

Sweden

Overview

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

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.

The supreme body for the Swedish standardization system is the Swedish Standards Council, SSR. The Council's members include the state, the Federation of County Councils, Association of Local Authorities, Confederation of Swedish Enterprises, Federation of Swedish Commerce and Trade and the Swedish Bankers Association.

SSR manages the register of both adopted and withdrawn Swedish standards and approves the standardization bodies in Sweden. All standardization is currently carried out by three accredited standardization bodies: The Swedish Standards Institute (SIS) handles most business areas, Informationstekniska Standardiseringen (ITS) handles telecommunication issues and Svensk Elstandard (SEK) handles electronic and electro-technical application standards.

All three standardization bodies are working on both European and global levels. Products tested and certified in the U.S. to American standards are likely to have to be retested and re-certified to European Union (EU) requirements as a result of the EU's different approach to the protection of the health and safety of consumers and the environment.

SIS is the Swedish member of the Council and Technical Board of ISO and serves on both the administrative and technical boards of the European Committee for Standardization. ITS acts as the national standardization body for Sweden at ETSI, European Telecommunication Standards Institute, and SEK is the Swedish member of both International Electrotechnical Commission, IEC and European Committee for Electrotechnical Standardization, CENELEC.

Standards Organizations

The organizations that develop standards in Sweden are:

Swedish Standards Institution, SIS
P.O. Box 3295,
S-103 66 Stockholm
Sweden
Tel: 46-8-610 3000
Fax: 46-8-30 1850
<http://www.sis.se>

CEN, European Committee of Standardization
<http://www.cen.eu>

SIS develops or revises over 1,300 Swedish and international standards annually within most business areas, by working closely with the private sector, Swedish authorities, consumer representatives and other stakeholders

Informationstekniska Standardiseringen, ITS
The Swedish Telecommunication Standardization Organization
2/13/2009
Box 1284
S-16429 Kista
Sweden
Tel. 46 8 444 1424
Fax. 46 8 444 1430
<http://www.its.se>

European Telecommunications Standards Institute ETSI
<http://www.etsi.org>

Since March 2002, ITS has been recognizing European standards (EN) directly instead of transposing them to Swedish SS standards. All new proposals of standards and changes/adoptions of technical regulations should be determined and adjusted in respect to existing international and European standards

SEK Svensk Elstandard
The Swedish Electro-technical Standards
Box 1284
S-16429 Kista
Sweden
Tel. 46 8 444 1400
Fax. 46 8 444 1430
<http://www.elstandard.se>
European Committee for Electrotechnical Standardization CENELEC
<http://www.cenelec.org>

SEK coordinates the electro-technical standardization through technical committees that directly reflect the work done on the international level at both IEC and CENELEC. The standardization and revision process is open to all Swedish organizations, companies, institutions and public sector offices.

Given 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 Morocco among others. Another category, called "partner standardization body" includes the standards organization of Mongolia and Australia, which are not likely to become a CEN member or affiliate for political and geographical reasons.

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.

Key Link: <http://www.cen.eu/cenorm/products/cwa/index.asp>

The role of standards in legislation is undergoing review. The Commission's proposal, which is now in its first reading at the European Parliament, clarifies the relationship between regulations and standards and confirms the role of the three European standards bodies in developing EN harmonized standards. The emphasis is also on referencing international standards where possible. For information, communication and technology products, the importance of interoperability standards has been recognized. Through a newly established mechanism, a board will decide which deliverables from fora and consortia will be acceptable for public procurement specifications. The European standards bodies have been encouraged to improve efficiency in terms of delivery and to look for ways to include more societal stakeholders in European standardization.

Key Link: http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/index_en.htm

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. Bodies that perform analysis, testing and certification in accordance with certain EC directives (medical devices, contracting (building and civil engineering) machinery, pressure vessels, toys etc.) must be notified to the European Commission. In Sweden, SWEDAC is the entity responsible for assessing and appointing these bodies, known as "Notified Bodies", by formally notifying them to the European Commission and exercising oversight on them. SWEDAC is also responsible for assessing Conformity Assessment Bodies.

