U.S. COMMERCIAL SERVICE
United States of America Department of Commerce

U.S. Country Commercial Guides

European Union

Year 2020

U.S. Department of Commerce | International Trade Administration

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Doing Business in the European Union

Market Overview

The United States and the Member States of the EU share the largest economic relationship in the world. Trade and investment flows between the United States and the EU are a key pillar of prosperity on both sides of the Atlantic. Transatlantic trade flows averaged $5.3 billion per day in 2017, and the total stock of transatlantic investment was $5.6 trillion in 2017. [1]

U.S. goods and services trade with the EU totaled nearly $1.3 trillion in 2018. The U.S. goods and services trade deficit with the EU was $109 billion in 2018. The U.S. goods trade deficit with the European Union was $169 billion in 2018. The U.S. services trade surplus with the EU was $60 billion in 2018.[2]

The European economy entered a sudden recession in the first half of 2020 with the deepest output contraction since World War II. In response to the global pandemic major containment measures were introduced. The euro area economy operated at between 25% to 30% below its capacity during the period of the strictest confinement.[3]

Overall, the euro area economy is forecasted to contract by about 8.7% in 2020 before recovering at an annual growth rate of 6% in 2021. Looking forward to the second half of the year and 2021, the European economy is expected to bounce back. The forecast for inflation in the euro area has been raised to 1.3% in 2020 and 1.4% in 2021, an increase of 0.1 percentage points for both years compared to the 2019 economic forecast.[4]

U.S. business continue to benefit from the EU's border-free Schengen area, which covers 22 of the 27 EU Member States[5] and eases the movement across air, land, and sea borders. Ireland opted out of the Schengen and it is not certain when Bulgaria, Croatia, Cyprus, and Romania will join.

Brexit

The United Kingdom left the European Union on January 31, 2020, after 47 years of EU membership. In accordance with the Withdrawal Agreement, it is now officially a third country to the EU and hence no longer participates in EU decision-making.

The EU and the UK have, however, jointly agreed on a transition period, which will last until December 31, 2020. Negotiations for an agreement covering the post-Brexit relationship are on-going with both sides stating the goal is to have an agreement in place by January 1, 2021.

1 The Executive Office of the President of the United States:2020 National Trade Estimate Report on Foreign Trade Barriers
2 Office of United States Trade Representative, European Union, Accessed June 21, 2020
3 European Commission Summer 2020 Economic Forecast, July 2020
4 European Commission Summer 2020 Economic Forecast, July 2020
5 Twenty-two EU Member States and four European Free Trade Association (EFTA) Member States participate in the Schengen Area. Of the six EU members which do not form part of the Schengen Area three – Bulgaria, Croatia, Cyprus and Romania – are legally obliged to join the area, while the other two – Ireland and the United Kingdom – maintain opt-outs. Four non-EU members – Iceland, Liechtenstein, Norway, and Switzerland – participate in the Schengen Area.

Until then, it will be business as usual for citizens, consumers, businesses, investors, students, and researchers in both the EU and the UK. EU law still applies to the United Kingdom until the end of the transition period.

Market Challenges

The US and the EU continue to work towards fair and balanced trade that can grow the Transatlantic economy, especially important given the global pandemic. Washington and Brussels are engaged in numerous trade and investment workstreams to ensure a level playing field for businesses, especially SME job creators. These include aircraft subsidies, digital privacy frameworks, digital taxation, simplified standard and certification procedures in medical devices, agricultural market access and other areas.

Issues exist as would be expected given the breadth and depth of the commercial relationship between the United States and the EU. These issues generally come in the form of compliance requirements established by EU legislation.

EU legislation generally takes two forms. "Regulations" have mandatory language and are directly applicable in Member States when implemented. "Directives" provide a general framework and must be "transposed" into national legislation at the member state level. Differences in how directives are transposed in Member States are common, which complicates compliance for U.S. companies doing business in the EU. Industry has raised concerns over perceived onerous regulations and unnecessarily high compliance costs.

The EU has legislative harmonization competence that it can choose to exercise in such areas as the free circulation of goods, services, and capital within the internal market as well as agriculture, fisheries, transport, and energy. Human health, tourism, and civil protection are examples of areas where the EU can only legislate in support of Member States' initiatives.

While the EU continues to move in the direction of a Single Market, the reality today is that U.S. exporters continue to face barriers to entry and challenges with regulations, testing, and standards. In several industries such as pharmaceuticals, chemicals, telecommunications, legal services, and government procurement, some of these barriers are more pronounced.

Discussions on a range of existing and proposed trade irritants are ongoing, including transparency in developing regulatory procedures and standards. U.S. trade agencies work closely and diligently with the business community to ensure that the EU and its Member States comply with their bilateral and multilateral trade obligations, and to minimize market access problems affecting U.S. firms.

For more information, please see:

- **Interagency Trade Enforcement Center**
- **The Executive Office of the President of the United States: 2020 National Trade Estimate Report on Foreign Trade Barriers p. 170 - 216**

Market Opportunities

For specific member state market opportunities, please consult the Commerce Department's Country Commercial Guides of the 27 individual EU Member States found at the following website: EU Member States' Country Commercial Guides

Market Entry Strategy

Although the European Commission continues to pursue the implementation of a single European market, by and large the European Union market is differentiated with each Member State having its own supply and demand needs and characteristics. While a pan-European business strategy is critical, individual market entry plans must be developed on a country-by-country basis. Working together with U.S. Commercial Service teams across Europe, U.S. firms can capitalize on opportunities in multiple countries across the region that share common rules, regulations and standards: Region-wide and Country-Specific Information.

For details of these tactics, please consult the Commerce Department's Country Commercial Guides of the 27 individual EU Member States found at the following website: EU Member States' Country Commercial Guides

Leading Sectors for U.S. Exports & Investments

Best Prospect Overview

Commercial Sector

U.S. Government engagement in such sectors as automotive (e-vehicles), chemicals, energy and environment (smart grids, renewables, LNG), health and medical technologies, manufacturing (advanced manufacturing, additive manufacturing, advanced materials), digital, and information and communications technology will continue to contribute towards U.S. businesses growth and job creation.

The Department of Commerce and the Commercial Service European Union office (CSEU) continue to be a major force, supporting and protecting U.S. commercial interests by: counseling U.S. firms on EU market entry requirements, standards, and legislation; monitoring legislative developments that may impact U.S. commercial interests; and advocating on behalf of U.S. companies to ensure that the EU remains open to U.S. commercial activity.

CSEU works to resolve market access barriers that impede U.S. commercial activities in Europe and works to reduce technical barriers to trade such as technical and standards regulations, product standards and testing, and certification procedures that hamper U.S. exports.

Overview

Unit: USD millions

Data Sources:

Includes UK	**2017**	**2018**	**2019 (estimates)**
GDP (current prices)	17,325 ^^	18,769^^	^^19,150
Total EU Exports to the world	2,123.9 *	2,308.6*	2116.1*
Total EU Imports from the world	2,103 *	2,341.8 *	2310.3*
Import of goods from the U.S.	288,729 *	313,941 *	323,844*
Export of goods to the U.S.	418,919 *	473,298 *	465,846*
Exchange Rate (Euro Zone) : 1 Euro ^	$1.1297 ^	$1.1810^	$1.14^^^

* Global Trade Atlas, U.S. Department of Commerce Bureau of Economic Analysis. 2019 based on 2 months of data available at time of report

^ Eurostat- Exchange Rates

^^ International Monetary Fund, World Economic Outlook Database, Oct 2018

^^^ March 2019 ECB staff macroeconomic projections for the euro area. European Central Bank; Eurosystem

Principal U.S. Exports to European Union in 2018:

Machinery (21.32%)

Pharmaceutical Products (9.76%)
Mineral Fuel, Oil, including LNG (8.92%)[1]
Aircraft, Spacecraft & Parts (8.53%)
Optical, Medical Instruments (8.39%)
Electrical Machinery (7.22%)
Note: Services exports were valued at $256 Billion*

Principal U.S. Imports from European Union in 2018:
Machinery (18.38%)
Pharmaceutical Products (14.02%)
Vehicles (12.21%)
Optical, Medical Instruments (7.38%)
Electrical Machinery (6.98%)
Organic Chemicals (5.21%)

Note: Services Imports were valued at $196 Billion*

Source: Global Trade Atlas, U.S. Department of Commerce Bureau of Economic Analysis

Additional information from the European Commission may be found here: European Commission, Directorate-General for Trade, EU-U.S. trade

Agricultural Sector
Bilateral agricultural and related products trade between the United States and the EU totaled $42.4 billion in 2019, making the EU the 4th largest export market for U.S. agricultural and related products after Canada, Mexico, and China. For the eighteenth year in a row, the U.S. has run a trade deficit in agriculture with the EU with a gap of $12.2 billion in 2019. The top five U.S. agricultural and related products exported to the EU by value are tree nuts ($3.1 billion), soybeans ($1.9 billion), , forest products ($1.5 billion), fish and fish products ($1.0 billion), and distilled spirits ($602 million). The top five EU agriculture and related products exported to the United States by value are wine and beer ($6.4 billion), essential oils ($3.2 billion), snack foods ($1.8 billion), processed fruits and vegetables ($1.4 billion), and cheese ($1.0 billion).

Global branding and further integration of European markets is continuing to produce a more homogeneous food and drink market in Europe although significant national differences in consumption remain. Nevertheless, certain common trends are evident throughout the EU: demand for greater convenience, more openness to non-traditional foods, and a growing interest in health foods, organics and niche markets. For a thorough analysis of what commodities and products offer the best opportunities, access FAS/USEU and consult Brussels' and the individual Member States' Food and Agricultural Import Regulation and Standards (FAIRS) Reports.

FAIRS Certification Report

Agricultural Documentation

Phytosanitary Certificates: Phytosanitary certificates are required for most fresh fruits, vegetables, and other plant materials.

Sanitary Certificates: For commodities composed of animal products or by-products, EU countries require that shipments be accompanied by a certificate issued by the competent authority of the exporting country. This applies regardless of whether the product is for human consumption, for pharmaceutical use, or strictly for non-human use (e.g., veterinary biologicals, animal feeds, fertilizers, research). The vast majority of these certificates are uniform throughout the EU, but the harmonization process is still ongoing. Most recently, certificates for a series of highly processed products including chondroitin sulphate, hyaluronic acid, hydrolyzed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids have been harmonized. In addition to the legally required EU health certificates, a number of other certificates are used in international trade. These certificates, which may also be harmonized in EU legislation, certify origin for customs purposes and certain quality attributes. Up-to-date information on harmonized import documentation can be found at the following website: FAIRS Export Certificate Report.

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.

There are also export guides to import regulations and standards available on the Foreign Agricultural Service's website.

Customs, Regulations, Labelling, and Standards

Trade Barriers

For information on existing trade barriers, please see the National Trade Estimate Report on Foreign Trade Barriers published by USTR. Information on agricultural trade barriers can be found at the following website: Foreign Agricultural Service.

To report existing or new trade barriers and get assistance in removing them, contact either the U.S. Mission to the European Union or the Trade Compliance Center.

Import Tariff

When products enter the EU, they need to be declared to customs according to their classification in the Combined Nomenclature (CN). All products entering the EU are classified under a **tariff code** that carries information on:

- duty rates and other levies on imports and exports
- any applicable protective measures (e.g. anti-dumping)
- external trade statistics
- import and export formalities and other non-tariff requirements.

The EU classification system consists of three integrated components. The Harmonized System (HS) which is a nomenclature developed by the World Customs Organization (WCO) comprising about 5,000 commodity groups, organized in a hierarchical structure by sections, chapters (2 digits), headings (4 digits) and subheadings (6 digits). The Combined Nomenclature (CN) which adds EU specific codes and information to become the EU's eight-digit coding system (in other words HS codes with further EU specific subdivisions). The CN both serves the EU's **common customs tariff** and provides statistics for trade inside the EU and between the EU and the rest of the world. The third component is the Integrated Tariff (TARIC) which provides information on **all trade policy and tariff measures** applicable to specific goods in the EU (e.g. temporary suspension of duties, antidumping duties, etc). It comprises the eight-digit code of the combined nomenclature plus two additional digits (TARIC subheadings).

The CN document is updated and published every year, and the latest version can be found on the European Commission's website.

U.S. exporters should consult "The Integrated Tariff of the Community", referred to as TARIC (Tarif Intégré de la Communauté), to identify the various rules which apply to specific products being imported into the customs territory of the EU.
The TARIC can be searched by country of origin, Harmonized System (HS) Code, and product description on the interactive website of the Directorate-General for Taxation and the Customs Union. The online TARIC is updated daily.

Key Link: TARIC

Import Requirements & Documentation

The TARIC (Tarif Intégré de la Communauté), described above, is also available to help determine if a license is required for a particular product. Moreover, the European Commission maintains an export to the EU Trade Helpdesk where information can be found using HS codes to determine potential requirements, tariffs, the EU market's import rules, and taxes among other information. Be aware that the EU Trade Helpdesk does not provide information for exports from the United States to the EU. With care, using a similar North American country such as exporting from Canada, an approximation of key requirements can be determined as a starting point using your most current HS code.

For information relevant to member state import licenses, please consult the relevant member state Country Commercial Guide: EU Member States' Country Commercial Guides EU Member States' Country Commercial Guides

Import Documentation

The Single Administrative Document

The official model for written declarations to customs is the Single Administrative Document (SAD). This form describes goods and their movement around the world and is essential for trade outside the EU or trade of non-EU goods. Goods brought into the EU customs territory are, from the time of their entry, subject to customs supervision until customs formalities are completed. Goods are covered by a Summary Declaration which is filed once the items have been presented to customs officials. The customs authorities may, however, allow a period for filing the Declaration which cannot be extended beyond the first working day following the day on which the goods are presented to customs.

The Summary Declaration is filed by:

- the person who brought the goods into the customs territory of the Community or by any person who assumes responsibility for carriage of the goods following such entry; or
- the person in whose name the person referred to above acted.

The Summary Declaration can be made on a form provided by the customs authorities. However, customs authorities may also allow the use of any commercial or official document that contains the specific information required to identify the goods. The SAD serves as the EU importer's declaration. It encompasses both customs duties and VAT and is valid in all EU Member States. The declaration is made by whoever is clearing the goods, normally the importer of record or his/her agent.

European Free Trade Association (EFTA) countries including Norway, Iceland, Switzerland, and Liechtenstein also use the SAD. Information on import/export forms is contained in Commission Delegated Regulation (EU) No. 2015/2446.

More information on the SAD can be found at:
Single Administration Document

The EU Customs Union and the Move to Use of an Electronic System

The EU customs union, in place since 1968, is a pillar of the EU's single market and vital to the free flow of goods and services across member states. In 2013, the EU adopted The Union Customs Code (UCC) which is the main legal framework for ongoing actions to modernize EU customs. Its substantive provisions went into effect in May 2016. Its goals are to 1) provide a comprehensive framework for customs rules and procedures in the EU customs territory and 2) create a paperless and fully automated customs union system.

A comprehensive framework for customs rules and procedures is needed because while customs rules are the same across the EU, member states' customs authorities have not always applied them in a consistent manner regarding customs duties and clearance creating fragmentation and additional administrative burdens. The UCC forms the basis for structural and administrative changes to customs policy, procedures, and implementation.

In addition, the UCC mandates a move to an all-electronic customs system. The system consists of 17 separate but interconnected components and was originally due to be in place by the end of 2020. While some systems are currently in place or expected to be in place by the December 2020, due to the complexity of the tasks a number of components are lagging (UCC Electronic Work Programme) and timeframes have been extended for some provisions till 2022 and others till 2025 (see Chapter 1 Article 278 UCC Consolidated Version).

Economic Operator Registration and Identification (EORI)
Since July 1, 2009, all companies established outside of the EU are required to have an EORI number if they wish to lodge a customs declaration or an Entry/Exit Summary declaration. All U.S. companies should use this number for their customs clearances. An EORI number must be formally requested from the customs authorities of the specific member state to which the company first exports. Member state customs authorities may request additional documents to be submitted alongside a formal request for an EORI number. Once a company has received an EORI number, it can use it for exports to any of the 27 EU Member States. There is no single format for the EORI number. Once an operator holds an EORI number s/he can request the Authorized Economic Operator (AEO: see below under "MRA") status, which can give quicker access to certain simplified customs procedures.

More information about the EORI number can be found at Economic Operator Identification and Registration

U.S. – EU Customs Cooperation: Since 1997, the United States and the EU have had a Customs Mutual Assistance Agreement (CMAA) on customs cooperation for matters relating to the application of customs laws. For additional information, please see Agreements with the United States

In 2012, the United States and the EU signed a Decision recognizing the compatibility of AEO (Authorized Economic Operator) and C-TPAT (Customs-Trade Partnership Against Terrorism), thereby facilitating faster and more secure trade between U.S. and EU operators. The World Customs Organization (WCO) SAFE Framework of Standards provides the global standard for AEO. AEO certification is issued by a national customs authority and is recognized by all Member States' customs agencies. As of April 17, 2017, an AEO can consist of two different types of authorization: "customs simplification" or "security and safety." The former allows for an AEO to benefit from simplification related to customs legislation, while the latter allows for facilitation through security and safety procedures. Shipping to a trader with AEO status could facilitate an exporter's trade as its benefits include expedited processing of shipments, reduced theft/losses, reduced data requirements, lower inspection costs, and enhanced loyalty and recognition. Under the revised Union Customs Code, in order for an operator to make use of certain customs simplifications, the authorization of AEO becomes mandatory.

