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Table of Contents

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Doing Business in Germany

Market Overview

The German economy is the fourth largest in the world and accounted for one quarter (24.2 percent) of the European Union's GDP in 2020. Germany is also the United States' largest European trading partner and the sixth-largest market for U.S. exports. Its "social market" economy largely follows market principles, but with a considerable degree of government regulation and wide-ranging social welfare programs.

With a population of 83.2 million, Germany is the largest consumer market in the European Union. The significance of the German marketplace goes well beyond its borders. An enormous volume of trade in Germany is conducted at some of the world's largest trade events, such as Medica, Hannover Fair, Automechanika, and the ITB Tourism Show, although it should be noted that many trade fairs in 2020 and 2021 were canceled or rescheduled due to the COVID-19 pandemic. Many trade fairs and events are expected to be held in digital or hybrid formats over the next months. The volume of trade, number of consumers, and Germany's geographic location at the center of the European Union make it a cornerstone around which many U.S. firms seek to build their European and worldwide expansion strategies.

In 2020 and 2021 Germany weathered the COVID-19 pandemic's devastating economic effects better than any of its EU neighbors thanks in large part to its fiscal space, a large current account surplus (USD 278 billion [EUR 232 billion] in 2020), generous economic stimulus packages, and flexible short-term work schemes that kept unemployment at only 5.7 percent in summer 2021. Projected GDP growth ranged from 3.2 percent to 3.9 percent in 2021 and 4.3 percent to 4.8 percent in 2022, with the most optimistic forecasts predicting full economic recovery by Q3 2021. All forecasts expect continued GDP growth from Q2 2021 onwards, accelerated by the easing of pandemic restrictions and the rebound of the services sector.

Demographic changes and resulting labor shortages, supply chain bottlenecks, burdensome debt especially on the municipal level, high inflation, and higher energy prices due to the phase-out of coal and nuclear energy in favor of renewable sources ("Energy Transition") are factors that could dampen near-term competitiveness.

Market Challenges

German policy poses relatively few formal barriers to U.S. trade or investment, apart from barriers associated with EU law and regulations. Germany has pressed the EU Commission to reduce regulatory burdens and promote innovation to increase EU Member States' competitiveness. Germany's acceptance of the EU's Common Agricultural Policy and German restrictions on biotech agricultural products pose obstacles for key U.S. products. While not overtly discriminatory, government regulation by virtue of its complexity may offer a degree of protection to established local suppliers. Rigorous application of safety and environmental standards can lead to increased bureaucratic efforts and complicate access to the market for U.S. products. American companies interested in exporting to Germany should make sure they know which standards apply to their product and obtain timely testing and certification. Compliance with German standards is especially relevant to U.S. exporters, as EU-wide standards are often based on existing German standards.

Market Opportunities

For U.S. companies, the German market – the largest in the EU – continues to be attractive in numerous sectors and remains an important element of any comprehensive export strategy to Europe. While U.S. investors must reckon with a relatively higher cost of doing business in Germany, they can count on high levels of productivity, a highly skilled labor force, quality engineering, good infrastructure, and a location in the center of Europe.

Market Entry Strategy

The most successful market entrants are those that offer innovative products featuring high quality and modern styling. Germans are responsive to innovative high-tech U.S. products, such as computers, computer software, electronic components, health care and medical devices, synthetic materials, and automotive technology. While Germany possesses an above-average Internet penetration rate within the EU for private households, high-speed internet access for business is only slightly above average. Multi-media, high-tech and service areas offer great potential. Certain agricultural products also represent good export prospects for U.S. producers. In many cases, price is not the overriding factor for German buyers, but instead quality and reliability.

The German market is decentralized and diverse, with interests and tastes differing from one German region to another. Successful market strategies consider regional differences as part of a strong national market presence. Experienced representation is a major asset to any market strategy, given that the primary competitors for most American products are domestic firms with established presences. U.S. firms can overcome such stiff competition by offering high-quality products and services at competitive prices, and locally based after-sales support. For investors, Germany's relatively high marginal tax rates and complicated tax laws may constitute an obstacle, although deductions, allowances and write-offs help to move effective tax rates to internationally competitive levels.