SWEDAC, Styrelsen for Ackreditering och Teknisk Kontroll
Swedish Board for Accreditation and Conformity Assessment
Box 878,

S-501 15 Boras, Sweden

Tel: 46-33-177 700

Fax: 46-33-101 392

[http://www.swedac.se/sdd/System.nsf/\(GUView\)/index_english.html](http://www.swedac.se/sdd/System.nsf/(GUView)/index_english.html)

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. Although CE marking is intended primarily for inspection purposes by Member State inspectors, the consumer may well perceive it as a quality mark.

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.

Swedish Bodies

The Swedish National Testing and Research Institute is accredited for certification in the fields of environment (ISO14001, EMAS, Environmental product declarations, EPD), quality (ISO9000 series, QS 9000, EU directives), the workplace in accordance with the National Board of Occupations Safety and Health Code Statutes AFS 2001:1) and products (CE marking, P-marking). The certification requirements are set out in product standards, voluntary specifications or specified by public authorities.

SP Swedish National Testing and Research Institute

Box 857

501 15 Borås

Sweden

Tel. 46 33 16 50 00

Fax. 46 33 13 55 02

<http://www.sp.se/en/Sidor/default.aspx>

Intertek Semco Certification AB, an approved certification body accredited by SWEDAC, offers certification to the ISO 9000 series, QS 9000, ISO 14001 and QS 9000, AFS 1996:6 (Working

Environment) and validations under EMAS, and also certification to SS 627799 (Information Security), and EPD (Environmental Product Declaration).

Intertek Semco Certification AB

Box 1103 164 22 Kista

Sweden

Tel. 46 8 750 0333

<http://www.intertek-sc.com>

Accreditation

SWEDAC is the national accreditation body, working under the Ministry for Foreign Affairs and Ministry of Enterprise & Energy. SWEDAC assesses the competence of laboratories, certification and inspection bodies and is also the public authority responsible for regulations and surveillance in the field of legal metrology. SWEDAC assesses the independence of laboratories and their competence to perform analysis, tests or calibration within IT, building technology, legal metrology, foodstuffs, medical technology, electrical technology, chemistry, clinical chemistry, mechanics, materials testing, water analysis or calibration within many different quantities.

The accreditation is performed in accordance with the international SS EN ISO/IEC 17025 standard. SWEDAC also issues certificates for Good Laboratory Practice (GLP) in accordance with OECD rules (OECD/GD[92] 32 - Paris 1992) to laboratories that perform investigations of chemicals other than pharmaceuticals, hygienic or cosmetic products.

In conjunction with the Chemicals inspectorate, SWEDAC is also responsible for accreditation of bodies for testing of plant protection products in efficacy trials in accordance with GEP, 'Good Efficacy Practice' (EPPO Guidelines 152, 181).

Swedac, Styrelsen for Ackreditering och Teknisk Kontroll

Swedish Board for Conformity and Technical Control

Box 878

S-501 15 Boras, Sweden

Tel: 46-33-177 700

Fax: 46-33-101 392

<http://www.swedac.se>

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

When it comes to technical regulations Sweden abides by the EU directives and WTO agreements and accordingly reports all proposals to both EU and WTO. The entity responsible for information and notification procedures for new national technical regulations is the National Board of Trade.

All the Swedish proposals and final regulations are listed on the EU data base TRIS, Technical Regulations Information System.

The National Board of Trade

Box 6803

113 86 Stockholm
Sweden
Tel. 46 8 690 4800
Fax. 46 8 30 67 59
Email: kerstin.carlson@kommers.se
<http://www.kommers.se>
http://ec.europa.eu/enterprise/tris/index_sv.htm

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?ihmlang=en>). It lists the standards reference numbers linked to legislation (http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm).

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) 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/notifyUS/data/index/index.cfm>

Labeling and Marking

Sweden does not require country of origin marking for imports. However, goods carrying incorrect designations of origin are prohibited, and products made to appear as produced or manufactured in Sweden may not be imported unless the correct foreign origin is clearly and durably marked thereon.