The United States and the EU recognize each other's security certified operators and will take the respective membership status of certified trusted traders favorably into account to the extent possible. The favorable treatment provided by the Decision will result in lower costs, simplified procedures and greater predictability for transatlantic business activities. It officially recognizes the compatibility of AEO and C-TPAT programs, thereby facilitating faster and more secure trade between U.S. and EU operators. The Decision was originally signed in May 2012 and was implemented in two phases. The first commenced in July 2012 with U.S. Customs and Border Protection (CBP) placing shipments coming from EU AEO members into a lower risk category. The second phase took place in early 2013, with the EU re-classifying shipments coming from C-TPAT members into a lower risk category. CBP identification numbers for foreign manufacturers (MID) are therefore recognized by customs authorities in the EU, as per Commission Delegated Regulation 2015/2446 (see above).

Key Links:

Electronic Customs Initiative
Modernized Community Customs Code Regulation
Legislation related to the Electronic Customs Initiative
Trade Helpdesk

What is Customs Valuation?

Pre-Arrival/Pre-Departure Declarations
AEO: Authorized Economic Operator
Contact Information at National Customs Authorities

Environmental Regulations – Requirements and Documentation

A key EU priority is to ensure products marketed in the region are safe for the environment and human health. U.S. manufacturers exporting to the European Union need to ensure their products meet these requirements to enter the market.

New Initiatives: European Green Deal & Circular Economy Action Plan II

On December 11, 2019, Commission President Ursula von der Leyen presented the European Green Deal. The goal of this policy and legislative program is to transform Europe into a climate neutral society by 2050. The European Green Deal affects all aspects of the European economy including agriculture, construction, finance and manufacturing.

The Communication "A new Circular Economy Action Plan For a cleaner and more competitive Europe" (CEAP II) sets out Commission's product policy within the European Green Deal. The CEAP II succeeds the 2014 Communication "Towards a circular economy: A zero waste program for Europe" and implements the European Green Deal. When implementing the CEAP II, the European Commission will promote legislation and other measures that encourage a wholistic assessment of a product's environmental footprint at the design phase of development. One legislative instrument the European Commission is looking to achieve this objective is the EU Ecodesign Directive. It will also look at other instruments including the EU Ecolabel and REACH.

Batteries

The EU Battery Directive adopted in 2006 applies to all batteries and accumulators placed on the EU market. This includes automotive, industrial and portable batteries. The Directive seeks to protect the environment by restricting the sale of batteries and accumulators that contain mercury or cadmium (with an exemption for emergency and alarm systems, medical equipment and cordless power tools) and by promoting a high level of collection and recycling. It places the responsibility on producers to finance the costs associated with the collection, treatment, and recycling of used batteries and accumulators. The Directive also includes provisions on the labeling of batteries and their removability from equipment. The European Commission publishes a FAQ document to assist interested parties in interpreting its provisions. The Directive was recently evaluated and the report was published in April 2019. A legislative proposal revising the EU Battery Directive is expected to be tabled in the fourth quarter of 2020 likely October. The revision will "notably encompass end-of-life and sustainability requirements".

Registration, Evaluation and Authorization and Restriction of Chemicals (REACH)

REACH applies to all chemicals manufactured or imported into the EU in quantities exceeding one metric ton. The regulation entered into force in 2007 (Regulation 1907/2006) and touches virtually every industrial sector, from automobiles to textiles. REACH imposes a registration obligation on all entities affected by the one metric ton. The European Chemicals Agency (ECHA) is the agency responsible for receiving and ensuring the completeness of such registrations. U.S. companies without a presence in Europe need to rely on an EU-based partner, typically either an importer or a specialized 'Only Representative'. ECHA will issue a registration number to any company that submits a complete registration dossier.

In addition to the registration requirement, REACH allows the European Commission to monitory, restrict or prohibit the use of hazardous substances and products containing such substances. The 'Candidate List' of Substances of Very High Concern (SVHCs) identifies substances the European Commission intends to restrict or prohibit in the EU. Under certain conditions, companies must notify ECHA when they export products containing Candidate List substances. The 'Authorization List' identifies substances that require a company to obtain permission from the European Commission to import into the EU. Lastly, the 'Restriction List' contains a list of substances that are subject to specific controls within the EU. U.S. exporters can find each list below.

Candidate List.

Authorization List

Restriction List

Classification, Labelling and Packaging of Hazardous Substances (CLP)

The CLP regulation (Regulation 1272/2008) implements the UN Global Harmonized System of classification, labelling and packaging of all hazardous substances. U.S. exporters must classify, label and package (including products containing such substances) hazardous substances according to the regulation's requirements. For certain hazardous substances, the European Commission will impose a common classification. Such a classification may affect EU demand for these substances. It may also trigger controls on product specific legislation. U.S. exporters can find the CLP regulation and the substances subject to common classification below.

CLP Regulation

Waste Electrical and Electronic Equipment (WEEE) Directive

EU rules on WEEE, while not requiring specific customs or import paperwork, may entail a financial obligation for U.S. exporters. The Directive requires U.S. exporters to register relevant products with a national WEEE authority or arrange for this to be done by a local partner. It also requires manufacturers to inform the consumer that their product should be recycled by including the "crossed out wheelie-bin" symbol on the product or with the packaging. (See the section entitled "Mandatory Marks and Labels" for more information.) The WEEE Directive was revised on July 4, 2012 and the scope of products covered was expanded to include all electrical and electronic equipment. U.S. exporters seeking more information on the WEEE Directive should visit the Commission's website here. There is additional information about the WEEE Directive in the Labeling/Marking Requirements section.

Restriction on Hazardous Substances in Electrical and Electronic Equipment (RoHS)

The ROHS Directive (Directive 2017/2102) imposes restrictions on the use of certain chemicals in electrical and electronic equipment. The directive applies to nearly all products that require power unless a specific exclusion or exemption applies. U.S. exporters certify a product meets the requirements of this legislation by affixing a "CE Mark" to their product. The U.S. exporter must retain a product file to support the CE Mark in the event of a control. (See the section entitled "Mandatory Marks and Labels" for more information.). U.S. exporters seeking more information on the RoHS Directive should visit:

ROHS 2

EU Cosmetics Regulation

The EU legislation harmonizing the regulation of cosmetic products has applied since July 11, 2013 (Regulation 1223/2009). The most controversial element of the regulation was the introduction of an EU-wide system for the notification of cosmetic products to the European Commission prior to their placement on the EU market. Only an EU-established entity may submit such a notification. Therefore U.S. exporters must either retain a "Responsible Person" to act on their behalf, rely on the entity responsible for the import of their product into the

EU, or establish a presence in an EU Member State. U.S. exporters seeking more information on marketing cosmetic products in the EU can be found in the EU's Cosmetics Regulation.

Agricultural Documentation

Phytosanitary Certificates: Phytosanitary certificates are required for most fresh fruits, vegetables, and other plant materials.

Sanitary Certificates: For commodities composed of animal products or by-products, EU countries require that shipments be accompanied by a certificate issued by the competent authority of the exporting country. This applies regardless of whether the product is for human consumption, for pharmaceutical use, or strictly for non-human use (e.g., veterinary biologicals, animal feeds, fertilizers, research). The vast majority of these certificates are uniform throughout the EU but the harmonization process is still ongoing. Most recently, certificates for a series of highly processed products including chondroitin sulphate, hyaluronic acid, hydrolyzed cartilage products, chitosan, glucosamine, rennet, isinglass and amino acids are being harmonized. Until harmonization is finalized, certain member state import requirements continue to apply. In addition to the legally required EU health certificates, a number of other certificates are used in international trade. These certificates, which may also be harmonized in EU legislation, certify origin for customs purposes and certain quality attributes. Up-to-date information on Harmonized Import Requirements.

Sanitary Certificates (Fisheries): In April 2006, the European Union declared the U.S. seafood inspection system to be equivalent to the European one. Consequently, a specific public health certificate must accompany U.S. seafood shipments. The U.S. fishery product sanitary certificate is a combination of Commission Decision 2006/199/EC for the public health attestation and of Regulation 1012/2012 for the general template and animal health attestation. Unlike for fishery products, the U.S. shellfish sanitation system is not equivalent to that of the EU's. The EU and the United States are currently negotiating a veterinary equivalency agreement on shellfish. In the meantime, the EU still has a ban in place (since July 1, 2010), that prohibits the import of U.S. bivalve mollusks, in whatever form, into EU territory. This ban does not apply to wild roe-off scallops.

The U.S. competent authority for issuing sanitary certificates for fishery and aquaculture products is the U.S. Department of Commerce, National Marine Fisheries Service (NOAA-NMFS).

In addition to sanitary certificates, all third countries wishing to export fishery products to the EU are requested to provide a catch certificate. This catch certificate certifies that the products in question have been caught legally.

For detailed information on import documentation for seafood, please contact the NOAA Fisheries office at the U.S. Mission to the EU (stephane.vrignaud@trade.gov) or visit the following NOAA dedicated website

Labeling/Marking Requirements

Summary

There is a broad array of EU legislation pertaining to the marking, labeling, and packaging of products in the EU. This overview is meant to provide the reader with a general introduction.

Introduction

The first step in investigating the marking, labeling, and packaging legislation that might apply to a product entering the EU is to draw a distinction between what is mandatory and what is voluntary. Decisions related to mandatory marking, labeling, and/or packaging requirements may sometimes be left to individual Member States. Furthermore, voluntary marks and/or labels are used as marketing tools in some EU Member States. This report is focused primarily on the mandatory marks and labels seen most often on consumer products and packaging, which are typically related to public safety, health, and/or environmental concerns. It also includes a brief overview of a few mandatory packaging requirements, as well as more common voluntary marks and/or labels used in EU markets.

It is also important to distinguish between marks and labels. A mark is a symbol and/or pictogram that appears on a product or its respective packaging. These range in scope from signs of danger to indications of methods of proper recycling and disposal. The intention of such marks is to provide market surveillance authorities, importers, distributors, and end-users with information concerning safety, health, energy efficiency and/or environmental issues relating to a product. Labels, on the other hand, appear in the form of written text or numerical statements, which may be required but are not necessarily universally recognizable. Labels typically indicate more specific information about a product, such as measurements, or an indication of materials that may be found in the product (such as in textiles or batteries).

Overview

Mandatory Marks & Labels

- Automotive
- Cosmetics
- Dangerous Substances
- Electrical & Electronic Equipment
- Energy Efficiency
- Explosive Atmosphere
- Food related
- Footwear
- Household Appliances
- Maritime
- Measuring instruments
- Noise Emissions
- Pricing
- Pyrotechnics

- Recycling - Separate Collection
- Tire labeling
- Textiles
- Units of Measurement
- Wood packaging

Voluntary Marks and Labels

- Cup/Fork Symbol (material in contact with food)
- 'e' Mark
- Eco-Label
- Green Dot
- Recycling Marks

Voluntary and mandatory marks and labels apply to all Member States of the EU, countries in the European Economic Area, European Free Trade Association, as well as candidate countries seeking membership to the EU.

Mandatory marks and labels

CE MARKING
This is probably the most widely used and recognized marking required by the EU. Found in all "New Approach" legislation with a few exceptions, the CE marking demonstrates that a product meets all essential requirements (typically related to safety, health, energy efficiency and/or environmental concerns) of applicable EU regulations. CE marking is required for the following products/product families:

- Cableway installations
- Civil explosives
- Construction products
- Electrical/electronic products
- Electromagnetic compatibility
- Low voltage
- Restriction of Hazardous Substances (RoHS)
- Energy efficiency
- Equipment and protective systems in potentially explosive atmospheres (ATEX)
- Gas appliances
- Hot water boilers
- Lifts
- Machinery

- Medical devices (3)
- Non-automatic weighing instruments
- Personal protective equipment
- Pressure equipment
- Pyrotechnics
- Radio equipment
- Recreational crafts
- Refrigeration appliances
- Simple pressure vessels
- Toys

Not all products must have the CE mark. Only products that fall under the regulations or directives for the categories above have the CE Mark. It is forbidden to use the CE mark on other products (such as cosmetics or chemicals). The CE mark does not indicate that the product has been approved by authorities. It is a declaration by the manufacturer that the product meets all EU legal requirements. CE marked products can be sold in all EU countries and the European Economic Area.

Note: Some Important Changes: The EU is currently finalizing new legislation that will impact CE marking for medical devices. The new regulations have a transition period with the new measures coming into force in May 2021 for medical devices and 2022 for in-vitro medical devices. In addition, the legislation covering the CE Mark for Machinery is undergoing revision. Machinery in the EU is broadly defined as consisting of an assembly of components, at least one of which moves, for a specific application. The drive system of machinery is powered by energy other than human or animal effort. The Machinery Directive revision is expected by the second quarter 2021. Finally, various articles of the Radio Equipment Directive are undergoing revision in 2020. Changes are expected to affect radio equipment with software uploaded after placing the equipment on the market, the security of internet-connected devices (the Internet of Things), and wearable radio equipment among others.

Important! **Starting on 16 July 2021, all CE marked products will need to have an EU address on the label.** This also applies to products sold on-line. The name and address must appear on the product or its packaging so that Customs and market surveillance authorities can have a contact person in case the product is suspected to present a risk. If your importer or distributor cannot play that role, you will have to appoint an Authorized Representative in the EU or use a shipping platform to play that role (see page 67).

Click here for more information on the CE Mark.

AUTOMOTIVE

The e Mark is an EU mark for approved vehicles and vehicle components. It is a type-approval given by a national certifying authority. The certifying body issues an e-marking certificate after inspection and approval of compliance. The number shown in the rectangle on the label indicates the Member State in which the approval process was conducted. A "base approval number" must also be provided adjacent to this certification. This four-digit number will correspond to the directive and type of device in question. The country-number correlation is as follows (this is not an exhaustive list):

1	Germany	6	Belgium	18	Denmark
2	France	9	Spain	21	Portugal
3	Italy	11	UK	23	Greece
4	Netherlands	13	Luxembourg	24	Ireland

For more information:
All existing directives on motor vehicles, in chronological order, available online at:

Existing Motor Vehicles Directives

Photometry

A similar marking is an 'E' surrounded by a circle, which applies to the testing of headlight lamps, brake light lamps and turning signal lamps of all vehicles seeking EU market entry. These include consumer vehicles, low-volume production trucks, light and heavy goods vehicles, trailers, motorcycles, cranes, agriculture and forestry tractors, and special-purpose and off-road vehicles. The number is the country number and in this case E4 refers to the Netherlands.

For more information:

Automotive Legislation

COSMETICS
Containers and/or packaging (in certain cases) must have the following:

- The name, trade name and address, or registered office, of the manufacturer or person responsible for marketing the cosmetic product within the Community
- The nominal contents at the time of packaging (by weight or volume)
- The date of minimum durability indicated by "Best before end", for products with a minimum durability of less than 30 months. In this case the following must figure on the packaging:

- The period after opening during which the product can be used without harm to the consumer, for products with a minimum durability of less than 30 months (indicated by a symbol representing an open cream jar, as shown below):

- Particular precautions for use
- The batch number or product reference, for identification
- The product's function

If it is impossible for practical reasons to print on the packaging all the conditions of use and warnings, an enclosed leaflet, label, or tape must be provided and the following symbol has to be on the packaging:

The Member States are to draw up procedures for providing the information set out above in the case of cosmetic products that have not been pre-packaged. The product function and list of ingredients also have to appear on the container or packaging. Member States may stipulate that the information on the label is provided in their national or official language(s).

About the labeling of nanomaterials present in cosmetics:

The Cosmetics Regulation indicates that from July 2013 "all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients" and that "the names of such ingredients shall be followed by the word 'nano' in brackets".

For more information

Regulation 1223/2009

DANGEROUS SUBSTANCES

Regulation on the Classification, Labeling and Packaging of Chemicals

The labeling of dangerous substances must indicate the following:

- The name of the substance
- The origin of the substance (the name and address of the manufacturer or distributor)
- The danger symbol and an indication of danger involved in the use of the substance
- A reference to the special risks arising from such dangers.

The dimensions of the label must not be less than a standard A8 sheet (52 x 74mm), and each symbol must cover at least one-tenth of the label's surface area. Member States may require their national language(s) to be used in the labeling of dangerous substances. Where the packaging is too small, the labeling may be affixed in some other manner. The packaging of products considered dangerous which are neither explosive nor toxic may go unlabeled if the product contains such small quantities of dangerous substances that there is no danger to users.

Symbols must be employed if the substance can be defined as any one of the following (as shown above): explosive, oxidizer, flammable, harmful, toxic irritant, corrosive, or harmful to environment. Containers of hazardous substances should include, in addition to the appropriate symbols, a raised triangle to alert the vision-impaired to their contents. Note that this directive has undergone numerous amendments relating, amongst other things, to the marking and labeling of additional substances. Accordingly, it is advisable to consult all literature.

Regulation 1272/2008 implements the classification, labeling and packaging requirements for chemicals based on the Worldwide United Nation's Globally Harmonized System (UN GHS).