Leading Sectors for U.S. Exports and Investment

Agricultural Sector

Overview

Germany is the second largest importer and third largest exporter of consumer oriented agricultural products worldwide, and by far the most important European market for foreign producers. The retail market's key characteristics are consolidation, market saturation, strong competition and low prices. Germany is an attractive and cost-efficient location in the center of the EU. While many consumers are very price sensitive, the market also provides many wealthy consumers who follow value-for-money concepts. These consumers are looking for premium quality products and are willing to pay higher prices. Germany still has some of the lowest food prices in Europe, and German citizens spend only about 14 percent of their income on food and beverages. Low food prices are a result of high competition between discounters and the grocery retail sale segment.

Key Market Drivers And Consumption Trends

- Fair trade and organic products have become more important on the German grocery market. Germany is the second largest organic market in the world (behind the United States) and presents good prospects for exporters of organic products (for more information, please see the GAIN report: Opportunities for Organic Exports to Germany).
- Aging population and increased health consciousness of consumers are fueling the demand for health and wellness products, as well as functional food products.
- Increasingly high-paced society and the rising number of single households are driving the demand for convenient ready-to-eat meals, desserts, and baking mixes.
- Ethnic foods, beauty and super foods, clean label foods, "free from" products (e.g. gluten or lactose free) and locally grown products are further trends that attract more and more German consumers.
- An increasing share of consumers views their purchasing decision as a political or life-style statement (no GMO, only free-range eggs, vegetarian, or vegan diet).
- Consumers increasingly require traceability and information about production methods.
- Germany remains a price-focused market, but the share of consumers who is willing to pay for quality is increasing in most cities.
- COVID-19 related lockdown measures impacted consumers' eating and purchasing patterns. A recently published evaluation report on the effects of COVID-19 on the German food and drink sector indicates four patterns influencing consumers' purchasing decisions: DIY-Food (do-it-yourself), freshness & convenience, storability, pleasure & brand value.

Leading Sub-Sectors

Tree Nuts

The category of tree nuts includes almonds, pistachios, pecans, hazelnuts, and walnuts. Germany does not produce significant quantities of these products, and supply therefore comes primarily from imports. The United States is the largest supplier of tree nuts to Germany. The leading competitor for the United States in the German tree nut market is Turkey. Many U.S. agricultural associations actively promote their products in

Germany, including the Almond Board of California, California Pistachio Commission and the California Walnut Commission. Most tree nuts are used as ingredients by the food processing sector. Almonds are the most important commodity within this category. Further products with good sales potential include walnuts, pistachios, and pecans.

in million USD	2018	2019	2020	2021 (Estimate)
Total Local Production	0	0	0	0
Total Exports	1,287	1,270	1,426	1,350
Total Imports	3,246	3,224	3,583	3,400
Imports from the US	730	751	829	780
Total Market Size	1,959	1,954	2,157	2,050

Source: Trade Data Monitor query dated July 6, 2021

Fishery Products

Fish and fishery products enjoy growing popularity in Germany. The German market offers lucrative opportunities for fish and seafood products. Fish consumption is growing as consumers associate fishery products with a healthy diet. The best prospects for U.S. seafood exports are Alaska pollock, salmon, caviar substitutes, hake, cod, dogfish, shrimps, crabs, cuttlefish and squid, sea urchin, catfish, lobster, and scallops. By value, the two most important U.S. fishery export products to Germany are Alaska pollock and salmon.

in million USD	2018	2019	2020	2021 (Estimate)
Total Local Production	2,534	2,364	2,438	2,500
Total Exports	2,865	2,631	2,548	2,500
Total Imports	6,080	5,903	5,922	5,800

Imports from the US	196	233	224	220
Total Market Size	5,401	5,636	5,812	5,800

Source: Trade Data Monitor query dated July 21, 2021

Wine

Germany is the world's largest importer of wine by volume and third largest by value. In 2020, German wine imports were valued at more than USD 2.9 billion. Italy, France, and Spain are the leading suppliers of wine to Germany with a combined import market share of 79 percent. U.S. wines, together with other “new-world” wines, have developed an increasingly good reputation for quality in the German market. In 2020, the value of Germany's imports of U.S. wines totaled USD 57 million.

in million liters	2018	2019	2020	2021 (Estimated)
Total Local Production	1039	845	851	900
Total Exports	375	384	359	350
Total Imports	1,475	1,489	1,437	1,430
Imports from the US	25	30	38	40
Total Market Size	2,139	1,950	1,929	1,980

