

U.S. Country Commercial Guides



Portugal

Year 2020

U.S. Department of Commerce

International Trade Administration

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Doing Business in Portugal

Market Overview

Mainland Portugal, along with the autonomous island regions of the Azores and Madeira, offers American exporters a market of approximately 10.3 million people in a country roughly the size of the State of Indiana. As a member of the European Union (EU) and the euro zone, it is fully integrated with the EU, uses the euro currency, and follows directives from the European Commission (EC) in Brussels. As with all EU countries, Portugal's borders and ports are completely open to the free flow of trade with other EU member countries. Portugal is politically stable with a democratically elected parliamentary government and welcomes foreign business and investment.

Prior to COVID-19, Portugal registered real GDP growth of 2.6% and 2.2% in 2018 and 2019, respectively. The country has also witnessed important declines in unemployment, which fell to 6.5% in 2019 from 7% in 2018 and 8.9% in 2017.

The structural reforms implemented since 2011 have created an economic and regulatory climate that is favorable to foreign investment which remains a priority for the government with a focus on tourism, renewable energy, high quality industrial components, technology services, and value-added agricultural products.

U.S. Census data indicates that Portuguese consumers bought approximately \$1.7 billion dollars worth of U.S. goods and services in 2019, a slight increase compared with the \$1.57 billion in 2018. In that same period, U.S. imports of Portuguese goods and services grew from \$3.88 billion in 2018, to \$3.89 billion in 2019.

A WorldCity analysis of latest U.S. Census Bureau data reveals that Portugal's trade with the U.S. rose to \$1.99 billion through the first four months of 2020. U.S. exports to Portugal decreased 5.6% and U.S. imports from Portugal increased 13.9%. The top five U.S. exports to Portugal through April 2020 were the categories of LNG, other petroleum gases; civilian aircraft parts; oil; misc. aircraft parts; and low value shipments. The top five categories of U.S. imports from Portugal through April 2020 were gasoline, other fuels; misc. natural cork; medicines in individual dosages; rubber tires; and speedometers and tachometers.

The top U.S. states exporting to Portugal are Louisiana, Texas, Pennsylvania, New Jersey, Indiana, California, Florida, Kansas and Ohio. Top U.S. exports include oil and gas products, aircarfts parts, machinery parts and agricultural products.

The United States is Portugal's largest trading partner outside the European Union and the UK. The total amount of U.S. goods sold into Portugal is likely higher than what the statistics reflect, as census data does not account for U.S. products imported into other EU countries and subsequently transported into Portugal for sale. It is common throughout the European Union for goods to be shipped to one EU location – often to take advantage of lower value added tax rates – and then to be distributed by ground transport to neighboring member state markets.

The United States continues to work closely with Portugal to find ways to expand and deepen two-way trade and investment that reflects historically strong political, geo-strategic, and security ties between the two countries. Portugal's continued drive to modernize and diversify its economy will offer possibilities for growth in U.S. trade and investment over the medium and long-term. Demand for high-quality, price-competitive U.S. products in Portugal is strong, and the high tech industries will continue to provide additional opportunities for investment.

Key links: <u>https://www.state.gov/u-s-relations-with-portugal/</u> <u>https://www.ustradenumbers.com/country/portugal/</u> <u>https://ine.pt/xportal/xmain?xpgid=ine_main&xpid=INE</u> <u>https://www.pordata.pt/en/Home</u>

Market Challenges

The government has promoted foreign investment and fostered economic stability and growth, enabling Portugal to surpass EU growth predictions. In 2018, Portugal registered its lowest budget deficit since the restoration of democracy in 1974, and after the recent financial crisis the country exited the EU's Excessive Deficit Procedure (bailout) in mid-2017.

The governing's Socialist Party (PS) strategy of steady fiscal consolidation drove Portugal to close 2019 with a historic surplus (at 0.2% of GDP) and has kept the debt/GDP ratio on a downward trend since 2014. However, entering 2020 the government estimated a 1.9% GDP growth that has mutated due to COVID-19 into a recession; Portugal's real GDP declined by a quarterly 3.8% (seasonally and working-day adjusted) in January-March, the sharpest contraction ever recorded and the first hard evidence of the magnitude of the current economic crisis due to the pandemic. Declines in private consumption were the main drivers of lowering GDP, falling by a quarterly 2.9% in the same time period. All business confidence indicators weakened and strong reductions in trade and services were felt. The second-biggest driver of the economic contraction was exports, which fell by 7%, significantly outpacing the import contraction of 3.1%. Investment increased by 1.8%, largely due to higher spending in construction and transport equipment – sectors largely shielded from the lockdown.

The crisis is expected to cause a fiscal deficit of at least 6.9% of GDP in 2020. However, the risk of a sovereign debt crisis is small and government schemes will cushion the impact on the labor market – even though the unemployment rate is likely to increase throughout the year.

American exporters face competition in Portugal from savvy European competitors. European companies are already familiar with aspects of the business culture, financing, regulations, standards, etc. In addition, they do not face import tariffs that U.S. companies have to pay to get their products into Portugal. Some U.S. companies have also reported that they are encountering Chinese competitors in Portugal.

Key link: https://country.eiu.com/portugal

Market Opportunities

Portuguese tend to perceive American products as high quality, but not price competitive. U.S. firms should stress price/quality competitive advantages when trying to enter the Portuguese market.

The Portuguese market is larger than it may initially appear. While there are only 10.3 million people in Portugal, there are well over 250 million people who speak Portuguese worldwide. Former Portuguese colonies, including Macau, Mozambique, Angola and Brazil, have close business ties with Portugal. U.S. companies can often find avenues to these other markets through Portugal and, indeed, the Portuguese Business Promotion Agency (AICEP) actively markets the country as a "gateway" economy into third markets, particularly in Lusophone Africa.

Portugal is an excellent entry point or test market for U.S. firms looking to establish access into the EU. The country is politically stable; the crime rate is relatively low; the bilateral relationship is strong; English is widely spoken; and the population is very friendly toward Americans. Both physical and IT Infrastructure are well developed, and the cost of doing business in Portugal is significantly lower as compared to other countries in Western Europe. Companies that have already penetrated one EU country will have met the requirements for Portugal as well. Additionally, there may be opportunities with the shifing of global supply chains; Portugal is actively working to re-shore supply chains as well as may be a potential target destination for firms re-shoring plans.

To manage the economic impact of the COVID-19 pandemic the Portuguese government developed the "Srategic vision for the economic recovery plan of Portugal 2020-2030," leveraging experience from the previous economic crisis, the government is developing measures to overcome the current instability, such as; investements, financing, business support and fostering inovation. Furthermore, there are calls with in the plan for infrastructure development projects (much fueled by EU recovery funds) and the development of a clean hydrogen industry.

Market Entry Strategy

The quickest and best way to enter the Portuguese market is to work with a local partner. Both small and large U.S. exporters can benefit from finding the right person or group in Portugal who can provide advice and contacts. The U.S. Commercial Service office in Portugal, located in the U.S. Embassy in Lisbon, offers a variety of services to help U.S. firms find the information they need about the market as well as identify potential agents, distributors, sales representatives for their products or services and strategic business partners.

First time exporters are urged to contact the nearest of over <u>100 U.S. Export Assistance Centers (USEAC)</u>. These USEACs are part of the worldwide network of U.S. Department of Commerce offices that support U.S. exporters.

The U.S. Commercial Service in Portugal recommends that U.S. firms acquainte themselves with the Portuguese market through the standard market research reports we publish, and which are publicly available through the USEACs and the Internet.

Leading Sectors for U.S. Exports and Investment

Agricultural Sector

Overview

For more information on opportunities for U.S. agricultural exports to Portugal, please contact the Foreign Agricultural Service at the American Embassy in Madrid.

Office of Agricultural Affairs covering Spain and Portugal Foreign Agricultural Service, USDA U.S. Embassy Madrid Tel: +34-91-587-2555 Email: AgLisbon@fas.usda.gov

Soybeans

Overview

	2018*	2019	2020
			(estimate)
Total Market Size	472,179	424,201	379,300
Total Local Production	0	0	0
Total Exports	565	2,819	700
Total Imports	472,744	427,020	380,000
Imports from the U.S.	220,635	183,770	120,000

Unit: USD thousands

Total Market Size = (Total Local Production + Total Imports) – (Total Exports)

Data Sources: Total Local Production: FAS Madrid estimates Total Exports: Trade Data Monitor Total Imports: Trade Data Monitor Imports from U.S.: Trade Data Monitor Data corresponding to Soybeans, (HS Code 1201) Trade Data Monitor

Opportunities

Soybeans in Portugal are crushed to obtain soybean meal for the feed industry and soybean oil for the biodiesel industry. Soybean oil represented nearly 10 percent of the feedstock used for biofuel production in 2019. Price competitiveness with other suppliers of feed ingredients (mostly located in South America) and other oilseeds determines demand for U.S. soybeans in the feed and biofuel markets. Since 2015, the extensive use of used cooking oils has resulted in a reduction of soybean oil use in biodiesel production. Portugal is also an importer of soybean meal. Price competitiveness with other suppliers (mostly located in South America) and other oilseeds determines demand for U.S. soybeans in the feed and biofuel markets. In 2018, Portuguese soybean crushers registered a nearly four-fold increase in the value of U.S. soybean imports. In 2019, a lower total soybean crush together with increased competitiveness of other soybean origins prevented this record figures of U.S. soybean sales to Portugal from

repeating. However, beyond price competitiveness, initiatives to minimize the EU's contribution to deforestation, could increase up market opportunities for U.S. soybeans in Portugal.

Resources

National Institute of Statistics Portugal

FAS GAIN Attaché Reports

FAS Contact - <u>AgMadrid@fas.usda.gov</u>

Grains

Overview

	2018	2019	2020
			(estimate)
Total Market Size	1,086,952	980,200	980,000
Total Local Production	205,355	197,676	205,000
Total Exports	128,827	110,348	95,000
Total Imports	1,010,424	892,872	870,000
Imports from the U.S.	45,937	10,435	6,000

Unit: USD thousands

Total Market Size = (Total Local Production + Total Imports) - (Total Exports)

Data Sources: Total Local Production: FAS Madrid estimates Total Exports: Trade Data Monitor Total Imports: Trade Data Monitor Imports from U.S.: Trade Data Monitor Data corresponding to Group 01 Trade Data Monitor

Opportunities

Over the past five years the gap between Portuguese grain consumption and production has consistently grown. Regardless of the size of the domestic grain crop, Portugal has a grain deficit of nearly 3.5 million metric tons. Bulk commodity trading companies based in the Iberian Peninsula are the main gateway to the Portuguese feed and food grains market. With an estimated consumption of 3.3 MMT, the Portuguese compound feed industry is the main grains buyer. Grains represent nearly 60 percent of the feed formula. The country's compound feed production was declining until 2015, when a combination of favorable input prices and increased efficiencies due to the consolidation of industries, resulted in higher compound feed production levels. This trend continued until 2019. While in 2020, we may witness some reduction in grains demand, Portugal will continue to import grain in order to meet its structural grains shortfall. Since June 2018, the EU 25 percent duty on U.S. corn limits exports possibilities, however opportunities still exist for corn processing by-products (DDGS), in quantities that fluctuate based on competition

from other sources. The U.S. also exports wheat, including durum wheat to Portugal, with export opportunities depending on competition from other origins.

Resources

National Institute of Statistics Portugal

FAS GAIN Attaché Reports

FAS Contact - <u>AgLisbon@fas.usda.gov</u>

Seafood

Overview

	2018	2019	2020
			(estimate)
Total Market Size	3,362,251	3,294,233	3,360,000
Total Local Production	2,020,000	2,050,000	2,100,000
Total Exports	981,035	927,355	920,000
Total Imports	2,323,286	2,171,588	2,180,000
Imports from the U.S.	26,942	30,706	31,000

Unit: USD thousands

Total Market Size = (Total Local Production + Total Imports) – (Total Exports)

Data Sources:

Total Local Production: FAS Madrid estimates

Total Exports: Trade Data Monitor

Total Imports: Trade Data Monitor

Imports from U.S.: Trade Data Monitor

Data corresponding to HS Code 03 (Fish and Crustaceans, Mollusks and other aquatic invertebrates).

Opportunities

The level of development of the fishing industry reflects the high level of consumption of fish and seafood in Portugal. Per capita consumption of seafood is the highest in the European Union and is amongst the highest in the world at around 56.8 kg/year per capita.

Portugal is a net importer of fish and seafood and sources from almost one hundred countries around the world. In 2019, Portugal's imports of fish and seafood from the United States were valued at \$20.7 million. U.S. seafood products are very well rated and in demand in the Portuguese market. Cod, salmon and caviar sturgeon were among the top imports from the United States in 2019.

Resources

Ministry of the Sea

NOAA Seafood Inspection Program

NOAA Fisheries "How to export seafood to the European Union"

FAS USEU Mission FAS GAIN Attaché Reports

FAS Contact - <u>AgLisbon@fas.usda.gov</u>

Hardwood

Overview

	2018	2019	2020
			(estimate)
Total Market Size	209,609	206,025	207,000
Total Local Production	175,000	179,000	180,000
Total Exports	24,513	24,944	25,000
Total Imports	59,122	51,969	52,000
Imports from the U.S.	24,325	19,910	20,000

Unit: USD thousands

Total Market Size = (Total Local Production + Total Imports) – (Total Exports)

Data Sources: Total Local Production: FAS Madrid estimaste Total Exports: Trade Data Monitor Total Imports: Trade Data Monitor Imports from U.S.: Trade Data Monitor) Data corresponding to HS Codes 440391, 440791 and 440890

Opportunities

Portugal has a well-developed timber processing industry. U.S. hardwood has a good reputation in the Portuguese market for its high quality and reliability. American oak is highly appreciated in the production of casks for Porto wine.

Resources

<u>National Institute of Statistics Portugal</u> <u>Ministry of Agriculture, Forestry and Rural Development</u> <u>American Hardwood Export Council (AHEC)</u>

<u>FAS USEU Mission</u> FAS GAIN Attaché Reports

FAS Contact - <u>AgLisbon@fas.usda.gov</u>

Tree Nuts

Overview

	2018	2019	2020 (estimate)
Total Market Size	49,670	27,968	30,000
Total Local Production	54,000	56,000	58,000
Total Exports	77,722	98,242	99,000
Total Imports	73,392	70,210	71,000
Imports from the U.S.	10,215	5,569	6,000

Unit: USD thousands

Total Market Size = (Total Local Production + Total Imports) – (Total Exports) Data Sources: Total Local Production: FAS Madrid estimates Total Exports: Trade Data Monitor Total Imports: Trade Data Monitor Imports from U.S.: Trade Data Monitor

Data corresponding to HS Code 0802 (Nuts NESOI, Fresh or dried) for Portugal.

Opportunities

The main source of tree nuts for Portugal is Spain. It is likely that part of these tree nuts have their origin in the United States, are imported though Spain and finally re-exported to Portugal. U.S. nut exports to Portugal are led by almonds, followed by walnuts and pistachios. The nuts are imported and reprocessed domestically for domestic consumption and to re-export them to third countries outside the European Union, the main destination of these nuts in 2019 were Brazil, Turkey, Canada and the United States.

Resources

National Institute of Statistics Portugal

Almond Board of California

FAS USEU Mission FAS GAIN Attaché Reports

FAS Contact - <u>AgLisbon@fas.usda.gov</u>

Pulses/Legumes

Overview

	2018	2019	2020 (estimate)
Total Market Size	47,888	56,335	51,800
Total Local Production	4,500	4,600	4,800
Total Exports	24,123	17,754	20,000
Total Imports	67,511	69,489	67,000
Imports from the U.S.	3,925	10,856	6,000

Unit: USD thousands

Total Market Size = (Total Local Production + Total Imports) – (Total Exports) Data Sources: Total Local Production: FAS Madrid estimates Total Exports: Trade Data Monitor Total Imports: Trade Data Monitor Imports from U.S.: Trade Data Monitor

Data corresponding to HS Code 0713 (Leguminous vegetables, dried shelled) for Portugal.

Opportunities

Domestic consumption of pulses is high in the Portuguese market, particularly for dry edible beans, which are an important component of the local diet. In 2019, U.S. exports were led by chickpeas, red kidney beans and lentils. Companies also process and re-export dry edible beans within the EU market.

Web Resources

Statistics Portugal United States Dry Bean Council and USA Dry Peas and Lentil Council

FAS USEU Mission FAS GAIN Attaché Reports

FAS Contact - <u>AgLisbon@fas.usda.gov</u>

Meat

Beef

Overview

	2018	2019	2020
			(estimate)
Total Market Size	1,046,370	1,014,824	1,000,000
Total Local Production	439,168	415,530	400,000
Total Exports	62,062	53,362	50,000
Total Imports	669,264	652,656	650,000
Imports from the U.S.	0	0	0

Unit: USD thousands

Total Market Size = (Total Local Production + Total Imports) – (Total Exports) Data Sources: Total Local Production: FAS Madrid estimates Total Exports: Trada Data Monitor (TDM) Total Imports: Trada Data Monitor (TDM) Imports from U.S.: Trada Data Monitor (TDM)

Data corresponding to HS Code 0201, 0202 for Portugal.

Opportunities

Beef (only from non-hormone treated cattle) has good sales potential in Portugal. Domestic production and consumption of beef is increasing especially high-end beef. Portugal is not self-sufficient in beef production being Spain the main source of beef. Additionally, Portugal imports around three percent of beef outside the EU mainly from Brazil, Uruguay, Argentina, and New Zealand.

Resources

Statistics Portugal

FAS GAIN Attaché Reports

FAS Contact - <u>AgLisbon@fas.usda.gov</u>

Pork

Overview

	2018	2019	2020
			(estimate)
Total Market Size	1,422,759	1,325,358	1,475,000
Total Local Production	1,133,901	1,052,980	1,200,000
Total Exports	111,672	128,375	150,000
Total Imports	400,530	400,753	425,000
Imports from the U.S.	0	0	0

Unit: USD thousands

Total Market Size = (Total Local Production + Total Imports) – (Total Exports) Data Sources: Total Local Production: FAS Madrid estimates Total Exports: Trada Dta Monitor (TDM) Total Imports: Trada Dta Monitor (TDM) Imports from U.S.: Trada Dta Monitor (TDM)

Data corresponding to HS Code 0203, 0210 for Portugal.

Opportunities

Pork (only ractopamine-free pork) has good sales potential in Portugal. Pork domestic production is increasing to attend domestic and external demand. Portugal is not self-sufficient in pork production being Spain the main source of pork. Due to the growth of pork exports mainly to China, pork imports in Portugal may increase.