For more information

Regulation 1272/2008/EC on the classification, labeling and packaging

THE WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT DIRECTIVE (WEEE)

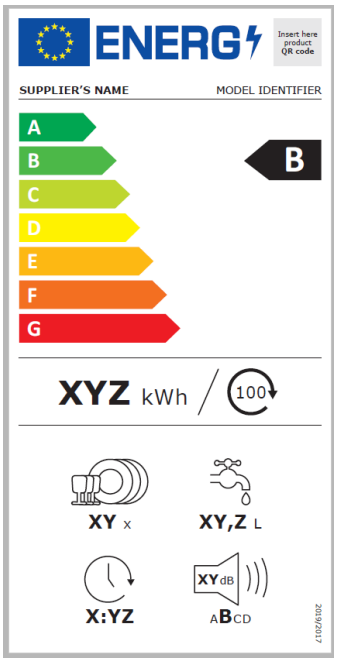
The WEEE directive (Directive 2012/19/EU) is designed to tackle the rapidly increasing waste stream of electrical and electronic equipment and complements European Union measures on landfills and waste incineration. It also impacts the design of products in order to reduce material use and facilitate reuse and recycling. It sets collection, recycling and recovery targets for all types of electrical and electronic equipment. Businesses have to check requirements for the EU member state to which the product is imported. Depending on the country and quantities placed on the market, The person responsible for placing the product on the market will have to register with authorities, join a producer compliance scheme, or set up an individual one to meet their take-back and recycling obligations.

The wheel-bin symbol indicates that the product is not to be discarded with normal household waste. In instances where this symbol cannot be displayed on the equipment itself, it should be included on the packaging. There is additional information about the WEEE Directive in the Import Requirements & Documentation section.

For more information

Directive 2012/19/EU
FAQs for the WEEE Directive
National WEEE registers

ENERGY LABELING



Energy labels show how appliances rank on a scale from A (green), the most energy efficient, to G (red) according to their energy consumption. These labels apply to different categories of household appliances including air conditioners, refrigerators, televisions, washing machines, space heaters, and solid fuel boilers among others. Regulation 2017/1369 on energy labeling). They are meant to help consumers choose the less energy consuming products and promote product eco-design. As of March 1, 2021, new energy labels will include QR cods that consumers can scan with smartphones. In order to facilitate the energy label use, the EU maintains a site for generating energy labels.

Since January 1, 2019 manufacturers, importers, and authorized representatives of non-EU manufacturers have to register all products requiring energy labels in EPREL, the European Product Database for Energy Labeling which will be available to EU consumers:

For more information
Information on Energy Label and Eco-Design

DEVICES FOR USE IN POTENTIALLY EXPLOSIVE ATMOSPHERE (ATEX)

In addition to applying a CE marking for products falling under the ATEX Directive (2014/34/EC), which defines essential health and safety requirements and conformity assessment procedures of equipment or protective systems intended for use in potentially explosive atmospheres (offshore platforms, mines, etc.), it is necessary to

display the Ex mark, which is a specific marking for hazardous location equipment showing compliance with the ATEX directive. Located next to the 'Ex' mark will be a symbol designating the product group or category as specified in the directive.

For more information

More Information on ATEX Directive 2014/34/EU

FOOD RELATED: **DO NOT EAT SYMBOL**

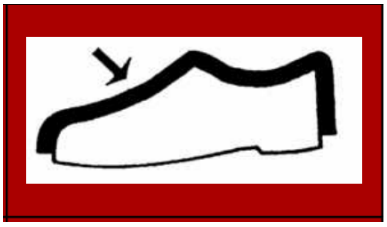
The regulation on active and intelligent materials and articles which comes in contact with food contains additional rules on labelling. One of these rules is the following:

To allow identification by the consumer of non-edible parts, active and intelligent materials and articles or parts thereof shall be labelled, whenever they are perceived as edible:
(a) with the words 'DO NOT EAT'; and
(b) always where technically possible, with the symbol reproduced in Annex I.

For more information

Article 11 of Regulation (EC) No 450/2009:

FOOTWEAR



Directive 94/11/EC covers labelling for the materials used in footwear, including parts sold separately, and rules regarding labeling. Labels must convey information relating to the upper part of the shoe (see logo), the lining and insole sock, and the outer-sole of the footwear article. The information must be conveyed by means of approved pictograms or textual information, as defined by the directive.

The label must be legible, firmly secured and accessible, and the manufacturer or the authorized representative established in the Community is responsible for supplying the label and for the accuracy of the information contained therein. Only the information provided for in the directive need be supplied. There are no restrictions preventing additional information being included on the label.

For more information
Footwear

MARITIME

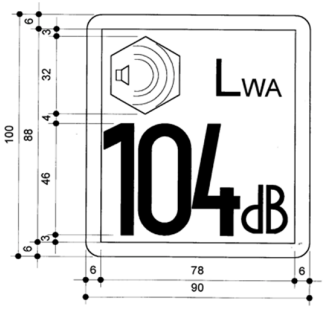
The "steering wheel" mark shown above is the equivalent of CE marking for marine equipment. It applies to equipment for use on board any new EU ship, wherever the ship is situated at the time of construction, and to equipment placed on board existing EU ships, whether for the first time or to replace equipment already carried on board. It does not apply to equipment already on board on the date on which the directive entered into force in 1997. The directive applies to the following equipment categories:

- Life-saving appliances
- Marine pollution prevention
- Fire protection
- Navigation equipment
- Radio-communication equipment

A revised Marine Equipment Directive (2014/90/EC) was adopted in July 2014 and is applicable since September 18, 2016.

For more information
Directive 2014/90/EC

NOISE EMISSION OF OUTDOOR EQUIPMENT



Machines used outdoors are subject to CE marking requirements in line with the Outdoor Noise Directive (2000/14/EC). Along with the CE mark, products which fall under the Directive must also have marking indicating the "Guaranteed Sound Power Level" (see above).

For more information see Noise Emissions

PACKAGING RECYCLING

The Mobius Loop: The "mobius loop" (sometimes known as the "chasing arrows"), based on an international standard, may be found on products throughout Europe and indicates that the product can be recycled. As well as being used on printed packaging, the chasing arrows symbol is sometimes featured in the molds of glass, metal, paper, or plastic products.

For more information

European Commission/Environment/Waste

The Mobius Loop with a number at the center and a letter code indicates the kind of plastic the packaging is made from. The symbol above is an example of how a plastic's type may be indicated on a product. As part of the EU voluntary identification system for plastics, the following marks are used for the most common types of plastics (Decision 97/129/EC):

EU Number	Abbreviated Description	Full Plastic Description
1	PET	Polyethylene Terephthalate
2	HDPE	High Density Polyethylene
3	PVC	Poly Vinyl Chloride
4	LDPE	Low Density Polyethylene
5	PP	Polypropylene
6	PS	Polystyrene

For more information see the European Strategy for Plastics

Glass

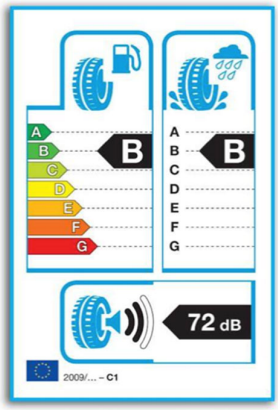
There are no EU-wide symbols used to designate the recyclable nature of glass. However, it is certainly encouraged on the national level with an array of symbols. The one shown above is just one small sample of the total existing to show recyclability.

TEXTILES

Textile products must be labeled or marked whenever they are put on the market for production or commercial purposes (sale). The names, descriptions and details of a textile's fiber content must be indicated on products available to consumers. With the exception of trademarks or the name of the undertaking, other types of required information must be listed separately. Member States may require that their national language be used on the labeling. Marking required by the regulation (1007/2011/EU) include textile fiber names, related labelling, and marking of the fiber composition of textile products.

For more information
Textiles Legislation

TYRE ENERGY LABELING



Tire label legislation requires that tire manufacturers declare fuel efficiency, wet pavement grip, and external rolling noise performance of C1, C2 and C3 tires (i.e. tires mainly fitted on passenger cars, light, and heavy-duty vehicles). The energy efficiency class ranges from A (most efficient) to G (least efficient). The wet grip class ranges from A (shorter braking distance on wet asphalt) to G (longest). The external noise class ranges from A (less noise outside the vehicle) to B (Regulation (EC)N. 1222/2009). The objective of the regulation is better information for the consumer and a contribution to a more energy efficient transport policy.

For more information:
Directive 1222/2009/EC
Directive 228/2011/EC (wet grip testing method for C1 Tires)

UNITS OF MEASUREMENT (METRIC)

The use of units of measurement in the EU is set down in the EU Metric Directive (Directive 80/181/EEC). The original EU Metric Directive (80/181/EEC), that went into effect on January 1, 2010, was modified to allow the continuation of both supplemental (U.S. customary, inch-pound) and metric units for consumer goods sold in the EU. The rule was published on May 7, 2009 in the Official Journal of the European Union. This modified Directive instructs the European Commission to produce a report to the EU Parliament and Council regarding the smooth functioning of the internal market and international acceptance of SI units by December 31, 2019. Based on this report the directive may be open for future revision.

In the same sphere as the EU Metric Directive, the EU pre-packaging legislation (Directive 76/211/EEC) specifies permissible ranges of nominal quantities, container capacities and the weights or volumes of prepackaged products. It helps guarantee the net quantity in prepacks and the volume of product in bottles. Manufacturers are advised to take note that all labels require metric units, although dual labeling is also acceptable. The e-mark is referred to as the estimated sign, ⟨e⟩, which also refers to the e-mark or *quantité estimée* and acts as a metrological "passport" to facilitate the free movement of prepackaged goods. It guarantees that certain liquids and other substances have been packed by weight or volume in accordance with the directives. While compliance is not mandatory, free movement throughout the EU is guaranteed for prepackaged products that do comply with the provisions of the directive.

Containers with an e-mark also bear an indication of the weight or volume of the product, known as its “nominal” weight or volume. The packer (or importer, if the container is produced outside the EU) is responsible for ensuring that the containers meet the directive’s requirements.

For more information
Prepackaging
Legal Metrology

Voluntary marks and labels

CUP/FORK SYMBOL: MATERIALS IN CONTACT WITH FOOD

Manufacturers of containers, plates, cups, and other material that is intended to come into contact with food are required to check the compliance of their product with EU chemical safety requirements. Using the symbol shown above shows compliance with these requirements. It is mandatory to comply with the legislation, but the use of the symbol is voluntary.

For more information

Legislation on Food Contact Materials

THE ECO-LABEL

The European Eco-label enables European consumers, including public and private purchasers, to easily identify officially approved green products across the European Union, Norway, Liechtenstein and Iceland. Introduced in 1992, the label communicates to the customer that the marked products meet specific eco-friendly criteria that have been developed to apply to everyday consumer goods and services. It is a voluntary mark but it can help open new business opportunities, particularly with the expansion of green public procurement in Europe.

The symbol may apply to approximately 25 product and services groups including cleaning products, electronic equipment, household equipment or gardening. See the Ecolabel product catalogue on How to apply for the EU Ecolabel. Manufacturers should be aware that similar eco-friendly markings are often used nationally, such as the Nordic Swan or the German Blue Angel.

GREEN DOT

The Green Dot system is a scheme in which participating bodies coordinate the collection, sorting, and recovery of used packaging. This system is administered according to national packaging laws (adhered to by packaging manufacturers, fillers, retailers and importers), and it should be noted that all participating national systems operate independently. The umbrella organization, PRO-Europe, is responsible for managing the Green Dot labeling system in Europe. Interested applicants should contact one of the national administering authorities.

For more information

Pro Europe

U.S. Export Controls

The United States imposes export controls to protect national security interests and promote foreign policy objectives. BIS's Export Enforcement (EE) is responsible for the enforcement of the EAR. BIS works closely with U.S. embassies, foreign governments, industry, and trade associations to ensure that exports from the United States are secure. In accordance with the EAR, BIS officials conduct site visits, also known as End-Use Checks (EUCs), globally with end-users, consignees, and/or other parties to transactions involving items subject to the EAR, to verify compliance.

An EUC is an on-site verification of a party to a transaction to determine whether it is a reliable recipient of U.S. items. EUCs are conducted as part of BIS's licensing process, as well as its compliance program, to determine if items were exported in accordance with a valid BIS authorization or otherwise consistent with the EAR. Specifically, an EUC verifies the *bona fides* of recipient(s) of items subject to the EAR, to include: confirming their legitimacy and reliability relating to the end use and end user; monitoring their compliance with license conditions; and ensuring such items are used and/or re-exported or transferred (in-country) in accordance with the EAR.

BIS officials rely on EUCs to safeguard items subject to the EAR from diversion to unauthorized end uses/users. The verification of a foreign party's reliability facilitates future trade, including pursuant to BIS license reviews. If BIS is unable to verify the reliability of the company or is prevented from accomplishing an EUC, the company may receive, for example, more regulatory scrutiny during license reviews or be designated on BIS's Unverified List or Entity List, as applicable.

BIS has developed a list of "red flags", or warning signs, intended to discover possible violations of the EAR. Also, BIS has "Know Your Customer" guidance.

BIS provides a variety of training sessions to U.S. exporters throughout the year. These sessions range from one to two-day seminars and focus on the basics of exporting as well as more advanced topics.Check a list of upcoming seminars and webinars.
BIS also provides online training.

The EAR does not regulate transactions involving all U.S. goods, services, and technologies. Other U.S. Government agencies regulate more specialized exports. For example, the U.S. Department of State's Directorate of Defense Trade Controls has authority over defense articles and services. A list of other agencies involved in export control can be found on the BIS website or in Supplement No. 3 to Part 730 of the EAR. The EAR is available on the BIS website and on the e-CFR (Electronic Code of Federal Regulations).

The Consolidated Screening List (CSL) is a list of parties for which the United States Government maintains restrictions on certain exports, reexports or transfers of items. The CSL consolidates a number of smaller lists of restricted parties that are maintained by a variety of U.S. Government agencies, including the Department of Commerce, as an aid to industry in conducting electronic screens of potential parties to regulated transactions.

Temporary Entry

Specific information on the ATA Carnet Customs procedure used for temporary importation, transit and temporary admission of goods designed for specific purposes, duty-free and tax-free (such as professional equipment for presentations or trade fairs).

For information on this topic please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides.

Prohibited & Restricted Imports

The Tarif Intégré de la Communauté (TARIC) is designed to show various rules applying to specific products being imported into the customs territory of the EU or, in some cases, when exported from it. To determine if a product is prohibited or subject to restriction, check the TARIC for the following codes:

CITES Convention on International Trade of Endangered Species
PROHI Import Suspension
RSTR Import Restriction
For information on how to access the TARIC, see the Import Requirements and Documentation Section.

Key Link: Taxation Customs and Tariffs

Customs Regulations

The following provides information on major regulatory efforts of the EC Taxation and Customs Union Directorate:

The Union Customs Code (UCC) was adopted in 2013 and its substantive provisions apply from 1 May 2016. It replaces the Community Customs Code (CCC). In addition to the UCC, the European Commission has published delegated and implementing regulations on the actual procedural changes. These are included in Delegated Regulation (EU) 2015/2446, Delegated Regulation (EU) 2016/341 and the Implementing Regulation (EU) 2015/2447.

There are a number of changes in the revised customs policy which also require an integrated IT system from the customs authorities. In April 2016, the European Commission published an implementing decision (number: 2016/578) on the work program relating to the development and deployment of the electronic systems of the UCC. In March 2018, the EC published a proposal (EU) No 2018/0040 for a draft regulation amending Regulation (EU) No 952/2013 to prolong the transitional use of means other than the electronic data-processing techniques provided for in the Union Customs Code. The EC continues to evaluate the timeline by which the EU-wide integration of the customs IT system can be implemented. The current deadline of December 2020 may be extended until 2025 (Proposed Regulation)

Key Link: Homepage of Customs and Taxation Union Directorate (TAXUD) Website

Customs Valuation – Most customs duties and value added tax (VAT) are expressed as a percentage of the value of goods being declared for importation. Thus, it is necessary to dispose of a standard set of rules for establishing the goods' value, which will then serve for calculating the customs duty.

Given the magnitude of EU imports every year, it is important that the value of such commerce is accurately measured for the purposes of:

- economic and commercial policy analysis;
- application of commercial policy measures;
- proper collection of import duties and taxes; and
- import and export statistics.

These objectives are met using a single instrument - the rules on customs value.
The EU applies an internationally accepted concept of 'customs value'.
The value of imported goods is one of three 'elements of taxation' that provides the basis for assessment of the customs debt, which is the technical term for the amount of duty that has to be paid, the other ones being the origin of the goods and the customs tariff.

Key Link: Customs Procedures

EU Legislation and CE Marking

Many products require the **CE Mark** before they can be sold in the EU (see page 48). The CE Mark indicates that a product has been assessed by the manufacturer and meets the essential health and safety requirements enshrined in what are commonly considered the CE Mark Directives and Regulations. These directive and regulations are legislative acts adopted by the EU as a whole and are considered to be "harmonized", which means that they apply across all EU member states and are mandatory. (Note however member states can have additional requirements in some cases). In order to attest that a product fulfills these harmonized EU essential health and safety requirements and qualifies for the CE Mark, manufacturers must create a technical file which documents how the product meets the directive or regulation requirements (generally through testing, design, and risk assessments). Each CE Mark directive or regulation determines how hazardous the product category is considered. For some less hazardous products, the testing and risk assessment (also called conformity assessment) may be done by the manufacturer themselves. In this case the manufacturer would assemble the "technical file" which will document how the product meets the essential health and safety requirements of the specific CE Mark directive or regulation. The manufacturer then issues themselves a declaration of conformity (DOC). It is this self-DOC which allows them to then affix the CE Mark to their product. The DOC is self-declared on the product and market surveillance organizations in the EU can and do call upon the manufacturer to produce the technical file that backs up the DOC. Where the product is considered more hazardous, third party testing is mandated, and certificates of conformity are issued by an EU approved third party testing organization called a Notified Body. The Nando database should be searched for a notified body which can certify specific products. The Blue Guide is an official, but non-legal EU document, which has an exhaustive discussion of the process and background to understanding compliance with harmonized legislation. Note that a product cannot be retroactively given a CE Mark DOC whether self-determined or determined through third party testing. The product must be CE Marked before being put or "placed" on the EU market. There is no official process to remedy the lack of a CE Mark once a product enters the EU.