German production data is only available on a volume basis; therefore, this table is in liters

Sources: German Office of Statistics (German production)

Trade Data Monitor query dated July 6, 2021

Pet Food

Germany is one of the leading countries for pet ownership in the world. Germans are willing to pay a premium to properly feed their pets, and interest in specialty health pet food products is growing rapidly. Most pet food is produced domestically, and the EU requires pet food to be derived from meat that can be used for human consumption. Despite the bureaucratic obstacles, opportunities for exporting pet food products to Germany are available given the considerable size of the market.

in million USD	2018	2019	2020	2021 (Estimated)
Total Local Production	3,490	3,563	3,950	4,200
Total Exports	1,764	1,819	2,188	2,300
Total Imports	1,446	1,487	1,632	1,700
Imports from the U.S.	4	4	5	4
Total Market Size	3,172	3,231	3,394	3,600

Source: Trade Data Monitor query dated July 21, 2021

Resources

Agricultural Attaché Reports

Attaché reports provide information on market opportunities, crop conditions, new policy developments and information about Germany's food industry. Some standard reports include: Retail Market Report, Exporter Guide, Food Service Report, and market briefs on wine, seafood and other select products. Attaché reports can be found at the Global Agricultural Information Network. In recent years, many of the German reports have been consolidated and are submitted as EU reports. We recommend that companies interested in the German market also review the EU reports.

U.S. Agricultural Commodity Associations Active in Germany

Several U.S. agricultural commodity and other trade associations conduct market development programs in Germany. In some cases, these associations maintain field offices in Germany, while others may have a trade representative or public relations company representing their interests. Others may cover Germany from elsewhere in Europe or from offices in the United States. The USDA-operated Market Access Program (MAP)

and Foreign Market Development Program (FMD) provide a portion of the funding for these associations' market development programs. For further information about the MAP and FMD programs or to know more about which associations are active in Germany, please contact the Office of Agricultural Affairs at the U.S. Embassy in Berlin.

Trade Shows

In Germany, trade fairs play a key role in presenting new products to the trade or in finding additional buyers and importers. The major international trade fairs are:

FRUIT LOGISTICA – The leading show for fruit and vegetables, dried fruits, and nuts. It is held on an annual basis in Berlin. Next show: February 9-11, 2022

Fish International – The leading fish and seafood show in Germany. It is held every two years in Bremen. Next show: February 13-15, 2022

Biofach – The leading European trade show for organic food and non-food products. It is held on an annual basis in Nuremberg. Next show: February 15-18, 2022

Prowein – The leading wine show in Germany. It is held on an annual basis in Dusseldorf. Next show: March 27-29, 2022

Interzoo – The world leading pet industry exhibition. It is held every two years in Nuremberg. Next show: May 24-27, 2022

ANUGA – The world´s leading food fair for the retail trade and the food service and catering market. It is held every two years in Cologne. Next show: October 7-11, 2023

Aerospace/Defense/Security

Overview

Total market size = (total local production + imports) – exports

Aerospace & Defense Market in USD millions

(The security market is not reflected in the table but in the written paragraph below.)

	2018	2019	2020	2021 (Estimated)
Local Production	47,240	45,900	35,408	42,780
Total Exports	35,902	35,343	26,202	32,085
Total Imports	18,621	21,139	17,314	17,112
Total Market Size	29,959	31,696	26,520	27,807
U.S. Imports = U.S. Market Share	8,903	10,353	8,097	9,716
EUR-USD Exchange Rate	1.1810	1.1195	1.1422	1.20 projected

U.S. aerospace & defense manufacturers produce the highest trade surplus, year after year, of all manufacturing sectors. According to TradeStats Express, a U.S. Department of Commerce-furnished database showing the latest global patterns of U.S. merchandise trade, the 2020 U.S. aerospace exports to Germany amounted to USD 8.10 billion. The trade surplus was USD 6.28 billion, representing a 20 percent decrease from 2019 (USD 7.85 billion). These figures are in stark contrast to the European statistics stating U.S. aerospace imports of USD 2.95 billion. This is due to a different approach in calculating the sale of sub-systems and components. Aerospace & defense is complemented by homeland security & public safety, an industry spanning across 15 vertical markets with a projected global turnover of more than USD 500 billion in 2021. Both industries are grappling with the impact of the coronavirus pandemic but, according to BNP Media's SDM Magazine, the "security segment fared much better than originally expected". This is true for the German market as well where some of the companies had their best year yet.

