Spain

Overview

EU
Products tested and certified in the United States to American standards are likely to have to be retested and re-certified to EU requirements as a result of the EU’s different approach to the protection of the 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. European Union standards created under the New Approach are harmonized across the 27 EU 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/europeanstandards/documents/harmonised-standards-legislation/listreferences/index_en.htm

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

Agricultural Standards
A general food law establishing the general principles of EU food law was passed in January 2002. 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.U.S.da.gov/posthome/Useu/

Spain
Spanish requirements for certification and testing standards have gradually adopted EU directives. A product that meets the standards and certification requirements of any other EU country can be imported and sold in Spain without further testing.


Spanish Standards are developed by AENOR, the Spanish Standards & Certification Association: www.aenor.es

Standards Organizations
EU 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 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.eu/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/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-EU companies that have interests in Europe and gives away some of 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 nongovernmental 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 EU technical legislation. Mandates can be checked online at http://ec.europa.eu/enterprise/policies/europeanstandards/standardisation-requests/index_en.htm

Due to the EU's vigorous promotion of its regulatory and standards system as well as its generous funding for its development, the EU's standards regime is wide and deep - extending well beyond the EU's political borders to include affiliate members (countries which are hopeful of becoming full members in the future) such as Albania, Belarus, FYR 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 and geographical reasons. 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 "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 EU legislation, expectations are that they will eventually serve as the basis for EU-wide standards.


The main standards organizations and conformity assessment bodies in Spain are:

**AENOR** (Asociación Española de Normalización y Certificación), the Spanish Standards & Certification Association: www.aenor.es develops voluntary standards and certification programs. AENOR promotes and coordinates elaboration of Spanish standards, UNE (unified Spanish standards), and participates in international and European standardization bodies.

AENOR’s structure incorporates Technical Committees for Normalization, AEN/CTN, which study and plan normalization projects by sector, before these norms become UNE rules. Once the committees approve norms, they are published in the Official Gazette (BOE) as a notification of an open forum during a specific period of time. During this period, all public comments should be addressed to AENOR. After these amendments, the text of the norm will be redrafted by the Committee and finally approved and published by AENOR.

AENOR website also includes a search engine for standards in Spain:
http://www.aenor.es/desarrollo/normalizacion/normas/buscadornormas.asp

**ENAC**, National Accreditation Entity: www.enac.es. This entity provides a detailed breakdown of Conformity Assessment (see Conformity Assessment, next section) bodies:

- Laboratories
- Inspection bodies
- Certification bodies
- Environmental verifiers

At the national level, most Spanish Ministries as well as Autonomous Communities and local governments use ENAC accreditations.

ENAC was nominated by the Ministry of Agriculture, Fisheries and Food as the body in charge of checking compliance with the principles of **Good Laboratory Practice (GLP)** by testing labs engaging in studies of phytosanitary products, such as pesticides, insecticides, and fungicides.

Authorized labs or certified bodies authorized by ENAC and AENOR grant certification once a norm is established (UNE norm for Spain, ISO international, etc.). Certification confirms that a firm, product, process, service or person follows the requirements established by a specific norm or technical specification.

**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 the manufacturer in the process of complying with specific EU legislation. The purpose of conformity assessment is to ensure consistency of compliance during all stages, from design to production, to facilitate acceptance of the final product. EU 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. Conformity assessment bodies in individual member states are listed in NANDO, the European Commission’s website. 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.

ENAC (Entidad Nacional de Acreditación – National Accreditation Entity) www.enac.es and AENOR (Spanish Standards & Certification Association) www.aenor.es are the major entities for conformity assessment in Spain. ENAC establishes the criteria and grants permits to the authorized certification labs. A full list of authorized certification labs and testing organizations is available at: http://www.enac.es/web/enac/acreditados

Product Certification
To sell products on the EU 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 EU-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.

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 marking 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 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.

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 EU. 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 test and certification laboratories, known as notified bodies, have been officially accredited by competent national authorities to test and certify to EU requirements.

"European Accreditation" is an organization representing nationally recognized accreditation bodies (http://www.europeanaccreditation.org/content/home/home.htm). 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.