Bear in mind that testing and certification to U.S. standards for the U.S. market is generally not sufficient for exporting to the EU. However, since EU legislation harmonizes mandatory requirements for product safety of CE marked products throughout the European Union, a manufacturer only needs to go through the process of determining compliance once and can then export to all 27 EU member states. With appropriate certification, goods travel freely within the borders of the Single Market.

Where products are not regulated by specific EU technical legislation (whether CE Marked or not), they are always subject to the EU's General Product Safety Directive as well as to possible additional national requirements.

CE Marking Step-by-Step

1. Find the applicable directive (legislation)

2. Determine the essential requirements in the directive (usually Annex I)

3. Note the harmonized European EN standards

4. Choose the appropriate conformity assessment module as described in the directive's annexes

5. Locate Notified Bodies (accredited test laboratories) – *if required*!

6. Create a Technical File and Declaration of Conformity and apply CE marking

Contact the U.S. Commercial Service at the U.S. Mission to the EU for more information or email office.brusslesEC@trade.gov
For an overview of EU product safety
Consider working with consultants

New requirements for CE marked products:

Going into force on July 16, 2021, the new EU Regulation on Market Surveillance and Product compliance (Regulation (EU) 2019/1020) (commonly called the "Goods Package") will bring important changes to market surveillance in the EU for more than 70 EU product laws and for product compliance for 20 categories of CE marked products. Some of these changes include reinforced controls at the border, new responsibilities for shipping platforms, new requirements for products sold online, and, most importantly for U.S. exporters, the mandatory appointment of a Responsible Person/Economic Operator based in the EU for certain products covered under Article 4 of the directive. The product categories affected under Article 4 of this directive include most of the CE Marked products. There is no small business, minimum value, or quantity exception for third country products placed on the EU market. Therefore, depending on the guidance to be released, a U.S. exporter would need to have a designated Responsible Person/Economic Operator based in the EU for the sale of even one item into the EU.

The mandatory Responsible Person/Economic Operator will be responsible, at a minimum, for ensuring the availability of the conformity documentation, cooperating with market surveillance authorities, and informing authorities when they have reasons to believe that a product presents a risk. Guidance for the application of Article 4 of the directive is expected to be published in late 2020.

The following CE marked product categories may be placed on the EU market only if a Responsible Person/Economic Operator established in the EU is appointed:
Construction products, Personal Protective Equipment, Machinery, Electrical and Electronic Equipment ('ROHS, EMC, Low Voltage'), Toys, recreational crafts, radio equipment, energy-related products ('Ecodesign'), gas appliances, outdoor equipment ('outdoor noise'), equipment for use in potentially explosive atmospheres ('ATEX'), pressure equipment, simple pressure vessels, pyrotechnic articles, measuring equipment, non-automatic weighing instruments.

The economic operator or 'EU Responsible Person' can be a manufacturer in the EU, the EU importer, an authorized representative appointed by the Manufacturer, or a fulfilment service provider. Whichever the option chosen, the name and address of this EU-based representative must appear on the product or packaging so that customs or market surveillance authorities can have a contact person in the EU in case the product presents a risk. This also applies to products sold on-line. Guidelines on the new regulation are expected in the fall 2020.

EU market surveillance authorities are under no legal requirement to notify the U.S. manufacturer or exporter when their product is considered a potential risk. They are required only to notify the EU responsible person or economic operator. Timing to respond to a market surveillance inquiry typically starts when the EU responsible person/economic operator is notified. Thus, it is important that any agreement with the U.S. exporter's chosen EU responsible person/economic operator specify the timeframe for notifying the U.S. exporter. Failure to respond in a timely manner can result in a product notification to the EU's product recall system which would preclude that product from the EU market.

Regulation on market surveillance and compliance of products
List of National Authorities Responsible for Product Safety
Safety Gate

Frequently Asked Questions:

Where do I find EU product legislation?
Under industry sectors on http://ec.europa.eu/growth/sectors_en

Where can I find European (EN) standards? http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en
https://standards.cen.eu/dyn/www/f?p=CENWEB:105::RESET::::
https://www.cenelec.eu/dyn/www/f?p=104:107:0::::FSP_LANG_ID:25
https://www.etsi.org/standards/get-standards#Pre-defined%20Collections

In the event that I need the services of a test laboratory – EU notified body, U.S. based subcontractor or conformity assessment body - where do I obtain a list? http://ec.europa.eu/growth/tools-databases/nando/
https://www.nist.gov/standardsgov/lists-recognized-us-cabs
https://2016.export.gov/cemark/eg_main_017274.asp

Want to understand CE marking in more detail? CE marking guidance booklet

Other Resources

CEN, European Committee for Standardization
CENELEC, European Committee for Electrotechnical Standardization
ETSI, European Telecommunications Standards Institute
ANSI, American National Standards Institute (to search for EN standards in U.S.)
European Accreditation
European Union law portal

Standards for Trade

Overview

Products tested and certified in the United States to U.S. regulations and 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.

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 which is often the case. For more on how the EU standards and regulatory system functions as a barrier to trade see page 177 in the National Trade Estimate.

In general, the harmonization of EU standards has greatly simplified technical regulation in Europe. Prior to harmonization, each country in the EU developed its own standards through their national standards body creating differing and conflicting standards, laws, and conformity assessment procedures. Thus, it became necessary to create a new, integrated, European system of standardization. The new system provided for three EU standards bodies to create standards on a Europe-wide level: (1) The European Committee for Standardization (CEN); (2) the European Committee for Electrotechnical Standardization (CENELEC); and (3) The European Telecommunications Standards Institute (ETSI). CEN/CENELEC activities are in the electrotechnical and other sectors, while ETSI specializes in telecommunications. CEN and CENELEC's principal members are member state national standards bodies. ETSI's membership has a broader range of interested parties. These three are the only recognized bodies from which a Harmonized European Standard (EN) can come. When the development of a European Harmonized Standard begins in one of these organizations, development of a national standard must stop. Harmonized Standards are standards that support European legislation. They (1) have been mandated by the European Commission, (2) have been developed by the European Standards Bodies above, (3) address essential health and safety requirements; and (4) notification of their development has been published in the Official Journal of the European Union.

Technically, the use of a Harmonized Standard is voluntary. That is, a manufacturer can elect to use a Harmonized Standard, or decide to use a non-Harmonized Standard (an American Standard, for example) to meet essential requirements. However, when using a Harmonized Standard, the manufacturer is presumed in conformity with the law (Presumption of Conformity). Specific EU harmonized standards which confer presumption of conformity are listed in the directive or regulation usually in Annex Z or ZZ. On the contrary, using a standard that is not a Harmonized Standard will impose additional responsibilities. The use of anything but an EU Harmonized Standard places a burden of proof upon the manufacturer that the product meets essential requirements. This proof may be provided by the manufacturer's Technical File, by the employment of a third party (consultant, testing house, etc.), or by a combination of the two.

In addition to the three EU standards developing organizations, the European Commission funds the participation in the standardization process of EU small- and medium-sized companies and EU non-governmental organizations, such as environmental, labor and consumer groups. The Commission also provides money to the European standards bodies when it mandates standards development for harmonized standards that will be linked to EU legislation. The Commission requests CEN/CENELEC or ESTI to develop standards - see Mandates.

There are also several European Standards (ENs) also developed by CEN, CENELEC, and ETSI that are not mandated by the Commission and which do not necessarily define essential requirements. In theory, their use is voluntary. They may define other characteristics, such as durability, appearance, quality levels, or even cultural preferences. They may be test methods, or measurement guides. These ENs often have the advantage of recognition in the European marketplace. A standard that does not emanate from one of the European Standards

Bodies is not always recognized by insurers, lending institutions, retailers, developers, market surveillance organizations, conformity assessment bodies, and consumers, and may hinder acceptance of the product in the marketplace, particularly when a well-known European Standard already exists for the same product.

Finally, 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 extends well beyond the EU's political borders to include affiliate members (countries which are hopeful of becoming full members in the future). Another category, called "companion standardization body" includes the standards organization of Morocco, Israel, Kazakhstan and Australia, among others which are not likely to become a CEN member or affiliate for political and geographical reasons.

View CEN and CENELEC's work plan for future standardization activities. Other than their respective annual work plans, CEN's "what we do" page provides an overview of standards activities by subject. Both CEN and CENELEC offer the possibility to search their respective database. ETSI's portal links to ongoing activities.

Key Link: Standardization Policy

Testing, Inspection and Certification

Conformity Assessment

Conformity Assessment is the demonstration that specified requirements relating to a product, process, system, or group are fulfilled. Conformity assessment can include: the supplier's declaration of conformity, different types of sampling and testing, inspection, certification, management system assessment and registration, the accreditation of the competence of those activities, and the recognition of an accreditation program's capability. Conformity Assessment is a mandatory step for the manufacturer in the process of complying with specific EU harmonized legislation. As mentioned above under CE Marking, EU harmonized product legislation gives manufacturers some choice regarding conformity assessment, depending on the level of risk involved in the use of their product. Certification for defined lesser risk products can be done by the manufacturer themselves by building a technical file in many cases. Higher risk products will need third party testing through accredited testing labs. Types of compliance certification ranges from self-certification, type examination and production quality control system certification, to full quality assurance system certification. In the case of CE Mark directives or regulations, each directive or regulation stipulates the processes which can be used for which products. This is usually found in an annex and called a "Module".

Modules vary in complexity. For example, Module A permits the manufacturer to assume total responsibility for conformity assessment. If the product is manufactured to Harmonized Standards, and if the risk is not unusually high (as in most machinery, for example), the manufacturer may rely on internal manufacturing checks. He or she compiles a Technical File, issues a Declaration of Conformity to the appropriate directives, and if appropriate, standards, applies the CE marking, and places the product on the market. Modules for higher risk products, for example, a medical device, on the other hand, could call for a type examination of the product plus a production

quality assurance system that conforms to the standard. Another choice for a medical device manufacturer would be a complete quality assurance program that would conform to ISO 9001 (or EN 29001) for example. These later modules may
call for the involvement of third party testing and assessment for a Declaration of Conformity. In Europe, these third parties are designated by member states' authorities, accepted by the European Commission, and are called Notified Bodies. Each directive provides the module choices available, but there are no choices beyond the modules specified.

When third party testing is required, that testing must be done by accredited member state organizations called Notified Bodies which must be domiciled in an EU27 member state. The official list of approved Notified Bodies for each EU harmonized directive/regulation is found in the EU Commission's website under NANDO.

Key Link: NANDO (the left navigation on this page allow a search by member state, by legislation, or by the name of the notified body)

The only exceptions to this EU-domiciled rule are U.S.-based organizations and test labs for products covered under U.S.-EU mutual recognition agreements (MRAs) for certain types of marine equipment, products under the Electromagnetic Compatibility MRA, and the Radio Equipment MRA.

Finally, to promote market acceptance for products in the EU, there are several voluntary conformity assessment programs. CEN and Cenelec's certification system is known as the Keymark. ETSI does not offer conformity assessment services.

Publication of technical regulations

Official Journal of the EU is the official publication of the European Union. It is published daily on the internet and consists of two series covering adopted legislation as well as case law, and studies by committees, among others. It also lists the standards reference numbers linked to legislation (Harmonized Standards).

National Institute of Standards and Technology's (NIST) Notify U.S. Service

Members of the World Trade Organization (WTO), such as the EU, are required under the Agreement on Technical Barriers to Trade (TBT Agreement) to notify to the WTO proposed technical regulations and conformity assessment procedures that could affect trade. **Notify U.S.** (www.nist.gov/notifyus) is a free, web-based e-mail registration service that captures and makes available for review and comment key information on draft regulations and conformity assessment procedures. Users receive customized e-mail alerts when new notifications are added by selected country or countries and industry sector(s) of interest and can also request full texts of regulations. This service and its associated web site are managed and operated by the USA WTO TBT Inquiry Point housed within the National Institute of Standards and Technology, part of the U.S. Department of Commerce.

Proposed EU member state technical regulations are published on the Commission's website to allow other countries and interested parties to comment.

Agricultural Standards

The establishment of harmonized EU rules and standards in the food sector has been ongoing for several decades, and in January 2002 the EU publicized 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.

There are also export guides to import regulations and standards available on the Foreign Agricultural Service's website: FAIRS Export Certificate Report

Contact Information for Standards

U.S. Mission to the EU
Flavie.Guerin@trade.gov
Tel: +32 2 811 4817

National Institute of Standard & Technology
Gordon Gillerman Standards Coordination Office 100 Bureau Dr.
Mail Stop 2100
Gaithersburg, Maryland 20899

Trade Agreements

For a list of trade agreements of the EU to other countries in the world, as well as concise explanations, please see EU Trade Agreements

U.S. – EU Trade Negotiations

In July 2018, President Trump and European Commission President Juncker issued a joint statement in Washington announcing the formation of an Executive Working Group to reduce transatlantic barriers to trade, including the elimination non-auto industrial tariffs and non-tariff barriers. In October 2018, U.S. Trade Representative officially notified Congress that the Administration intended to start negotiations following the completion of necessary domestic procedures. This began a congressionally-mandated 90-day consultation period under Trade Promotion Authority prior to the launch of negotiations and resulted in the publication of the report "United States-European Union Negotiations Summary of Specific Negotiating Objectives, January 2019" which lay out the goals and objectives of U.S. negotiations with the EU.

USTR U.S. – EU Trade Negotiations

Licensing Requirements for Professional Services

The recognition of skills and qualifications acquired by EU citizens in EU Member States, including the corresponding recognition procedures and charges are the responsibility of Member States. Similarly, recognition of skills and qualification earned in third countries is also a national responsibility

If an individual with a foreign qualification was recognized in a member state and now wants to move to another EU country and has worked for **at least 3 years** in the EU country that has first recognized the qualifications, that individual can apply for professional recognition in another EU country under the rules that apply to professionals that have received their qualification from an EU country.

To prove the necessary experience to exercise a profession, a certificate issued by the EU country that first recognized your qualifications may be needed. This applies to both **EU citizens** and **non-EU citizens**.

However, the European Commission takes the initiative to facilitate recognition procedures. For example:

- Recognition of professional qualifications obtained in one Member State for the purposes of access and pursuit of regulated professions in another Member State is subject to Directive 2005/36.
- Recognition of qualifications for academic purposes in the higher education sector, including school-leaving certificates is subject to the *Lisbon Recognition Convention*. The ENIC-NARIC network provides advice on (cross-border) recognition of these qualifications.

Recognition in other cases is assessed and granted (or denied) by the receiving educational provider or employer. An **understanding of the level, content, and quality** is needed for them to be able to recognize skills and qualifications. The Commission currently explores the possibilities on how to better support these recognition decisions.

The "Your Europe" website maintains a webpage dedicated to help citizens identify what the regulated professions are and what document are needed for their recognition in each Member State. Please see: Recognition of Professional Qualification.

Selling U.S. Products & Services

Distribution & Sales Channels

Using an Agent or Distributor to Sell U.S. Products and Services

Companies wishing to use distribution, franchising and agency arrangements need to ensure that the agreements they put into place are in accordance with EU laws and member state national laws. Council Directive 86/653/EEC establishes certain minimum standards of protection for self-employed commercial agents who sell or purchase goods on behalf of their principals. The Directive establishes the rights and obligations of the principal and its agents, the agent's remuneration, and the conclusion and termination of an agency contract. It also establishes the notice to be given and indemnity or compensation to be paid to the agent. U.S. companies should be particularly aware that according to the Directive, parties may not derogate from certain requirements. Accordingly, the inclusion of a clause specifying an alternate body of law to be applied in the event of a dispute will likely be ruled invalid by European courts.

Key Link: Self Employed Commercial Agents

The European Commission's Directorate General for Competition enforces legislation concerned with the effects on competition in the internal market of "vertical agreements." U.S. small- and medium-sized companies (SMEs) are often exempt from these regulations because their agreements likely would qualify as "agreements of minor importance," meaning they are considered incapable of impacting competition at the EU level but useful for cooperation between SMEs. However, companies with fewer than 250 employees and an annual turnover of less than €50 million are considered small- and medium-sized companies. The EU has indicated that agreements that affect less than 10 percent of a particular market are generally exempted (Commission Notice 2014/C 291/01).

Key Link: European Law

The EU also looks to combat payment delays. Directive 2011/7/EU covers all commercial transactions within the EU, whether in the public or private sector, primarily dealing with the consequences of late payment. Transactions with consumers, however, do not fall within the scope of this Directive. Directive 2011/7/EU entitles a seller who does not receive payment for goods and/or services within 30 days of the payment deadline to collect interest (at a rate of eight percent above the European Central Bank rate) as well as 40 Euro as compensation for recovery of costs. For business-to-business transactions a 60-day period may be negotiated subject to conditions. The seller may also retain the title to goods until payment is completed and may claim full compensation for all recovery costs.