In the aviation segment, the situation was quite different. Perhaps no other industry has been harder hit overall than aviation, particularly the airline industry. In May 2021, German air traffic decreased by 85.5 percent

compared to May 2019 and increased by 582.5 percent compared to May 2020. Due to the long order cycles and a significant backlog in aircraft production, aerospace manufacturing suffered a lot less than aviation. Last year's CCG projected that German aerospace manufacturing would shrink by 35 percent in 2020. In April 2021, the German Aerospace Industries Association (BDLI) reported that the revenues only declined by 24.4 percent, from EUR 41 billion or USD 45,9 billion in 2019 to EUR 31 billion or USD 35.4 billion in 2020. A promising "take-off" could be seen in the first half of 2021 and year-on-year growth of around 15 percent is expected. It is noteworthy that some 8,200 aerospace manufacturing jobs were lost until April 2021 because of COVID-19. During the rebound, U.S. manufacturers should be well-positioned to benefit from gradual market growth in Western Europe, especially Germany.

Germany has plenty of trade shows which could be significant for making first inroads into the market. It hosts the world's third-largest trade show for aerospace & defense (ILA Berlin Air Show), the world's largest trade show for aircraft cabin interiors (Aircraft Interiors Expo/AIX), and Europe's largest trade show for general aviation (AERO). The major safety & security shows that are relevant for the German market are held in Essen (Security Essen) and Düsseldorf (A+A), but also in London (DSEI) and Paris (Milipol). All of them are ideal platforms for U.S. companies to meet with potential buyers and partners, either virtually or in person.

Leading Sub-Sectors

Germany has the third-largest aerospace & defense market in Europe, with 2020 revenues at USD 35.4 billion, following the UK and France. Some three quarters, around USD 26.2 billion, of the German production are exported. France received a fourth of the German exports with USD 6.7 billion. To a large degree, these exports are attributable to Airbus intra-company trade as part of their geographically dispersed production model with major sites in Germany and France.

Looking at the security market, according to the Federal Association of the German Security Industry (BDSW), the German homeland security & public safety market amounted to EUR 15 billion or USD 17.2 billion in 2020, compared to EUR 17.2 billion or USD 20.4 billion three years ago. The decline appears quite significant in view of the strong sales development in some submarkets since the outbreak of the coronavirus pandemic at the beginning of 2020. It is safe to assume that the industry saw modest but steady growth until then, mostly due to ongoing upgrades of the German internal security and migration enforcement infrastructure and an increased need for security services. Last year, the security services market made up more than half of the overall market and grew by 4.5 percent to EUR 9.2 billion or USD 10.5 billion from EUR 8.8 billion or USD 9.9 billion in 2019.

Aerospace occupies a prominent position in the German government's strategic considerations. The Federal Ministry of Economic Affairs and Energy (BMWi) lists aerospace as a key industry with high growth rates and a strong industrial core in Germany. The revised and updated "2020 Technology Strategy of the German Aerospace Industry" builds on BMWi's earlier "Aerospace Strategy", underlining the particular importance of the aerospace sector for Germany as an industrial country both technologically and economically. Besides aiming at increased competitiveness, the aerospace sector promises to make significant contributions to overarching societal goals, mainly with regards to the aspirational target of achieving climate neutrality by 2050, developing sustainable aviation fuels (SAFs), reducing the noise pollution, and improving the environmental record of aircraft. Moreover, the BMWi has initiated the 6th iteration of the Aerospace Research Program (LuFo), a grant program for aerospace research and technology projects, in 2018. In May 2020, the German government approved a EUR 9 billion (USD 10.26 billion) aid package for German flag carrier Lufthansa, turning them into the single largest shareholder in Europe's second-largest airline. Similar measures were taken in France (Air France, KLM), Ireland, Spain, and the UK (IAG: Aer Lingus, British Airways, Iberia,

Level, Vueling). These measures mainly helped to stabilize the European air transport industry. European aviation has been hit especially hard and the crisis is still ongoing. With varying restrictions from country to country and travel bans that cover entire regions, lethargic recovery of international air travel has not been successful to date. As mentioned above, aerospace manufacturing was less affected than aviation and able to adapt to the current challenges well, but ultimately it relies on the return of the global air transport industry to pre-corona levels. Lufthansa expects that it could take until 2024.