Resources

Statistics Portugal

FAS GAIN Attaché Reports

FAS Contact - <u>AgLisbon@fas.usda.gov</u>

Aerospace and Defense

Overview

The aerospace and defense industry in Portugal has a small but strong industrial base in several areas including engines, air traffic infrastructures, aircraft, cabin interiors, electronics, tools and support technologies, structures, material and production, among others. The aviation maintenance sector is also important and recognized internationally in both civil and military aircrafts.

The Aerospace, Defense and Space (AED) continue to be a priority for the Portuguese Government. AED Portugal cluster created in 2016 currently has more than 70 entities which export around 87% of its production generating a turnover of more than 1.72 billion euros.

Portugal recently approved a new military programming law and forecasts expenditures of approximately \$5.3 billion for 10 years through 2030. The country is primarily focused on enhancing its defense capabilities to secure its maritime borders, develop its cyber warfare capabilities and reinforce its assets to better support missions where Portugal is involved under NATO, UN or EU mandates. The planned defense expenditure may contribute to improve Portugal's NATO attainment of two percent GDP dedicated to military spending.

The U.S. is traditionally an important supplier of aerospace and defense equipment and components, competing directly with other countries like Israel and EU countries such as Italy, Austria or Spain. U.S. manufacturers are well-positioned to benefit from a growing market where defense imports are expected to increase over the next couple of years with the recent agreement by the Portuguese military to acquire the KC-390 from Embraer and other planned strategic acquisitions.

More recently, all aerial firefighting operations and management were transferred to the Portuguese Air Force, who is assessing its current fleet of aircrafts in order to upgrade or acquire new equipment that can be used in aerial firefighting. They are also responsible to tender and lease the necessary aircrafts ranging from light helicopters to amphibious waterbombers needed to combat wildfires. The Portuguese Air Force launched a tender for aerial firefighting at the end of 2019 for a period of 3 years (2020 - 2023) which is longer than the previous contracts but not the same as before 2017 where contracts were for 5 years.

Nevertheless, U.S. exporters should be aware that like in many EU countries, there is a push to buy European, namely from the European Defense Agency. It is highly recommended to engaged with the Portuguese Government and identify local partners as early as possible.

Leading Sub-Sectors

The best prospects for U.S. exporters exist in the following segments: commercial aircraft, business jets, turboprops, helicopters, UAVs, structures, propulsion systems, subsystems for aerospace vehicles; military aircraft, air defense systems; spacecraft, launch systems, communications systems; access control, identity management, integrated systems, security services.

Opportunities

U.S. exporters looking to export into Portugal must demonstrate a clear competitive advantage. It is important for a U.S. company to commit both time and resources to enter or expand within the Portuguese aerospace and defense market. Identifying a local partner is the least risky market entry strategy for most U.S. suppliers to enter the Portuguese aerospace and defense supply chain.

U.S. suppliers interested in the Portuguese market should connect with the U.S. Commercial Service in Portugal and should consider participating in the upcoming virtual event - AED Days 2020 – scheduled for October 6-7, 2020 (https://aeddays.com/2020/)

Portuguese companies often seek technology that may add value to the projects they plan on delivering in Portugal and abroad. They are often pro-active in reaching out to U.S. suppliers with specific requests for quotes.

As far as potential future opportunities, these include helicopters, armored vehicles, surveillance vessels, upgrading the existing fleet of F-16 and other aircrafts and aerial firefighting equipment and solutions.

Resources

AED Portugal Cluster: https://www.aedportugal.pt/en/

Portuguese Ministry of Defense: https://www.portugal.gov.pt/pt/gc22/area-de-governo/defesa-nacional

Portugal Space Agency: https://www.ptspace.pt/

APSEI - Associação Portuguesa de Segurança Electrónica e de Protecção Incêndio: http://www.apsei.org.pt

Portuguese National Civil Protection : <u>http://www.prociv.pt/en-us/Pages/default.aspx</u>

Portuguese Ministry of Internal Affairs: https://www.portugal.gov.pt/en/gc21/ministries/internal-administration

Automotive and Automotive Parts

Overview

There are about 5.8 million registered vehicles in Portugal. In 2019, 267,828 vehicles were sold in Portugal. Most of those vehicles are passenger vehicles with a growth of 20.5% compared to 2018. The automotive sector in Portugal consists of the 29,000 companies that manufacture automobiles and components, creates 124,000 direct jobs and generates a business volume of 23.7 billion Euro, equivalent to 21.6% of the total fiscal revenues in Portugal. This sector accounts for 11% of total exports from Portugal. Portugal hosts over 220 automotive supplier companies and 4 major car manufacturers—Toyota/Salvador Caetano, PSA Peugeot Citroen, Mitsubishi Trucks and Volkswagen AutoEuropa.

Interface and Industria 4.0 are two public programs with incentives to support innovation in the sector.

The automotive sector is a key performer in the Portuguese economy. In recent years, it has become increasingly significant as it plays an important role in the economy's GDP. The automotive sector is responsible for almost 8.5% of Portugal's industry and 2.1% of the Portuguese economy industrial production. It employs 0.7% of the population and accounts for 4.8% of the manufacturing industry. According to ACAP (Automobile Association of Portugal), the automotive sector in Portugal is responsible for 11% of the total Portuguese exports. In 2019, the number of vehicles produced reached a total of 345,000, a 17.4% increase compared with the previous year, and out of which 97.3% were exported, mainly to Europe.

However, ACAP-Associação Automóvel de Portugal (Automobile Association of Portugal), reported that the pandemic forced car production in Portugal to drop 46.1 percent in March compared to the same month of 2019. In March 2020 a total of 13,686 light passenger vehicles were produced (47.1 percent less than in the same month of the previous year), 3,203 light commercial vehicles (-39.3 percent) and 207 heavy vehicles (-61.1 percent). The pandemic had a significant impact on the activity of national and international economic actors, be it consumers, businesses, banks, or public administration entities. According to the ACEA Associação dos Construtores Europeus de Automóveis – (Association of the European Automobile Constructors), EU demand from January to April of 2020 for new passenger cars contracted by 38.5%, with a decline of 76.3% in April on a comparison posted year-on-year, being this the reflection of the first full month with COVID-19 restrictions. The impact of the coronavirus crisis on the production lost. This figure includes passenger cars, trucks, vans, buses and coaches. Production losses are obviously set to increase if shutdowns are extended or additional plants are brought to a halt.

In the first quarter of 2020, there was a drop of 18.3 percent in automobile production, a total of 77,204 units were manufactured, a production decrease of 20.5 percent in passenger cars, 4.5 percent in light commercial vehicles and 36.4 percent heavy vehicles.

Of all the automobiles produced in Portugal until March 2020, 98.1 percent were for exports, Europe absorbs 97.5 percent of these exports; Germany (19.4 percent), France (16.9 percent), Italy (15.7 percent), Spain (11.2 percent) and the United Kingdom (9.8 percent) were the main markets for Portuguese car exports.

The automotive components industry in Portugal has recently registered an annual turnover of around 10 billion which represents 5% of the country's GDP with a workforce of over 50,000 people and one of the main exporting sectors in Portugal. About 85% of total automotive components produced in the country are exported. The automotive components industry has grown 200% over the past 15 years and presently Portugal is supplying carmakers with batteries, glass, plastic molds, interiors, tires, metal works, cables and harnesses, car seats and electronics.

Source: https://mobinov.pt

For the manufacture of automobiles, the U.S. exports many automobile parts and components to Portugal. In 2019 Portugal imported a total of USD 20.4 million. The top 10 exports are:

HS 8708950000--AIRBAGS FOR MOT VEH FOR HDS 8701 TO 8705, PARTS

HS 9029900000--PTS FOR REVOLUTION COUNTERS, ODOMETER, ETC

HS 8544300000--INSULATED WIRING SETS FOR VEHICLES SHIPS AIRCRAFT

HS 8512908000--WINDSHIELD WIPERS/DEFROSTERS/DEMISTER PARTS

HS 8482500000--OTHER CYLINDRICAL ROLLER BEARINGS

HS 8708998175--PARTS AND ACESSORIES FOR VHCLS 8701 TO 8705, NESOI

HS 8507904000--LEAD-ACID STORAGE BATTERY PARTS

HS 8708295170--PTS AND ACCESSORIES, NESOI, OF BODIES HDG 8701,8705

HS 8708807000--PARTS AND ACESSORIES FOR SUSPENSION SYSTEMS

8409914000--PARTS F SPARK IGN ENG F RD TR, BUS, AUTO OR TRUCKS

Source: United States Department of Commerce, Bureau of the Census, Foreign Trade Division TPIS Database: USHS EXPORTS, Revised Statistics for 1989-2019

Market Entry

The most effective way to enter the Portuguese market is to partner with a local company that can act as a local representative as well as provide insights about the local market environment and trends.

Barriers

The mandatory European approval and certification process can be challenging for U.S. vehicles and parts when exporting to Portugal. There are no customs duties on imports from European Union (EU) countries. The VAT in Portugal is 23 percent. The VAT is applied to all imports, including European and local suppliers.

Current Market Trends and Demand

Motorcycles

U.S. motorcycles such as Harley-Davidson, Buell, Polaris /IPS are sold in Portugal. Portuguese continue to look for other means of transportation such as scooters and motorcycles.

Electric Vehicles and Hybrid Vehicles

Zero emissions vehicles (ZEV) and hybrid vehicles continue to gain market share. These vehicles include Tesla, Toyota Prius, Honda Civic Hybrid, Lexus LS, GS and RX Hybrid, Segway among others. Portugal benefits from the first nationwide, fully interoperable electric mobility system, where any user can charge any vehicle at any of the more than 1,250 charging points. An emerging cluster around new mobility concepts and services in Portugal is attracting the partnership of large corporations. A perfect example of that is Tesla, which started Model 3 deliveries in February 2019, sold 1979 cars in national territory in 2019, giving Tesla a 27.8% market share. Additionally, Portugal has one of the largest reserves in Europe with an estimate reserve of 2–10 million tons of lithium.

In alternative engines to fossil fuels, sales of electric and plug-in hybrids are also noteworthy. There was an increase of 3.3% in electric/gasoline hybrids to 8545 units and almost zero growth in electric/diesel hybrids (+0.3% for 883 cars sold). On other hand plug-in/gasoline grew 1.8% to 4653 cars bought; and plug-in/diesel grew 0.4% to 1145 units. As a result, pure plug-in or hybrids, increased the market share to 8.5%.

Aftermarket Accessories

The market for automotive accessories and specialty equipment in Portugal and distribution channels largely consist of small importers. Although it is considered a small market when compared to neighboring Spain, it is an ideal market for product acceptance studies, serving as a gateway to other European and Portuguese-speaking markets.

Acceptance of U.S. products and new technology in Portugal is very high and well received by local companies and consumers. Portuguese over the past years have become fans of a wide range of products such as, passive and active security systems, automotive eco-friendly solutions, diagnostic and testing tools, as well as car entertainment systems.

In general, all products with cutting-edge technology can be placed into the Portuguese market. As a rule, Portuguese are ready to take into consideration new products and pay extra money for something that is, or seems to be, new and innovative.

Smaller Engines

Europe's best-selling car models can be equipped with 3-cylinder engines of 1000cc or less. This is the measure taken by brands to meet emission limits for pollution gases and to contain the production and sales costs of the latest cars, thus providing more technology while maintaining similar prices.

SUV

The SUV market grew 2.7% in 2019, corresponding to 24% of car sales in Europe. It is expected to continue growing, as the implementation of new technologies in these cars will make them safer, more comfortable, and more practical. In Portugal, SUVs are divided into four sub-segments: small or mini, compact, medium and large. The most popular are the mini SUVs, mainly due to it more competitive price. According to ACAP official numbers, by October 2019, the number of new registrations of SUVS reached 59,030, of which 29,819 were mini SUVs, followed closely by the compacts, 21,223, which offer family characteristics. Medium-sized SUVs registered were 6,836, while large SUVs accounted for a total of 1,152.

Gasoline engine VS Diesel engine

Diesel cars are losing market share. According to ACAP - Associação Automóvel de Portugal (Automobile Association of Portugal), of the 223,799 light passenger cars bought in 2019, 49.2% have a gasoline engine and 40% have a diesel engine. Despite that, the number of diesel engine commercial vehicles is still overwhelming: 99.1% of the 38,454 cars in this market are diesel and only 0.2% (90 vehicles) have a gasoline engine.

Leading Sub-Sectors

This industry is divided into three main groups: motor vehicles for all purposes, including tractors; parts and accessories; and chassis, bodywork, trailers and semi-trailers.

Main Competitors

U.S. exporters generally will face strong competition from European and Chinese suppliers but are well positioned as a supplier to the Portuguese automotive market, mainly in electric vehicles, where Tesla leads

Opportunities

Electric Drive Vehicles Market Summary

The administrator of EDP, the Portuguese Electric Utilities Company, António Coutinho, foresees that by 2025, 10 percent of car sales in Portugal will be electric cars, a figure that is estimated increases to 40 percent by 2040. He believes the future lies in the electrification of transportation. The European Commission is preparing a major economic stimulus package to include 20 billion euros (\$22 billion), to offer consumers in the 27-nation bloc incentives to buy environmentally friendly passenger cars, over which there have been some discussions and disagreements, among EU members, on how to define "clean cars".

Mobility applications

Applications such as Uber, Cabify or Taxify have and continue to disrupt the automotive market. Portugal has embraced mobility apps and usage in the urban areas and the trend is towards increasing use of these type of applications, especially for complementary transports such as electric scooters.

Trade Events

ENVE 2020 – National Electric Vehicles Meeting

September 19-20, 2020 | Lisbon, Portugal |

https://www.uve.pt/page/encontro-nacional-de-veiculos-eletricos-2020-em-lisboa/

As in previous editions of ENVE, the event will hold several conferences, conferences, networking to share of sharing experiences between electric vehicle users, exhibition of all types of electric vehicles, electric vehicle test-drive and

animation. ENVE is the largest electric mobility event in Portugal, precisely in the year that celebrates the distinction of Lisbon as European Green Capital.

ENVE aims to enhance the dissemination of electric mobility in Portugal, with a national meeting that highlights all electric vehicles: light and heavy vehicles, passenger and commercial vehicles, motorcycles, scooters, and bicycles, presently marketed in Portugal, including some national premier models. All manufacturers and marketers of electric chargers, for both public and private networks, fast chargers, semi-fast or normal, in DC or AC, for domestic use or in condominiums will be present.

Resources

Automobile Association of Portugal: http://www.acap.pt

Portuguese Association of Automotive Suppliers: <u>http://www.afia.pt</u>

Automotive Cluster MOBINOV: http://www.mobinov.pt/index.php/en/

https://ec.europa.eu/transport/modes/rail/ertms/countries/portugal_en

https://oec.world/en/profile/country/prt

http://www.portugalin.gov.pt/automotive-industry/

https://www.publico.pt/2019/04/12/economia/opiniao/novo-automovel-influencia-tendencias-consumo-revolucaoi40-1869027

https://sol.sapo.pt/artigo/683032/producao-de-carros-bate-recorde-em-portugal-em-2019

http://www.apdc.pt/iniciativas/agenda-apdc/-o-futuro-da-industria-automovel-

https://visao.sapo.pt/atualidade/sociedade/2019-03-09-como-o-mercado-automovel-esta-a-mudar-e-muitorapidamente/

https://comprasegura.standvirtual.com/tendencias-sector-automovel-2019/

https://www.caixabankresearch.com/en/economics-markets/activity-growth/portugal-automotive-industry-leadsexports-goods

https://ec.europa.eu/transport/modes/rail/ertms/countries/portugal_en

Energy

Overview

Portugal is one of the EU countries with the highest energy dependence, around 77.7% in 2017. This is mainly due to the lack of fossil energy sources which continue to have a significant impact on the total consumption of primary energy. Nevertheless, Portugal over the last two decades focused heavily on developing renewable energy, primarily wind and solar which helped the country lower its energy dependence to levels below 80%; the main fossil fuels which account for the total primary energy supply are oil, natural gas and coal. It is estimated that Portugal fossil fuels dependence by 2030 will be around 65%.

Portugal continues to be a global leader in renewable energy production. A well-structured incentive mechanism and the adoption of ambitious targets helped this sector grow over the last couple of years. Portugal's new

ambitious national energy and climate plan for 2030 and roadmap to carbon neutrality by 2050 targets at least 80% of electricity production coming from renewables and to further decarbonize the energy sector.

The government is committed to a policy that will support the development of the market and ensure decarbonization goals are met in the most cost-effective manner. There is a strong focus in electricity and natural gas interconnection to unlock the potential of Portugal's solar and wind resources and liquefied natural gas capacity to support local economic development and European energy security. In order to achieve these ambitious goals, Portugal has announced that they anticipate the close of the country's two coal-fired thermoelectric power plants by 2023. The country has also developed a hydrogen strategy with the intent to decrease natural gas imports and reduce greenhouse gas emissions by 2030.

Leading Sub-Sectors

Renewable Energy

At the end of June 2020, the installed capacity in units of production of electric energy from renewable sources was 14,4 8 MW which generated around 56% of Portugal electricity according to EU Directive 2009/28/EC. The main sources of renewable energy included hydro, followed by wind, biomass and solar.

Portugal continues to be an attractive market for the development of renewable energy. However, decision-making tends to be bureaucratic and collaborative relationships with local companies is typically the most appropriate market entry strategy. Any major project usually requires some type of joint venture. A sustained local presence, product exposure, and/or track record in the renewable energy industry will also prove to be an advantage while the market continues to develop.

A recent example are the solar auctions, the first one launched in 2019 awarded 1,400 MW, at an average tariff of 20.4EUR per MWh, where the lowest reached 14.7EUR per MWh. The second auction to award 700 MW was held in August, 2020.

Installed Capacity (MW)	2011	2020 (June)
Hydro	5,330	7,129
Wind	4,378	5,454
Biomass	575	703
Urban Solid Waste	86	89
Biogas	51	93
Geothermal	29	34
Photovoltaic	175	935
TOTAL	10,624	14,438

Source: DGEG June 2020

Electricity Produced (GWh)	2011	2020 (June)
Hydro	12,114	14,036
Wind	9,162	12,980
Biomass	2,467	3,053

Urban Solid Waste	592	610
Biogas	161	237
Geothermal	210	214
Photovoltaic	280	1429
TOTAL	24,692	32,296
% of Renewable Energy (Real)	45.1%	59.9%
% of Renewable Energy		
(Directive 2001/77/EC)	45.8%	56.4%

Source: DGEG June 2020

Green Hydrogen

The Government is promoting an industrial policy around hydrogen and renewable gases, which is based on the definition of a set of public policies that guide, coordinate and mobilize public and private investment in projects in the areas of production, storage, transport and consumption of renewable gases in Portugal.