Spain has established specific certification requirements for certain products. This certification procedure is referred to as "homologation" and requires product testing by approved laboratories. Local homologation requirements and testing standards have adapted Spanish legislation which is in line with EU directives.

At present, there are no requirements for either ISO 9000 certification or its EU equivalent. Nonetheless, demand is growing for companies that meet these standards as a guarantee of quality in product and manufacturing processes.

**Publication of Technical Regulations**

In Spain, the Spanish National Gazette is Boletín Oficial del Estado (BOE). There is an English version of the website at: http://www.boe.es/g/eng/index.php. BOE publishes a monthly list of all new technical regulations approved by the Spanish Ministry of Industry, plus amendments to technical regulations or cancelled regulations. However, the full text of the documents with the technical regulations does not appear in the BOE and should be requested through AENOR.

Both AENOR (www.aenor.es) and ENAC (http://www.enac.es/web/enac/larevista-de-enac) have newsletters and publications that provide a broad range of information on developments in these areas.

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://eurlex.europa.eu/JOIndex.do). It lists the standards reference numbers linked to

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/notifyU.S./data/index/index.cfm

**Labeling and Marking**

Manufacturers should be mindful that, in addition to the EU’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 the language of the country of consumption.


**The Eco-label**

The EU eco-label is a voluntary label which U.S. 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 its manufacture, use, and disposal. These criteria are reviewed every three to five years to take into account advances in manufacturing procedures. There are currently twentythree different product groups, and approximately 250 licenses have been awarded for several hundred products.

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 EUR 300 – 1,300 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 EUR 500 and
maximum EUR 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

In view of the complexity and rapid change in marking, labeling and testing requirements in Spain, U.S. exporters are advised to request pertinent instructions from their importers prior to shipment.

Basic labeling requirements apply in certain product categories:

- **Electrical products**: that operate in a range of 50 to 1,000 volts alternating current or 75 to 1,500 volt direct current must comply with the EU low-voltage directive. There are three accepted forms of proof of conformity with this regulation: a mark issued by an authorized EU agency, a certificate issued by an approved EU authority or a declaration issued by the manufacturer, which can self-certify the product.
- **Used equipment**: Spain now allows the entry of used equipment, material and goods subject to the same standards concerning safety as new imports in the same product category.
- **Foodstuffs**: The Directorate General of Health implements human consumption standards for the preparation, residue content and storage media for virtually all foodstuffs. Labeling must conform to EU requirements and must be in Spanish. [http://www.fas.usda.gov/posthome/useu/fairs.html](http://www.fas.usda.gov/posthome/useu/fairs.html)
- **Food and Animal Feed**: New EU legislation requiring labeling and traceability in food and animal feed came into effect on April 18, 2004. As of this date, all genetically modified organism- (GMO) containing products must be labeled “contains GMOs”. “Traceability” through the production chain is required by the new legislation. The GMO content of products must be documented along the production chain and kept on file for five years. [http://www.fas.usda.gov/posthome/useu/GMOs.html](http://www.fas.usda.gov/posthome/useu/GMOs.html)
- **Agricultural products**: Labeling requirements are fully harmonized with the EU labeling system and labels must be in Spanish. [http://www.fas.usda.gov/posthome/useu/label.html](http://www.fas.usda.gov/posthome/useu/label.html)

- 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 an EU general food law establishing general principles. This Regulation introduced mandatory traceability of 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: [http://www.fas.usda.gov/posthome/useu/](http://www.fas.usda.gov/posthome/useu/)
- Spanish requirements for certification and testing standards have gradually adopted EU directives. A product that meets the standards and certification
requirements of any other EU country can be imported and sold in Spain without further testing.


- Spanish Standards are developed by AENOR, the Spanish Standards & Certification Association: [www.aenor.es](http://www.aenor.es)

- **Textiles:** Customs and point-of-sale regulations require that all textile goods and ready-made clothing have a Spanish label. Standard Spanish textile nomenclature and content requirements must be stated on the label. Requirements relating to textile content, labeling and packaging are specific and extensive.