Special marking regulations and labeling requirements exist for pharmaceuticals, chemicals, food products and other product categories. Sweden has very strict health, sanitary and labeling rules and sophisticated capabilities for monitoring product quality.

A retail-size food package must show the name of the manufacturer, packer or importer, commercial name of the product, net metric weights or volume, ingredients in descending order of weight, last recommended date of consumption, and storage instructions if perishable or intended for infants. The information described above should be in Swedish and the local importers can assist NTM companies in arranging for proper labeling information.

Inspection and food labeling requirements were changed to conform to E.U. regulations when Sweden became a member of the E.U. on January 1, 1995.

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 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

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](#)

Contacts

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115 89 Stockholm, Sweden

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P.O. Box 3295,

S-103 66 Stockholm, Sweden

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<http://www.swedac.se>

SP Swedish National Testing and Research Institute
Box 857
S-501 15 Boras
Sweden
Tel. 46 33 16 50 00
Fax. 46 33 13 55 02
<http://www.sp.se>

Intertek Semco Certification AB
Box 1103 164 22 Kista
Sweden
Tel. 46 8 750 0333
<http://www.intertek-sc.com>

The National Board of Trade
Box 6803
113 86 Stockholm
Sweden
Tel. 46 8 690 4800
Fax. 46 8 30 67 59
Email: kerstin.carlsosn@kommers.se
<http://www.kommers.se>

Livsmedelsverket (National Food Administration)
Box 622
751 26 Uppsala
Email: livsmedelsverket@slv.se
Tel: 4618 17 55 00 Fax: 4618 10 58 48

Lakemedelsverket (Medical products Agency)
Box 26
751 03 Uppsala

Tel: 46 18 17 46 00 Fax: 4618 54 85 66
Kemi (Swedish Chemical Agency)
Box 1384
171 27 Solna
Email: kemi@kemi.se
Tel: 46 8 783 11 00 Fax: 46 8 735 76 98

Trade Agreements

Importers from certain countries and/or groups of countries and economic areas are entitled to lower or no customs duty when exporting to EU countries, including its member state Sweden. This applies to the majority of goods originating from these countries. The origin of goods must be established by a Certificate of Origin, issued by a legal authority in the country of export. Preferential treatment of imports into the EU is possible for import of goods originating from the following countries and areas/zones:

EES (Iceland, Liechtenstein and Norway)

EFTA

The Faroes

Andorra

Central-and Eastern Europe

Western Balkans (Albania, Bosnia-Herzegovina, Croatia and Federal Republic of Yugoslavia including Kosovo)

Slovenia

Turkey

Israel

The West Bank and Gaza

Maghreb (Alger, morocco, Tunis)

Mashrek (Lebanon, Egypt, Jordan, Syria)

South Africa

Mexico

ACP Countries (African, Caribbean and Pacific States)

OCT (Overseas Countries and Territories)

Developing countries

More information on these agreements can be found at <http://www.tullverket.se/en>

Web Resources

Swedish Customs <http://www.tullverket.se/en/Business/>

National Inspectorate of Strategic Products ISP <http://www.isp.se/nyaengelska/indexeng.htm>

Livsmedelsverket (National Food Administration) www.slv.se

Lakemedelsverket (Medical Products Agency) <http://www.mpa.se/eng/index.shtml>

Kemikalieinspektionen (Swedish Chemicals Agency) www.kemi.se

Swedish Board of Agriculture <http://www.sjv.se>

National Board of Fisheries <http://www.fiskeriverket.se>

National Board of Trade <http://www.kommers.se>

Swedish Standards Institution SIS www.sis.se

European Committee of Standardization www.cenorm.be

Swedish Telecommunication Standardization Organization www.its.se

European Telecom Standards Institute www.etsi.se

Swedish Electro-Technical Standards <http://www.elstandard.se>

European Committee of Electrotechnical Standardization www.cenelec.org

Swedish Board of Accreditation and Conformity Assessment www.swedac.se

EU Conformity Assessment Bodies <http://europa.eu.int/comm/enterprise/nando-is/home/index.cfm>

Swedish National Testing and Research Institute www.sp.se

Certification body www.intertek-etlsemko.com

European accreditation www.european-accreditation.org