Key Link: Late Payments

Companies' agents and distributors can take advantage of the European Ombudsman when victim of inefficient management by an EU institution or body. Complaints can be made to the European Ombudsman only by businesses and other bodies with registered offices in the EU. The Ombudsman can act upon these complaints by investigating cases in which EU institutions fail to act in accordance with the law, fail to respect the principles of

good administration, or violate fundamental rights. In addition, SOLVIT, a network of national centers, offers online assistance to citizens and businesses who encounter problems with transactions within the borders of the single market.

Key Links:

European Ombudsman
EU Solvit

Establishing a local Office

Establishing an office in Europe, whether a subsidiary or a new business, requires knowledge of the relevant national legislations in the country of interest.

While there are several EU level policies in effect, many key areas such as taxation are still largely a member state prerogative.

The European Commission manages the Your Europe website where investors can find useful information on various topics ranging from taxation and customs to employment contracts.

For further information on this topic please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

Franchising

U.S. businesses looking to franchise within the European Union will likely find that the market is quite robust and friendly to franchise systems in general. There are several laws that govern the operation of franchises within the EU, but these laws are fairly broad and generally do not constrain the competitive position of U.S. businesses. The potential franchiser should take care to look not only at the EU regulations, but also at the local laws concerning franchising. More information on specific legislation can be found on the website of the European Franchise Federation.

Direct Marketing

The EU has yet to adopt legislation harmonizing the direct selling of consumer products. However, there is a wide range of EU legislation that impacts the direct marketing sector. Compliance requirements are elevated for marketing and sales to private consumers. Companies need to focus on the clarity and completeness of the information they provide to consumers prior to purchase and on their approaches to collecting and using customer data. The following gives a brief overview of the most important provisions flowing from EU-wide rules on distance-selling and on-line commerce. In addition, it is important for exporters relying on a direct-selling business model to ensure they comply with member state requirements.

Processing Customer Data

The EU has strict laws governing the protection of personal data, including the use of such data in the context of direct marketing activities. For more information on these rules, please see the Data Privacy section.

Distance Selling Rules

In 2011, the EU overhauled its consumer protection legislation and merged several existing rules into a single rulebook - "the Consumer Rights Directive". The provisions of this Directive have been in force since June 13, 2014. The Directive contains provisions on core information to be provided by traders prior to the conclusion of consumer contracts. It also regulates the right of withdrawal, includes rules on the costs for the use of means of payment and bans pre-ticked boxes. There are updates to these rules that will apply from May 2022.

The Commission has a useful tool to learn about consumer rules.

More information:

Consumer Rights Directive

The EU also adopted in March 2019 a set of two directives which govern EU-wide contract rules for the online sales of goods and the supply of digital content and services, but these rules do not apply until January 2022.

More information:

Digital Contact Rules

Alternative Dispute Resolution

In 2013, the EU adopted rules on Alternative Dispute Resolution which provide consumers the right to turn to quality alternative dispute resolution entities for all types of contractual disputes including purchases made online or offline, domestically or across borders. A specific Online Dispute Resolution Regulation, operational in January 2016, sets up an EU-wide online platform to handle consumer disputes that arise from online transactions.

Key Links:
Consumer Affairs Homepage
Consumer Rights

Distance Selling of Financial Services

Financial services are the subject of a separate directive that came into force in June 2002 (2002/65/EC). This piece of legislation amended three prior existing Directives and is designed to ensure that consumers are appropriately protected with respect to financial transactions taking place where the consumer and the provider are not face-to-face. In addition to prohibiting certain abusive marketing practices, the Directive establishes criteria for the presentation of contract information. Given the special nature of financial markets, specifics are also laid out for contractual withdrawal.

Key Link: Distance Marketing

Direct Marketing over the Internet

The e-Commerce Directive (2000/31/EC) imposes certain specific requirements connected to the direct marketing business. Promotional offers must not mislead customers and the terms that must be met to qualify for them have

to be clear and easily accessible. The Directive stipulates that marketing e-mails must be identified as such to the recipient and requires that companies targeting customers on-line must regularly consult national opt-out registers where they exist. When an order is placed, the service provider must acknowledge receipt quickly and by electronic means, although the Directive does not attribute any legal effect to the placing of an order or its acknowledgment; this is a matter for national law. Vendors of electronically supplied services (such as software, which the EU considers a service and not a good) must also collect value added tax (see Electronic Commerce section below). The European Commission has performed a stakeholder's consultation and the e-Commerce Directive could be revised. Please see the Data Privacy Section.

Key Link: e-Commerce Directive

Joint Ventures/Licensing

For information on this topic please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides.

Express Delivery

For information on this topic please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

Due Diligence

Product safety testing and certification is mandatory for the EU market. U.S. manufacturers and sellers of goods have to perform due diligence in accordance with mandatory EU legislation prior to exporting.

Limitation on Selling U.S. Products and Services

N/A

eCommerce

In 2015, the European Union launched an ambitious overhaul (the so-called Digital Single Market Strategy) of policy and legislation relevant to the digital economy. The overall objective was to bring down barriers, regulatory or otherwise, and to unlock online opportunities in Europe. E-commerce was a priority area, to ensure better access for consumers and businesses to online goods and services across Europe and to remove key differences between the online and offline worlds.

New pieces of legislation have been adopted to facilitate cross-border portability of online content, increase transparency of cross-border parcel delivery, and update and harmonize contract rules for online sales of goods and supply of digital content and services. For more information: Digital Single Market

The Electronic Commerce Directive (2000/31/EC) provides rules for online services in the EU. It requires providers to abide by rules in the country where they are established (country of origin). Online providers must respect consumer protection rules such as indicating contact details on their website, and clearly identifying

advertising and protecting against spam. The Directive also grants exemptions to liability for intermediaries that transmit illegal content by third parties and for unknowingly hosting content.

Key Links:

eCommerce

e-Commerce Directive

For information on this topic, consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

Selling Factors & Techniques

For Trade Promotion and Advertising

General Legislation

Laws against misleading advertisements differ widely from member state to member state within the EU. To respond to this issue in the internal market, the Commission adopted a directive, in force since October 1986, to establish minimum and objective criteria regarding truth in advertising. The Directive was amended in October 1997 to include comparative advertising. Under the Directive, misleading advertising is defined as any "advertising which in any way, including its presentation, deceives or is likely to deceive the persons to whom it is addressed or whom it reaches and which, by reason of its deceptive nature, is likely to affect their economic behavior or which for those reasons, injures or is likely to injure a competitor." Member States can authorize even more extensive protection under their national laws.

Comparative advertising, subject to certain conditions, is defined as "advertising which explicitly or by implication identifies a competitor or goods or services of a competitor." Member States can, and in some cases have, restricted misleading or comparative advertising.

The EU's Audiovisual Media Services Directive (AVMS) lays down legislation on broadcasting activities allowed within the EU. Since 2009, the rules allowing for U.S.-style product placement on television with exceptions. The AVMS was revised recently to extend the scope of the Directive to video-sharing platforms and social media in some circumstances Children's programming is subject to a code of conduct that includes a limit on junk food advertising to children, but organizations subject to the AVMS Directive are encouraged to do more to protect children. Following the adoption of the 1999 Council Directive on the Sale of Consumer Goods and Associated Guarantees, product specifications, as laid down in advertising, are considered as legally binding on the seller.

The EU adopted Directive 2005/29/EC concerning fair business practices in a further attempt to tighten consumer protection rules. These rules outlaw several aggressive or deceptive marketing practices such as pyramid schemes, "liquidation sales" when a shop is not closing down, and artificially high prices as the basis for discounts in addition to other potentially misleading advertising practices. Certain rules on advertising to children are also set out.

Key Links:

Audiovisual Media Services Directive
Misleading Advertising
Unfair Commercial Practices Directive

Medicines

The advertising of medicinal products for human use is regulated by Council Directive 2001/83/EC, as amended by Directive 2004/27/EC. The advertising of medicinal products is forbidden if market authorization has not yet been granted or if the product in question is a prescription drug. Mentioning therapeutic indications where self-medication is not suitable is not permitted, nor is the distribution of free samples to the general public. The text of the advertisement should be compatible with the characteristics listed on the product label and should encourage rational use of the product. The advertising of medicinal products destined for professionals should contain essential characteristics of the product as well as its classification. Inducements to prescribe or supply a medicinal product are prohibited, and the supply of free samples is restricted.

Key Link: Health and Medicine

Nutrition & Health Claims

On July 1, 2007, a regulation on nutrition and health claims entered into force. Regulation 1924/2006 sets EU-wide conditions for the use of nutrition claims such as "low fat" or "high in vitamin C" and health claims such as "helps lower cholesterol." The regulation applies to any food or drink product produced for human consumption that is marketed in the EU. Only foods that fit a certain nutrient profile (below certain salt, sugar and/or fat levels) can carry claims. Nutrition and health claims are only allowed on food labels if they are included in one of the EU's positive lists. Food products carrying claims must comply with the provisions of nutritional labeling Directive 90/496/EC and its amended version Directive 1169/2011.

In December 2012, a list of approved functional health claims went into effect. The list includes generic claims for substances other than botanicals which will be evaluated at a later date. Disease risk reduction claims and claims referring to the health and development of children require an authorization on a case-by-case basis, following the submission of a scientific dossier to the European Food Safety Authority (EFSA). Health claims based on new scientific data will have to be submitted to EFSA for evaluation, but a more simplified authorization procedure has been established.

Nutrition claims, in place since 2006, can fail one criterion, i.e. if only one nutrient (salt, sugar or fat) exceeds the limit of the profile, a claim can still be made provided the high level of that particular nutrient is clearly marked on the label. For example, a yogurt can make a low-fat claim even if it has high sugar content but only if the label clearly states, "high sugar content." A European Union Register of nutrition claims has been established and is updated regularly. Health claims cannot fail any criteria.

In May 2020, as part of the EU Green Deal, the Commission announced that it would set nutrient profiles to restrict promotion of food high in salt, sugars and/or fat as required by Regulation 1924/2006 before the end of

2022. Currently, the implementation of Regulation 1924/2006 on nutrition and health claims made on foods remains incomplete since the Commission did not established nutrient profiles that had to be set by January 2009. In that context, nutrient profiles are thresholds of nutrients such as fat, sugars and salt above which nutrition and health claims are restricted or prohibited. This proposal builds on the results of the EU's regulatory fitness and performance program (REFIT) evaluation of the EU legislation on nutrition and health claims launched in 2015.

Detailed information on the EU's Nutrition and Health Claims policy can be found on the USEU/FAS website at USEU/FAS website and in the USDA Food and Agricultural Import Regulations and Standards EU 28 2020.

Key Link: EU Register of Nutrition and Health Claims

Food Information to Consumers

Currently, the Food Information to Consumers (FIC) Regulation is the main EU labeling legislation. More information can be found in the USDA Food and Agricultural Import Regulations and Standards EU 28 2020.

In 2015, the EU adopted a new regulation on novel foods (2015/2283) amending the provision of food information to consumers (1169/2011). Novel foods and food ingredients must not present a danger for the consumer or mislead him and should not differ from the ingredients that they are intended to replace to such an extent that normal consumption would represent a nutritional disadvantage for the consumer. It is important to mention that the European Commission may decide, on its own initiative or upon a request by a Member State, by means of implementing acts (a sort of decree), whether or not a particular food falls within the definition of novel food. More information can be found on the Commission's website. Most provisions of this new Novel Foods Regulation become applicable on January 1, 2018. More information can be found

The Common Organization of the Markets establishes the specific information that must accompany fishery and aquaculture products sold to consumers and mass caterers. These requirements compliment the general EU rules on the provision of food information to consumers and contribute to more transparency on the market as they enable consumers to make informed choices on the products they buy. The new rules have become applicable since December 13, 2014. The Commission has published a pocket guide to the EU's new fish and aquaculture consumer labels.

Detailed information on the EU's new food labeling rules can be found on the USEU/FAS website at EU Labelling Requirements and in the USDA Food and Agricultural Import Regulations and Standards EU 28 2020.

Key Links:

Provision on Food Information

U.S. FDA Food

Food Supplements

Directive 2002/46/EC harmonizes the rules on labeling of food supplements and introduces specific rules on vitamins and minerals in food supplements. Ingredients other than vitamins and minerals are still regulated by Member States.

Regulation 1925/2006, applicable as of July 1, 2007, harmonizes rules on the addition of vitamins and minerals to foods. The regulation lists the vitamins and minerals that may be added to foods. This list was most recently revised in 2014. A positive list of substances other than vitamins and minerals has not been established yet, although it is being developed. Until then, member state laws will govern the use of these substances.

Key Link: Labelling Nutrition Supplements

Tobacco

The EU Tobacco Advertising Directive bans tobacco advertising in printed media, radio, and internet as well as the sponsorship of cross-border events or activities. Advertising in cinemas and on billboards or merchandising is allowed, though these are banned in many Member States. Tobacco advertising on television has been banned in the EU since the early 1990s and is governed by the Audiovisual Media Services Directive. A 2016 revision to the legislation includes the requirement for bigger, double-sided health pictorial warnings on cigarette packages and possibility for plain packaging along with health warnings, tracking systems.

Key Link: Tobacco Products

Pricing

Sales Service/Customer Support

Conscious of the discrepancies among Member States in product labeling, language use, legal guarantee and liability, the redress of which inevitably frustrates consumers in cross-border shopping, the EU institutions have launched a number of initiatives aimed at harmonizing national legislation. Suppliers within and outside the EU should be aware of existing and upcoming legislation affecting sales, service, and customer support.

Product Liability

Under the 1985 Directive on Liability of Defective Products, amended in 1999, the producer is liable for damage caused by a defect in his product. The victim must prove the existence of the defect and a causal link between defect and injury (bodily as well as material). A reduction of liability of the manufacturer is granted in cases of negligence on the part of the victim.

Key Link: Liability of Defective Products

Product Safety

The 1992 General Product Safety Directive introduced a general safety requirement at the EU level to ensure that manufacturers only place safe products on the market. It was revised in 2001 to include an obligation on the

producer and distributor to notify the Commission in case of a problem with a given product, provisions for its recall, the creation of a European Product Safety Network, and a ban on exports of products to third countries that are not deemed safe in the EU.

Key Link: Product Safety Legislation

Legal Warranties and After-sales Service

Under the 1999 Directive on the Sale of Consumer Goods and Associated Guarantees, professional sellers are required to provide a minimum two-year warranty on all consumer goods sold to consumers (natural persons acting for purposes outside their trade, businesses or professions), as defined by the Directive. The remedies available to consumers in case of non-compliance are:

- Repair of the good(s)
- Replacement of the good(s)
- A price reduction
- Rescission of the sales contract.

Other issues pertaining to consumers' rights and protection, such as the New Approach Directives, CE marking, quality control and data protection are dealt with in the Trade Regulations section of this report.

Key Link: Sales and Guarantees

For more information on this topic please consult the Commerce Department's Country Commercial Guides on EU Member States.

Trade Financing

Methods of Payment

For information on methods of payment please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

Banking Systems

For information on banking systems please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

Foreign Exchange Controls

For additional information on foreign exchange controls please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

US Banks & Local Correspondent Banks

For information on U.S. banks and local correspondent banks please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

Protecting Intellectual Property

Protecting Your Intellectual Property in the EU:

Several general principles are important for effective protection of intellectual property ("IP") rights in the EU. First, it is important to have an overall strategy to protect your IP. Second, IP may be protected differently in the EU than in the United States. Third, rights must be registered and enforced in the EU under local laws. For example, your U.S. trademark, design, and patent registrations will not protect you in the EU without further registrations in the corresponding regional or local level.

Most copyrighted works created in the U.S. will be automatically protected in the EU from the moment of creation or publication according to international agreements. However, the extension of protection will vary according to the laws of each EU Member State. Protection against unauthorized use will vary depending on the national laws of each country.

Obtaining patent grants in the EU is based on a first-to-file basis. Similarly, most trademark and design rights are based on a first-to-file registration system, so you should consider how to obtain patent, design, or trademark protection before introducing your products or services to the EU market. It is vital that companies understand that intellectual property rights are primarily private rights and that the U.S. government cannot enforce them for private individuals in the EU. It is the responsibility of the rights holders to register, protect, and enforce their rights where relevant, retaining their own counsel and advisors. Companies may wish to seek advice from local attorneys or IP consultants who are experts in EU law. The U.S. Commercial Service can provide a list of local lawyers upon request.

While the U.S. government stands ready to assist, there is little that can be done if the rights holders have not taken these fundamental steps necessary to securing and enforcing their IP in a timely fashion. Moreover, in many countries, rights holders who delay enforcing their rights on a mistaken belief that the U.S. government can provide a political resolution to a legal problem may find that their rights have been eroded or abrogated due to legal doctrines such as statutes of limitations, laches, estoppel, or unreasonable delay in prosecuting a law suit. In no instance should U.S. government advice be regarded as a substitute for the responsibility of a rights holder to promptly pursue its case.