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. The main vertical markets for homeland security & public safety in Germany are airport security, smart borders, telecommunications and critical infrastructure, and police modernization.

Policy Objectives and Challenges

U.S. suppliers should be aware of the effects of the U.S. Export Control Reform (ECR) regarding changes to the EAR and ITAR for U.S. aerospace & defense companies. The Commercial Service will continue to support U.S. companies by conducting frequent and active outreach to the Federal Office of Bundeswehr Equipment, Information Technology and In-Service Support (BAAINBw) in Koblenz, Rhineland-Palatinate, and following the latest aerospace, defense and security-related policy developments and discussions in Germany. On an international level, insights will be gained from organizations such as the Aerospace and Defense Industries Association of Europe (ASD), the U.S. Aerospace Industries Association (AIA) and Homeland Security Research (HSR) in Washington, D.C. to understand their positions on transatlantic trade issues, and communicate U.S. objectives.

In several recent tenders, the German military and some state police forces have imposed non-ITAR/EAR/PESCO clauses on prospective bidders, asking them to attest that their products do not fall under the respective regimes. This excludes many U.S.-designed and U.S.-made defense-sector goods.

Opportunities

Opportunities include a 4.5 gen fighter jet program for the German Air Force (a preliminary decision has been made in April 2020 but the parliamentary approval is outstanding); future maritime mine countermeasures for the German Navy; the TEN-DLBO tactical radio program for the German MOD; gas turbines for 4 multi-role combat ships (MKS 180) for the German Navy; Scalable Space Inertial Reference Units (SSIRU-L) for SARah, Germany's radar reconnaissance satellite constellation; large twin-engine transport helicopters for the German Federal Police.

Web Resources

Trade Events

- inter airport Europe, Munich, November 9-12, 2021
- Aviation Forum, Hamburg, December 7-8, 2021
- AERO, Friedrichshafen, April 27-30, 2022

- ILA Berlin, Berlin, June 22-25, 2022
- Aircraft Interiors Expo, Hamburg, June 14-16, 2022
- DSEI, London, September 12-15, 2023
- Security Essen, Essen, September 20-23, 2022
- A+A, Düsseldorf, October 24-27, 2023

Other Web Resources

- German Aerospace Industries Association (BDLI)
- German Airport Technology & Equipment (GATE Alliance)
- HANSE-AEROSPACE e.V. (Largest independent association of aerospace suppliers and service providers in Germany)
- ALROUND (Association of aerospace-oriented SMEs in Germany)

Advanced Manufacturing

Overview

Advanced Manufacturing (AM) is the convergence of information and communications technologies with manufacturing processes to drive real-time control of energy, productivity, costs and information across factories and companies. In 2011, it was identified as one of the highest-priority manufacturing technology areas by the Federal German government.

The OPC Foundation (Open Platform Communications) is cooperating with the German Mechanical Engineering Industry Association (VDMA). In June 2016, these two parties signed a MOU to build an international standards regime utilizing the OPC UA Machine Vision Companion Specification. This machine protocol has been developed to help all automation companies to implement Industry 4.0/IoT with robotics, automation, and machine vision software language with their products. For the interfaces UMATI (universal machine technology interface) has been set up. Both OPC UA and UMATI enable higher-level data processing in a standardized and more secure manner.

Policy Objectives and Challenges

A major challenge for industry and government is the definition of reference architecture and frameworks necessary for interoperability. They are also challenged with how to build confidence around new and innovative approaches to security. In April 2016, the two major international players, the International Internet Consortium (IIC) and the German-led Industry 4.0, agreed to collaborate for the benefit of interoperability of systems from these different domains. Major German trade associations such as the ZVEI (The German Association for Electrical & Electronic Industry), VDMA (German Engineering Association), Bitkom (Federal Association for Information Technology, Telecommunications and New Media) are driving these discussions.

Leading Sub-Sectors

Over the next several years, Advanced Manufacturing is expected to provide excellent export potential for industries such as machine tools/general industrial equipment, robotics, information and communication technology, process control instrumentation as well as electronics industry production equipment, additive manufacturing, and advanced materials. By 2025, 84 percent of German manufacturers plan to be investing EUR 10 billion annually into smart manufacturing technologies, incl. the automotive industry at approx. 1.2 billion per year, machinery & equipment and plant engineering and construction at 1.5 billion, electronics and microelectronics industry at approx. 817 million per year, and the metal working industry at 424 million per year. Today, 75 percent of the German companies in most industries have implemented digital solutions, and 15 million employees are directly and indirectly involved in advanced manufacturing industries in Germany.