- **Drugs, Pharmaceuticals and Cosmetics:** These goods are subject to technical inspection and registration by the Directorate General of Health prior to entry. There are also detailed marking and labeling requirements, somewhat similar to those for foodstuffs, which include detailed chemical composition.

- **Fertilizers and Fungicides:** Imported fertilizers must be registered with the local Ministry of Agriculture. Inspection and analysis will be performed prior to customs clearance. The Ministry of Agriculture must approve all printed advertising and publicity materials, and labels must be in Spanish and include detailed precautions. The Ministry web page includes a link for “phytosanitary products” and the on-line register at: [http://www.mapa.es/en/agricultura/pags/fitos/registro/menu.asp](http://www.mapa.es/en/agricultura/pags/fitos/registro/menu.asp)

- **Firearms:** The Spanish government must clear all firearms, which must bear stamps of certifications.

- **Motor Vehicles:** Each vehicle will be inspected for engraved serial numbers on both the engine and chassis. If both of these are not present, Spanish customs levies a special charge for stamping the number.

- **Tires and Tubes:** All tires and inner tubes must be marked with serial numbers.

**Contacts**

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**Trade Agreements**
Spain has been a member of the EU since 1986. The EU has free trade agreements with other economic associations (e.g., the European Free Trade Association or EFTA).
and countries, providing a higher level of mutual market access. For a list of trade agreements with the EU and its member states, as well as concise explanations, please see http://tcc.export.gov/Trade_Agreements/index.asp.

**Web Resources**

**EU Links:**


Taxation and Customs Union:

http://ec.europa.eu/taxation_customs/customs/index_en.htm

Regulation (EC) 648/2005: Security and Safety Amendment to the Customs Code

Decision N° 70/2008/EC:


Regulation (EC) 450/2008: Modernized Community Customs Code

Legislation related to the Electronic Customs Initiative:


International Level: Customs value

What is Customs Valuation?


Customs and Security: Two communications and a proposal for amending the Community Customs Code


Establishing the Community Customs Code: Regulation (EC) n° 648/2005 of 13 April 2005

Pre Arrival/Pre Departure Declarations: Pre Arrival / Pre Departure Declarations

AEO: Authorized Economic Operator

Contact Information at National Customs Authorities:

http://ec.europa.eu/taxation_customs/taxation/personal_tax/savings_tax/contact_points/index_en.htm


Cenelec, European Committee for Electrotechnical Standardization:

http://www.cenelec.eu/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/cenorm/homepage.htm

Standardisation – Mandates:

http://ec.europa.eu/enterprise/standards_policy/mandates/

Nando (New Approach Notified and Designated Organizations) Information System:
http://ec.europa.eu/enterprise/newapproach/nando/
European Co-operation for Accreditation: http://www.europeanaccreditation.org/content/home/home.htm
Standards Reference Numbers linked to Legislation:
http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/whatsnew.html

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Metrology, Pre-Packaging – Pack Size:
http://ec.europa.eu/enterprise/prepack/packsize/packsiz_en.htm
EU Eco-label: http://ec.europa.eu/comm/environment/ecolabel/index_en.htm

U.S. Links:
National Trade Estimate Report on Foreign Trade Barriers:
Trade Compliance Center: http://www.trade.gov/tcc
The Latest on REACH: http://www.buyusainfo.net/docs/x_8086174.pdf
WEEE and RoHS in the EU: http://www.buyusa.gov/europeanunion/weee.html
Overview of EU Certificates: http://useu.usmission.gov/agri/certificates-overview.html
Center for Food Safety and Applied Nutrition: http://www.cfsan.fda.gov/
EU Marking, Labeling and Packaging: http://www.buyusainfo.net/docs/x_4171929.pdf
The European Union Eco-Label: http://buyusainfo.net/docs/x_4284752.pdf
Trade Agreements: http://tcc.export.gov/Trade_Agreements/index.asp

Spanish Links:
Ministry of Industry, Energy and Tourism: http://www.minetur.gob.es
AENOR: Comunicación@aenor.es, www.aenor.es
ENAC: ENAC@enac.es, www.enac.es