According to the government, Portugal has a competitive advantage over other countries due to its lower electricity production costs and considering that hydrogen production, through electrolysis, is only competitive if electricity prices are around or below 25 EUR per MWh. The main objective of the government is to incorporate hydrogen as a sustainable and integrated pillar linked with various sectors of the economy and in line with the strategy of transition to a decarbonized economy. This has generated interest from local and foreign companies to develop hydrogen projects and look for synergies and partnerships.

There are opportunities for U.S. companies to participate in Portugal's emerging hydrogen cluster. U.S. investors and exporters of technology, parts or components for the hydrogen sub-sector can take advantage the favorable business environment and ongoing efforts related with developing the new hydrogen cluster and planned projects to produce green hydrogen using a renewable-powered electrolysis that splits water (H2O) to make environmentally friendly hydrogen (H2) gas that can be used in zero-emission energy generation applications.

Natural Gas

Portugal was the first European country to receive U.S. liquefied natural gas (LNG) via the Port of Sines in 2016. According to the latest statistics from the U.S. Department of Energy, Portugal between February 2016 and May 2020 received 33 cargoes of U.S. LNG totaling 106 billion cubic feet (Bcf) of natural gas. Portugal currently ranks 16th worldwide (and 6th in Europe) with 2.2% of total imports of U.S. LNG. The United States is Portugal's second largest supplier of natural gas after Nigeria.

There are opportunities for U.S. and Portuguese investors to further expand the infrastructure at the Port of Sines due to its strategic position for LNG exports to Europe. The Port of Sines is Portugal's largest deep-water port hosting the country's only LNG regasification terminal and the closest EU port to the United States. The Port also offers a contiguous refinery, one of two located in Portugal, and an industrial park which plays an important role in the supply chain of energy products and raw materials to the country's manufacturing industry. There is interest by the government to build additional bunkering facilities and if the Midi-Catalonia pipeline were to be built, connecting the Iberian Peninsula pipeline network to Western Europe, further opportunities for LNG exports could be expected.

Portugal can act as an Atlantic LNG service station for vessels that use this energy source, using Sines port complemented with LNG Floating Bunkering units and/or ship-to-ship transfer solutions. The country operates a virtual LNG pipeline between mainland Portugal and the Island of Madeira which uses LNG ISO containers

transported in a conventional containership, alongside other commodities, cutting LNG shipping costs. This concept can be further developed for LNG short-sea shipping to other regions lacking pipeline infrastructure

Mining

Portugal is a small country but quite diverse in terms of mineral resources. The country is one of the EU's major producers of copper, tin, lithium and tungsten and a global producer of marble, limestone and granite. According to DGEG, in 2018 the Portuguese mining industry had a production value of 1186 million EUR, the export value of 1022 million EUR and employed 10,234 people; in 2018 there were 843 active mines, quarries and bottling/hydrotherapy entities.

The government is committed to further developing the industry and a cluster around lithium and battery industry, which the concession of new prospection licenses. These may lead to the construction of lithium hydroxide refineries and battery materials laboratories, in addition to technology and equipment necessary for lithium extraction and processing.

Opportunities

The sector is receptive to advances in technology, which presents opportunities for market entry via collaborative research or partnerships with local companies.

U.S. products and solutions enjoy a good reputation in terms of reliability and high quality. Nevertheless, purchase decisions are based on several factors including cost, financing, after sales service, and technology transfer, among others. Obtaining up to date information on market dynamics is very important, given the fast-developing nature of the industry and the constant introduction of new technologies.

Portugal continues to be interested in playing a major role in Europe's energy mix, both to improve Europe's energy security and increase competition. Portuguese companies are also looking for partnerships at all levels.

The renewable energy sector will continue to be a dynamic sector due to government and EU commitments to reduce oil dependency and greenhouse gas emissions. U.S. manufacturers and exporters of parts and systems for large and small hydro power, controls, pumps, valves and monitors, biomass or biogas technology, engineered parts and systems, low cost solar water heaters, grid-connected solar kits, among other solutions should seek the assistance of the U.S. Commercial Service in Portugal.

Resources

Ministry of Environment and Climate Change: <u>https://www.portugal.gov.pt/pt/gc22/area-de-governo/ambiente-e-acao-climatica</u>

Directorate-General for Energy and Geology: <u>http://www.dgeg.gov.pt/</u>

Portuguese Association for Renewable Energy: <u>https://www.apren.pt/</u>

Renewable Energy Government Auctions (Solar): <u>https://leiloes-renovaveis.gov.pt/</u>

National Strategy for Hydrogen – Public Consultation: <u>https://participa.pt/pt/consulta/en-h2-estrategia-nacional-para-o-hidrogenio</u>

Portuguese Association for the Extractive and Manufacturing Industry: <u>http://www.aniet.pt/en/</u>

Information and Communications Technology

Overview

According to the EU Digital Economy and Society Index 2020, Portugal ranks 19th out of the 28 EU Member States. Though the ranking has not improved since 2018, there have been positive developments over the last two years in

areas such as digital public services and connectivity; however, Portugal is still lagging behind other EU countries in terms of digital literacy and use of internet services.

The Government of Portugal, through the Ministry of Economy and Digital Transition has implemented measures to promote digital competencies and the digitalization of the economy as part of the second phase of the Indústria 4.0 in addition to launching artificial intelligence and advance computing strategies.

The current pandemic crisis has had a major impact on the use of internet services as isolation restrictions encouraged people and businesses to increase reliance on Internet based services and products. As a result Portugal reinforced and accelerated measures to achieve a more robust digital transformation and economic recovery ranging from supporting the digitization of the health system and expanding tools to manage health resources and patients, introducing new and additional online public services to its citizens and business and developing initiatives for digital home schooling and tele-schooling. Portugal is also deploying high capacity networks but is behind comparable nations with implementing 5G. The 5G spectrum auction has faced several delays and is now being planned for October 2020 according to the regulator ANACOM.

The ICT broadband infrastructure in Portugal has been expanding due to public investment and competition between private operators, for example a local fiber operator recently announced the expansion of its high-speed fiber networks and a new cut in wholesale fiber optic prices following the recommendation of ANACOM. Portugal is also looking to replace the Atlantic submarine cable by 2023, which is nearing end life, linking the mainland with the Islands of Madeira and Azores. In December 2019, ANACOM chaired a working group that submitted a report with twelve recommendations, which included flagging this project (CAM RING) as a priority for Portugal, doing an analysis of the need to replace the interconnections in the Azores and Madeira archipelagoes and setting up a neutral operator with the end goal of improving territorial cohesion and fostering economic development over the next 25 years. Another submarine cable is being considered between Lisbon and Marseille. More recently, a submarine cable system connecting Fortaleza and Sines is expected to enter service during the first quarter of 2021.

As far as digital technology integration, electronic information sharing, big data, cloud services and ecommerce has a significant place in businesses, but it is below EU average and less active compared with other EU countries. In 2019, the government launched several initiatives to promote the digitalization of businesses in order to increase the levels of digital literacy in businesses, expand cyber-infrastructure and establish cooperation agreements with other EU countries to explore how to develop and deploy advanced infrastructure such as quantum communication and networks.

Leading Sub-Sectors

Key segments and topics of interest include cybersecurity, internet of things (IoT), big data, health IT, cloud computing, business IT including ERP, Data centers, smart social business platforms, integrated systems, virtual & augmented reality and digital factory.

Opportunities

There is strong demand for U.S. products and services across all the above segments. Leading U.S. companies like Microsoft, IBM, Oracle and CISCO are well established in the market.

The U.S. Embassy in Lisbon and the U.S. Commercial Service Portugal follow closely ICT developments and work with stakeholders such as associations and multipliers and the American Chamber of Commerce in Portugal to identify opportunities and flag policy concerns.

Resources

AICEP Portugal Global – ICT Cluster: <u>http://www.portugalglobal.pt/EN/SourceFromPortugal/prominent-clusters/ICT/Pages/ICT.aspx</u>

Portuguese ICT Cluster: https://www.tice.pt/

Ministry of Economy and Digital Transition: <u>https://www.portugal.gov.pt/pt/gc22/area-de-governo/economia-transicao-digital</u>

Portuguese Regulator for the Communications Sector (ANACOM): https://www.anacom.pt/

Medical Equipment and Devices

Overview

With a population of 10.28 million (2019) and GDP \$237.98 (2018), Portugal is an important market for medical equipment and devices where imports are a fundamental component.

Approximately 90% of NHS (SNS) funding comes from the State Budget (OE), representing, on average, for the period 2013-2019, 4.5% of GDP. From the funds allocated to SNS more than half are used to cover 3-year period contracts with EPEs (Public Business Entities). During the period 2013-2019 the average annual spending with those contracts was 4,411 M \in while the OE (state Budgets) for the SNS total forecast for that period was 8,100 M \in .

Portuguese expenditures of medical equipment are concentrated at 80% in the public sector while the remaining 20% of sales are to private entities. The market for medical equipment has improved in recent years and we anticipate increased opportunities for U.S. exporters. Pricing is the key consideration for purchasing decisions, both by the public and private sectors.

Total annual expenditures for new equipment are determined in the annual budgets of hospitals. The recent pandemic crisis has impacted government decisions and priorities, favoring increased spend in the health sector.

Some major U.S. companies with offices and distribution in Portugal include GE Medical Systems, 3M, and Johnson & Johnson medical. Non-U.S. companies, such as Siemens and Philips also have a strong presence in the country. There are approximately 200, mostly small or medium-sized, companies distributing medical products employing, on average, 15 to 60 people.

The market is very receptive to U.S. products. A considerable portion of the market is penetrated by foreign products and imports from the U.S. can be very competitive. To enter the Portuguese medical equipment market, U.S. suppliers should be familiar with the European Union (EU) directives concerning registration, CE mark, marketing, and health/safety standards required. U.S. suppliers should also be aware of regulations that are specific to Portugal, as it is considered one of the strictest countries in the EU. It is therefore advisable to work with a local partner/distributor.

As a member of the European Union (EU), Portugal follows European Commission (EC) directives and the same medical device classification as all other EU member states. Medical devices are classified according to risk into Classes I, IIa, IIb and III.

Before manufacturers can start marketing their medical devices in Portugal, they must make sure that their product has been CE-marked, which is a sign of conformity with current EU regulations, allowing for the device to be sold freely in the European market. The CE marking has its own design and must be applied by the manufacturer in a legible, visible and indelible form on all medical devices, except those that are custom-made or intended for clinical research.

All medical devices are subject to conformity assessment. However, for some classes, the involvement of a third party – the Notified Body – in this assessment is required. The Notified Body is an evaluation body appointed by the National Authority and recognized by the EC, which assigns it a four-digit identity code. This code accompanies the CE marking on the products evaluated by that body. The Notified Body's functions are as follows: conduct the conformity evaluation procedures; authorize the affixing of the CE mark; issue conformity certificates; renew, or not, certificates of conformity; ensure that the manufacturer complies fully with his duties under the approved quality system; cooperate with the national Regulatory Authorities; cooperate with other Notified Bodies in EU Member-States.

In addition to the CE marking, all classes of medical devices to be placed on the Portuguese market must go through a device registration process; the requirements for registration of Class I medical devices are different than the ones for registration of Class IIa, IIb, III and implantable active medical devices.

The Portuguese Regulatory Authority (RA) is INFARMED (*Autoridade Nacional do Medicamento e Produtos de Saúde* / National Authority of Medicines and Health Products), an agency within the Portuguese Ministry of Health, which evaluates, authorizes, regulates and supervises the market, regardless of the origin of the devices, guaranteeing the protection of public health.

Regulation requirements for medical devices may be consulted on Infarmed's website at:http://www.infarmed.pt/web/infarmed-en/medical-devices.at:http://www.infarmed.pt/web/infarmed-en/human-medicines.

Regulation requirements for medical devices may be consulted on Infarmed's website at: <u>http://www.infarmed.pt/web/infarmed-en/medical-devices</u>. For pharmaceuticals at: <u>http://www.infarmed.pt/web/infarmed-en/human-medicines</u>.

Regulation requirements for medical devices may be consulted on Infarmed's website at:http://www.infarmed.pt/web/infarmed-en/medical-devices.at:http://www.infarmed.pt/web/infarmed-en/medical-devices.

Third party commercial entities (distributors) are required to notify the Competent Authorities of all medical devices they are placing on the Portuguese market. They can communicate this to the Authorities through the online registration database, different than the one used by manufacturers themselves. The manufacturer relinquishes an essential part of his control over his product in Portugal by registering his devices through his distributor. If a manufacturer ever decides to end their relationship with their distributor, he would be required to remove the product completely from the market until it is re-registered.

When a medical device manufacturer has his head office outside the European Economic Area (EEA), he must be represented by an Authorized Representative (AR) established in the Community. The representative assumes the manufacturer's liability before the authorities and other official bodies in the Community. The manufacturer may only be represented by a single AR for each type of device. Thus, to enter the Portuguese market of medical devices, U.S. manufacturers of medical devices are required to appoint an AR, which will assist with all the details regarding the registration process and assist completing requirements under the Portuguese regulation. To complete these requirements, after being designated, the AR will need to be presented with the following: EC Declaration of Conformity; CE Certificate; Labeling (must be in Portuguese); Instructions For Use (must be in Portuguese); Technical file. After the documentation review, U.S. manufactures can proceed with the registration with INFARMED.

Purchases for hospitals under the NHS are centralized at the Shared Services of the Ministry of Health (SPMS) that advertises and opens official tenders. <u>https://www.spms.min-saude.pt/compras-de-bens-e-servicos-transversais-2/</u>

There is a pre-selection process among the competing companies prior to the open bid. During pre-selection, the bidding vendors submit a proposal to the hospital with the product description and their quote. After accessing the proposals, the hospital elects the one that best fits. Typically, private hospitals do not use tenders and they pick their

suppliers from whom they make direct purchases. Non-EU and U.S. companies need to have either a Portuguese distributor or their own branch in Portugal in order to participate in official tenders, to avail of other market opportunities and to provide the after-sales service and aftermarket support required by law.

The DGS coordinates the European and international relations of the Ministry of Health. https://www.dgs.pt/internacional1.aspx

Government tenders are available online at: http://www.medicaltenders.com/medical_tenders_portugal.htm

Leading Sub-Sectors

The best sales potential are personalized medicine segment together with mini-invasive robotic technologies for surgery, mostly in the areas of cardiology; surgery equipment; patient monitoring systems; mini invasive surgery (MIS) equipment; noninvasive medial apparatus; video endoscopes; X-Ray equipment; digital image processing; magnetic resonance imaging (MRI) equipment; picture archiving systems.

Opportunities

There is a Supplementary Budget announced in the beginning of August that foresees an increase of 504 million euros for the health sector. The Medical Devices Market in Portugal shows opportunities on hospital equipment; innovative medical devices; control systems for monitorization the health status of the population and diagnostic equipment with the developed tools to support clinical decisions.

There are prospects for advanced digital solutions to integrate healthcare and telemedicine devices; tele triage, teleconsultation, telemonitoring systems. 80% of NHS hospitals are using telehealth, with tele tracking and teleconsultation being the most used. However artificial intelligence projects are just starting and have not yet reached half of the health institutions in Portugal.

About 75% of health institutions have already implemented telehealth projects, including primary health care. From the total 225 NHS hospitals (public), 87% of the units already apply these health tools. More than half of hospitals use remote screening, particularly in dermatology, and more than 50% have teleconsultations. The Pharma industry requires raw materials and substances essential for vaccines and drugs.

Resources

https://ec.europa.eu/info/sites/info/files/file_import/joint-report_pt_en_2.pdf

https://www.cfp.pt/uploads/publicacoes_ficheiros/publicaco-ocasional-n-1-2019-contratualizacao-com-as-epe.pdf

Regulation requirements for medical devices may be consulted on Infarmed's website at: <u>http://www.infarmed.pt/web/infarmed-en/medical-devices</u>.

For pharmaceuticals at: http://www.infarmed.pt/web/infarmed-en/human-medicines

Purchases for hospitals under the NHS are centralized at the Shared Services of the Ministry of Health (SPMS) that advertises and opens official tenders. <u>https://www.spms.min-saude.pt/compras-de-bens-e-servicos-transversais-2/</u>

The DGS coordinates the European and international relations of the Ministry of Health. https://www.dgs.pt/internacional1.aspx

Government tenders are available online at: http://www.medicaltenders.com/medical_tenders_portugal.htm

Customs, Regulations and Standards

Trade Barriers

For information on existing trade barriers, please see the National Trade Estimate Report on Foreign Trade Barriers (NTE), published by USTR and available through the following website: https://ustr.gov/sites/default/files/2020 National Trade Estimate Report.pdf

Information on agricultural trade barriers can be found at the following website: http://www.usda-eu.org/

To report existing or new trade barriers and get assistance in removing them, contact either the Trade Compliance Center at <u>http://tcc.export.gov/</u> or the U.S. Mission to the European Union at <u>http://export.gov/europeanunion/</u>

Market research section on the website of the U.S. Mission to the EU: https://www.export.gov/Market-Intelligence

Import Tariffs

When products enter the EU, they need to be declared to customs according to their classification in the Combined Nomenclature (CN). The CN document is updated and published every year, and the latest version can be found on the European Commission's website: <u>https://ec.europa.eu/taxation_customs/business/calculation-customs-duties/what-is-common-customs-tariff/combined-nomenclature_en</u>

U.S. exports to the European Union enjoy an average tariff of just three percent. All the same, U.S. exporters should consult "The Integrated Tariff of the Community", referred to as <u>TARIC</u> (Tarif Intégré de la Communauté), to identify the various rules which apply to specific products being imported into the customs territory of the EU. To determine if a license is required for a specific product, check the TARIC. 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 Links:

http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/customs_tariff/index_en.htm https://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp

Please note that European importers must pay the value-added tax (VAT) in full at the time of importation from a non-EU country, in Portugal VAT/IVA is currently 23%. Imports from EU countries only pay the VAT when a product is sold. This detail encourages many distributors to import indirectly from the United States via other E.U. countries.