Robotics and Automation

Germany is the fifth largest robot market in the world with about 20,000 industrial robots currently utilized in various industries. After having reached a peak in 2018, the number of installed robots dropped by 23 percent to 20,473 units. The main industries using them are automotive, electrical and electronics, metal working, chemical rubber and plastics, logistics, medical, and the food industry.

The automotive industry remains the most important customer of industrial robots (28 percent of all industrial robot installations take place here) even though it was down by 16 percent to 105,379 units in 2019.

Please note that this data includes the industrial/commercial use of robotics only. The Robotics + Automation Association in Germany represents three industry segments: Robotics, machine vision and integrated assembly solutions with combined annual turnover of almost EUR 12 billion in 2020 (USD 13.2 billion). Service robots (medical robots, logistics robots and field robots) for professional use had a combined turnover of USD 8.5 billion in 2019. By 2023, the combined turnover for this sector is estimated to reach USD 22.1 billion.

With 2.7 million industrial robots operating in factories worldwide, the sector increased by 12 percent in 2020 compared to 2019. Conversely, sales of new robots decreased by 12 percent in 2019. However, experts predict an average increase of 12 percent annually between 2020 and 2022, when the economic situation has recovered more from the effects of the pandemic. Indeed, the pandemic has strongly impacted the sector, but also offered a chance for modernization and digitalization and it will probably take until 2022 or 2023 to reach the pre-crisis level.

In terms of robot density (robots' utilization per 10,000 workers), Germany ranks 4th in the world with 346 in 2019, behind Singapore (918), South Korea (868) and Japan (364). The USA ranks 9th with 228, China is 15th (187).

Future trends in this sector are the utilization of artificial intelligence, human-robot collaboration, digital transformation in production, and service robotics in the commercial and health industry, collaborative robots, and mobile platforms, e.g. AGV's, robot leasing like Robot as a Service - RaaS.

Overall, the global economic crisis attached to the COVID-19 pandemic has impacted industrial robot sales in 2020. In the medium term, this crisis will be a digitalization booster that will create growth opportunities for the robotics industry worldwide. The long-term perspectives remain excellent.

Additive Manufacturing and Advanced Materials

The actual size of the additive manufacturing (AM) market in Germany is difficult to measure due to varying definitions and a lack of statistics. What can be ascertained is that the German AM market is growing. Germany is Europe's largest AM market with an average growth rate of 10-15 percent over the next few years. With its high-tech market structure, Germany offers a ready playing field for innovative AM. Most of the local AM companies are small- to medium-sized, with many being active globally. A recent study by the European Patent Office reveals that nearly 50 percent of all AM patents registered in Europe are from German firms, such as Siemens; BASF; MTU; Evonik and EOS. German firms increasingly use AM to produce components that are more sustainable, at a lower cost than traditional production means or more lightweight. One notable example is Airbus' AM printed lightweight injector head for the Ariane 5 rocket, saving 2 tons in weight. Besides medical products, custom-tailored or individualized products have gained importance in other industries. Porsche, for example, is offering individualized seats for their clients. Main drivers in the German AM market are: Medical, transportation, aerospace, and automotive. Over the past year, AM has expanded into new applications, including the printing of sand molds and cores for metal casting, consumer goods, and jewelry. Furthermore, the development of standards for AM is of high importance in Germany.

The United States is considered a global AM market leader in Germany. Therefore, the German market is highly receptive to U.S. AM technology and materials. In addition to selling directly to an OEM or using a distributor, it can be an advantage to partner with a local AM provider which is offering a supplemental line of business. U.S. companies seeking to enter the German market can find German and other international business contacts at Europe's prime trade show for AM: Formnext. Being a major event for U.S. AM businesses, the show was selected for the U.S. Department of Commerce's Trade Event Partnership Program. The last in-person Formnext

in 2019 attracted 852 exhibitors (including 58 U.S. companies) and 34,532 visitors. The next in-person Formnext takes place in Frankfurt, November 16-19, 2021. The show will host a U.S. Pavilion. The U.S. Commercial Service will provide U.S. companies with on-the-show-floor assistance and business counseling. In conjunction with the show, an AM standards forum will take place.

