EU standards development 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. Nongovernmental organizations, such as environmental and consumer groups, are actively encouraged to participate in the process of European standardization. Many standards in the EU are adopted from international standards bodies such as the International Standards Organization (ISO). The drafting of specific EU standards is handled by three European standards organizations:

- CENELEC, European Committee for Electrotechnical Standardization (<http://www.cenelec.org/Cenelec/Homepage.htm>)
- ETSI, European Telecommunications Standards Institute (<http://www.etsi.org/>)
- CEN, European Committee for Standardization, handling all other standards (<http://www.cen.eu/cen/pages/default.aspx>)

Standards are developed or amended 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-EU 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 funds standards bodies when it mandates standards development to the European Standards Organization for harmonized standards that will be linked to EU technical Regulations. In the last year, the Commission began listing their mandates on line and they can be seen at http://ec.europa.eu/enterprise/policies/european-standards/index_en.htm . All the EU harmonized standards, which provide the basis for CE marking, can be found on <http://www.newapproach.org/>.

Due to the EU's vigorous promotion of its regulatory and standards system as well as its generous funding for its business development, the EU's standards regime is wide and deep - extending well beyond the EU's political borders to include affiliate members such as Albania, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Egypt, FYR of Macedonia, Georgia, Israel, Jordan, Lebanon, Libya, Republic of Moldova, Montenegro, Serbia, Tunisia, Ukraine, and Turkey. Another category, called "partner standardization bodies" includes the standards organizations of Australia, which has an interest in participating in specific CEN

technical committees. Partners agree to pay a fee for full participation in certain technical committees and agree to implement the committee's adopted standards as national standards. Many other countries are targets of the EU's extensive technical assistance program, which is aimed at exporting EU standards and technical Regulations to developing countries, especially in the Mediterranean and Balkan countries, Africa, as well as programs for China and Latin America. To know what CEN and CENELEC have in the pipeline for future standardization, it is best to visit their websites. CEN's "business domain" 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.

European standards organizations have been looking for "new deliverables" which are standard-like products delivered in a shorter timeframe in order to respond and grow their market share. While few of these "new deliverables" have been linked to EU Regulations, expectations are that they will eventually serve as the basis for EU-wide standards.

Key Link: <http://www.cenorm.be/cenorm/workarea/sectorfora/index.asp>.

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

Conformity assessment is a mandatory step for a manufacturer to comply with specific EU legislation. The purpose of conformity assessment is to ensure consistent compliance during all stages of the production process. A positive assessment facilitates acceptance of the final product. EU product legislation gives manufacturers some choice in conformity assessment, depending on the level of risk involved in the use of their product. These choices range from selfcertification, type examination and production quality control system, to a full quality assurance system. A list of conformity assessment bodies by country are listed at this link:

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 the European Standard Agreement Group. CENELEC has its own initiative. ETSI does not offer conformity assessment services.

Product Certification

In order to sell products on the EU market, 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 mark legislation offers manufacturers some choices but also some decision trees to

determine which safety/health concerns must be addressed, which conformity assessment module is best suited to the manufacturing process, and whether or not to use EU-wide harmonized standards. Obtaining a CE mark is a complex process and the following is offered as general guidance.

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 EU. A manufacturer can choose not to use the harmonized EU 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 U.S. Commercial Service mission to the EU watch for such situations.

The CE mark addresses the requirements of national control authorities of EU Member States, and simplifies the task of market surveillance of regulated products. Although CE marking is intended primarily for inspection purposes by Member State inspectors, the consumer may 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, or the documents accompanying the product.

Accreditation

Independent certification bodies, known as notified bodies, have been officially accredited by competent authorities to test and certify to EU requirements. However, under U.S.-EU 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 EU specifications, and vice versa. The costs for assessments in the U.S. are often significantly lower. At this time, the U.S.-EU 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.

Accreditation is handled at Member State level. "European Accreditation" (http://www.european-accreditation.org/default_flash.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 EN ISO/IEC **17011**.

Key Link: <http://ts.nist.gov/Standards/Global/mra.cfm>

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, questions from the European Parliament, studies by committees, and related content

(http://publications.europa.eu/official/chapter_en.htm). It lists the standards reference numbers linked to legislation:

<http://www.newapproach.org/Directives/DirectiveList.asp>.

National technical Regulations are published on the Commission's website

<http://ec.europa.eu/comm/enterprise/tris/> to allow 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 your access to international markets. Register online at Internet URL: <http://tsapps.nist.gov/notifyus/data/index/index.cfm>

Labeling and Marking

In addition to the EU's mandatory and voluntary schemes, national voluntary labeling schemes might still apply. These schemes may be highly valued by consumers, and thus, become unavoidable for marketing purposes.

Manufacturers are advised to take note that all labels require metric. The EU encourages multilingual labeling information, but preserves the right of Member States to require the use of local language in the country of consumption.

The EU has mandated that certain products be sold in standardized quantities. Council Directive 2007/45/EC, to replace 80/232/EC in April 2009, harmonizes packaging of wine and spirits throughout the EU. 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

EU legislation distinguishes environmentally friendly products and services through a voluntary labeling scheme called the Eco-label. Currently, the scheme applies to seven product groups: cleaning products, appliances, paper products, clothing, lubricants, home and garden products and tourism services. The symbol, a green flower, is a voluntary mark to encourage consumers to buy "eco friendly products". The Eco-label is awarded to producers who can show that their product is less harmful to the environment than similar products. However, the scheme does not establish ecological standards that all manufacturers are required to meet to place product on the market. Products without the EU Ecolabel can still enter the EU as long as they meet the existing health, safety, and environmental standards and Regulations.

Key Links: http://buyusainfo.net/docs/x_4284752.pdf

http://ec.europa.eu/comm/environment/ecolabel/index_en.htm

<http://www.eco-label.com/>

Trade Agreements

Romania has signed a significant number of bilateral Double Tax Agreements (DTAs). Most of these agreements follow the OECD model. The Double Tax Agreements prevail over domestic legislation, provided that a certificate

confirming the foreign fiscal residency of the taxpayer is presented to the Romanian tax authorities. The DTAs also contain provisions related to withholding taxes. Companies based in countries with which Romania has signed DTAs benefit from a reduced level of withholding taxes.

The revision made for the harmonization of the Fiscal Code with the VAT Directive no. 112/2006 by Law no. 343/2006 applicable from 01.01.2007 (since 01.01.2007 the Fiscal Code was revised several times the last revision being made by Law no. 188/2010) and a Fiscal Procedure Code entered into force in January 2004. The Fiscal Code provides for a significant simplification of taxation procedures as well as for harmonization with European Union fiscal practices.