

Germany

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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. 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.

Most manufacturers believe the EU's attempt to harmonize the various product safety requirements and related standards for industrial products of its member states has generally helped open member state markets. It did not, however, eliminate entirely voluntary national requirements, a fact which complicates the issue. Theoretically, during a transition period, national requirements must be met. (After the transition period, the EU "CE" mark supersedes all other compliance certificates, provided the products in question are covered by an EU directive.) The EU's efforts to harmonize standards through the "New Approach" certification-facilitating directives (and separately developed European standards) are incomplete as far as sectors covered. In some cases, U.S. firms (for example, in the automotive or pharmaceutical sectors) will have to worry about complying with the specific requirements of all applicable "Old Approach" product-specific EU technical legislation.

This is doubly important because, to the extent EU-wide standards are developed, there is a high probability that the existing German standard will form the basis for the eventual European standard. In many cases, Germany will also be the first member country to implement EU-wide standards. The implementation of electromagnetic compatibility standards (EMC), despite a five-year phase-in period, surprised many affected companies - not only foreign, but also German.

German buyers may require additional performance or quality marks, which are not necessarily legally required, but which greatly enhance a product's chances of being marketed. Both EU requirements and the standards for a German quality or performance mark will, in many cases, require modifications for an imported product. Even if the product does not require modification, it may still need testing and certification before it can be marketed. Two non-mandatory marks which may still be critical to successfully marketing products in Germany are the "geprüfte Sicherheit" (GS) mark, for mechanical products, and the "Verband Deutscher Elektrotechniker" (VDE) mark for electrical components. Neither the "GS" nor the "VDE" mark are mandatory for most products sold in Germany except for products for use in certain work place applications, where these marks are required to meet insurance requirements. However, many German consumers look for these marks as an additional sign of quality, similar to the UL mark in the U.S., regardless of legal requirement

Standards Organizations

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 (www.cenelec.org/Cenelec/Homepage.htm)

ETSI, European Telecommunications Standards Institute (www.etsi.org/)

CEN, European Committee for Standardization, handling all other standards (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. The German organization that compiles standards is the Deutscher Industrie Normenausschuss - DIN (German Standards Institute, www.din.de). The DIN also compiles the standards that lay down the requirements for a "GS" mark. Since 1975, DIN has been recognized by the German government as the national standards body and represents Germany's interests at the international and EU levels. DIN offers a forum in which interested parties meet in order to discuss and define their specific standardization requirements and to record the results as German Standards. In DIN, standard work is carried out by some 26,000 external experts, serving as voluntary delegates in more than 4,000 committees. Draft standards are published for public comment, and all comments are reviewed before final publication of the standard. Published standards are reviewed for continuing relevance at least every five years.

According to DIN, standards are designed to promote rationalization, quality assurance, safety, and environmental protection, as well as improving communication between industry, technology, science, government, and the public domain. The input of external experts into standardization is organized through standards committees and working groups. Each standards committee is responsible for a distinct area of activity and coordinates the corresponding standardization work at the EU and international levels. As a rule, the standards committee in DIN includes a number of technical sub-committees. There are currently 76 standards committees that maintain their own websites. Basic details of their area of activity and a list of the standards are published in English. Links to these committees are available on the [DIN](http://www.din.de) website **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:

<https://tsapps.nist.gov/notifyus/data/index/index.cfm>

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 of the production process 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. You can find conformity assessment bodies in individual Member State country in this list by the European Commission.

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

Accreditation of conformity assessment bodies Conformity assessment bodies evaluate the competence of German entities to carry out tests and certifications in accordance with third country law. Following a successful appraisal, the entities are accredited, and the scope of their accredited work is designated by the conformity assessment body of a Federal Ministry. EC agreements with third countries The Mutual Recognition Agreements on Conformity Assessment (MRAs) form the basis of the accreditation and designation of conformity assessment bodies. These agreements stipulate that the authority in the importing country recognizes the evaluation of devices or quality management systems conducted by a conformity assessment body located in the exporting country. This situation means that EU manufacturers can receive confirmation of compliance with third country regulations from EU conformity assessment bodies. The agreements imply the mutual acceptance of conformity assessment bodies and systems. They do not however imply mutual recognition (harmonization) of regulation. Thus, the regulations of the importing contract party apply.