Import Requirements and Documentation

The TARIC (Tarif Intégré de la Communauté), described above, is available to help determine if a license is requiredfor a product. Moreover, the European Commission maintains an export helpdesk with information on importrestrictionsofvariousproducts:

http://trade.ec.europa.eu/tradehelp/import-restrictions

Many EU Member States maintain their own list of goods subject to import licensing. For example, Germany's "Import List" (Einfuhrliste) includes goods for which licenses are required, their code numbers, any applicable restrictions, and the agency that will issue the relevant license. The Import List also indicates whether the license is required under German or EU law.

For information relevant to member state import licenses, please consult the relevant member state Country Commercial Guide: EU Member States' Country Commercial Guides <u>https://export.gov/ccg/</u> or conduct a search on the Commerce Department's Market Research Library, available from: <u>https://www.export.gov/Market-Intelligence</u>

The Single Administrative Document

The official model for written declarations to customs is the Single Administrative Document (SAD). The SAD describes goods and their movement around the world and is essential for trade outside the EU, or 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 Council Regulation (EEC) No. 2454/93, which lays down provisions for the implementation of the Community Customs Code (Articles 205 through 221). Articles 222 through 224 provide for computerized customs declarations and Articles 225 through 229 provide for oral declarations.

The Union Customs Code (UCC) was adopted in 2013 and its substantive provisions went into effect on 1 May 2016. It has replaced the Community Customs Code (CCC). In addition to the UCC, the European Commission published delegated and implementing regulations on the actual procedural changes.

Security and Safety Amendment to the Customs Code: https://eur-

lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:117:0013:0019:en:PDF

More information on the SAD can be found at:

http://ec.europa.eu/taxation_customs/customs/procedural_aspects/general/sad/index_en.htm

Key link: http://ec.europa.eu/taxation_customs/customs/customs_code/union_customs_code/index_en.htm

Modernised Community Customs Code: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:do0001

Regulation EC No 450/2008 laying down the Community Customs Code (Modernised Customs Code): <u>https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:145:0001:0064:EN:PDF</u>

Pre arrival/pre departure declarations: <u>https://ec.europa.eu/taxation_customs/business/customs-procedures/general-overview/pre-arrival-pre-departure-declarations_en</u>

Electronic Customs Initiative: <u>https://eur-</u>

lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:023:0021:0026:EN:PDF

Legislation related to the Electronic Customs Initiative: <u>https://ec.europa.eu/taxation_customs/general-information-customs/electronic-customs en</u>

Contact Information at National Customs Authorities: <u>https://ec.europa.eu/taxation_customs/individuals/personal-taxation/taxation-savings-income/contact-points_en</u>

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 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 EU Member States. There is no single format for the EORI number. Once an operator holds an EORI number s/he can request the <u>Authorized Economic Operator</u> (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: <u>http://ec.europa.eu/taxation_customs/dds2/eos/eori_home.jsp?Lang=en</u>

U.S. - EU Mutual Recognition Arrangement (MRA)

The U.S. and the EU have had a Customs Cooperation and Mutual Assistance in Customs Matters Agreement (CMAA) since 1997 when the U.S. - EU Agreement on Customs Cooperation and Mutual Assistance in Customs Matters came into force. For additional information, please see <u>Agreements with the United States</u>.

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, 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.

Additional Information on the Decision

Introduction

A key EU priority is ensuring 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: Circular Economy & Plastics Strategy

On 25 September 2014, the European Commission published the Communication "Towards a circular economy: A zero waste programme for Europe". The Communication acknowledges the intense competition for resources within Europe and the need to ensure market mechanisms eliminate waste. When implementing this package, the European Commission will promote regulatory and voluntary measures that encourage the "design out" of waste during the product development cycle. These measures include introducing mandatory recycling targets for waste, improvements to energy and resource use (e.g. water) and eliminating the use of materials in products that inhibit the collection, recycling and reuse of materials in products.

On 16 January 2018, the European Commission published what is arguably the most important measure towards implementing the circular economy. On that day it adopted a strategy document entitled, "A European Strategy for Plastics in a Circular Economy". The strategy acknowledges that plastics have a positive and negative impact on the environment, while calling for voluntary and regulatory measures aimed at mitigating the environmental harm caused by plastics. These measures address marine litter caused by the shipping industry; measures addressing the chemical

composition of plastics to encourage recycling; potential regulation on single use plastics; and funding for the development of chemical and mechanical recycling.

Batteries

The <u>EU Battery Directive</u> 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. For more information, see our <u>market research report</u>.

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

<u>REACH</u> 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 imposed a registration obligation on all entities affected by the one metric ton criteria by May 31, 2018. The European Chemicals Agency (<u>ECHA</u>) 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'.

In addition to the registration requirement, U.S. exporters should carefully review the REACH 'Candidate List' of Substances of Very High Concern (SVHCs) and the 'Authorization List'. Under certain conditions, substances on the Candidate List are subject to communication requirements prior to their export to the EU. Companies seeking to export chemicals on the 'Authorization List' will require an authorization. The Candidate List can be found at: http://echa.europa.eu/web/guest/candidate-list-table.

The Authorization List is available at: https://echa.europa.eu/authorisation-list

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 WEEE and RoHS in the EU: <u>https://2016.export.gov/europeanunion/weeerohs/index.asp</u> Key Link: https://ec.europa.eu/environment/waste/weee/index_en.htm

Restriction on Hazardous Substances RoHS

The ROHS Directive imposes restrictions on the use of certain chemicals in electrical and electronic equipment. It does not require specific customs or import paperwork; however, manufacturers must self-certify that their products are compliant and affix a "CE" mark. (See the section entitled "Mandatory Marks and Labels" for more information.) The 2011 revisions to the ROHS Directive significantly expanded the scope of covered products. U.S. exporters had until July 22, 2019 to bring products into compliance that were once outside the scope.

U.S. exporters seeking more information on the RoHS Directive should visit: https://ec.europa.eu/environment/waste/rohs_eee/index_en.htm

Cosmetics Regulation

The EU legislation harmonizing the regulation of cosmetic products was applied on July 11, 2013. 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.

For more general information, see: https://ec.europa.eu/growth/sectors/cosmetics/legislation_en

Agricultural Documentation

<u>Phytosanitary Certificates</u>: 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, several 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 can be found at the following website: <u>http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/fairs-export-certificate-report/</u>.

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.

Since June 2009, the only 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 (<u>stephane.vrignaud@trade.gov</u>) or visit the following <u>NOAA dedicated website</u>.

Overview of EU Certificates (FAS): <u>https://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/fairs-export-certificate-report/</u>

Labeling and Marking Requirements

Summary

There is a broad array of EU legislation pertaining to the marking, labeling and packaging of products, with neither an "umbrella" law covering all goods nor any central directory containing information on marking, labeling and packaging requirements. This overview is meant to provide the reader with a general introduction to the multitude of marking, labeling and packaging requirements or marketing tools to be found in the EU.

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

- Textiles
- Cosmetics
- Dangerous Substances
- Explosive Atmosphere
- Electrical & Electronic Equipment
- Household Appliances
- Pricing
- Footwear
- Units of Measurement
- Automotive
- Tire labeling
- Maritime
- Materials in Contact with Food
- Noise Emissions
- Wood packaging
- Energy Efficiency
- Recycling Separate Collection

Voluntary Marks and Labels

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

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 <u>CE marking</u> demonstrates that a product meets all essential requirements (typically related to safety, health, energy efficiency and/or environmental concerns). 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
- 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
- Radio equipment
- Recreational crafts
- Refrigeration appliances
- Simple pressure vessels
- Toys

For each "New Approach" law there is a separate list of references to harmonized European standards, the use of which provides the manufacturer with the 'presumption of conformity' with essential requirements. While other non-EU standards may be used to demonstrate a product's compliance with the applicable directive(s), the manufacturer will have to provide detailed information regarding the compliance process. An array of standardized safety warning symbols/pictograms may also be applicable to each of the above product categories.

In 2008, the EU adopted a package of measures known as the New Legislative Framework (NLF) which provides a regulatory 'toolbox' for new and revised EU product safety legislation. The framework is designed to improve market

surveillance, more clearly define the responsibilities of manufacturers, importers and distributors, and clarify the meaning of CE marking across a wide range of product groups. In February 2014, to align product harmonization legislation with the provisions of the NLF (most notably Decision 768/2008), the European Union adopted an "Alignment Package" consisting of eight revised CE marking directives. These newly aligned directives are in force since 2016.

Note: The EU is currently finalizing new legislation that will impact CE marking for medical devices. Upon finalization of the new legislation in mid-2017, there will be a transition period with the new measures coming into force in 2020 for medical devices and 2022 for in-vitro medical devices.

For more information

http://ec.europa.eu/growth/single-market/ce-marking/index_en.htm http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/index_en.htm http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/index_en.htm

THE WASTE ELECTRICAL AND ELECTRONIC EQUIPMENT DIRECTIVE (WEEE)



This directive is designed to tackle the rapidly increasing waste stream of electrical and electronic equipment and complements European Union measures on landfills and waste incineration. Increased recycling of electrical and electronic equipment, in accordance with the directive requirements, limits the total quantity of waste going to final disposal. This directive affects the following product categories:

- Large and small household appliances
- Consumer equipment
- Lighting equipment
- IT and Telecommunications equipment
- Electrical and Electronic Tools
- Toys and Sports equipment
- Medical Devices
- Monitoring and control equipment
- Automatic dispensers

The symbol shown above must be displayed on all products that fall under this directive and indicates that the product is not to be discarded with normal household waste. It is a required mark on batteries. In instances where this symbol cannot be displayed on the equipment itself, it should be included on the packaging.

For more information:

Directive 2012/19/EU is available online at: http://ec.europa.eu/environment/waste/weee/legis_en.htm

ENERGY LABELING

Energy Manufacturer Model	Fridge-Freezer
More efficient	A
D E F C	
Energy consumption kWh/year (Based on standard test results for 24Pt) Actual consumption will depend on how the applance is used and where it is located	325
Fresh food volume I Frozen food volume I	190 126 ★ ★ ★ ★
Noise (dB(A) re 1 pW)	
Further information is contained in product brochures Nom EN 153 May 1980 Refrigerator Label Directive B40/EC	

Directive 2010/30/EU "on the indication by labeling and standard product information of the consumption of energy and other resources by energy-related products" sets a framework for the adoption of product-specific directives on the proper energy efficiency labeling for each concerned product. This 2010 directive broadens substantially the energy labeling scope. This law is undergoing review; the proposed legislation, simplifying labeling categories and extending the scope will likely be adopted in 2017.

Suppliers are to supply free of charge labels or product fiches containing information about consumption of electric or other energy sources to their dealers. Dealers display labels in a visible and legible way and make the fiche available in product brochures or other literature.

For more information: <u>http://www.consilium.europa.eu/en/press/press-releases/2017/06/26/clearer-energy-labelling/</u> <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:153:0001:0012:EN:PDF</u>

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), it is necessary to display the Ex mark, which is a specific marking of explosion protection. Located next to the 'Ex' mark will be a symbol designating the product group or category as specified in the directive.

The revised ATEX Directive (2014/34/EC) was adopted in February 2014 as part of the New Legislative Framework alignment package. It replaced the existing directive and became applicable on April 20, 2016.

For more information: <u>http://ec.europa.eu/growth/sectors/mechanical-engineering/atex/index_en.htm</u> Directive 2014/34/EU: <u>http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014L0034&from=EN</u>

NOISE EMISSION OF OUTDOOR EQUIPMENT



Machines used outdoors are subject to CE marking requirements. Noise emission levels are covered separately. The sample mandatory label shown above specifies noise emission levels.

For more information: http://ec.europa.eu/growth/sectors/mechanical-engineering/noise-emissions/index en.htm

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 is available online at: <u>http://eur-lex.europa.eu/legal-</u>content/EN/TXT/?uri=uriserv:OJ.L .2014.257.01.0146.01.ENG

TEXTILES

Textile products must be labeled or marked whenever they are put onto 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. Except for trademarks or the name of the undertaking, information other than that required by the directive must be listed separately. Member States may require that their national language be used on the labeling and marking required by the directive.

For more information: http://ec.europa.eu/growth/sectors/fashion/textiles-clothing/legislation/index_en.htm

FOOTWEAR



Labels must convey information relating to the upper, 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 agent 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: http://ec.europa.eu/growth/sectors/fashion/footwear/index_en.htm

COSMETICS

Containers and/or packaging (in certain cases) must bear, in indelible, easily legible and visible characters, 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):



- 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 is available online at: <u>http://ec.europa.eu/growth/sectors/cosmetics/legislation/index_en.htm</u>

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 can be found at <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:EN:PDF</u>

Legal Metrology and Metric Units of Measurement

This legislation specifies permissible ranges of nominal quantities, container capacities and the weights or volumes of prepackaged products. Manufacturers are advised to take note that all labels require metric units, although dual labeling is also acceptable.

For more information: https://ec.europa.eu/growth/single-market/goods/building-blocks/legal-metrology/

PRICE DISPLAY

The directive requires an indication of the selling price, and price per unit of measurement, on all products offered to consumers. The aim is to improve the information available to the consumer and to facilitate price comparison. This information must be unambiguous, clearly legible and easily identifiable. If advertising mentions the item's selling price, it must also indicate its unit price. For products sold in bulk, the unit price is the only item whose indication on the label is mandatory. National authorities may provide alternatives for products sold by small retail business operations.

For more information:

Directive 98/6/EC, on the indication of the prices of products offered to consumers, available online at: <u>http://eur-lex.europa.eu/resource.html?uri=cellar:b8fd669f-e013-4f8a-a9e1-2ff0dfee7de6.0008.02/DOC_1&format=PDF</u>

AUTOMOTIVE



Nearly every vehicle component must be certified for safety as specified under the various directives relating to automobiles. The number shown in the rectangle on the label indicates the particular 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, are available online at: https://ec.europa.eu/growth/sectors/automotive/legislation/

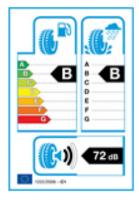
Photometry



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.

For more information: https://ec.europa.eu/growth/sectors/automotive/legislation/

TIRE LABELING



Tire label legislation requires that tire manufacturers declare fuel efficiency, wet 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 objective of the regulation is better information for the consumer and a contribution to a more energy efficient transport policy.

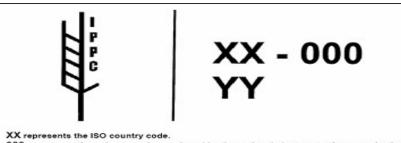
For more information: <u>http://ec.europa.eu/energy/en/topics/energy-efficient-products-and-labels/tyres</u> Directive 1222/2009/EC: <u>https://eur-</u> <u>lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:342:0046:0058:en:PDF</u> Directive 228/2011/EC: <u>http://eur-</u> <u>lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:062:0001:0016:EN:PDF</u>

PACKAGING MATERIAL

The EU Packaging and Packaging Waste Directive harmonized member state legislation regarding packaging material composition and the management of packaging waste. Composition of packaging material is addressed in a series of EU-wide standards. For the management of packaging waste through recycling targets and collection and recycling systems, Member States have adopted voluntary marking mentioned in the following pages.

For more information: <u>https://ec.europa.eu/environment/waste/packaging/legis.htm</u> Directive 94/62/EC on packaging and packaging waste, available online at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31994L0062&from=en</u>

WOOD PACKAGING



000 represents the unique number assigned by the national plant protection organization. YY represents either HT for heat treatment or MB for methyl bromide fumigation.

Like the United States, the EU has adopted legislation to ensure pest control in wood packaging. The marking used for regulated materials is based on the International Plant Protection Convention compliance symbol shown above.

For more information:

http://ec.europa.eu/food/plant/plant_health_biosecurity/non_eu_trade/wood_packaging_dunnage/index_en.htm Regulation (EU) 2016/2031 on protective measures against plant pests ("Plant Health Law"), available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R2031&from=EN

VOLUNTARY MARKS AND LABELS

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:

http://ec.europa.eu/food/safety/chemical_safety/food_contact_materials/legislation/index_en.htm Commission Regulation (EC) No 1935/2004 available at: <u>https://eur-lex.europa.eu/legal-</u> content/EN/TXT/PDF/?uri=CELEX:02004R1935-20090807&from=EN

THE e-MARK



The e-mark, shown above, 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: <u>http://ec.europa.eu/growth/single-market/goods/building-blocks/legal-metrology/pre-packaging/index_en.htm</u>

Directive 76/211/EEC on the approximation of the laws of the Member States relating to the making-up by weight or by volume of certain prepackaged products, available at: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31976L0211&from=EN</u>

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.

The symbol may apply to the following product and services groups:

All-purpose cleaners and cleaners for sanitary facilities	Household cleaning products	Textile products
Bed mattresses	Laundry detergents	Tissue paper
Campsite Services	Light bulbs	Tourist accommodation service
Copying and graphic paper	Lubricants	Vacuum cleaners
Detergents for dishwashers	Paints and varnishes	Washing machines

Dishwashers	Personal computers	Wooden coverings
Footwear	Printed paper products	Wooden furniture
Furniture	Refrigerators	
Growing media and Soil improvers	Soaps, shampoos and hair conditioners	
Hand dishwashing detergents	Soil improvers	
Hard floor coverings	Televisions	
Heat pumps	Textile coverings	

Manufacturers should be aware that similar eco-friendly markings are often used nationally, such as the Nordic Swan or the German Blue Angel, shown below.



The Eco-label program has recently been expanded to cover fish and fishery products. This means that eco-labeled products have been produced in accordance with specific environmental standards.

Private Eco labels have been developed by the seafood industry to "influence the purchasing decision of consumers and the procurement policies of retailers selling seafood products, in order to reward producers involved in responsible fishing and aquaculture practices leading towards sustainable use of natural resources."

There are multiple eco-label schemes, and logos, developed by a variety of operators and according to different characteristics. This confusing situation has led to a need for harmonization and coherence. In response, the UN Food and Agriculture Organization (FAO) has developed a "Guideline for the Eco-Labeling of Fish and Fishery Products from Marine Capture Fisheries" (http://www.fao.org/3/i1119t/i1119t.pdf).

The U.S. government has decided not to engage in the development of such marketing tool. Instead, NOAA Fisheries has developed a comprehensive website where stakeholders, including consumers, can find facts about a specific species of fish and related fisheries. Consumers can then make their own purchasing choice: http://www.fishwatch.gov/

The European Commission is currently preparing, at the request of the European Parliament and the Council, a feasibility report on options for a Union-wide eco-label scheme for fishery and aquaculture products. Some EU Member States have already created their own National eco label.

