

European Union

### **Overview** [Return to top](#)

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/european-standards/documents/harmonised-standards-legislation/list-references/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/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*

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 law establishing the general principles of EU 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.U.S.da.gov/posthome/Useu/>

### **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 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 EU technical legislation. Mandates can be checked on line at [http://ec.europa.eu/enterprise/policies/european-standards/standardisation-requests/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/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](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.

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 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. 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 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" (<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.

## 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](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](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 EU has mandated that certain products be sold in standardized quantities. Council Directive 2007/45/EC 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/packsiz/packsiz\\_en.htm](http://ec.europa.eu/enterprise/prepack/packsiz/packsiz_en.htm)

### *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 twenty-three 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 €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% 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](#)

**Trade Agreements** [Return to top](#)

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](http://tcc.export.gov/Trade_Agreements/index.asp).

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EU websites:

Online customs tariff database (TARIC):

[http://ec.europa.eu/taxation\\_customs/common/databases/taric/index\\_en.htm](http://ec.europa.eu/taxation_customs/common/databases/taric/index_en.htm)

The Modernized Community Customs Code (MCCC):

[http://ec.europa.eu/taxation\\_customs/customs/procedural\\_aspects/general/community\\_code/index\\_en.htm](http://ec.europa.eu/taxation_customs/customs/procedural_aspects/general/community_code/index_en.htm).

ECHA: [http://echa.europa.eu/doc/press/pr\\_08\\_38\\_candidate\\_list\\_20081028.pdf](http://echa.europa.eu/doc/press/pr_08_38_candidate_list_20081028.pdf)

Taxation and Customs Union: [http://ec.europa.eu/taxation\\_customs/customs/index\\_en.htm](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:

[http://ec.europa.eu/taxation\\_customs/customs/policy\\_issues/electronic\\_customs\\_initiative/electronic\\_customs\\_legislation/index\\_en.htm](http://ec.europa.eu/taxation_customs/customs/policy_issues/electronic_customs_initiative/electronic_customs_legislation/index_en.htm)

Regulation (EC) 450/2008):

[Modernized Community Customs Code](#)

Legislation related to the Electronic Customs Initiative:

[http://ec.europa.eu/taxation\\_customs/customs/policy\\_issues/electronic\\_customs\\_initiative/electronic\\_customs\\_legislation/index\\_en.htm](http://ec.europa.eu/taxation_customs/customs/policy_issues/electronic_customs_initiative/electronic_customs_legislation/index_en.htm)

International Level:

[Customs value](#)

What is Customs Valuation?

[http://ec.europa.eu/taxation\\_customs/customs/customs\\_duties/declared\\_goods/index\\_en.htm](http://ec.europa.eu/taxation_customs/customs/customs_duties/declared_goods/index_en.htm)

Customs and Security:

[Two communications and a proposal for amending the Community Customs Code](#)

[http://ec.europa.eu/taxation\\_customs/customs/policy\\_issues/customs\\_security/index\\_en.htm](http://ec.europa.eu/taxation_customs/customs/policy_issues/customs_security/index_en.htm)

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

New Approach Legislation: [http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/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/](http://ec.europa.eu/enterprise/standards_policy/mandates/).

[http://ec.europa.eu/enterprise/policies/european-standards/standardisation-requests/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/standardisation-requests/index_en.htm)

ETSI – Portal – E-Standardisation :

[http://portal.etsi.org/Portal\\_Common/home.asp](http://portal.etsi.org/Portal_Common/home.asp)

CEN – Sector Fora:

<http://www.cen.eu/cenorm/sectors/index.asp>

Nando (New Approach Notified and Designated Organizations) Information System:

<http://ec.europa.eu/enterprise/newapproach/nando/>

Mutual Recognition Agreements (MRAs):

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

European Co-operation for Accreditation:

<http://www.european-accreditation.org/content/home/home.htm>

Eur-Lex – Access to European Union Law:

<http://eur-lex.europa.eu/en/index.htm>

Standards Reference Numbers linked to Legislation:

[http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/index_en.htm)

<http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/whatsnew.html>

National technical Regulations:

[http://ec.europa.eu/enterprise/tris/index\\_en.htm](http://ec.europa.eu/enterprise/tris/index_en.htm)

NIST - Notify U.S.: <http://tsapps.nist.gov/notifyU.S./data/index/index.cfm>

Metrology, Pre-Packaging – Pack Size:

[http://ec.europa.eu/enterprise/prepack/packsizes/packsiz\\_en.htm](http://ec.europa.eu/enterprise/prepack/packsizes/packsiz_en.htm)

European Union Eco-label Homepage:

[http://ec.europa.eu/comm/environment/ecolabel/index\\_en.htm](http://ec.europa.eu/comm/environment/ecolabel/index_en.htm)

Eco-Label Catalogue:

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

U.S. websites:

National Trade Estimate Report on Foreign Trade Barriers:

<http://www.ustr.gov/about-us/press-office/reports-and-publications/2009/2009-national-trade-estimate-report-foreign-trade>

Agricultural Trade Barriers:

<http://www.fas.usda.gov/posthome/Useu/>

Trade Compliance Center:

<http://www.trade.gov/tcc>

U.S. Mission to the European Union:

<http://www.buyusa.gov/europeanunion>

The New EU Battery Directive:

[http://www.buyusainfo.net/docs/x\\_8086174.pdf](http://www.buyusainfo.net/docs/x_8086174.pdf)

The Latest on REACH:

<http://www.buyusa.gov/europeanunion/reach.html>.

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 – An Overview

[http://www.buyusainfo.net/docs/x\\_4171929.pdf](http://www.buyusainfo.net/docs/x_4171929.pdf).

The European Union Eco-Label:

[http://buyusainfo.net/docs/x\\_4284752.pdf](http://buyusainfo.net/docs/x_4284752.pdf)

Trade Agreements:

[http://tcc.export.gov/Trade\\_Agreements/index.asp](http://tcc.export.gov/Trade_Agreements/index.asp)