MRA with the United States The Agreement on Mutual Recognition with the United States of America was signed with the EU on May 18, 1998, and came into effect June 22, 1998. The texts of the agreement and further information can be found on the EU website, http://trade.ec.europa.eu/doclib/docs/2003/october/tradoc_111718.pdf. All conformity assessment bodies accredited are obliged to participate in the confidence-building exercises and in the national MRA information exchange. This information exchange of the notified bodies is in accordance with the Medical Devices Law (EK-Med).

Recognized conformity assessment bodies An overview of existing recognized conformity assessment bodies can be found on the website of the European Commission, http://europa.eu/index_en.htm

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.

Organizations responsible for testing and certification are, for example, Underwriters Laboratories or the "Technischer Überwachungsverein e.V. - TÜV" (Technical Inspection Association). TÜVs are private companies set up by various German states to inspect and test

products for compliance with German safety standards. Individual TÜVs have also been authorized by the German Government to test products for compliance with EU legislation and many have established representative offices in the United States. Within the DIN group, certification services are offered by: DIN CERTCO (product and services certification), and DQS (management systems).

For the VDE (Association for Electrical, Electronic & Information Technologies) mark, which is applicable for electrical products only, companies can obtain information directly from the VDE (www.vde.com). The process for "VDE" certification is the same as that of the "GS" mark. Firms interested in certification should contact a U.S.-based test laboratory or a Conformity Assessment Body (see: <http://ts.nist.gov/Standards/Global/europe.cfm>).

Self-Certification For certain products, self-certification by manufacturers (through a Manufacturer's Declaration of Conformity) is sufficient. Further information is available from the contacts listed at the end of this chapter (see <http://www.buyusa.gov/europeanunion>).
Agreements on Certification CB - IEC System for Conformity Testing to Standards for safety of electrical equipment CCA - CENELEC Certification Agreement CECC - CENELEC Electronic Components Committee - System for electronic components of assessed quality ENEC - ENEC Agreement HAR - CENELEC Agreement for the use of an agreed marking for cables and cords in combination with harmonized standards IECQ - IEC System for the quality assessment of electronic components and associated materials.

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 are significantly lower which results in U.S. products becoming more competitive. At this time, the U.S.-EU MRAs cover the following sectors: Electromagnetic Compatibility (in force), Radio and telecommunications terminal equipment (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.

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

The German Accreditation Council (DAR) is a working group established in 1991 by ministries of the German Federal Government, ministries of the German federal states, and by representatives of the German industry.

The DAR coordinates the activities in the field of accreditation and recognition of laboratories, certification, and inspection bodies as far as they are represented in the DAR; it represents German interests in national, European and international organizations dealing with general issues of accreditation and recognition, including voluntary and mandatory (KOGB) areas. The DAR itself does not carry out any accreditations or recognitions.

All accreditation bodies represented in the DAR are operating on the basis of the EN 45000/EN ISO/IEC 17000 standard series and the DAR resolutions. With permission of the DAR, they may therefore use DAR certificates for accreditation.

Publication of Technical Regulations

Technical regulations are published by the publishing house of DIN, Beuth Verlag:
www.beuth.de

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 more (<http://eur-lex.europa.eu/JOIndex.do>). It lists the standards reference numbers linked to legislation (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 other countries and interested parties to comment.

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 language of the country of consumption. The EU Metric Directive (80/181/EEC), scheduled to go into effect January 1, 2010, has been modified to allow the continuation of both supplemental (U.S. customary, inch-pound) and metric units for consumer goods sold in the EU.

The EU Eco-label EU legislation in 1992, revised in 2000, distinguishes environmentally friendly products and services through a voluntary labeling scheme called the Eco-label. Currently, the scheme applies to 7 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. The Eco-label is awarded to producers who can show that their product is less harmful to the environment than similar products. This "green label" also aims to encourage consumers to buy green 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 Eco-label can still enter the EU as long as they meet the existing health, safety, and environmental standards and Regulations.

The EU Eco-label is a costly scheme (up to EUR 1,300 for registration and up to EUR 25,000/year for the use of the label, with a reduction of 25% for SMEs) and has therefore not been widely used so far. However, the Eco-label can be a good marketing tool and, given the growing demand for green products in Europe, it is likely that the Eco-label will become more and more a reference for green consumers. http://buyusainfo.net/docs/x_4284752.pdf
http://ec.europa.eu/comm/environment/ecolabel/index_en.htm <http://www.eco-label.com>