For more information: European Union Eco-Label: <u>https://ec.europa.eu/environment/ecolabel/</u> <u>https://ec.europa.eu/info/consultations/eu-ecolabel-fishery-and-aquaculture-products_en</u>

RECYCLING



The "mobius loop" (sometimes known as the "chasing arrows"), based on an international standard, may be found on products throughout Europe and is meant to help consumers identify and participate in recycling schemes for product packaging and materials. 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. Various kinds of loops indicate whether the product is recyclable, recycled or contains recycled material.

For more information: https://ec.europa.eu/environment/waste/target_review/consultation.htm

PLASTICS



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	РЕТ	Polyethylene Terepthalate	
2	HDPE	High Density Polyethylene	
3	PVC	Poly Vinyl Chloride	
4	LDPE	Low Density Polyethylene	
5	РР	Polypropylene	
6	PS	Polystyrene	

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.

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. More than 460 billion pieces of packaging marked with the Green Dot, shown above, are distributed worldwide. Interested applicants should contact one of the national administering authorities.

http://www.pro-e.org/

U.S. Export Controls

The United States imposes export controls to protect national security interests and promote foreign policy objectives related to dual-use goods through implementation of the Export Administration Regulations (EAR). The Bureau of Industry and Security (BIS) is comprised of two elements: Export Administration (EA), which is responsible for processing license applications, counseling exporters, and drafting and publishing changes to the Export Administration Regulations; and Export Enforcement (EE), which 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 and comply with the EAR. BIS officials conduct site visits, 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 non-U.S. party to a transaction to determine whether the party 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 transactions subject to the EAR, to include: confirming the legitimacy and reliability of the end-use and end-user; monitoring compliance with license conditions; and ensuring items are used, re-exported or transferred (in-country) in accordance with the EAR. These checks might be completed prior to the export of items pursuant to a BIS export license in the form of a Pre-License Check (PLC), or following an export from the U.S. during a Post-Shipment Verification (PSV).

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 application reviews or be designated on BIS's Unverified List or Entity List, as applicable.

BIS has developed a list of "<u>red flags</u>", or warning signs, and compiled "<u>Know Your Customer</u>" guidance intended to aid exporters in identifying possible violations of the EAR. Both of these resources are publicly available, and their dissemination to industry members is highly encouraged to help promote EAR compliance.

BIS also provides a variety of training sessions to U.S. exporters throughout the year. These sessions range from one to two-day seminars that focus on the basics of exporting to coverage of more advanced, industry-specific

topics. Interested parties can check <u>list of upcoming seminars and webinars</u> or reference BIS provided <u>online</u> <u>training</u>.

BIS and the EAR regulate transactions involving the export of "dual-use" U.S. goods, services, and technologies. For advice and regulatory requirements, exporters should consult the other U.S. Government agencies which regulate more specialized items. For example, the U.S. Department of State's Directorate of Defense Trade Controls has authority over defense articles and services, or munitions. A list of other agencies involved in export control can be found on the <u>BIS website</u> or in Supplement No. 3 to Part 730 of the EAR.

The EAR is available on the <u>BIS website</u> and on the <u>e-CFR</u> (Electronic Code of Federal Regulations) and is updated as needed. The <u>Consolidated Screening List</u> (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 eleven export screening lists of the Departments of Commerce, State and the Treasury into a single data feed as an aid to industry in conducting electronic screens of parties to regulated transactions. Exporters are encouraged to classify their items prior to export, as well as consult the CSL to determine if any parties to the transaction may be subject to specific license requirements.

Temporary Entry

Foreign goods may enter Portuguese territory under temporary duty-free admission. Temporary entry can be allowed for goods in transit, for manufacturing, for temporary storage in bonded warehouses or for temporary importation. Generally, temporary entry of goods requires the deposit of a guarantee for import duties and VAT.

In some cases, however, exemptions and partial guaranties can be made. In-transit merchandise can enter without guarantee by residents of the EU who make regular entries or a carnet TIR, carnet ATA or a NATO 302 form may be used. Guaranties are reimbursed when the merchandise leaves the territory of the EU. Professional materials, merchandise to be presented in exhibitions, teaching materials, and other materials can be temporarily imported duty-free under a carnet ATA. Temporary importation allows the merchandise to stay in EU territory as foreign merchandise for a period of 24 months.

Samples and Carnets: Samples with no intended commercial value enter Portugal free of duties and taxes. When sending such samples parcel post, the sender must specify the types of samples are being shipped. "No commercial value" should be written on the appropriate shipping documents.

For samples of commercial value to enter Portugal duty- and tax-free, a bond or deposit of the total amount of duties and taxes must be arranged. Samples must be re-exported within one year if the deposit is to be recouped. An alternative to placing such a deposit is applying for an ATA Carnet.

ATA Carnet: An ATA carnet is a special international customs document designed to simplify and streamline customs entry procedures for merchandise into participating countries for up to one year. The initials "ATA" are an abbreviation of the Portuguese and English words "Admissão Temporária/Temporary Admission." Customs authorities in the United States and Portugal accept carnets as a guarantee that all customs duties and taxes will be paid if any of the items covered by the carnet are not re-exported within the time period allowed. Carnets may be used for commercial samples, professional equipment, and goods destined for exhibitions and fairs.

To inquire about or apply for an ATA Carnet, please consult the following website: http://www.atacarnet.com

Further 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 example) can be found here: <u>https://www.export.gov/article?id=ATA-Carnet</u>

Prohibited and 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: <u>http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/customs_tariff/index_en.htm</u>

Customs Regulations

The following provides information on the 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 several 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. 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.

Key Link: https://ec.europa.eu/taxation_customs/business/customs-procedures_en

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 the 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.

Customs Valuation: <u>https://ec.europa.eu/taxation_customs/business/calculation-customs-duties/customs-valuation_en</u>

Customs procedures for import and export: http://ec.europa.eu/taxation_customs/business/customs-procedures_en

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

European Union legislation and standards created under the New Approach are harmonized across the Member States and European Economic Area countries to allow for the free flow of goods. An example of the New Approach is CE marking.

The concept of New Approach legislation is slowly disappearing as the New Legislative Framework (NLF), which entered into force in January 2010, was put in place to serve as a blueprint for existing and future CE marking legislation. Existing legislation has been reviewed to bring them in line with the NLF concepts, which means that, as of 2016, new requirements are being addressed and new reference numbers are to be used on declarations of conformity. For more information about the NLF, go to http://ec.europa.eu/growth/single-market/goods/new-legislative-framework/

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.

Internal Market, Industry, Entrepreneurship and SMEs – New legislative framework: <u>https://ec.europa.eu/growth/single-market/goods/new-legislative-framework/</u> Internal Market, Industry, Entrepreneurship and SMEs – Standardization requests – mandates: <u>https://ec.europa.eu/growth/single-market/european-standards/requests/</u>

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 at: <u>http://www.usda-eu.org</u>

There are also export guides to import regulations and standards available on the Foreign Agricultural Service's website: <u>http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/certification/fairs-export-certificate-report/</u>

Standards

EU standards setting is a process based on consensus initiated by industry or mandated by the European Commission and carried out by independent standards bodies, acting at the national, European or international level. There is strong encouragement for non-governmental organizations, such as environmental and consumer groups, to actively participate in European standardization.

Many standards in the EU are adopted from international standards bodies such as the International Standards Organization (ISO). The drafting of specific EU standards is handled by three European standards organizations:

- 1. CEN, European Committee for Standardization
- 2. <u>CENELEC, European Committee for Electrotechnical Standardization</u>
- 3. ETSI, European Telecommunications Standards Institute

Standards are created or modified by experts in Technical Committees or Working Groups. The members of CEN and CENELEC are the national standards bodies of the Member States, which have "mirror committees" that monitor and delegate experts to participate in ongoing European standardization. CEN and CENELEC standards are sold by the individual Member States standards bodies. ETSI is different in that it allows direct participation in its technical committees from non-EU companies that have interests in Europe and provides some of its individual standards at no

charge on its website. In addition to the three standards developing organizations, the European Commission plays an important role in standardization through its funding of the participation in the standardization process of smalland medium-sized companies and 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. Mandates – or requests for standards - can be checked on line at: <u>http://ec.europa.eu/growth/tools-databases/mandates/index.cfm</u>.

Given the EU's vigorous promotion of its regulatory and standards system as well as its generous funding for its development, the EU's standards regime is wide and deep - extending well beyond the EU's political borders to include affiliate members (countries which are hopeful of becoming full members in the future) such as the Western Balkan countries among others. 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.

To view what CEN and CENELEC have in the pipeline for future standardization, it is best to visit their websites. 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 (https://portal.etsi.org/home.aspx) links to ongoing activities.

The European Standardization system and strategy was reviewed in 2011 and 2012. The new standards regulation 1025, adopted in November 2012, clarifies the relationship between regulations and standards and confirms the role of the three European standards bodies in developing EN harmonized standards. The emphasis is also on referencing international standards where possible. For information, communication and technology (ICT) products, the importance of interoperability standards has been recognized. Through a relatively recent mechanism, a "Platform Committee" reporting to the European Commission will decide which deliverables from fora and consortia might be acceptable for public procurement specifications. The European standards bodies have been encouraged to improve efficiency in terms of delivery and to look for ways to include more societal stakeholders in European standardization. The Joint Initiative on Standardization, launched in 2016 with a number of action items to improve European standardization, aims to speed up and better prioritise standard setting across the board.

Key Link: https://ec.europa.eu/growth/single-market/european-standards/policy/

CEN - Sectors: https://www.cen.eu/work/areas/Pages/default.aspx

CEN – Search Standards: <u>https://standards.cen.eu/dyn/www/f?p=CENWEB:105::RESET::::</u>

Internal Market, Industry, Entrepreneurship and SMEs – Harmonized Standards: <u>https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en</u>

News: https://ec.europa.eu/growth/news/

Testing, Inspection and Certification

Conformity Assessment

Conformity Assessment is a mandatory step for the manufacturer in the process of complying with specific EU legislation. The purpose of conformity assessment is to ensure consistency of compliance during all stages, from design to production, to facilitate acceptance of the final product. EU product legislation gives manufacturers some choice regarding conformity assessment, depending on the level of risk involved in the use of their product. These range from self-certification, type examination and production quality control system, to full quality assurance system. Conformity assessment bodies in individual Member States are listed in the New Approach Notification and Designated Organizations (NANDO) information system.

Key Link: https://ec.europa.eu/growth/tools-databases/nando/

To promote market acceptance of the final product, there are several voluntary conformity assessment programs. CEN's certification system is known as the Keymark. Neither CENELEC nor ETSI offer conformity assessment services.

Product Certification

To sell products in the EU market of 28 Member States as well as in EFTA (Norway, Liechtenstein Iceland, Switzerland) and Turkey U.S. exporters are required to apply CE marking whenever their product is covered by specific product legislation. CE marking product legislation offers manufacturers several choices and requires decisions to determine which safety/health concerns need to be addressed, which conformity assessment module is best suited to the manufacturing process, and whether to use EU-wide harmonized standards. The CE marking process is very complex, and this section attempts to provide some background and clarification.

Products manufactured to standards adopted by CEN, CENELEC or ETSI, and referenced in the Official Journal as harmonized standards, are presumed to conform to the requirements of EU legislation. The manufacturer then applies the CE marking and issues a declaration of conformity. With these, the product will be allowed to circulate freely within the EU. A manufacturer can choose not to use the harmonized EU standards, but then must demonstrate that the product meets the essential safety and performance requirements. Trade barriers occur when design, rather than performance, standards are developed by the relevant European standardization organization, and when U.S. companies do not have access to the standardization process through a European presence.

The CE marking addresses itself primarily to the national control authorities of the Member States, and its use simplifies the task of market surveillance of regulated products. As market surveillance was found lacking, the EU adopted the New Legislative Framework, which went into force in 2010. As mentioned before, this framework is like a blueprint for all CE marking legislation, harmonizing definitions, responsibilities, European accreditation and market surveillance.

The CE marking is not intended to include detailed technical information on the product, but there must be enough information to enable the inspector to trace the product back to the manufacturer or the local contact established in the EU. This detailed information should not appear next to the CE marking, but rather on the declaration of conformity (which the manufacturer or authorized agent must be able to provide at any time, together with the product's technical file), or the documents accompanying the product.

Accreditation

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

"European Accreditation" (<u>http://www.european-accreditation.org</u>) is an organization representing nationally recognized accreditation bodies. Membership is open to nationally recognized accreditation bodies in countries in the European geographical area that can demonstrate that they operate an accreditation system compatible to appropriate EN and ISO/IEC standards.

Publication of Technical Regulations

The <u>Official Journal of the EU</u> 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, studies by committees. It also lists the standards reference numbers linked to legislation (<u>Harmonized Standards</u>).

National technical regulations are published on the <u>Commission's website</u> to allow other countries and interested parties to comment.

Prevention of technical barriers to trade: https://ec.europa.eu/growth/tools-databases/tris/en/

Contact Information

Members of the World Trade Organization (WTO) 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.** (<u>www.nist.gov/notifyus</u>) 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 (NIST), part of the U.S. Department of Commerce.

For more information on the National Institute of Standards and Technology (NIST): https://www.nist.gov/

<u>U.S. Mission to the EU</u> Marianne Drain, Standards Attaché <u>Marianne.Drain@trade.gov</u> Tel: +32 2 811 5034

Liliana Popescu, Commercial Specialist Liliana.Popescu@trade.gov Tel: +32 2 811 5001

National Institute of Standard & Technology

Gordon Gillerman Standards Coordination Office 100 Bureau Dr. Mail Stop 2100 Gaithersburg, Maryland 20899 Tel: (301) 975-4000

CEN- European Committee for Standardization

Avenue Marnix 17 B – 1000 Brussels, Belgium Tel: 32.2.550.08.11 Fax: 32.2.550.08.19

CENELES- European Committee for Electrotechnical Standardization

Avenue Marnix 17 B – 1000 Brussels, Belgium Tel: 32.2.519.68.71 Fax: 32.2.519.69.15

ETSI- European Telecommunications Standards Insitute

Route des Lucioles 650 Sophia Antipolis F-06560 Valbonne France Tel: 33.4.92.94.42.00 Fax: 33.4.93.65.47.16

SBS- Small Business Standards

4, Rue Jacques de Lalaing B-1040 Brussels Tel: 32.2.285.07.27 Fax : +32-2/230.78.61

ANEC- European Association for the Co-ordination of Consumer Representation in Standardization Avenue de Tervuren 32, Box 27 B – 1040 Brussels, Belgium Tel: 32.2.743.24.70 Fax: 32.2.706.54.30

ECOS- European Environmental Citizens Organization for Standardization

Rue d'Edimbourg 26 B – 1050 Brussels, Belgium Tel: 32.2.894.46.68 Fax: 32.2.894.46.10

EOTA- European Organization for Technical Assessment

Avenue des Arts 40 B – 1040 Brussels, Belgium Tel: 32.2.502.69.00 Fax: 32.2.502.38.14

Trade Agreements

For a list of trade agreements with the EU and its Member States, as well as concise explanations, please see: http://ec.europa.eu/trade/policy/countries-and-regions/agreements/

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, in correspondence with article 165 of the TFEU, the responsibility of Member States. Similarly, recognition of skills and qualification earned in third countries is also a national responsibility.

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

- Recognition of <u>professional qualifications</u> obtained in one Member State for the purposes of access and pursuit of <u>regulated professions</u> in another Member State is subject to Directive 2005/36.
- Recognition of qualifications for academic purposes in the <u>higher education sector</u>, including schoolleaving 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. For them to be able to recognise skills and qualifications an understanding of the level, content and quality is needed. 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: https://europa.eu/youreurope/citizens/work/professional-qualifications/regulated-professions/index_en.htm

Selling US Products and Services

Distribution & Sales Channels

Overview

The Portuguese population is concentrated along the coast. The major distribution centers are Lisbon in the south and Porto in the north, although the regional centers of Braga (north of Porto) and Setubal (south of Lisbon) have come into their own in recent years. The Lisbon Metropolitan Area accounts for about 28% of Portugal's population. Major industries as well as the head offices of many large corporations are located in Lisbon. Most financial institutions have also chosen the capital to locate their headquarters. The Lisbon area has the highest purchasing power in the country and suffers, like many metropolitan areas, from traffic congestion and rising costs.

Porto is the most dynamic industrial development area in Portugal. It accounts for about 17% of the Portuguese population and is also an area of high purchasing power. Most importers and distributors have offices in Porto; U.S. firms looking to appoint a distributor in Portugal should not overlook this fact. Porto is connected to Lisbon by a direct and well-maintained highway and bridge over the Douro River, and is also easily reached by train and direct flights.

Portugal is a relatively small country, and most sales channels cover the entire territory. Although distribution centers tend to be located in Lisbon and Porto, many large importers and wholesalers have branch sales offices and/or sub-agents or dealers in other principal cities and towns, including those in the Portuguese islands of Madeira and the Azores.

Portugal's main industries are: oil refineries, petro chemistry, cement production, automotive and ship industries, electrical (mainly from renewable sources) and electronics industries, machinery, pulp and paper industry, injection molding, plastic products, textiles, footwear, leather, furniture, ceramics, beverages and food industry and cork.

Using an Agent or Distributor

When doing business in Portugal, U.S. companies should keep the following points in mind:

- Local Representative: Having a local representative with good contacts is very important to establish business contacts. Portugal is a small country; knowing people in your industry is very important.
- Exclusive Distributor: One distributor that is appointed on an exclusive basis is ideal.
- The Iberian Peninsula: Portugal and Spain do not constitute a homogeneous marketing area. Normally, your Spanish distributor should not be asked to cover Portugal unless the Spanish company is willing to set up a separate Portuguese entity to handle this area.
- Impact of the EU: Many projects are EU-funded, so an EU partner is desirable (and often fundamental) when bidding.
- Slow Down: Conducting business takes longer compared to the U.S. or northern Europe as personal contacts are very important. Your customers will want to get to know you before they fully trust you.
- Business is Honorable: There are relatively few trade complaints. The business community is close-knit and many distributors are family-owned companies, which mean trade disputes are few and are often resolved out of court. If you do have to resort to the courts, be prepared to wait. Despite some recent reforms and improvements, the Portuguese legal system remains slow and is the single biggest cause of unresolved U.S. company trade complaints.
- English is Common: Although Portugal is a European country; it faces the Atlantic and has a long tradition of international trade. Portugal discovered trade routes to Africa before Columbus landed in America. The Portuguese also opened the first major trading routes to India and the Far East and administered a vast colonial empire for 500 years. The U.S. is well respected in the market and companies can usually do business in English.