It is always advisable to conduct due diligence on potential partners. A good partner is an important ally in protecting IP rights. Consider carefully, however, whether to permit your partner to register your IP rights on your behalf. Doing so may create a risk that your partner will list itself as the IP owner and fail to transfer the rights should the partnership end. Keep an eye on your cost structure and reduce the margins (and the incentive) of would-be bad actors. Projects and sales in the EU require constant attention. Work with legal counsel familiar with the EU laws to create a solid contract that includes non-compete clauses, and confidentiality/non-disclosure provisions.

It is also recommended that small and medium-size companies understand the importance of working together with trade associations and organizations to support efforts to protect IP and stop counterfeiting. There are a number of these organizations, in both the EU and the U.S. These include:

- The U.S. Chamber and local American Chambers of Commerce
- National Association of Manufacturers (NAM)
- International Intellectual Property Alliance (IIPA)
- International Trademark Association (INTA)
- The Coalition Against Counterfeiting and Piracy
- International Anti-Counterfeiting Coalition (IACC)
- Pharmaceutical Research and Manufacturers of America (PhRMA)
- Biotechnology Industry Organization (BIO)

IP Resources

A wealth of information on protecting IP is freely available to U.S. rights holders. Some excellent resources for companies regarding intellectual property include the following:

- For information about patent, trademark, or copyright issues -- including enforcement issues in the United States and other countries -- call the STOP! Hotline: **1-866-999-HALT** or visit STOP Fakes
- For more information about registering trademarks, designs and patents (both in the United States as well as in foreign countries), contact the U.S. Patent and Trademark Office (USPTO) at: **1-800-786-9199**
- For more information about registering copyrighted works in the United States, contact the U.S. Copyright Office at: **1-202-707-5959**.
- For more information about how to evaluate, protect, and enforce intellectual property rights and how these rights may be important for businesses, please visit the "Resources" section of the STOPfakes website.
- For information on obtaining and enforcing intellectual property rights and market-specific IP Toolkits visit: STOPfakes Business tools. The toolkits contain detailed information on protecting and enforcing IP in specific markets (e.g. EU toolkit) and also contain contact information for local IPR offices abroad and U.S. government officials available to assist SMEs.

For more information, please see the following article on Protecting Intellectual Property, and Stopfakes.gov.

The Office of the United States Trade Representative (USTR) publishes the Special 301 Report on an annual basis. This report provides a review of IP protection and enforcement for U.S. trading partners around the world. In the 2020 edition of the Report, USTR highlights the negative market access implications for U.S. producers due to the EU's protection of geographical indications (GIs) and third-country markets. Romania is the lone EU Member State named in the 2020 Special 301 Report, as it remains on the Watch List.

The U.S. Department of Commerce has positioned IP attachés in key markets around the world. Here is the contact information for European-based IP attachés:

WTO - World Trade Organization (based in Geneva, Switzerland)
Deborah Lashley-Johnson
deborah_e_lashley-johnson@ustr.eop.gov

WIPO - World Intellectual Property Organization (based in Geneva, Switzerland)
Kristine Schlegelmilch
SchlegK@state.gov

European Union (based in Brussels, Belgium)
Susan Wilson

Susan.Wilson@trade.gov

Central Eurasia (based in Kyiv, Ukraine)
Dorian Mazurkevich
dorian.mazurkevich@trade.gov

For more information, contact ITA's Office of Standards and Intellectual Property (OSIP) Director, Stevan Mitchell at Stevan.Mitchell@trade.gov.

For additional information on Member States' protection of property rights, please consult the Commerce Department's Country Commercial Guides of the 27 EU Member States found at the following website: EU Member States' Country Commercial Guides

Key Links:

Copyright
European Patent Office (EPO)
EU Intellectual Property Office (EUIPO)
World Intellectual Property Organization (WIPO) Madrid

Selling to the Public Sector

Selling to the Government

Government procurement in Europe is governed by both international obligations under the WTO Government Procurement Agreement (GPA) and EU-wide legislation under the EU Public Procurement Directives. U.S.-based companies can bid on public tenders covered by the GPA, while European subsidiaries of U.S. companies may bid on all public procurement contracts covered by the EU Directives in the European Union.

The EU directives on public procurement have been revised and legislation on concession has also been adopted. Member States were required to transpose the provisions of the new directives by April 16, 2016. The four relevant directives are:

- Directive 2014/24/EU (replacing Directive 2004/18/EC) on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts applies to the general sector.
- Directive 2014/25/EU (replacing Directive 2004/17/EC) coordinates the procurement procedures of entities operating in the water, energy, transport, and postal services sectors.
- Directive 2009/81/EC on defense and sensitive security procurement. This Directive sets Community rules for the procurement of arms, munitions and war material (plus related works and services) for defense purposes, but also for the procurement of sensitive supplies, works and services for non-military security purposes.
- Directive 2014/23/EU on the award of concession contracts. A concession contract (either for the delivery of works or services) is conducted between a public authority and a private enterprise that gives the right to the company to build infrastructure and operate businesses that would normally fall within the jurisdiction of the public authority (e.g. highways).

The EU has "remedies" directives imposing common standards for all member states to abide by in case bidders identify discriminatory public procurement practices.

Electronic versions of the procurement documentation must be available through an internet URL immediately upon publication of the Official Journal of the European Union (OJEU) contract notice. Full electronic communication (with some exceptions) are mandatory for all public contracts since October 2018. Central purchasing bodies are required to publish their contracts and requests for tenders since April 2017.

Electronic invoicing (e-invoicing) was introduced beginning of the 3rd quarter of 2018, based on the requirement set forth in Directive 2014/55/EU. The Directive makes the receipt and processing of electronic invoices in public procurement obligatory. Standards for e-invoicing are being developed by the European Committee for Standardization (CEN).

There are restrictions for U.S. suppliers in the EU utilities sector, both in the EU Utilities Directive and in EU coverage of the GPA. Article 85 of Directive 2014/25 allows EU contracting authorities to either reject non-EU bids where the proportion of goods originating in non-EU countries exceeds 50 percent or give preference to the EU bid if prices are equivalent (meaning within a three percent margin). Moreover, the Directive allows EU contracting authorities to retain the right to suspend or restrict the award of service contract to undertakings in third countries where no reciprocal access is granted.

There are also restrictions in the EU coverage of the GPA that apply specifically to U.S.-based companies. U.S. companies are not allowed to bid on works and services contracts procured by sub-central public contracting authorities in the following sectors:

- Water sector
- Airport services
- Urban transport sector as described above, and railways in general
- Dredging services and procurement related to shipbuilding

Key Link: EU Tenders Database (for European Public Procurement)

Project Financing

EU financial assistance programs provide a wide array of grants, loans, loan guarantees and co-financing for feasibility studies and projects in a number of key sectors (e.g., environmental, transportation, energy, telecommunications, tourism, public health). A number of centralized financing programs are also generating procurement and other opportunities directly with EU institutions.

The EU supports economic development projects within its Member States, as well as EU-wide "economic integration" projects that cross both internal and external EU borders. In addition, the EU provides assistance to candidate and neighbor countries.

The EU provides project financing through grants from the EU budget and loans from the European Investment Bank. Grants from the EU Structural and Investment Funds program are distributed through the Member States' national and regional authorities. Projects in non-EU countries are managed through the Directorate-Generals International Cooperation and Development and European Civil Protection and Humanitarian Aid Operation

EU Structural and Investment Funds (ESIF)

EU Structural Funds, including the European Regional Development and the European Social Fund, were created in 1975 with the aim to mitigate economic and social differences between the regions of the European Union. New budgets are approved every seven years for all Member States. The budgets and the allocation of funding between the different priorities (social, economic, or environmental) are based on the conclusions of the "Partnership Agreements" (PAs) which are negotiated between the European Commission and the member state national authorities. For the period of 2014 – 2020, the EU has earmarked 352 billion euros for regional development and cohesion policy projects. For information on approved programs that will result in future project proposals.

For projects financed through ESIF, member state regional managing authorities are the key decision-makers. They assess the needs of their country, investigate projects, evaluate bids, and award contracts. To become familiar with available financial support programs in the Member States, it is advisable for would-be contractors to develop a sound understanding of the country's cohesion policy indicators.

Tenders issued by Member States' public contracting authorities for projects supported by EU grants are subject to EU public procurement legislation. All ESIF projects are co-financed by national authorities and many may also qualify for a loan from the European Investment Bank and EU research funds under Horizon 2020, in addition to private sector contribution. For more information on these programs, please see the market research section on the website of the U.S. Mission to the EU: U.S. Mission to the EU website

The Cohesion Fund

The Cohesion Fund is another instrument of the EU's regional policy. Its 63 billion Euro (2014-2020) budget is used to finance projects in two areas: Trans-European transport projects including transport infrastructure, and environment, including areas related to sustainable development and energy for projects with environmental benefits.

The fund supports projects in Member States whose Gross National Income (GNI) per inhabitant is less than 90 % of the EU average, such as Bulgaria, Croatia, Cyprus, the Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, and Slovenia.

These projects are, in principle, co-financed by national authorities, the European Investment Bank, and the private sector.

Key Link: The Cohesion Fund

Other EU Grants for Member States

Other sets of sector-specific grants such as Horizon Europe offer assistance to EU Member States in the fields of science, technology, communications, energy, security, environmental protection, education, training and

research. Tenders related to these grants are posted on the websites of the European Commission and the relevant Member State authorities. Participation is usually restricted to EU-based firms or tied to EU content. Information pertaining to each of these programs can be found at: EU Funding and Tenders

External Assistance Grants

Directorate-General for International Cooperation and Development (DG DEVCO) is responsible for implementing EU development policies through programs and projects across the world. Its website offers extensive information on the range of grant programs, the kind of projects that are eligible, as well as manuals to help interested parties understand the relevant contract law. However, participation in these calls for tender is reserved for enterprises located in EU Member States or in the beneficiary countries and requires that the products used to respond to these projects are manufactured in the EU or in the aid recipient country. Consultants of U.S. nationality employed by a European firm are allowed to participate. European subsidiaries of U.S. firms are eligible to participate in these calls for tender.

For more information: International Cooperation and Development

The European Neighborhood Instrument (ENI) provides assistance to countries that are the Southern Mediterranean and Eastern neighbors of the EU. ENI is the follow-up to the European Neighborhood Policy program (ENPI) covering the countries of Algeria, Armenia, Azerbaijan, Belarus, Egypt, Georgia, Israel, Jordan, Lebanon, Libya, Moldova, Morocco, the occupied Palestinian territory, Syria, Tunisia and Ukraine. The ENI budget is 15.4 billion euros for 2014-2020. Additional information can be found at: EU External Action

Instrument for Pre-accession Assistance II (IPA II) is an EU program for pre-accession countries that provides support for political and economic reforms, preparing the beneficiaries for the rights and obligations that come with EU membership and that are linked to the adoption of the *acquis communautaire* (the body of European Union law that must be adopted by candidate countries as a precondition to accession). These programs are intended to help build up the administrative and institutional capacities of these countries and to finance investments designed to aid them in complying with EU law. IPA II runs from 2014 to 2020 and finances projects in: Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Kosovo, Montenegro, Serbia, and Turkey. The budget of IPA II for 2014-2020 is 11.7 billion euros.

For more information, see:
http://ec.europa.eu/enlargement/instruments/overview/index_en.htm#ipa2

The **Connecting Europe Facility (CEF)** is an EU financing mechanism that uses the EC budget as well as the Cohesion Funds to finance projects in three key areas: energy, transport and telecom. It was created by Regulation 1316/2013 on December 11, 2013.

Along with the European Fund for Strategic Investments (EFSI), CEF is expected to play a role in bridging the investment gap in Europe, which is one of the Commission's top priorities. In all three main categories the focus

is on creating better conditions for growth and jobs. Annual and multi-annual work programs specify the priorities and the total amount of financial support allocated for these priorities in a given year.

Only actions contributing to projects of common interest in accordance with Regulations 1315/2013, No 347/2013 and a Regulation on guidelines for trans-European networks in the area of telecommunications infrastructure, as well as program support actions, are eligible for support.

Projects supported through the CEF mechanism focus on the following:

- cleaner transport modes,
- high speed broadband connections, and
- the use of renewable energy (in line with the Europe 2020 Strategy), integration of the internal energy market, reduction of the EU's energy dependency and ensuring security of supply.

The total budget of the CEF for the period 2014 to 2020 is set at €30.44 billion. This amount is distributed between the main priority areas as follows:

a) transport sector: €24.05 billion;
b) telecommunications sector: €1billion;
c) energy sector: €5.35 billion

Please see: Connecting European Facility

Loans from the European Investment Bank

Headquartered in Luxembourg, the European Investment Bank (EIB) is the financing arm of the European Union. Since its creation in 1958, the EIB has been a key player in building Europe. As a non-profit banking institution, the EIB assesses, reviews, and monitors projects, and offers cost-competitive, long-term lending. Best known for its project financial and economic analysis, the EIB makes loans to both private and public borrowers for projects supporting four key areas: innovation and skills, access to finance for smaller businesses, climate and environment, and infrastructure. The EIB opens credit lines for financial institutions that then lend funds to creditors.

While the EIB mostly funds projects within the EU, it lends outside the EU as well (e.g., in Southeastern Europe, Africa, Latin America, and Pacific and Caribbean states). In 2016, the EIB loaned 76 billion euros for projects. The EIB also plays a key role in supporting EU enlargement with loans used to finance improvements in infrastructure, research, and industrial manufacturing to help those countries prepare for eventual EU membership.

The EIB presents attractive financing options for projects that contribute to the European objectives cited above, as EIB lending rates are lower than most other commercial rates.

Projects financed by the EIB must contribute to the socio-economic objectives set out by the EU, such as fostering the development of less favored regions, improving European transport and environment infrastructure, supporting the activities of SMEs, assisting urban renewal and the development of a low-carbon economy, and

generally promoting growth and competitiveness in the EU. The EIB website displays lists of projects to be considered for approval.

Multilateral Development Banks

World Bank

With 189-member countries, the World Bank is an international financial institution that provides loans to countries of the world for capital programs.

European Bank for Reconstruction and Development (EBRD)

The European Bank for Reconstruction and Development (EBRD) was founded in 1991 to create a new post-Cold War era in central and eastern Europe, furthering progress towards 'market-oriented economies and the promotion of private and entrepreneurial initiative'.

The Commercial Service maintains Commercial Liaison Offices in each of the main Multilateral Development Banks, including the European Bank for Reconstruction and Development and the World Bank. These institutions lend billions of dollars in developing countries on projects aimed at accelerating economic growth and social development by reducing poverty and inequality, improving health and education, and advancing infrastructure development. The Commercial Liaison Offices help American businesses learn how to get involved in bank-funded projects, and advocate on behalf of American bidders. Learn more by contacting the Commercial Liaison Offices to the *European Bank for Reconstruction and Development* and the *World Bank*.

Local Professional Services

Local service providers focusing on EU law, consulting, and business development can be viewed on the website maintained by the Commercial Service at the U.S. Mission to the European Union.

For information on professional services located within each of the EU Member States, please see EU member state Country Commercial Guides which can be found at the following website EU Member States' Country Commercial Guides

Principle Business Associations

Organizations in Brussels focused on representing U.S. business interests and engaging with EU institutions including the European Commission, European Parliament and the Council include:

AmChamEU

Value Added Tax (VAT)

The EU's VAT system is semi-harmonized. While the guidelines are set out at EU level, the implementation of VAT policy is the prerogative of Member States. The EU VAT Directive allows Member States to apply a minimum 15 percent VAT rate. However, they may apply reduced rates for specific goods and services or temporary derogations. Therefore, the examination of VAT rates by Member State is strongly recommended. These and other rules are laid out in the VAT Directive.

The EU applies Value Added Tax (VAT) to sales by non-EU based companies of Electronically Supplied Services (ESS) to EU-based non-business customers. U.S. companies that are covered by the rule must collect and submit VAT to EU tax authorities. From 1 January 2015, all supplies of telecommunications, broadcasting and electronic services are taxable at the place where the customer resides. In the case of businesses this means either the country where it is registered or the country where it has fixed premises receiving the service. In the case of consumers, it is where they are registered, have their permanent address, or usually live.

As part of the legislative changes of 2015, the Commission launched the Mini One Stop Shop (MOSS) scheme, the use of which is optional. It is meant to facilitate the sales of ESS from taxable to non-taxable persons (B2C) located in Member States in which the sellers do not have an establishment to account for the VAT. In 2021, this service will be extended to cover online sales of goods and services other than ESS. For more information please check the official guide on MOSS issued by the European Commission.

This (optional) plan allows taxable persons (sellers) to avoid registering in each Member State of consumption. A taxable person who is registered for the Mini One Stop Shop in a Member State (the Member State of Identification) can electronically submit quarterly Mini One Stop Shop VAT returns detailing supplies of ESS or other to non-taxable persons in other Member States (the Member State(s) of consumption), along with the VAT due. On February 12, 2020 the EU adopted Commission Implementing Regulation (EU) 2020/194 concerning the VAT on e-commerce. The regulation provides the details for the registration in the VAT One Stop Shop, including the Import One Stop Shop, and for the VAT One Stop Shop return.

In addition, in November 2019, the Council adopted new detailed measures that will pave the way for a smooth transition to new VAT rules for e-Commerce, such as:

- Council Directive (EU) 2019/1995 amending Directive 2006/112/EC regarding provisions relating to distance sales of goods and certain domestic supplies of goods.
- Council Implementing Regulation (EU) 2019/2026 amending Implementing Regulation (EU) No 282/2011 regarding supplies of goods or services facilitated by electronic interfaces and the special schemes for taxable persons supplying services to non-taxable persons, making distance sales of goods and certain domestic supplies of goods.