Agricultural Products

General Veterinary Requirements: In April 1997, the U.S. and the EU reached an equivalency agreement on an overall framework for recognizing each other's veterinary inspection systems. The veterinary equivalency agreement covers more than USD 1.5 billion in U.S. animal product exports to the EU and an equal value of EU exports to the United States. The agreement preserved most pre-existing trade in products, such as pet food, dairy, and egg products. All

beef and pork exported to Germany for human consumption must come from slaughterhouses, cutting plants, and cold stores approved for export to the EU. Since 1989, the EU has prohibited imports of beef from cattle treated with growth hormones. Soon after this ban went into effect, an agreement was reached between the United States and the EU that allows American producers of beef from animals not treated with hormones to export to the EU under certain conditions. Beef: The EU beef market is largely insulated from the world market by high import duties. Import opportunities do exist, however, for selected products that are covered by fixed, relatively low tariffs or special quota. Most notably, the EU grants market access through a quota for annual imports of up to 11,500 MT of high-quality beef (HQB) from the United States and Canada. Beef entering the EU under the HBQ tariff-rate quota are subject to a 20 percent duty. In addition, starting in 2009, an autonomous tariff quota for high quality beef at zero percent duty was established for up to 20,000 MT per July/June marketing year.

Pork: Selected market opportunities exist for imports of pork. Market access within the EU has improved through the creation of a tariff-rate quota (TRQ) totaling 67,869 MT. The TRQ includes a 40,265 MT allocation for tenderloins, boneless loins and boneless hams. In addition, a 4,722 MT TRQ is reserved for boneless loins and boneless hams from the United States.

Poultry: Unfortunately, U.S. and EU negotiators have not been able to reach agreement on a number of important points during the veterinary equivalency negotiations, particularly in the poultry sector. The most contentious issue is the use of pathogen reduction treatments in U.S. poultry processing. Most forms of anti-microbial treatments are prohibited in the EU. The EU's ban on anti-microbial treatments effectively blocks U.S. poultry exports to the EU, which were estimated at USD 50 million in 1996.

Dairy Products: The veterinary agreement allows for U.S. dairy products export to Germany and the EU from approved establishments under a fixed tariff.

Pet food: U.S. pet food exports to the EU must comply with EU regulation 1774/2002. This regulation, implemented in 2004, requires that animal by-products used in the production of feeds and pet food be derived from the carcasses of animals declared fit for human consumption following veterinary inspection. Provisions include a ban on intra-species recycling, fallen stock and restrictions on yellow grease. Certain categories of pet food have to be denatured with specified substances. Pet food plants have to be dedicated to the production of product fit for human consumption.

Plant Health: As part of the Single Market exercise, plant health regulations in the 27 European Union Member States have been harmonized. The regulations went into effect on June 1, 1993, for the 15 members then in the EU and in 2004 for the new accession countries. The EU has been successful in reducing the number of phytosanitary restrictions and new marketing opportunities have been created for U.S. horticultural exports. Phytosanitary certificates are required for many imported fresh products. With respect to the use of solid wooden packing materials (SWPM), it is important to note that the EU requires that all SWPM be either heat treated or fumigated beginning July 1, 2009. In addition to these treatment requirements, the material has to be free of bark. EU scientists fear that improperly treated SWPM is at risk for re-infestation. International plant protection standards as agreed upon by the United States do not require the absence of bark. Exporters should carefully follow the status of EU import requirements to avoid problems at the EU port of entry.

Horticultural Products: Germany is an important market for United States horticultural products. Principal products include almonds, walnuts, pistachios, prunes, raisins, citrus, and pears. Horticultural products entering Germany face a number of import restrictions. In addition to considerable tariffs that vary by product, imports of selected produce (tomatoes, cucumber, artichokes, zucchini squash, citrus, table grapes, apples, pears, apricots, cherries, peaches, nectarines and plums) are subject to an entry price system. Under such a system, imports that have a price at or above the respective entry price are assessed only the appropriate ad valorem duty. Imports, which have a price below, but within a certain range of the entry price, are assessed the ad valorem duty plus a specific duty that is the difference between the import price and the entry price. "Within a certain range" generally means within eight percent of the entry price. Imports having a price more than 8% below the entry price are assessed the ad valorem duty plus a very large specific duty (known as the tariff equivalent) which generally takes the cost of the product (import price plus duties) far above the entry price.