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 (Directive 86/653/EECL): http://eur-

lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31986L0653:EN:HTML

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. Companies with fewer than 250 employees and an annual turnover of less than ϵ 50 million are considered small- and medium-sized. The EU has additionally indicated that agreements that affect less than 10 percent of a market are generally exempted (Commission Notice 2014/C 291/01).

Key Link (Commission Notice 2014/C 291/01 on agreements of minor importance which do not appreciably restrict competition under Article 101(1) of the Treaty on the Functioning of the European Union): <u>http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2014.291.01.0001.01.ENG</u>

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 (Directive 2011/7/EU on combating late payment in commercial transactions): <u>http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:048:0001:0010:EN:PDF</u>

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: <u>https://www.ombudsman.europa.eu/en/home</u> http://ec.europa.eu/solvit/

Establishing an Office

The process of setting up a business in Portugal has been simplified over the past couple of years. There are several available methods from which to choose. The Business Gateway (Portal da Empresa) offers a program called "On-the-Spot Firm", which is described below. There is also an "On-line Company" registration method, along with the traditional commercial registry office process. The online registration process can take as little as one to two days.

The "On-the-Spot Firm" method facilitates the establishment of a single shareholder limited liability company, a private limited company or partnership, or a public limited company in less than 60 minutes. All the procedures are

carried out in one place if the partners have all the necessary documentation and the company is registered through the "On-the-Spot Firm" Program. This service is available throughout the country.

Key Link: https://justica.gov.pt/Servicos/Empresa-na-Hora

Guide on how to incorporate a company in Portugal: <u>https://justica.gov.pt/Portals/0/IRN/incorporating-company-guide-LINKS.PDF?ver=2020-01-30-214952-110</u>

To use the "On-Line Company" method, digital certification from the user is required (e.g., citizen ID card). Through this method, it is possible to set up companies of any type, except for European Public Limited companies and companies whose capital is paid through contributions in kind. For the latter, transfer of assets to the company by shareholders must be done through a more formal process.

Key Link: https://justica.gov.pt/Servicos/Empresa-na-Hora

The traditional method requires various visits to different entities but has the advantage of personal contact. The "Company Space" website provides information and assistance in setting up a business.

Key Link: https://eportugal.gov.pt/en/inicio/espaco-empresa

Companies must also register with the Directorate General for Economic Activity (DGAE), the Tax Authority (AT), and with the Social Security administration. The online registration process can take as little as one to two days.

In line with the EU, Portugal defines an enterprise as micro, small, and medium-sized based on its headcount, annual turnover, or the size of its balance sheet. To qualify as a micro-enterprise, a company must have less than 10 employees and no more than \notin 2 million in revenues or \notin 2 million in assets. Small enterprises must have less than 50 employees and no more than \notin 10 million in revenues or \notin 10 million in assets. Medium-sized enterprises must have less than 250 employees and no more than \notin 50 million in revenues or \notin 43 million in assets. The SME Support Institute (IAPMEI) offers financing, training, and other services for SMEs based in Portugal: <u>http://www.iapmei.pt/</u>.

More information on laws, procedures, registration requirements, and investment incentives for foreign investors in Portugal is available at AICEP's website:

http://www.portugalglobal.pt/EN/InvestInPortugal/howtosetupacompany/Paginas/HowtoSetupaCompany.aspx

Any American entity interested in establishing a company in Portugal should contact the U.S. Commercial Service office of the U.S. Embassy in Lisbon to discuss the project and obtain additional information.

Key Link: http://www.portugalglobal.pt/EN/INVESTINPORTUGAL/Pages/index.aspx

For further information on establishing an office in Europe, please consult the European Commission which manages the Your Europe (<u>http://europa.eu/youreurope/business/index_en.htm</u>) website where investors can find useful information.

Franchising

Overall, the economic climate in Portugal is open to franchises, especially for new and innovative concepts. The outlook for the franchise sector continues to be fairly positive, mainly due to the number of outlets and shopping malls in the country. The entire national territory offers opportunities for expansion and the market still has room for new, internationally known franchising concepts, but the bigger opportunities are on the Porto disctrict, the Algarve region and the Greater Lisbon area.

According to the 23rd Franchising Census, in 2017 (latest data available), there were 610 brands operating in this model (of which 66% were Portuguese, 17.9% Spanish and 4.6% American) – which correspondend to an increase of 6.3% (with 40 new brands) from the previous year. In 2017, all franchising units generated a turnover of about USD 6,146 million (2.84% of the national GDP) and secured 129,280 jobs (2.72% of the total national employment), an increase of 0.17% when compared to 2016. Around a quarter of the 610 brands had up to 4 franchising units in 2017. In sectoral terms, within the scope of new brands, most were service related; commerce came second, followed by

catering. At the level of competencies, entrepreneurial spirit and business profile were the most sought after attributes by brands for future franchisees.

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 a number of 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: http://www.eff-franchise.com/; <a href="http://www.eff-franchise

Direct Marketing

Distance selling and eCommerce have become effective direct marketing methods and their popularity have grown rapidly. According to the Portuguese Direct Marketing Association (AMD), the sector is estimated to continue its sales growth rate of 10% per year, with more than 80 direct marketing firms operating in Portugal.

Key Link: http://www.amd.pt

The EU has yet to adopt legislation harmonizing the direct-selling of consumer products. However, there is a widerange of EU legislation that impacts the direct marketing sector. Compliance requirements are stiffest for marketing and sales to private consumers. Companies need to focus, in particular, 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 distanceselling 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.

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.

Consumer Rights Directive: <u>https://eur-lex.europa.eu/eli/dir/2011/83/oj</u> https://ec.europa.eu/info/law/law-topic/consumers/consumer-contract-law/consumer-rights-directive_en_

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.

New Legislation

In December 2015 the European Commission released a package of two draft Directives, respectively on "contracts for the supply of digital content" and another on "contracts for the online and other distance sales of goods." This package addresses the legal fragmentation and lack of clear contractual rights for faulty digital content and distance selling across the EU. The package only addresses B2C contracts, although its scope uses a very broad definition of both digital content (including music, movies, apps, games, films, social media, cloud storage services, broadcasts of

sport events, visual modelling files for 3D printing) and distance selling goods so as to cover Internet of Things (such as connected households' appliances and toys). It could also apply to transactions whether in the context of a monetary transaction or in exchange of (personal) consumer data. Healthcare, gambling and financial services are excluded from the proposal.

Key Links:

Consumer Affairs Homepage: <u>https://ec.europa.eu/info/departments/justice-and-consumers_en</u> Consumer Rights: <u>https://ec.europa.eu/info/policies/consumers/consumer-protection_en</u>

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.

DIRECTIVE 2002/65/EC concerning the distance marketing of consumer financial services: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32002L0065&from=EN</u>

Direct Marketing over the Internet

The eCommerce 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 is currently assessing the opportunity to propose a revision of the eCommerce Directive.

eCmmerce Directive (2000/31/EC): <u>https://eur-lex.europa.eu/legal-</u>content/EN/TXT/PDF/?uri=CELEX:32000L0031&from=EN

Joint Ventures/Licensing

Joint ventures and licensing are alternative ways to enter the Portuguese market. Joint ventures between American and Portuguese firms are treated under Portuguese law as foreign investment operations, which may take the form of any type of business firm. With regard to tax treatment and incentives, both domestic and foreign-owned firms are treated equally.

Licensing is a contractual arrangement, in which the licensor makes available or sells its know-how, patents, trademarks or copyrights to a licensee for compensation. Franchising could be considered an important form of know-how licensing.

American firms should be reminded that, as a fully integrated member of the EU, Portugal abides by the foreign trade and investment rules that govern the rest of the EU. Whatever applies in other EU countries applies to Portugal. If an American firm is complying with EU regulations prior to exporting or investing in the EU, it has already done its homework for Portugal. However, enforcement of some intellectual property rights laws continues to be weak.

Express Delivery

Major global organizations such as DHL, FedEx, UPS and others operate in Portugal and offer express delivery services. Transit times vary but for packages shipped from the US to Portugal, the average time is 2-5 days, not including the customs clearance process.

Customs procedures and requirements are standard and can be found on the Portuguese Customs Website.

Key Link: https://aduaneiro.portaldasfinancas.gov.pt/jsp/main.jsp

Due Diligence

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

The U.S. Commercial Service at the U.S. Embassy in Lisbon assists U.S. firms in identifying both opportunities and risks associated with cross border transactions. In general, our office supports bids in competitive tenders, briefs U.S. firms as required, provides information on key risks in the business environment, and advocates on behalf of U.S. firms, as appropriate.

For complex transactions and issues, our office can provide lists of attorneys and law offices, as well as accounting/consulting firms specialized in due diligence, to help investors achieve the best value for a transaction.

Commercial background checks on Portuguese companies can be obtained through the U.S Commercial Service in Portugal as well as private sector resources.

eCommerce

Assessment of Current Buyer Behavior in Market

The Portuguese B2C eCommerce market has been growing steadily in recent years and accounted for USD 3 billion in 2018. But in the first 6 months of 2020, eCommerce experienced a substantial increase of international and national digital shopping. According to local media, and a consumer habits study by MARCO "Post Covid-19 Consumer Habits", a Madrid based consultant, more than 50% of Portuguese purchased online in the period of March through May, which contributed to unprecedented sector growth.

According to a December 2019 report, prepared by Deloitte for APED - Portuguese Association of Retailing Companies, Portugal is ranked 30th in the global eCommerce competitiveness ranking (compiled by Eshopworld) and is expected to grow above the average of European countries by 2021. Metrics include logistics performance, sector revenues, number of buyers, online commerce penetration and the latest developments. It is estimated that the value of eCommerce transactions carried out in 2017 by Portuguese consumers amounted to 4.6 billion euros, corresponding to 2.5% of national GDP.

As stated on a survey carried out jointly by CIP-Confederação Empresarial de Portugal (Portuguese Entrepreneurs Association) and ISCTE-Business School, sales through digital channels are worth close to a quarter of the revenues of Portuguese companies that have diversified traditional sales methods and strategies. The estimated proportion of digital sales in companies selling through this channel is 23%, which may help Portuguese companies position themselves for EU support – which has a initiatives supporting the development of digital channels. Of the 652 companies surveyed, 56% started selling digitally after the start of the pandemic. About 15% of these companies recorded an increase between 11% and 20% in sales and 2.5% of companies recorded an increase of 40% in sales.

For brands and online sales platforms, this is the time to capitalize on the change in consumer habits, by adopting user loyalty strategies – such as ensuring an accessible and effective delivery process, sites that provide a simple and safe shopping experience and with different payment options.

As reported by Unicre (Portuguese credit card management system), the top 5 online shopping cities in Portugal during the pandemic were Porto, Lisbon, Coimbra, Aveiro and São Miguel. According to the previously mentioned <u>report</u>

from Deloitte, the most purchased products online by the Portuguese are electronic products, clothing, travels, books, beauty articles, food, bets and applications.

Data from Nielson, DBI and GfK, shows that, in Portugal, purchases during the lockdown equaled the entire year of 2019. This trend will remain, as this period changed Portuguese mindsets on eCommerce, with over 30% of the Portuguese population wanting to continue to purchase online.

Local eCommerce Sales Rules & Regulations

Regulations for eCommerce in Portugal, are distributed among 6 regulatory agents:

- The National Communications Authority (ANACOM) is the official entity regulating the communications sector, including electronic communications;
- The Competition Authority (AC) has the mission to enforce competition rules and foster the implementation of a culture of competition;
- The General Directorate of Consumers (DGC) promotes the policy of safeguarding consumers' rights, and coordinates and implements measures aimed to protect the consumer;
- The Food and Economic Security Authority (ASAE) supervises and prevents non-compliance with the regulatory legislation, and is the national liaison body with its similar entities, at European and international levels;
- The Tax and Customs Authority (AT) has the mission to administer taxes, customs duties and other feeds attributed to purchases, and exercises border control within the European Union and;
- Banco de Portugal has two essential missions: maintaining price stability and promoting stability in the financial system.

Currently, there is no working group for cooperation between the 6 regulatory bodies mentioned above.

Nevertheless, there is an Interinstitutional Group for eCommerce that includes: Authority for Working Conditions (ACT), Food and Economic Security Authority (ASAE), Tax and Customs Authority (AT), National Republican Guard (GNR), Public Security Police (PSP), Maritime Police (PM) and Foreigners and Borders Service (SEF). This national cooperation activity aims to strengthen institutional relations and enhance the existing synergies between the various entities, with the objective of guaranteeing compliance with the law and benefiting the various economic operators and citizens with the performance, in a single act, of several entities.

Following laws must be generally observed:

- <u>Decree-Law 7/2004</u>, known as eCommerce law;
- <u>Law 46/2012</u> on data protection and privacy in electronic communications;
- <u>Decree Law 63/85</u>, known as the copyright code;
- <u>Decree-Law 330/90</u>, known as the Advertising Code;
- <u>Decree-Law 138/90</u>, known as the Consumer Price Law;
- Law 24/96, known as the Consumer Law;
- Law 67/98, known as the Personal Data Protection Act;
- <u>Decree-Law 143/2001</u>, known as the law on distance contracts and;
- <u>Decree-Law 70/2007</u>, known as the law on price reductions.

There are more laws regulating commercial activity and some are intended only for specific sectors, so this is not a comprehensive collection of all legislation applicable to eCommerce.

We highlight from Decree Law 7/2004, known as eCommerce law, the implications that it has on the information that must be permanently available in your online store, namely:

- Identification of the managing entity of the site;
- Geographical address;
- E-mail address;

- Taxpayer number and;
- Other public registers.

We also highlight Law 46/2012 which implies that the acceptance of cookies is previously granted by the visitor and which places most eCommerce systems in operation outside the law.

The European Union's Digital Single Market Initiative

Creating a Digital Single Market (DSM) is one of the ten priorities of the European Commission (EC). The overall objective is to bring down barriers, regulatory or otherwise, and to unlock online opportunities in Europe, from eCommerce to e-government. By doing so, the EU hopes to do away with the current fragmented national markets and create one borderless market with harmonized legislation and rules for the benefit of businesses and consumers alike throughout Europe.

The EC set out its vision in its May 6, 2015 DSM Strategy which has been followed by several concrete legislative proposals and policy actions. They are broad reaching and include reforming eCommerce sector, VAT, copyright, audio-visual media services, consumer protection, and telecommunications laws. New legislation has already been finalized on portability of online content and geo-blocking.

Many DSM proposals are still going through the legislative process. DSM-related legislation will have a broad impact on U.S. companies doing business in Europe.

In addition, a new data protection legislation, the General Data Protection Regulation (GDPR) entered into force on 25 May 2018 (see separate section in this report). The three main pillars of the strategy are:

- Pillar I: Better access for consumers and businesses to digital goods and services across Europe; Better access for consumers and businesses to online goods and services across Europe; Remove key differences between the online and offline worlds to break down barriers to cross-border online activity.
- Pillar II: Shaping the right environment for digital networks and services to flourish; Achieve high-speed, secure and trustworthy infrastructures and content services; Set the right regulatory conditions for innovation, investment, fair competition and a level playing field.
- Pillar III: Creating a European Digital Economy and society with growth potential; Invest in technologies such as cloud computing and Big Data, and in research and innovation to boost industrial competitiveness and skills; Increase interoperability and standardization

For more information: <u>https://ec.europa.eu/info/strategy/priorities-2019-2024/europe-fit-digital-age_en</u> DSM Strategy: <u>http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52015DC0192&from=EN</u>

EU's General Data Protection Regulation (GDPR) (2016/679/EC on the protection of natural persons with regard to the processing of personal data and on the free movement of such data), available at: <u>https://eur-lex.europa.eu/eli/reg/2016/679/oj</u>

Rules for the protection of personal data inside and outside the EU: <u>https://ec.europa.eu/info/law/law-topic/data-protection_en</u>

Information on contracts for transferring data outside the EU: <u>https://ec.europa.eu/info/law/law-topic/data-protection/international-dimension-data-protection/standard-contractual-clauses-scc_en</u>

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, 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.

Comprehensive Market Research on eCommerce in the EU is available upon request.

eCommerce Directive (2000/31/EC): <u>https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32000L0031&from=EN</u>

Value Added Tax (VAT)

The EU's VAT system is semi-harmonized. While the guidelines are set out at the 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 January 1, 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.

• This 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 to non-taxable persons in other Member States (the Member State(s) of consumption), along with the VAT due.

Until 2021, goods imported from countries outside the European Union with a value of less than EUR 22 will remain exempt from VAT. This limit is lower in some Member States. Imported goods are sometimes deliberately undervalued in order to remain exempt from VAT. In 2018, VAT laws were amended to prevent these price distortions from continuing and it was determined that all goods imported from third countries, regardless of their value, will no longer be exempt from paying VAT from 2021 onwards. Also, from this date 2021, large marketplaces will be responsible for collecting VAT from the consumer corresponding to purchases of goods from outside the European Union.

In 2024 the European Union will launch a mega database with detailed information on cross-border online shopping to reduce eCommerce tax fraud.

The Commission has received numerous complaints in relation to the new rules on ESS and is in the process of revising them (<u>draft proposal</u>).

The most important pieces of legislation on VAT are the <u>EU VAT Directive 2006/112/EC</u> and its <u>Implementing</u> <u>Regulation 282/2011</u>.