On 8 May 2020, because of the practical difficulties created by the lockdown measures taken to contain the coronavirus pandemic, the Commission proposed to postpone the introduction of new e-commerce VAT rules by six months. Once adopted by the Council, the rules will apply as of July 1, 2021 instead of January 1, 2021, giving Member States and businesses enough time to prepare.

Further information relating to VAT on ESS:
https://ec.europa.eu/taxation_customs/business/vat/telecommunications-broadcasting-electronic-services/

Data Privacy and Protection

The EU General Data Protection Regulation (GDPR), which governs how personal data of individuals in the EU may be processed and transferred, went into effect on May 25, 2018. The GDPR is a comprehensive privacy legislation that applies across sectors and to companies of all sizes. It replaces the Data Protection Directive 1995/46. The overall objectives of the measures are the same – laying down the rules for the protection of personal data and for the movement of data.

The GDPR is broad in scope and uses broad definitions. "Personal data" is any information that relates to an identified or identifiable living individual (data subject) such as a name, email address, tax ID number, online identifier, etc. "Processing" data includes actions such as collecting, recording, storing and transferring data.

A company that is not established in the Union may have to comply with the Regulation when processing personal data of EU and EEA residents (EEA countries include Norway, Lichtenstein and Iceland) and Switzerland:
a) If the company offers goods or services to data subjects in the EU; or,
b) If the company is monitoring data subjects' behavior taking place within the EU.

The mere accessibility of a company's website in the EU is insufficient to subject a company to GDPR, but other evidence of the intent to offer goods or services to data subjects in the EU would be relevant. For instance, conducting advertising campaigns directed at EU markets or mentioning an EU member state in relation to the good or service could be relevant. The European data protection authorities published guidelines to help companies determine whether they fall within the GDPR's territorial scope.

As a general rule, companies that are not established in the EU but that are subject to the GDPR must designate in writing an EU representative for purposes of GDPR compliance. There is an exception to this requirement for small scale, occasional processing of non-sensitive data.

Fines in case of non-compliance can reach up to 4% of the annual worldwide revenue or 20 million euros – whichever is higher. Companies of all sizes and sectors should consider GDPR as part of their overall compliance effort with assistance of legal counsel.

The European Commission and Data Protection Authorities released official guidelines to help companies with their compliance process. These documents relate, for instance, to the role of the data protection officer, personal data breach notification, data protection impact assessment.

Note: the EU is currently updating its e-privacy legislation governing confidentiality of communications. If enacted, this legislative instrument could add several requirements in addition to the GDPR. We encourage U.S. exporters to monitor this situation as it evolves through the EU legislative process.

For more information:

Full GDPR text
Official Press Release

European Commission guidance:
https://ec.europa.eu/info/law/law-topic/data-protection_en
https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en
https://edpb.europa.eu/edpb_en
https://edpb.europa.eu/our-work-tools/general-guidance/gdpr-guidelines-recommendations-best-practices_en

Transferring Customer Data to Countries outside the EU

The General Data Protection Regulation (GDPR) provides for the free flow of personal data within the EU but also for its protection when it leaves the region's borders.

The GDPR sets out obligations on data controllers (those in charge of deciding what personal data is collected and how/why it is processed), on data processors (those who act on behalf of the controller) and gives rights to data subjects (the individuals to whom the data relates). These rules were designed to provide a high level of privacy protection for personal data and were complemented by **measures to ensure the protection is maintained when data leaves the region**, whether it is transferred to controllers, processors or to third parties (e.g. subcontractors). EU legislators put restrictions on transfers of personal data outside of the EU, specifying that such data could only be exported if "adequate protection" is provided.

The European Commission is responsible for assessing whether a country outside the EU has a legal framework that provides enough protection for it to issue an "adequacy finding" to that country. The U.S. does not have an adequacy decision (see section on the EU-U.S. Privacy Shield below). This means that U.S. companies can only receive personal data from the EU if they:

- Provide appropriate safeguards (e.g. standard contractual clauses, binding corporate rules), or,
- Refer to one of the GDPR's derogations.

For more information:

EU data protection authorities' FAQs on data transfers to the U.S.

Important note:

The legal environment for data transfers to the United States continues to evolve. Companies that transfer EU citizen data to the United States as part of a commercial transaction should consult with an attorney, who specializes in EU data privacy law, to determine what options may be available for a transaction.

The EU-U.S. Privacy Shield

On July 16, 2020, the Court of Justice of the European Union (CJEU) issued a judgment declaring as "invalid" the European Commission's Decision (EU) 2016/1250 of July12, 2016 on the adequacy of the protection provided by the EU-U.S. Privacy Shield. As a result of that decision, the EU-U.S. Privacy Shield Framework is no longer a valid mechanism to comply with EU data protection requirements when transferring personal data from the European Union to the United States. This decision does not relieve participants in the EU-U.S. Privacy Shield of their obligations under the EU-U.S. Privacy Shield Framework.

The EU-U.S. Privacy Shield Framework was designed by the U.S. Department of Commerce and the European Commission to provide companies on both sides of the Atlantic with a mechanism to comply with EU data protection requirements when transferring personal data from the European Union to the United States in support of transatlantic commerce. While it is no longer a valid transfer mechanism under the GDPR, as U.S. Secretary of Commerce Wilbur Ross noted on July 16, 2020, "The Department of Commerce will continue to administer the Privacy Shield program, including processing submissions for self-certification and re-certification to the Privacy Shield Frameworks and maintaining the Privacy Shield List."

For more information:

Commerce FAQs on Privacy Shield following CJEU decision of July 16

EU-U.S. Privacy Shield

Other transfer mechanisms

Cyber-security

Network and Information Systems (NIS) Security Directive

The European Network and Information Systems (NIS) Security Directive, applicable since 2016, sets a minimum baseline of requirements to ensure better protection of critical infrastructures in Europe. The legislation sets basic principles for Member States for common minimum capacity building and strategic cooperation. It also directs operators of essential services (OES) and digital service providers (DSP) to ensure they apply basic common security requirements.

DSPs are broadly defined to include: online/e-commerce marketplaces (including app stores); online search engines (with the exclusion of search function limited to a specific website); and Cloud computing services. NIS systems are considered the e-communications network, connected devices and digital data. Obligations for both OES and DSP include: to take technical and organizational measures to NIS risk management; to prevent and minimize the impact of NIS security incidents; to notify, without undue delay, incidents having a significant impact on the continuity of the essential services they provide. Member states have implemented the rules in different manners, particularly regarding OES, so it is important to check the local transpositions. Because the current approach is relatively unharmonized across the EU, the European Commission may modify the NIS Directive.

For more information:

NIS Directive

Cybersecurity Act

The EU adopted the Cybersecurity Act in March 2019 to set up a mechanism to develop voluntary EU certification schemes for ICT security products, processes and services. The Cybersecurity Act does not set out requirements in details but lays out elements that should be in any given scheme to provide assurance on security requirements for all ICT products, services and processes. The areas that would benefit from certification schemes will either

be proposed by the European Commission through an annual work program or by stakeholder group. Product manufacturers and service providers are encouraged to monitor the development of these schemes. The EU cybersecurity agency ENISA creates ad-hoc stakeholder groups to help it create certification schemes, and companies can apply to participate in these groups.

More information:

EU Cybersecurity Act

EU Cybersecurity Agency, ENISA

Business Travel

Business Customs

For information on this topic please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

Travel Advisory

State Department Travel Website

Visa Requirements

U.S. Companies that require travel of foreign businesspersons to the United States should be advised that security evaluations are handled via an interagency process. Visa applicants should go to the following links.

State Department Visa Website

For information on this topic please consult the Commerce Department's Country Commercial Guides on EU Member States:

EU Member States' Country Commercial Guides

Currency

The euro is the result of the European Union's project for economic and monetary union which came fully into being on January 1, 2002. The Euro is used by the institutions of the European Union and by the Eurozone states, which account for 19 of the 27 Member States of the European Union:

Austria, Belgium, Cyprus, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Portugal, Slovakia, Slovenia, Spain.

Telecommunications/Electric

For information on telecommunications/electric please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

Transportation

For information on transportation please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

Language

The official languages of the EU are Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, Gaelic, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovene, Spanish and Swedish.

Health

For information on health please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

Local Time, Business Hours and Holidays

The European Institutions generally follow the holidays of the EU member state in which they are located. During the month of August, most EU organizations are staffed with minimum personnel. For information on local holidays in the EU Member States, please see individual member state's Country Commercial Guides. The following is a list of holidays observed in Belgium during calendar year 2020:

January 1	Monday, New Year's Day
April 10	Good Friday
April 13	Easter Monday
May 1	Belgian Labor Day
May 8	European Day
May 21	Ascension Day
June 1	Whit Monday
July 21	National Day
August 14	Assumption Day
November 2	All Saints Day
November 11	Veterans Day
December 25	Christmas Day
December 28	Boxing Day

The U.S. Mission to the European Union is closed on most U.S. and Belgian holidays. For individual Member States' local time and business hours, please refer to the EU Member States' Country Commercial Guides

Business travelers to the European Union seeking appointments with officials in the U.S. Mission to the European Union in Brussels, Belgium, should contact the Commercial Service in advance. The Commercial Service at the U.S. Mission to the European Union can be reached by telephone at +32-2 811-4817 or by e-mail at office.brusselsec@trade.gov. Additional information can be found on our website at U.S. Mission to the European Union. A current directory of staff and locations worldwide may be accessed on the Commercial Service website Staff directory and locations.

Temporary Entry of Materials or Personal Belongings

For information on this topic please consult the Commerce Department's Country Commercial Guides on EU Member States: EU Member States' Country Commercial Guides

Commercial Service at the U.S. Mission to the European Union

General E-mail Address:

Office.brusselsec@trade.gov

Investment Climate Statement

Executive Summary

The U.S. Department of State's Investment Climate Statements, prepared annually by U.S. embassies and diplomatic missions abroad, provide country-specific information and assessments of the investment climate in foreign markets. Topics include: market barriers, business risk, legal and regulatory system, dispute resolution, corruption, political violence, labor issues, and intellectual property rights. To access the ICS report for the European Union as well as for individual EU member countries, visit the U.S. Department of Department of State's Investment Climate Statement website.

Openness to, & Restrictions upon Foreign Investment

For specific information on Member States' openness to foreign investment, please consult the Commerce Department's Country Commercial Guides of the 27 EU Member States found at the following website: EU Member States' Country Commercial Guides

Bilateral Investment Agreements & Taxation Treaties

The EU does not have any traditional bilateral investment treaties (BITs), though it is currently negotiating BITs with China and Burma, and virtually all the Member States have extensive networks of such treaties with third countries. Other agreements with preferential trading partners have contained provisions directly addressing treatment of investment, generally providing national treatment after establishment and repatriation of capital and profits.

On 5 May 2020, 23 Member States signed the agreement for the termination of intra-EU bilateral investment treaties ("termination agreement"). The termination agreement implements the March 2018 European Court of Justice judgment (Achmea case), where the Court found that investor-State arbitration clauses in intra-EU bilateral investment treaties ("intra-EU BITs") are incompatible with the EU Treaties.

Signatories of the termination agreement are Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia and Spain. Website: Intra-EU BIT Termination

The adoption in December 2009 of the Lisbon Treaty has changed how the EU treats investment. Since Lisbon makes foreign direct investment an exclusive EU competence, a broad definition of FDI extends EU authority over much of the subject matter hitherto addressed under member state BITs. The Council has so far granted the

Commission authority to negotiate investment chapters in free trade agreements. The Commission has indicated that it does not plan to develop a model investment treaty, preferring instead to establish general objectives and principles.

Other regional or multilateral agreements addressing the admission and treatment of investors to which the Community and/or its Member States have adhered include:
a) The OECD codes of liberalization, which provide for non-discrimination and standstill for establishment and capital movements, including foreign direct investment;
b) The Energy Charter Treaty (ECT), which contains a "best efforts" national treatment clause for the making of investments in the energy sector but full protections thereafter; and
c) The GATS, which contains national treatment, market access, and MFN obligations on measures affecting the supply of services, including in relation to the mode of commercial presence.

Legal Regime
The European Commission, which has the sole authority to propose EU-wide laws, publishes an Annual Work Program setting forth its intent to legislate on particular matters in the coming year. This report can be found at: Annual Work Program

Inclusion of planned regulation in this list is usually followed by the issuance of a "roadmap" that generally describes possible options and spells out the process for developing a proposal. Such steps include a public consultation intended to inform the Commission's development of a formal legislative proposal, and a supporting impact assessment. In turn, member state officials examine and amend these proposals in Council, as does the European Parliament; Council and Parliament positions are publicly available. Where those positions differ, the three institutions – Commission, Council, and Parliament –agree on the final text of legislation through closed-door negotiations known as "trilogues." All adopted measures are published in all EU languages in the EU's Official Journal.

In many instances, the European Commission has broad discretion to promulgate detailed rules with less or no review by other bodies, and with varied procedures depending on context. For example, EU primary regulations often include authority for the Commission to elaborate additional or more detailed aspects in the form of either "delegated" or "implementing" acts. The Commission's proposals are subject either to an override by the Council or Parliament, or to approval by Member States.

In 2016, as part of its "Better Regulation" agenda, the Commission began, in at least some cases, to publish the draft texts of these proposed delegated or implementing acts for a four-week public review, which to some extent, coincides with requirements to notify proposed measures to the WTO. However, many contexts, such as standard setting or chemicals, include upstream procedures to evaluate product hazards that are dominated by member state expert committees and "independent" agencies such as ECHA (European Chemicals Agency) and EFSA (European Food Safety Authority) that are not subject to the new Better Regulation frameworks. Furthermore, many sectors subject to more specific regulations set forth in the secondary legislation described above - delegated

and implementing acts - are in effect governed via meetings and processes involving expert groups of member state representatives and designated European companies.

Despite new opportunities for public "feedback" and debate in the early phases of rulemaking as part of the "Better Regulation" program, U.S. companies and other stakeholders continue to struggle in their efforts to obtain detailed draft text and key information in a timely manner concerning the Commission's legislative proposals. Without this information, stakeholders are limited in their ability to fully understand and determine potential compliance or operational costs to trade and investment in the EU. As a result, there is no opportunity for the public to comment on the actual text of proposed legislation until after the Commission has sent its formal proposal forward for consideration by its "legislative" branches, the Council and Parliament. In a manner that is inconsistent with good regulatory practices observed by many OECD member states, the actual draft is not made available during the key phase when the Commission could still make technical amendments. Rather, Commission directorates issue more general consultation documents, usually accompanied by questionnaires, soliciting public views before a Commission proposal is particularly developed. As it develops the details of its proposal, the Commission may call invitation-only meetings with experts as a means of obtaining specific information; however, these meetings are not necessarily designed to include all potential global stakeholders and may be restricted to only European stakeholders. Consequently, the impact assessment developed by the Commission during this period is only published with its final proposal, rather than being made available for public review and comment at an earlier stage.

Another example of a systemic lack of transparency and access for U.S. exporters is standards development. In order to participate in EU standards making, a company must have a physical presence in the European Union. To the extent that EU regulations allow private conformity assessment bodies (CABs) to perform conformity assessment activities for products, they do not recognize U.S. CABs conduct of conformity assessments on U.S. soil, except under the U.S.-EU Telecom MRA, where qualified U.S organizations can obtain Notified Body status under the Radio Equipment Directive and the Electromagnetic Compatibility (EMC) Directive.

For specific information on member states' openness to foreign investment, please consult the Commerce Department's Country Commercial Guides of the 27 EU member states found at the following website: EU Member States' Country Commercial Guides

Industrial Policies

EU law provides that Member States may designate parts of the Customs Territory of the Community as "free zones". The EU considers the free zones to be mainly a service for traders to facilitate trading procedures by allowing fewer customs formalities. Information on free zones is contained in Section 3, Article 243 and following of Council Regulation (EU) no. 952/2013 establishing the Community Customs Code, titled, "Free Zones"

The use of free zones varies across Member States. For example, Germany maintains a number of free ports or free zones within a port that are roughly equivalent to U.S. foreign-trade zones, whereas Belgium has none. A full list of EU free zones last updated in April 2020.

Protection of Property Rights

For specific information on Member States' protection of property rights policies, please consult the Commerce Department's Country Commercial Guides of the 27 EU Member States found at the following website: EU Member States' Country Commercial Guides

Financial Sector

For specific information on Member States' capital markets and portfolio investment, please consult the Commerce Department's Country Commercial Guides of the 27 EU Member States found at the following website: EU Member States' Country Commercial Guides

State-Owned Enterprises

For specific information on Member States' competition from state-owned enterprises, please consult the Commerce Department's Country Commercial Guides of the 27 EU Member States found at the following website: EU Member States' Country Commercial Guides

Responsible Business Conduct

For specific information on Member States' responsible business conduct, please consult the Commerce Department's Country Commercial Guides of the 27 EU Member States found at the following website: EU Member States' Country Commercial Guides

Corruption

Corruption, including bribery, raises the costs and risks of doing business. Corruption has a corrosive impact on both market opportunities overseas for U.S. companies and the broader business climate. It also deters international investment, stifles economic growth and development, distorts prices, and undermines the rule of law.