German Machine Tool and Precision Tool Market

The ongoing boom in almost all user industries worldwide has already driven production output to more than EUR 12.2 billion in 2020 (USD 13.42 billion). The COVID-19 pandemic has significantly impacted the German machine tool industry, recording a 28 percent drop in production. Imports from the USA have been about EUR 98 million (USD 107.8 million) for machines and equipment. The capacity utilization was at about 70.9 percent in 2020 according to the German machine tool association. The German domestic consumption is about EUR 6.2 billion (USD 6.8 billion).

Germany's best prospect import segments within the Machine Tool industry are: Laser-, ultrasonic-machines; machine centers; lathes; drilling machines; grinding, honing and lapping machines; gear cutting machines; sawing, cutting-off machines; bending, folding, and straightening machines (incl. presses). The figures for the German precision tools industry show a decrease of 22.6 percent in 2020 to EUR 8.2 billion (USD 9.43 billion), and an expected production for 2021 of EUR 9.4 billion (USD 10,81 billion) which will be an increase of 14.6 percent.

Current trends include high-performance processes, Industry 4.0, micro processing, direct drives, energy and resource efficiency, composite technology, additive manufacturing, laser beam sources, complete machining and shortening of process chains, besides others. The worldwide production of machine tools in 2020 fell by 20 percent, in euro terms, to a volume of EUR 58.0 billion (USD 63.8 billion). The COVID crisis left a serious impact on virtually all markets. However, machine tool orders may experience a strong turnaround in 2021.

Sensors and Measuring Technology

Sensors and measurement technology are another growth subsector. In 2020, the annual turnover of all market players was estimated at EUR 35 billion. 2,500 companies and institutes employed about 250,000 people. In 2017 and 2018, we have seen growth rates of 9 percent and 10 percent, whereas the market in 2019 stagnated at -1 percent. The export quota is 70 percent. Major markets are the following industries: Automotive, electronics, consumer electronics, security, machinery & equipment, besides others. Major competitors include SICK AG, Siemens Sensor Systems, Bosch Sensortec and Beckhoff Automation. German industry expects further growth opportunities after COVID-19, particularly through the industrial automation/internet of things.

Opportunities

Germany's advanced manufacturing companies usually require in-country partners. These partners could be agents and distributors selling to OEMs as final consumers or OEMs as distributors for an exclusively built component. An in-country facility and a membership in one of the German associations is recommended, and system integrators are often the ideal partner for automation and internet of things products and services.

Challenges & Barriers

Germany maintains a highly open and transparent business environment, and there are few formal market access barriers. Probably the greatest challenge to entering the German market is conforming with German

electro-technical standards and conformity assessment procedures, which differ markedly from those in the United States. For most electrical components such as plugs and cables, U.S. and European standards are nonaligned. In practice, this means that for most U.S. machinery makers, the additional labor required to assemble machinery for the German market will affect pricing by inflating the price paid by the customer while decreasing the cost competitiveness compared with domestic and other European-made machines. As part of the European Commission's Machinery Directive, machinery sold throughout the EU is required to obtain a CE marking whenever the product is covered by specific product legislation. CE stands for "Conformité Européenne", and is intended to demonstrate compliance with European safety and environmental standards.

Healthcare and Medical Technology

Overview

Germany has a very robust and well-established medical equipment market. Brands such as Siemens, Carl Zeiss and Drägerwerk were founded at the end of the 19th century and vouch for the long history of producing high quality medical equipment, with an emphasis on diagnostic imaging, precision medical and dental instruments, and optical technologies. Germany claims the third-largest medical technology market in the world after the United States and Japan, and it is by far the largest European market, twice the size of the French market and three times as large as those of Italy, the United Kingdom and Spain. The German medical device market is one of the most lucrative healthcare markets worldwide accounting for roughly USD 35.8 billion annually, or 25.6 percent of the European market total.