Further information relating to VAT on ESS:

https://ec.europa.eu/taxation_customs/business/vat/telecommunications-broadcasting-electronic-services/

Legal and Competitive Obstacles

According to a December 2019 <u>report</u>, prepared by Deloitte for APED - Portuguese Association of Retailing Companies, in order to identify the existing barriers to a higher growth in sales made through digital channels in Portugal, it was concluded that:

- Counterfeiting and piracy cost Portuguese companies 9.5% of their annually sales, which is equivalent to approximately 1150 million euros;
- Portuguese consumers buy from retailers outside the EU often in search of more competitive prices;

- Portugal has the highest proportion of cross-border online orders in the EU (85% of the total), thus it is particularly exposed to the actions of non-EU operators who, although subject to the same legal framework in force for the entire Digital Single Market, present increased difficulties for regulatory authorities in sanctioning violations of the law;
- Portugal has high levels of digital and financial illiteracy, which contribute to a greater inhibition to experimenting online shopping and limits consumer's ability to assess different payment methods and financing. In addition, the lack of information on consumers rights means that Portuguese consumers, in case of dissatisfaction with their purchase, are inhibited from reporting to the authorities when products are defective or do not otherwise comply with EU law;
- Given the high complexity of customs tax control for eCommerce, Portugal is not managing to meet all the challenges of collecting the correct amounts of VAT and customs duties on goods and services traded over the Internet;
- Although European legislation is seen as being at the forefront of regulating consumer rights and fostering the sector, there are discrepancies between the law and the effective consumer protection resulting from its enforcement;
- Late availability of internationally available digital payment methods hampers the competitiveness of national operators;
- Portuguese companies do not find enough talent in quantity and quality in the national labor market to perform functions in the areas of engineering, technology and information technology;
- The activity of operators is affected by the national and European regulatory framework, which presents two major challenges from the interlocution point of view;
- On the one hand, the dispersion of responsibilities among the six different entities with supervisory powers in Portugal over eCommerce transactions leads to the frequent requirement for operators to maintain multiple contacts and communication channels for the same occurrence and;
- On the other hand, legal differences persist within the EU, so the same commercial practice can be assessed differently from country to country, leading to an environment of greater regulatory risk for eCommerce in Europe.

To address the identified challenges, a set of potential measures to minimize the identified constraints and enhance the competitiveness of the sector in Portugal was proposed:

- Create an eCommerce supervisory center, materialized in an independent body, responsible for assessing the consistency, compliance and sustainability of legislation and regulations applicable to eCommerce and for adopting measures to promote transparency, regulatory effectiveness, the quality of economic policy decisions and strengthening the credibility of digital operators accessible on national territory;
- Encourage the training and capacity building of regulatory authorities' resources in legal, business and technology matters, so that they can apply the law and supervise the market in a correct and adequate manner;
- Ensure the use and promotion of intra-Community and international administrative cooperation channels in order to ensure compliance with the law by operators based outside Portugal and re-establish competition in the digital market;
- Regularly monitor selectively, rather than randomly, orders that have characteristics that are often associated with products that do not meet consumer safety and protection standards and;
- Strengthen the compliance with tax obligations of operators selling in the national area, adopting measures that strengthen compliance with the law and penalize unfair behavior;

Key link: <u>https://www2.deloitte.com/content/dam/Deloitte/pt/Documents/consumer-business/Deloitte_Obstaculos%20ao%20desenvolvimento%20do%20ecommerce.pdf</u> IDC Portugal: <u>https://www.idcdx.pt/insights/</u>

ACEPI – Portuguese Association of Electronic Commerce and Interactive Advertising: <u>https://www.acepi.pt/artigosCategoria.php?idCategoria=3</u>

Local eCommerce Business Service Provider Ecosystem

Portuguese Business Promotion Agency (AICEP)

Due to the new business context caused by the pandemic, the Portuguese Business Promotion Agency (AICEP) announced in April 2020 a set of initiatives to support eCommerce companies. One of the initiatives is an eCommerce self-diagnostic tool, available on the <u>Portugal Exporta platform</u>, which allows companies to understand their level of preparation to start exporting online. Companies will receive a report with recommendations on how to prepare themselves or how to start taking advantage of online exporting.

Additionally, AICEP is promoting a set of webinars dedicated to international eCommerce, held through AICEP's elearning platform – the <u>e.Academia Internacionalizar</u>. The agency will also invest in e-learning courses so that companies can acquire more skills in eCommerce, as a necessary evolution for its internationalization. Furthermore, AICEP promotes partnerships with marketplaces to give Portuguese companies the opportunity to know the business potential and operation of such platforms.

Just Happy Days eCommerce Platform

<u>Just Happy Days</u> is a Portuguese eCommerce platform – launched in its current version as an online shopping center for traditional commerce, designers and industry in November 2018 – that intends to support international trade. It is a multi-brand web shop where a wide range of physical stores can have their online store. The aim of the platform is to respect the identity of each store or brand and to stimulate the autonomous involvement of each one in the management of its online store. The products are always sent by each store or brand, with packaging and external branding from Just Happy Days, but with inside wrapping of the store or brand where the purchased item is from. Through the platform, the customer can make several purchases simultaneously – using the same shopping cart – and finish them with just one payment.

Toogas eCommerce Platform

<u>Toogas</u>, created in 2008, provides establishment, maintenance and consultancy services for eCommerce stores, using the eCommerce platform Adobe Magento. The services provided include: Integrations, Web Design, Development, Migration, Optimization, Support, Online Marketing and Application Creation. The goal is to guide their customers in the global eCommerce environment and generate exponential growth for their businesses, by developing innovative eCommerce solutions and increasing their online presence.

e-Commerce Connect 2020

On January 29 and 30, 2020, Portugal hosted for the third time the <u>E-Commerce Connect</u>, an event dedicated to eCommerce, whose main objective is to bring online stores closer to the best and most innovative technological services, which will be able to increase the performance of their digital presence by making them aware of multiple solutions and services, both national and global. During the two days, more than 50 success stories were presented, more than 1000 one-on-one meetings were held, and international keynotes were shared.

The next edition of this event will take place on January 27 and 28, 2021.

Key Link – eCommerce News: <u>https://ecommercenews.pt/</u>

Selling Factors & Techniques

Overview

In Portugal, modern techniques coexist with traditional practices. Modern sales techniques are generally accepted and are effective, but traditional values continue to be respected. Many businesspeople still consider a personal contact and a handshake to be a kind of informal contract, but they are also accustomed to formal contract procedures.

Direct sales, large "hypermarkets" and shopping malls are common. For consumer goods, the decisive selling factors may be price, quality, brand name or the product's innovative features. However, the institutional buyer is quality conscious and very sensitive to pricing. Most tenders consider price first and quality second. These characteristics, as well as its market size, sometimes make Portugal a difficult destination for some American exporters. A good understanding of market needs and the demand for new opportunities should lead to profitable niches for the American exporter.

Trade Promotion and Advertising

As in all Western countries, some of the preferred techniques for reaching Portuguese buyers effectively are advertising and trade promotion events. Portugal offers a reasonably priced market in which to advertise. Advertising media are the same as in the majority of developed Western countries: newspapers, magazines, TV, and Internet advertising are the most popular.

In Portugal there are a number of annual specialized international trade shows. Major venues include the International Fair of Lisbon (FIL - Feira Internacional de Lisboa) and the Exponor trade center near Porto, both of which offer excellent means for finding prospective local partners. In addition, various associations' commercial bulletins are good avenues for client-directed promotional activities.

The U.S. Commercial Service at the U.S. Embassy in Lisbon can provide a list of major newspapers and business journals, upon request.

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 (AMSD) lays down legislation on broadcasting activities allowed within the EU. Since 2009, the rules allowing for U.S.-style product placement on television and the three-hour/day maximum of advertising has been lifted. However, a 12-minute/hour maximum remains. The AMSD is currently under revision. The European Commission is aiming to extend the scope of the Directive to video-sharing platforms which tag and organize the content. The Commission is also aiming to provide more flexibility about the 12-minute/hour maximum restriction. Children's programming is subject to a code of conduct that includes a limit on junk food advertising to 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, 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.

Consumer protection policies, strategies and statistics: <u>https://ec.europa.eu/info/policies/consumers/consumer-protection_en</u>

Key Links:

http://ec.europa.eu/consumers/consumer_rights/unfair-trade/false-advertising/index_en.htm http://ec.europa.eu/consumers/consumer_rights/unfair-trade/unfair-practices/index_en.htm https://ec.europa.eu/digital-single-market/en/audiovisual-media-services-directive-avmsd

Medicines

The advertising of medicinal products for human use is regulated by Council Directive 2001/83/EC, as amended by Directive 2004/27/EC. Generally speaking, 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 particular medicinal product are prohibited and the supply of free samples is restricted.

Key Link: https://ec.europa.eu/health/home_en

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 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 later. 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.

The development of nutrient profiles, originally scheduled for January 2009, has been delayed. The original proposal has been withdrawn. In October 2015 the European Commission released a new roadmap on the potential development of nutrient profiles and botanicals. To obtain stakeholders' inputs, two consultations and an external study was launched in mid-2017. The European Commission is now assessing the opportunity to proceed with a proposal and then potentially draft it. 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.

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 2017

Key Link: EU Register of Nutrition and Health Claims

Regulation on Food Information to Consumers: Regulation 1169/2011

EU-28 FAIRS EU Country Report on Food and Labeling requirements: <u>USDA Food and Agricultural Import</u> <u>Regulations and Standards EU 28 2020</u>

Health & Nutrition Claims: http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm

Tobacco: http://ec.europa.eu/health/tobacco/policy/index_en.htm

Food Information to Consumers

On January 1, 2018, the EU's <u>new framework regulation 2015/2283</u> on Novel Foods became applicable. Regulation 2015/2283 repeals regulations 258/97 and 1852/2001.

Under the new regulation, a novel food is defined as food that has not been consumed to a significant degree in the EU before May 15, 1997 AND falls within at least one of the 10 categories listed in Article 3 of the new regulation. An <u>Information and Guidance Document on "human consumption to a significant degree"</u> is posted on the Commission's website.

For more details, please visit the USEU/FAS Novel Foods website.

Detailed information on the EU's new food labeling rules can be found on the USEU/FAS website at <u>EU Labelling</u> <u>Requirements</u> and in the <u>USDA Food and Agricultural Import Regulations and Standards EU 28 2017</u>

Key link: Provision on Food Information

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: http://ec.europa.eu/food/food/labellingnutrition/supplements/index_en.htm

<u>Tobacco</u>

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: http://ec.europa.eu/health/tobacco/products/

Pricing

Pricing is the most common explanation cited for why several U.S. products offered in Portugal are not competitive. Pricing of U.S. products sometimes reflects the dealer price in the United States. This often includes the exporter's marketing overhead.

The most appropriate method for pricing a product for the Portuguese market is marginal cost pricing. This would be the marginal unit cost of production in the United States, plus Portuguese market-specific costs associated with overseas promotion, labeling and packaging expenses. A profit margin added to the other pricing components should keep the product competitive.

Portuguese importers currently accept the more common terms of international trade (C.I.F, C&F., F.A.S., F.O.B. or Ex point of origin). They prefer to receive C.I.F. quotations or at least F.O.B. quotations including detailed product

description, gross and net shipping weight, volume and time of shipment (from where the delivery is made) and delivery. Pro-forma invoices with all the above details are not mandatory but are advisable and desirable.

The value-added tax (VAT) on most products and services is 23% in mainland Portugal, 18% in Azores, and 22% in Madeira. This tax is charged upon sale.

Sales Service/Customer Support

Business customers demand a high level of support and most wholesalers or distributors offer excellent customer service. The need to replace broken parts very quickly can present a logistics problem for smaller U.S. suppliers who do not warehouse replacement parts in Europe. Thus, we recommend that U.S. companies make sure that their prospective partners have the capacity and the intent to provide some local warehousing.

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 several 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 it's 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. The first step in the review process of this law was launched at the end of 2016.

Key link: https://ec.europa.eu/growth/single-market/goods/free-movement-sectors/liability-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. The legislation is still undergoing review.

More information on the General Product Safety Directive can be found at: <u>https://ec.europa.eu/info/general-product-safety-directive_en</u>

Key link: https://ec.europa.eu/info/general-product-safety-directive_en

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; or
- 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.

Directive 1999/44/EC on certain aspects of the sale of consumer goods and associated guarantees: <u>https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31999L0044</u> Key link: <u>https://europa.eu/youreurope/citizens/consumers/index_en.htm</u>

Local Professional Services

Using an attorney is not mandatory for doing business in Portugal. Most transactions may be accomplished without an attorney, including the establishment of small, non-complex businesses. However, attorneys are strongly recommended to solve some types of trade disputes and for the establishment of local offices such as joint venture investments with local entities or as 100% subsidiaries. For complex types of licensing, representation/distribution and franchising, an attorney is also recommended to assure compliance with local laws.

The same professional services that are available in other highly developed market economies are readily available locally in Portugal.

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 at: http://export.gov/europeanunion/businessserviceproviders/index.asp

Principle Business Associations

The Confederation of Portuguese Business (CIP) is the most representative business confederation in Portugal. It represents about 114,000 companies of all sizes and sectors, through both sectorial and regional associations, as well as all Chambers of Commerce and Industry of Portugal.

Key Link: https://cip.org.pt/en/presentation/

The Portuguese Industrial Association (AIP) is headquartered in Lisbon. Its primary objective is to contribute to the progress of the companies and associations affiliated, in the areas of technical, economic, commercial, social, cultural and associative network.

Key Link: http://www.aip.pt/?lang=en&page=homepage/homepage.jsp

The Portuguese Business Association (AEP) is a national and multi-sectorial business organization that has its headquarters in Porto. Its main objective is the defense of the business interests and the representation of its members by providing a wide range of services including business exhibitions and conferences, information and business support, consultancy, missions, promotion for investors and professional training.

Key Link: http://www.aeportugal.pt/

Limitations on Selling U.S. Products and Services

N/A

Trade Financing

Methods of Payment

Depending on the size of the order and payment history of the buyer, the terms of the sale will vary. For larger transactions or where the seller is less comfortable with the credit worthiness of the buyer, foreign products are often imported using irrevocable letters of credit against documents, particularly during the first year of business. Opening irrevocable letters of credit is a straightforward process in Portugal through which importers can insure against exchange risk with their banks. When a long-term relationship has been established between a supplier and a customer, more favorable credit terms may be negotiated.

Payment terms are frequently 30, 60 and 90 days. Large corporations, including large retailers, negotiate or impose longer payment terms that can last up to six months. The government defers all payments. Depending on the department, payments can be deferred up to one year. Product pricing must also include the necessary financial charges.

Aside from letters of credit, methods of payment most commonly used in Portugal for international trade are:

Checks (Cheques): While bank checks offer security in transactions, (since the bank issuing the check needs the guarantee of the transfer to issue it), personal checks do not provide adequate guarantees against commercial risk, as the bank does not guarantee the funds in the account of the person issuing the check.

Payment Order (Letras): In this case, the importer gives an order to the bank and, by using a correspondent bank in the same country, pays the exporter's bank the amount due. The initiative for payment in this case is the importer's responsibility. These transfers, via SWIFT, are a common practice in the Portuguese banking system.

Documents against payment (Cartas de Crédito): Exporters use this instrument to ensure the possession of the merchandise until the collection of funds, or at least until the importer accepts a bill of exchange.

Documentary Credit (Crédito Documentário): This method of payment offers safer conditions in the transaction, due to the involvement of banks in both countries. In this case, the importer's bank ensures against the entrance of a third party (an exporter, the bank or a correspondent bank).

Credit Card (Cartão de Crédito) for Small Online Purchases: Even though credit card purchases over the Internet are still not widespread in Portugal, this option should not be excluded.

A U.S. exporter looking to recover debts should contact the Portuguese Credit and Collection Management Association (APERC) for information on and contact with debt collecting agencies. The Association can be reached at: <u>http://www.aperc.pt</u>

Credit reports on Portuguese companies can be obtained by contacting any of the sources below:

Dun & Bradstreet Portugal R Barata Salgueiro 28,3° 1250-044 Lisboa, Portugal Tel.: +351 213 500 300 Fax: +351 213 578 939

Igerinform - Relatórios de Crédito Avenida Columbano B Pinheiro 75,7° 1070-061 Lisboa, Portugal Tel.: +351 213 588 800 Fax: +351 213 588 801

You may also take advantage of customized credit report provided by the U.S. Commercial Service at the U.S. Embassy in Lisbon. Our reports will help you assess the risk, reliability and capability of the Portuguese company. This service is called the International Company Profile (ICP).

For more information about the methods of payment or other trade finance options, please read the Trade Finance Guide available at <u>https://www.trade.gov/trade-finance-guide-quick-reference-us-exporters</u>.

Banking Systems

The Portuguese banking system has witnessed significant structural changes over the last three decades, with a shift from a government-controlled system to a market-driven environment fully integrated with the European Union. These profound structural and operational changes such as the abolishment of administrative interest rates in the 1980s, liberalization and harmonization in the 1990s and related implementation legislation have brought Portuguese banking regulations in line with EU legislative practices.

As a member of the EU, Portugal offers a modern banking system with advanced financial products. The country has one the most advanced inter-banking networks in the world. ATMs and bank branches are easily found all over Portugal. Electronic banking is widespread, and Internet banking is offered by all major banks. Major credit and debit cards are accepted in most Portuguese hotels, shops, restaurants and gas stations.

Most banks are open Monday to Friday from 8:30 am to 3:00 pm and are closed on weekends and public holidays.

The entity supervising the banking sector in Portugal is the Portuguese Central Bank (Bank of Portugal), a member of the European System of Central Banks (ESCB).

In a February 2016 post-bailout program monitoring report, the IMF warned that the Portuguese banking system's balance sheets needed "to be strengthened to avoid further negative surprise and protect taxpayers." The report also noted banks need to further reduce their debt burden, which was "holding back the economy's growth potential." The government has taken steps to address problems in the banking sector, facilitating the recapitalization or restructuring of four of the five largest banks in 2016 and 2017.

The largest Portuguese banks are Novo Banco, Caixa Geral de Depósitos (CGD), BCP, BPI and Santander Totta, which raised around 50 million more in 2019 than in 2018. However, in 2019, in total, Caixa Geral de Depósitos, Santander Totta, BCP, BPI and Novo Banco ended the year with 30,201 employees, 990 less than the 31,191 with which the year ended 2018.

Key links: <u>https://www.dinheirovivo.pt/banca/cinco-maiores-bancos-arrecadaram-mais-de-1-800-milhoes-em-comissoes-em-2019/</u>

https://country.eiu.com/portugal

According to the Bank of Portugal, the banking system's total assets decreased by 1.3%, in the fourth quarter of 2019. This was largely liked to the sale of subsidiaries abroad by one of the major Portuguese banks. Developments in assets reflected the reduction in the portfolio of loans to customers (-1.3%) and exposure to public debt securities (-3.9%). The financing obtained from central banks decreased by 7% to 4.4% of assets. The loan-to-deposit ratio reached 87.3% (-0.7% percentage points), due to a higher decrease in the loan portfolio than in customer deposits (0.5%). The liquidity coverage ratio increased 7.5 p.p., standing at 218.4%, benefiting from the performance of highly liquid assets.

Non-performing loans (NPLs) decreased by around \notin 4.5 billion (20.9%) in the 4th quarter of 2019. This resulted in a decline in the NPL ratio to 6.1% (-1.6 p.p.). The NPL ratio net of impairments reached 3.0% (-0.6 p.p.).