It is important for U.S. companies, irrespective of their size, to assess the business climate in the relevant market in which they will be operating or investing, and to have an effective compliance program or measures to prevent and detect corruption, including foreign bribery. U.S. individuals and firms operating or investing in foreign markets should take the time to become familiar with the relevant anticorruption laws of both the foreign country and the United States in order to properly comply with them, and where appropriate, they should seek the advice of legal counsel.

The U.S. government seeks to level the global playing field for U.S. businesses by encouraging other countries to take steps to criminalize their own companies' acts of corruption, including bribery of foreign public officials, by requiring them to uphold their obligations under relevant international conventions. A U.S. firm that believes a competitor is seeking to use bribery of a foreign public official in international business, for example to secure a contract, should bring this to the attention of appropriate U.S. agencies, as noted below.

U.S. Foreign Corrupt Practices Act: In 1977, the United States enacted the Foreign Corrupt Practices Act (FCPA), which generally makes it unlawful for U.S. persons and businesses (domestic concerns), and U.S. and

foreign public companies listed on stock exchanges in the United States or which must file periodic reports with the Securities and Exchange Commission (issuers), to offer, promise or make a corrupt payment or anything of value to foreign officials to obtain or retain business. The FCPA also applies to foreign firms and persons who take any act in furtherance of such a corrupt payment while in the United States. In addition to the anti-bribery provisions, the FCPA contains accounting provisions applicable to public companies. The accounting provisions require issuers to make and keep accurate books and records and to devise and maintain an adequate system of internal accounting controls. The accounting provisions also prohibit individuals and businesses from knowingly falsifying books or records or knowingly circumventing or failing to implement a system of internal controls. In order to provide more information and guidance on the statute, the Department of Justice and the Securities and Exchange Commission published A Resource Guide to the U.S. Foreign Corrupt Practices Act. For more detailed information on the FCPA generally, see the Department of Justice FCPA website.

Other Instruments: It is U.S. government policy to promote good governance, including host countries' implementation and enforcement of anti-corruption laws and policies pursuant to their obligations under international agreements. Since enactment of the FCPA, the United States has been instrumental to the expansion of the international framework to fight corruption. Several significant components of this framework are the Convention on Combating Bribery of Foreign Public Officials in International Business Transactions negotiated under the auspices of the OECD (Antibribery Convention), the United Nations Convention against Corruption (UN Convention), the Inter-American Convention against Corruption (OAS Convention), the Council of Europe Criminal and Civil Law Conventions, and a growing list of U.S. free trade agreements.

OECD Antibribery Convention: The Antibribery Convention entered into force in February 1999. As of July 2020, there are 44 parties to the Convention, including the United States. Major exporters China and India are not parties, although the U.S. Government strongly endorses their eventual accession to the Antibribery Convention. The Antibribery Convention obligates the Parties to criminalize bribery of foreign public officials in international business transactions, which the United States has done under U.S. FCPA.

UN Convention: The UN Convention entered into force on December 14, 2005, and there are 187 parties to it as of July 2020. The UN Convention requires countries to establish criminal and other offences to cover a wide range of acts of corruption, from basic forms of corruption such as bribery and solicitation, embezzlement, and trading in influence on the concealment and laundering of the proceeds of corruption. The Convention contains transnational business bribery provisions that are functionally similar to those in the OECD Antibribery Convention and contains provisions on private sector auditing and books and records requirements. Other provisions address matters such as prevention, international cooperation, and asset recovery.

OAS Convention: In 1996, the Member States of the Organization of American States (OAS) adopted the first international anticorruption legal instrument, the Inter-American Convention against Corruption (OAS Convention), which entered into force in March 1997. The OAS Convention, among other things, establishes a set of preventive measures against corruption, provides for the criminalization of certain acts of corruption, including transnational bribery and illicit enrichment, and contains a series of provisions to strengthen the cooperation between its States Parties in areas such as mutual legal assistance and technical cooperation. As of

July 2020, the OAS Convention has 34 parties and the follow-up mechanism created in 2001 (MESICIC) has 33 members.

Council of Europe Criminal Law and Civil Law Conventions on Corruption: Many European countries are parties to either the Council of Europe (CoE) Criminal Law Convention on Corruption, the Civil Law Convention on Corruption, or both. The Criminal Law Convention requires criminalization of a wide range of national and transnational conduct, including bribery, money-laundering, and accounting offenses. It also incorporates provisions on liability of legal persons and witness protection. The Civil Law Convention includes provisions on whistleblower protection, compensation for damage relating to corrupt acts, and nullification of a contract providing for or influenced by corruption, inter alia. The Group of States against Corruption (GRECO) was established in 1999 by the CoE to monitor compliance with these and related anti-corruption standards. Currently, GRECO comprises 49 Member States (48 European countries and the United States). As of January 2016, the Criminal Law Convention has 44 parties and the Civil Law Convention has 35.

Free Trade Agreements: While it is U.S. government policy to include anticorruption provisions in free trade agreements (FTAs) that it negotiates with its trading partners, the anticorruption provisions have evolved over time. The most recent FTAs negotiated now require parties to adopt or maintain laws that criminalize the offering of an undue advantage to a public official (or the solicitation of such an advantage by a public official), as well as other acts of corruption in matters affecting international trade or investment. Parties also commit to effectively enforce their anticorruption laws and regulations. All U.S. FTAs may be found at the U.S. Trade Representative Website.

Local Laws: U.S. firms should familiarize themselves with local anticorruption laws, and, where appropriate, seek legal counsel. While the U.S. Department of Commerce cannot provide legal advice on local laws, the Department's U.S. and Foreign Commercial Service can provide assistance with navigating the host country's legal system and obtaining a list of local legal counsel.

Assistance for U.S. Businesses: The U.S. Department of Commerce offers several services to aid U.S. businesses seeking to address business-related corruption issues. For example, the U.S. and Foreign Commercial Service can provide services that may assist U.S. companies in conducting their due diligence as part of the company's overarching compliance program when choosing business partners or agents overseas. The U.S. and Foreign Commercial Service can be reached directly through its offices in every major U.S. and foreign city, or through its website at U.S. Commercial Service or Foreign Commercial Service .

The United States provides commercial advocacy on behalf of exporters of U.S. goods and services bidding on public sector contracts with foreign governments and government agencies. An applicant for advocacy must complete a questionnaire concerning its background, the relevant contract, and the requested U.S. Government assistance. The applicant must also certify that it is in compliance with applicable U.S. law, that it and its affiliates have not and will not engage in bribery of foreign public officials in connection with the foreign project, and that it and its affiliates maintain and enforce a policy that prohibits bribery of foreign public officials. Problems,

including alleged corruption by foreign governments or competitors, encountered by U.S. companies in seeking such foreign business opportunities can be brought to the attention of appropriate U.S. government officials, including local embassy personnel, and reported through the Department of Commerce Trade Compliance Center "Report a Trade Barrier" website. Potential violations of the FCPA can be reported to the Department of Justice via email to FCPA.Fraud@usdoj.gov.

Guidance on the U.S. FCPA: The Department of Justice's (DOJ) FCPA Opinion Procedure enables U.S. firms and individuals and issuers to request a statement of the Justice Department's present enforcement intentions under the anti-bribery provisions of the FCPA regarding actual, prospective business conduct. The details of the opinion procedure are available on DOJ's Fraud Section website and general information is contained in Chapter 9 of the publication A Resource Guide to the U.S. Foreign Corrupt Practices Act. Although the Department of Commerce has no enforcement role with respect to the FCPA, it supplies general information to U.S. exporters who have questions about the FCPA and about international developments concerning the FCPA. For further information, see the Office of the General Counsel, U.S. Department of Commerce website . More general information on the FCPA is available at the websites listed below.

Exporters and investors should be aware that generally all countries prohibit the bribery of their public officials and prohibit their officials from soliciting bribes under domestic laws. Most countries are required to criminalize such bribery and other acts of corruption by virtue of being parties to various international conventions discussed above.

Anti-Corruption Resources

Some useful resources for individuals and companies regarding combating corruption in global markets include the following:

- Information about the U.S. Foreign Corrupt Practices Act (FCPA), including *A Resource Guide to the U.S. Foreign Corrupt Practices Act*, translations of the statute into numerous languages, documents from FCPA related prosecutions and resolutions, and press releases are available at the U.S. Department of Justice's website and FCPA
- The U.S. Securities and Exchange Commission FCPA Unit also maintains a FCPA website. The website, which is updated regularly, provides general information about the FCPA, links to all SEC enforcement actions involving the FCPA, and contains other useful information.
- General information about anticorruption and transparency initiatives, relevant conventions and the FCPA, is available at the Department of Commerce Office of the General Counsel website.
- The Trade Compliance Center hosts a website with anti-bribery resources. This website contains an online form through which U.S. companies can report allegations of foreign bribery by foreign competitors in international business transactions
- Additional country information related to corruption can be found in the U.S. State Department's annual Human Rights Report.
- Information about the OECD Anti-Bribery Convention including links to national implementing legislation and country monitoring reports.

- (See also Anti-bribery Recommendation; and Good Practice Guidance Annex for companies.)
- GRECO Monitoring Reports
- MESICIC Monitoring Reports
- The Asia Pacific Economic Cooperation (APEC) Leaders have also recognized the problem of corruption and APEC Member Economies have developed anticorruption and ethics resources in several working groups, including the Small Medium Enterprises Working Group, and the APEC Anti-Corruption and Transparency Working Group.

There are many other publicly available anticorruption resources which may be useful, some of which are listed below without prejudice to other sources of information that have not been included. (The listing of resources below does not necessarily constitute U.S. government endorsement of their findings.)

- Transparency International (TI) publishes an annual Corruption Perceptions Index (CPI). The CPI measures the perceived level of public-sector corruption in approximately 180 countries and territories around the world. TI also publishes an annual *Global Corruption Report* which provides a systematic evaluation of the state of corruption around the world. It includes an in-depth analysis of a focal theme, a series of country reports that document major corruption related events and developments from all continents, and an overview of the latest research findings on anti-corruption diagnostics and tools. See Transparency.
- The World Bank Institute's Worldwide Governance Indicator (WGI) project reports aggregate and individual governance indicators for 215 economies over the period 1996-2014, for six dimensions of governance (Voice and Accountability, Political Stability and Absence of Violence, Government Effectiveness, Regulatory Quality, Rule of Law, and Control of Corruption). The World Bank Business Environment and Enterprise Performance Surveys may also be of interest. See also the World Bank Group Doing Business reports, a series of annual reports measuring regulations affecting business activity.
- The World Economic Forum publishes every two years the Global Enabling Trade Report, which assesses the quality of institutions, policies and services facilitating the free flow of goods over borders and to their destinations. At the core of the report, the Enabling Trade Index benchmarks the performance of 138 economies in four areas: market access; border administration; transport and communications infrastructure; and regulatory and business environment.
- Global Integrity, a nonprofit organization, publishes its annual Global Integrity Report, which typically assesses anti-corruption and good governance mechanisms in diverse countries.

Political & Security Environment

For specific information on political violence in Member States, please consult the Commerce Department's Country Commercial Guides of the 27 EU Member States found at the following website: EU Member States' Country Commercial Guides

Labor

Issues such as employment, worker training and social benefits remain primarily the responsibility of EU Member States. However, the Member States are closely coordinating their efforts to increase employment through

macroeconomic policy cooperation, guidelines for action, the exchange of best practices, and programmatic support from various EU programs. The best information regarding conditions in individual countries is available through the labor and social ministries of the Member States.

Helpful information from the EU can be found on the websites for the European Commission's Directorate-General for Employment and Social Affairs and on the Eurostat website .

In general, the labor force in EU countries is highly skilled and offers virtually any specialty required. Member States regulate labor-management relations, and employees generally enjoy strong protection. EU Member States have among the highest rates of ratification and implementation of ILO conventions in the world. Numerous provisions in the Treaty on the Functioning of the European Union (TFEU), EU labor law and policy guidelines aim to strengthen social dialogue and the role of the "social partners" (labor and management organizations) at EU, national, sectoral, local, and company levels.

There is a strong tradition of labor unions in most Member States. In many cases, the tradition is stronger than the modern reality. While Nordic Member States (Denmark, Finland, and Sweden) still have high levels of labor union membership, many other large Member States, notably Germany and the United Kingdom, have seen their levels of organization membership drop significantly to levels around 20-30 percent. French labor union membership, at less than 10 percent of the workforce, is lower than that of the United States.

OPIC and Other Investment Insurance Programs

OPIC programs are not available in the EU, although individual Member States have benefited from such coverage.

Foreign Direct Investment and Foreign Portfolio Investment Statistics

For specific information on Member States' foreign direct investment statistics, please consult the Commerce Department's Country Commercial Guides of the 27 EU Member States found at the following website: EU Member States' Country Commercial Guides

Contact for More Information on the Investment Climate Statement

For specific information on contacts for more information on the Investment Climate Statement in Member States, please consult the Commerce Department's Country Commercial Guides of the 27 EU Member States found at the following website: EU Member States' Country Commercial Guides

Political Environment

For background information on the political and economic environment of individual Member States, please click on the link below to the U.S. Department of State Background Notes.

How the E.U. Emerged

In 1951, after World War II, six European countries, Belgium, France, West Germany, Italy, Netherlands, and Luxembourg created the European Coal and Steel Community to help unify and rebuild Europe after the war. The Community was designed to prevent any future wars between France and Germany by promoting peaceful economic cooperation, political stability, secure economic growth, and increasing economic ties among countries, all for the purpose of moving towards a single market.

Under the threat of a more divided Europe during the Cold War, the six Western European states adopted the Treaty of Rome in 1957 to establish a common European market known as the European Economic Community (EEC).

By 1991, the Cold War was nearly over and the EEC with its twelve members (Germany, France, Italy, the Netherlands, Belgium, Luxembourg, Denmark, Ireland, United Kingdom, Greece, Spain, and Portugal) signed The Maastricht Treaty which radically changed the functioning of the organization. It officially created the European Union, expanded the scope of the EU's competencies, and set budgetary and mandatory monetary criteria for Member States that led to the creation of the Euro Area.

After the Cold War, Central and Eastern European nations were no longer bound to the Soviet Union. The political and economic benefits of the EU's democratic integration became appealing to the new Eastern European countries. As of 1993, in addition to budgetary commitments, new Member States had to adhere to the Copenhagen Criteria requiring nations to have stable institutions that guarantee democracy, a working market economy to handle the EU's competitive market, and the ability to commit to the obligations of EU membership (i.e. observing the goals of a political, economic, and monetary union). Additional members of the European Union are Austria, Sweden, Finland, Malta, Cyprus, Estonia, Latvia, Lithuania, Poland, Czech Republic, Slovakia, Slovenia, Hungary, Bulgaria, Romania and Croatia.
In June 2016, the UK voted in a referendum to leave the EU. On March 29, 2017, the UK formally triggered Article 50 of the EU's Lisbon Treaty and exited the EU on January 31, 2020. The U.K. and the EU are negotiating their future relationship and trade deal during a transition period that ends December 31, 2020.

Lisbon Treaty

In 2009, the Lisbon Treaty created various amendments to the existing Treaty of Rome and the Maastricht Treaty, revising the constitutional basis of the European Union. The major changes of the Lisbon Treaty were the creation of a long-term President of the European Council, recognizing the European Council as an official EU institution, and the creation of a new role of High Representative for Foreign Affairs and Security Policy. Under the Lisbon Treaty, Council decisions in most policy areas are now made under double majority, requiring the support of a minimum of 55 percent of Council of the European Union members and representing at least 65 percent of EU citizens. At the same time, for legislation to pass, the Parliament must have a simple majority (a majority of parliamentarians present) or 50 percent of the votes in favor. The need for adoption by both the Parliament and the Council of the European Union is called "ordinary legislative procedure" (formerly known as "co-decision.")

The Lisbon Treaty significantly increased the influence of the European Parliament including in the nomination of Commissioners and equally dividing budgetary authority between the Parliament and the Council of the European Union.

Main EU Institutions

European Council: The European Council is made up of the leaders (Heads of States or Government) of the EU member states. It defines the EU's overall political direction and priorities.

European Commission: As the executive branch of the EU, the European Commission holds the right to initiate and propose legislation and the budget to the Council of the European Union and to the Parliament. It is also charged with implementing decisions and acts as guardian of the EU's treaties. Each of the 27 Commissioners holds a different member state nationality but is obligated to remain neutral and above national politics.

European Parliament: The Parliament's role is several-fold and includes: 1) debating and passing European laws along with the Council once they have been proposed by the European Commission; 2) scrutinizing the work of the European Commission and other EU institutions; 3) debating and adopting the EU's budget along with the Council; and 4) vetting new Commissioner nominees.

Elections are every five years, the last taking place in May 2019 with citizens voting in national elections for their Members of European Parliament (MEPs). The total number of MEPs elected dropped from 751 to 705, after the withdrawal of the UK.

Council of the European Union (Council of Ministers): The Council of the European Union represents the governments of the 27 Member States in the EU. The Presidency of the Council rotates every six months between the 27 Member States. In addition to the European Parliament, the Council of Ministers shares the main legislative role of the EU. In July 2020, Germany took the reins starting in July 2020 through the end of the year, followed by Portugal.

European Court of Justice (ECJ): The purpose of the ECJ is to interpret EU law to make sure it is applied evenly across all EU Member States. Additionally, it may also engage in settling legal disputes between EU governments and EU institutions. Individuals, companies and organizations have the ability to bring cases before the ECJ if they feel their rights have been violated by an EU institution.