Organic Products: Until 2008 the German organic market had been growing at near double digit rates annually. In 2009, this growth leveled off as demand for organic products in conventional food stores decreased by several percentage points. Sales through specialized organic food stores are still increasing. The share of organic production in German agriculture is estimated to be about five percent. There are currently two regulations for organics in the EU, one for standards and one for imports. Implementation of the new import regulation framework for organic products started on January 1, 2009. Previously imported products had to be checked by the Member State for each individual product in an import authorization procedure. Under the new regulation, in countries such as the U.S. that are not on the equivalency list, products can be certified by control bodies. These control bodies must be directly approved for by the EU Commission. There is a transition period where it is still possible to import organic products through the old system. This possibility ends on January 1, 2013.

Consumer-Ready Products: Imports of consumer-ready food products into Germany face many market access restrictions and very strict food laws. In addition to bound import duties, the EU has established a complex system of border protection measures for food products. Depending on the world market situation for basic agricultural commodities, such as dairy products, sugar and cereals the EU mechanism of flexible tariffs may require variable import duties to protect European consumer-ready food products from imports made with lower-price inputs. Therefore, at many times processed products entering the EU are subject to additional import charges based on the percentage of sugar, milk fat, milk protein, and starch contained in the product. These additional import charges have made many imported processed food products non-competitive in the EU market. Reports on the German retail and gastronomy sectors are available under "attaché reports" at <http://www.fas.usda.gov/scripts/attacherep/default.asp>.

Packaging Disposal: With the tremendous increase in waste and disposal problems, Germany has established legislation that contains certain rules for the disposal of packaging materials. In response to this legislation, a cooperative effort for the collection and recycling of packaging materials was initiated. The organization involved is called the "Duales System Deutschland" and it administers the use of the "Green Dot," a recycling symbol that is found on the packaging material of virtually all products sold in Germany. While packaging materials for products sold in Germany are not legally required to carry the Green Dot, it is almost impossible to market a product in Germany without it. Typically, the importer pays a license fee to the user of the Green Dot, depending on the type and amount of packaging, and provides the exporter with the information necessary. In 2003, German retailers began requesting a deposit for disposable or "one-way" drink packages, i.e., soft drink or beer cans. Since the requested deposit is about three times as high as that requested for returnable beer bottles, it could disadvantage imported drinks.

U.S. Agricultural Commodity Associations Active in Germany A number of U.S. agricultural commodity and other trade associations conduct market development programs in Germany. In some cases, these associations maintain field offices in Germany, while others may have a trade representative or public relations company representing their interests. Others may cover Germany from elsewhere in Europe or from offices in the United States. The USDA-operated Market Access Program (MAP) and Foreign Market Development program (FMD) provides a portion of the funding for the market development programs of these associations. For further information about the MAP and FMD program or to know more about which associations are active in Germany, please contact the Office of Agricultural Affairs at the U.S. Embassy in Berlin (<http://germany.usembassy.gov/fas/>).

Trade Agreements

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

1. Product legislation:

http://ec.europa.eu/enterprise/index_en.htm <http://www.ts.nist.gov/ts/htdocs/210/217/export-alert.htm>

2. CE Mark legislation:

<http://europa.eu.int/comm/enterprise/newapproach/legislation/guide> www.newapproach.org

3. European standards:

<http://europa.eu.int/comm/enterprise/newapproach/legislation/guide> www.newapproach.org
www.cenorm.be/catweb

4. EU Notified bodies: <http://ec.europa.eu/enterprise/newapproach/nando>

5. Test laboratories:

<http://www.ts.nist.gov/ca>

6. Deutscher Akkreditierungsrat (DAR):

www.dar.bam.de

7. TÜV:

www.tuvamerica.com

8. Other Sources:

BMU – (Federal Environment Ministry) www.bmu.de

BMWA –(Federal Ministry of Economics and Labor) www.bmwi.de

DAR – (German Accreditation Council) www.dar.bam.de

DIN – (German Standards Institute) www2.din.de

NIST – National Institute of Standards and Technology www.nist.gov

UL - Underwriters Laboratories, Inc. www.ul.com

VDE – Verband der Elektrotechnik, Elektronik und Informationstechnik (Association for Electrical, Electronic & Information Technologies.) <http://www.vde.de>

VDMA - Verband deutscher Maschinen- und Anlagenbau e.V. www.vdma.de

ZLG – Zentralstelle der Länder für Gesundheitsschule bei Arzneimitteln und Medizinprodukten (Central Authority of the Federal States for Health Protection regarding Medicinal products and Medical Equipment) www.zlg.nrw.de

ZVEI - Zentralverband Elektrotechnik- und Elektronikindustrie e.V. (Central Federation for the German Electrical and Electronics Industry) www.zvei.de