In 2019 return on assets (ROA) increased from 2018, to stand at 0.75%. Return on equity (ROE) rose to 8.1%. ROA developments chiefly reflected a net reversal of provisions and, to a lesser extent, the increase in profits from financial operations and net interest income. However, this positive contribution to ROA was mitigated by an increase in impairment and less so by an increase in operational costs and a deterioration of the item other profit or loss. The cost-to-income ratio fell 1.1 p.p. to 59.2% as a result of a higher increase in total operating income than in operational costs. The loan loss charge stood at 0.50%, up by 0.09 p.p. from 2018 due to an increase in credit impairments above that of the portfolio of loans to customers.

In the 4th quarter of 2019 the total capital ratio and the Common Equity Tier 1 (CET1) ratio stood at 16.7% and 14.1% respectively, both increasing by 0.3 p.p. The 1.8% decrease in risk-weighted assets was the main driver behind this increase. The leverage ratio remained well above the minimum benchmark set by the Basel Committee on Banking Supervision (3%). This requirement will become mandatory as of the new CRR application date (28 June 2021). It is important to note that the COVID-19 pandemic has put a strain on the banking system; however, the government is implementing measures to support stability of this sector.

Key link: <u>https://www.bportugal.pt/sites/default/files/anexos/pdf-boletim/overviewportuguesebankingsystem 2019q4 en.pdf</u>

Foreign Exchange Controls

There are no exchange controls in Portugal. Portugal does not restrict currency holdings by residents or nonresidents, nor does it limit the foreign exchange supply. Residents and nonresidents are free to hold deposits in any currency with Portuguese banks. There are no official guarantees against inconvertibility.

Reporting requirements apply to banks and other financial institutions. Such institutions must provide information between March and April on their positions in derivatives and report cross-border investments and lending in excess of EUR 50 million on an annual calendar year basis.

Transactions of less than EUR 12,500 are exempt from the notification requirement. Any party that transfers an amount larger than this outside Portugal in foreign banknotes, gold, travelers' checks or bearer securities must declare it to the Portuguese customs authority. Money laundering rules are being tightened in accordance with worldwide trends. Full information about clients, notaries, art dealers and any other entities are required when transactions of more than EUR 10,000 are undertaken. Suspicious transactions must be reported.

U.S. Banks and Local Correspondent Banks

CITIGROUP/ CITIBANK Edifício Fundação Rua Barata Salgueiro, 30-4º 1269-056 Lisboa, Portugal Tel.: (+351) 21 311 63 00 Fax: (+351) 21 311 63 99 http://www.citibank.com

JP MORGAN CHASE (former Chase Manhattan Bank) Rua Barata Salgueiro, 30 - 3°Dto. 1250-044 Lisboa, Portugal Tel.: (+351) 210 403 520 Fax: (+351) 213 551 454 http://www.jpmorganchase.com

MERRILL LYNCH (acquired by Bank of America) Global Wealth Management EDIFICIO DUARTE PACHECO 26 Av. Engenheiro Duarte Pacheco, 26 6 Piso A Lisboa, 1070-110 Tel:+351-21-351-2350 http://www.ml.com

AMERICAN EXPRESS (Credit Card Service Company) MillenniumBCP Departamento American Express Av. Professor Doutor Cavaco Silva Ed.3/2B Tagus Park 2740-256 Porto Salvo, Portugal Tel.: 707 504 050 From Abroad: (+351) 214 278 205 http://www.americanexpress.com/portugal/homepage.shtml

Protecting Intellectual Property

Protecting Your Intellectual Property in Europe:

Several general principles are important for effective management 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 and patent registrations will not protect you in the EU. There is no such thing as an "international copyright" that will automatically protect an author's writings throughout the entire world. Protection against

unauthorized use in a country depends, basically, on the national laws of that country. However, most countries do offer copyright protection to foreign works in accordance with international agreements.

Granting patents registrations generally is based on a first-to-file (or first-to-invent, depending on the country) basis. Similarly, registering trademarks is based on a first-to-file (or first-to-use, depending on the country), so you should consider how to obtain patent and trademark protection before introducing your products or services to the EU market. It is vital that companies understand that intellectual property is primarily a private right and that the U.S. government cannot enforce rights 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 we can do 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 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, both EU and U.S.-based. 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 <u>STOP Fakes</u>
- For more information about registering trademarks and patents (both in the United States as well as in foreign countries), contact the <u>U.S. Patent and Trademark Office</u> (USPTO) at: 1-800-786-9199
- For more information about registering for copyright protection in the United States, contact the <u>U.S.</u> <u>Copyright Office</u> 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 <u>STOPfakes website</u>.

For information on obtaining and enforcing intellectual property rights and market-specific IP Toolkits visit: <u>STOPfakes Business tools.</u> The toolkits contain detailed information on protecting and enforcing IP in specific markets and contain contact information for local IPR offices abroad and U.S. government officials available to assist SMEs. IPR Toolkit: <u>https://www.stopfakes.gov/servlet/servlet.FileDownload?file=015t00000004q81</u>

Modernization of the EU copyright rules: <u>https://ec.europa.eu/digital-single-market/en/modernisation-eu-copyright-rules</u>

EU Intellectual Property Office (EUIPO): <u>https://euipo.europa.eu/ohimportal/en/home</u> World Intellectual Property Organization (WIPO) Madrid: <u>http://www.wipo.int/madrid/en</u>

European Patent Office (EPO): http://www.european-patent-office.org/

In any foreign market companies should consider several general principles for effective protection of their intellectual property. For background on these principles please link to the following article on <u>Protecting Intellectual</u> <u>Property</u> and <u>Stopfakes.gov</u>, or contact ITA's Office of Intellectual Property Rights Director, Stevan Mitchell at <u>Stevan.Mitchell@trade.gov</u>The U.S. Department of Commerce has positioned IP attachés in key markets around the world. Contact information for European based IP attachés in below:

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For more information, contact ITA's Office of Intellectual Property Rights: https://legacy.trade.gov/mas/ian/oipr/index.asp

Selling to the Public Sector

Selling to the Government

Portuguese Public Procurement Regulation derives mostly from the European Union's regulations on public procurement. Government procurements may be issued in various ways, based on the amount or characteristics of the tender. The Portuguese Public Contracts Portal (BASE) created by the Portuguese Government back in 2010 improved the transparency of award procedures in Portugal.

Key Link: http://www.base.gov.pt/Base/pt/Homepage http://www.base.gov.pt/Base/en/FrequentlyAskedQuestions

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 are allowed to 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 recently been revised and new legislation on concession has also been adopted. Member States were required to transpose the provisions of the new directives into domestic law by April 16, 2016. The four relevant pieces of legislation are:

- <u>Directive 2014/24/EU</u> (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;
- <u>Directive 2014/25/EU</u> (replacing Directive 2004/17/EC) coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors;
- <u>Directive 2009/81/EC</u> 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;
- <u>Directive 2014/23/EU</u> 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 three remedy 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 on publication of the Official Journal of the European Union (OJEU) contract notice. Full electronic communication (with some exceptions) will become mandatory for all public contracts from October 2018. Central purchasing bodies are required to publish their contracts and requests for tenders since April 2017.

Electronic invoicing (e-invoicing) will be introduced beginning 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 undertaking 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

Many governments finance public works projects through borrowing from the Multilateral Development Banks. Please refer to "Financing of Projects" Section in "Selling to the Public Sector" for more information.

EU Funding and Government Procurement Sectors:

https://2016.export.gov/europeanunion/marketresearch/eufundingandgovernmentprocurementsectors/index.asp

Advocacy

U.S. companies bidding on government tenders may also qualify for U.S. Government advocacy. A unit of the U.S. Commerce Department's International Trade Administration, the Advocacy Center coordinates U.S. Government interagency advocacy efforts on behalf of U.S. exporters bidding on public sector contracts with international governments and government agencies. The Advocacy Center works closely with our network of the U.S. Commercial Service worldwide and inter-agency partners to ensure that exporters of U.S. products and services have the best possible chance of winning government contracts. Advocacy assistance can take many forms but often involves the U.S. Embassy or other U.S. Government agencies expressing support for the U.S. bidders directly to the foreign government. Consult Advocacy for Foreign Government Contracts for additional information.

Financing of Projects

Project finance and Public Private Partnerships (PPP) had traditionally been popular models in Portugal since the early 90's, thanks to a stream of state-funded projects that included the construction of the second Tagus Bridge, development of major roads and highways, hospitals and more recently the high-speed rail and airports. Energy projects had also been abundant, particularly renewable energy projects like solar, wind and photovoltaic plants. Although, recently PPPs have become a subject of political debate especially in the healthcare sector.

EU financial assistance programs provide a wide array of grants, loans, loan guarantees and co-financing for feasibility studies and projects in several key sectors (e.g., environmental, transportation, energy, telecommunications, tourism, public health). Several 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 aids 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 Enlargement, Development and Cooperation (EuropeAid), Humanitarian Aid and Civil Protection (ECHO).

EIB-financed projects: http://www.eib.org/projects/index.htm?lang=-en

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, please visit: http://ec.europa.eu/regional_policy/index_en.cfm

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: https://www.trade.gov/Market-Intelligence

The Cohesion Fund

The Cohesion Fund is another instrument of the EU's regional policy. Its 63 billion-euro budget (2014-2020) 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: https://ec.europa.eu/regional_policy/en/funding/cohesion-fund/

Other EU Grants for Member States

Other sets of sector-specific grants such as Horizon 2020 aid 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: <u>EU</u> Funding and Tenders.

EU Grants and Loans index: <u>https://europa.eu/european-union/about-eu/funding-grants_en</u> EU Tenders Database: <u>http://ted.europa.eu/TED/main/HomePage.do</u>

External Assistance Grants

"Development and Cooperation – EuropeAid" is the Directorate–General (DG) 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 the 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 can participate. European subsidiaries of U.S. firms are eligible to participate in these calls for tender.

The European Neighborhood Instrument (ENI) aids 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: <u>EU External Action</u>

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: https://ec.europa.eu/neighbourhood-enlargement/instruments/overview_en#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 <u>Regulation 1316/2013</u> on December 11, 2013.

Along with the <u>European Fund for Strategic Investments (EFSI)</u>, 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 each year.

Only actions contributing to projects of common interest in accordance with <u>Regulations 1315/2013</u>, <u>No 347/2013</u> and a <u>Regulation on guidelines for trans-European networks in the area of telecommunications infrastructure</u>, 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 €33.24 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: https://ec.europa.eu/inea/en/connecting-europe-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 action, and strategic infrastructure.

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). EIB's lending activities are mainly funded via bond issuance in the international capital markets. Its annual funding program for 2020 is EUR 60 billion. 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 <u>projects</u> to be considered for approval.

Multilateral Development Banks and Financing Government Sales

Price, payment terms, and financing can be a significant factor in winning a government contract. Many governments finance public works projects through borrowing from the Multilateral Development Banks (MDB). A helpful guide for working with the MDBs is the Guide to Doing Business with the Multilateral Development Banks. The U.S. Department of Commerce's (USDOC) International Trade Administration (ITA) has a Foreign Commercial Service Officer stationed at each of the five different Multilateral Development Banks (MDBs. Learn more by contacting the:

- <u>Advocacy Liaison for World Bank</u>
- Advocacy Liaison for European Bank for Reconstruction and Development.

Business Travel

Business Customs

Portugal is a democratic republic located on the Iberian Peninsula in south-western Europe and is the western-most country in continental Europe. Portugal is bordered by Spain to the north and east and by the Atlantic Ocean to the west and south. In addition, Portugal includes two archipelagos in the Atlantic, the Azores and Madeira Islands.

The Portuguese business community is very formal; titles such as Doctor, Engineer, and Architect are commonly used. Make sure you ask the title of the person with whom you are meeting and always use it before the person's last name. Writing in red ink is considered an insult and, therefore, never used in the business community. When greeting a businessperson, a handshake is proper, and kisses on the cheek between sexes after a friendship is established; this traditional greeting has changed because of the pandemic and now a nod of the head or a touch of the elbow is becoming common. Courtesy, in business and other spheres, is expected and easily extended. Legal contracts don't have the strength in business associations that personal confidence, built over years of experience, offers. Aggressiveness is not acceptable in marketing because it may be interpreted as socially offensive. Pragmatism, of the American variety, is respected but only when presented as a possible option, not as a hard sell.

In terms of everyday business the Portuguese are outstanding and civil. They respect the time of their appointments and expect the same from others. They are thorough to a fault, often poring over all documents relative to a negotiation, and not eager "to just hit the highlights." This is done partly to be careful (conservative) but also to demonstrate their grasp of the matter - exhibiting pedantic merit rather than pragmatic merit.

The quality of housing in Portugal is of European standards but so are rents. Executive location costs in Portugal are now in the same category as any major commercial center in the European Union. Food supplies are plentiful though there are seasonal variations in prices for perishable items. Supermarkets are fully stocked. Prices are very close to those found in the United States and often exceed them for packaged goods.

Travel Advisory

In previous years there have been no travel advisories for Portugal; however, with the pandemic travel advisories and frequent changes are common so it is best to refer to the Portuguese Embassy in Washington D.C. and the U.S. Embassy in Lisbon for the latest travel guidance for travel to Portugal.

Refer to the U.S. Embassy website for the latest COVID-19 information: <u>https://pt.usembassy.gov/covid-19-information/</u>

Visa requirements

Portugal is a party to the Schengen Agreement. This means that U.S. citizens may enter Portugal for up to 90 days for tourist or business purposes without a visa within any 180-day period. Your passport should be valid for at least three months beyond the period of stay. You need sufficient funds and a return airline ticket. For additional details about travel into and within Schengen countries, please see our Schengen fact sheet.

State Department Portugal Information: <u>https://travel.state.gov/content/passports/en/country/Portugal.html</u>

U.S. Companies that require travel of foreign businesspersons to the United States are advised that security evaluations are handled via an interagency process. Visa applicants should go to the following link(s): <u>State Department Visa</u> <u>Website</u>.

Currency

ATMs are commonplace in cities and towns throughtout Portugal, both on street, in retail outlets and gas stations and visitors should be aware that bank transaction fees may apply, including foreign transaction fees and conversion fees. Traveler's checks are not generally accepted for purchases.

For currency or other numerical quantities, a decimal point (period) is commonly used to mark off the thousands position and a comma to denote decimal amounts – unlike the practice in the United States.

Telecommunications/Electronics

Portugal is a fully "wired" country with regard to communications, making available all the services found anywhere else in Europe: long-distance calls on Stateside credit cards; cellular telephones (can be rented from Vodafone at the airport departures area); video-conferencing in state-of-the-art facilities; Internet services; e-mail, etc. In Europe, Electrical sockets can be either "Type C" Europlug or "Type E" and "Type F" Schuko. If your appliance's plug doesn't match the shape of these sockets make sure that you bring a travel plug adapter in order to plug in. Portugal Electrical sockets usually supply electricity at between 220 and 240 volts AC. The ATM system in Portugal is one of the best in the world, as it enables you to do most payments and money transfers at an ATM terminal anywhere in Portugal.

Transportation

Before the pandemic, Portugal has direct airline connections from Lisbon, Porto and Ponta Delgada hubs to all major cities in the European Union, Atlanta, Chicago, San Francisco, New York, Newark, Miami, Philadelphia, Boston and Washington, DC. Direct connections also exist between Lisbon and a number of Portuguese-speaking countries in Africa and major cities in Brazil. Since, COVID-19 airtravel to/from Portugal has been negatively impacted; routes have been reduced, discontinued and are subject to frequent changes. It is advisable that business travelers check with the latest travel restrictions, confirm flights with airlines, and consider alternate routing in case of travel disruptions.

Language

Many Portuguese speak two, often three or four languages. English is the second language of choice followed by Spanish and French. American business travelers can generally conduct their meetings with business and government contacts in English.

Health

Health care in Portugal is a constitutional right, but the public health facilities are overburdened and, therefore, not able to offer the level of service considered normal in the United States. There are a number of private clinics and small private hospitals that are adequate, plus there are several new hospitals planned to be built in the near future to offer better conditions to patients.

Portugal has a National Vaccination Plan which is universally available and free of charge to everyone. Babies born in Portugal are routinely given vaccinations at birth and then they follow a calendar of regular vaccinations during their first six months. There are no special immunizations or medications necessary for most trips to Portugal. However, it is recommended the revaccination every 10 years for Tetanus-diphtheria.

U.S. citizens should contact the Portuguese authorities if they have been in contact with an infected person or if experiencing symptoms of COVID19.

Portuguese COVID-19 Health Hotlines (Serviço Nacional de Saúde)

Mainland Portugal – (+ 351) 808 24 24 24 Azores – (+351) 808 24 60 24 Madeira – (+351) 800 24 24 20

Local time, business hours, and holidays

Listed below are the American and Portuguese holidays which will be observed by the American Embassy in Lisbon in 2020:

Temporary Entry of Materials and Personal Belongings

Personal belongings may enter the country without barriers imposed by Portuguese Customs. If Portuguese Customs see that personal belongings are of very high value (such as jewelry, and other high end electronic material) they may require a monetary guarantee that will be reimbursed when leaving the country.

Entry of materials meant to be distributed at trade shows such as promotional literature, gadgets, tourism and technical information and brochures may enter the country but the company carrying these will have to fill out a customs request to bring them into the country and hand them out.

Companies that plan to temporarily bring materials and equipment not for sale will be requested to fill out a formal request of Temporary Importation of Products.

The Portuguese Customs Authority supplies this form upon entering the country. This will enable the U.S. company to take the equipment back without having to pay customs. If the equipment is sold while in Portugal, the U.S. company will have to pay the duties related to the specific equipment.

Investment Climate Statement (ICS)

The U.S. Department of State Investment Climate Statements provide information on the business climates of more than 170 economies and are prepared by economic officers stationed in embassies and posts around the world. They analyze a variety of economies that are or could be markets for U.S. businesses.

Topics include Openness to Investment, Legal and Regulatory systems, Dispute Resolution, Intellectual Property Rights, Transparency, Performance Requirements, State-Owned Enterprises, Responsible Business Conduct, and Corruption.

These statements highlight persistent barriers to further U.S. investment. Addressing these barriers would expand high-quality, private sector-led investment in infrastructure, further women's economic empowerment, and facilitate a healthy business environment for the digital economy. To access the ICS, visit the U.S. Department of State Investment Climate Statement website.

Political Environment

For background information on the political and economic environment of the country, please click on the link to the U.S. Department of State <u>Countries & Areas</u> website.