The Healthcare/Life Sciences (HCT) industry is a priority for both the EU and Germany as reflected in the European Regional Development Fund (ERDF – or EFRE, in German) program and cohesion policy 2021-2027, as well as the German Länder implementation and tendering of this program. "Horizon Europe", a European Incentive Program for Research and Innovation agreed upon by the EU Council and Parliament and retroactively entered into force on January 1, 2021 after final adoption in April 2021, also focuses on health and health-sector-related R&D and innovation. Projects target conquering cancer, smart health, aging, and digital models of care. All of this aims to increase opportunities for U.S. suppliers to participate in healthcare infrastructure, hospital development projects and to partner with German and EU firms. However, the German healthcare system, because of its decentralized and self-governing structure, is complex and slow in adapting new trends. German health minister Jens Spahn is determined to move the German health system into the digital age and has amended the regulatory environment with several laws to mandate progress. This will offer excellent export and partnering opportunities for innovative U.S. health solution providers throughout the health technologies supply chain.

Medical Technologies (MED) is the key sector of the HCT industry. The U.S. is home to the world's leading medical device manufacturers. One in eight Americans is employed by the U.S. healthcare industry; there are 20 million medical-related jobs with about USD 1.0 trillion in annual payroll, according to the U.S. Census Bureau. Roughly 90 percent of the over 7,000 medical device manufacturers are export-ready SMEs, and many of the world's largest medical device manufacturers are U.S.-based. All major U.S. suppliers, such as GE Healthcare, Johnson & Johnson, Becton Dickinson, Abbott, Abbvie, Thermo Fisher Scientific, Stryker, Zimmer, 3M, McKesson, Cardinal Health, Henry Schein, to name a few, have subsidiaries in Germany. Within the EU, Germany is the largest importer as well as exporter of medical devices (source: Medtech Europe, Facts & Figures 2021). U.S. medical device exporters continue to hold a 30 percent share of the German import market. Key industry drivers include the power of innovation, a solid financial basis of the industry (80 percent of which are SMEs) and a vibrant startup scene, all based on a strong German economy and the commitment to a high-quality health system.

Germany has a strong healthcare system, especially with regards to infrastructure, hospital beds and trained staff. In 2019, there were 494,300 beds in 1,914 hospitals (545 public hospitals, 645 non-profit and 724 private hospitals), 1,112 rehabilitation centers, and in 2020, the number of pharmacies was 18,753. Well-established infrastructure makes the healthcare industry the largest employer in Germany with currently 5.7 million employees (source: Health Ministry). Under a broader definition of the German Federal Ministry for Economic Affairs, 7.5 million employees in the health sector account for 16.7 percent of the total labor market. In 2020, the number of doctors was 372,000 and thus constituted a physicians' density of 4.5 per 1,000 individuals, making Germany the country with the fourth largest density within the OECD. One out of six jobs in Germany

is linked to the healthcare sector, which generates an economic footprint of EUR 678.2 billion (USD 798 billion), or roughly 12 percent of Germany's GDP. With EUR 131.2 billion (USD 154.4 billion) generated through foreign sales, HCT contributes 8.3 percent to Germany's total exports (source: BMWi). The German medical device market grew by 4 percent in 2019 and by 3 percent in 2020 despite COVID-related pressure on the industry. According to estimates by Fitch Solutions, the expected CAGR of the German medical equipment market for 2020-2025 is 5.1 percent in euro-terms and 6.8 percent in USD-terms. This projection is based on the expected improvement of the pandemic in Germany, with increasing vaccination and fewer cases reported. All these developments have enabled a strong economic recovery. Further growth factors include the digitalization of the health economy and tackling the double-digit investment backlog in the hospital market with the funds allocated by the Hospital Future Act. This law was enacted in October 2020 providing EUR 3 billion (USD 3.5 billion) of federal funding and additional EUR 1.3 billion (USD 1.5 billion) of state funding to modernize and digitalize the German hospital system.

Developments during the COVID-19 pandemic

The coronavirus outbreak continues to affect the German medtech industry in multiple ways. The industry has witnessed substantive changes in 2021, particularly with regards to the industry's regulatory framework. Below are some key developments:

- After initial postponement, the Medical Device Regulation (MDR) has been fully in force since May 26, 2021. Based on the MDR, the new German law for medical devices MPDG (in German, "Medizinprodukterecht-Durchführungsgesetz") and the Medical Device-EU Adaptation Law provide a European framework for the German market; the MPDG replaced the established MPG (in German, "Medizinproduktegesetz") law on May 26, 2021. The In-Vitro Medical Devices Regulation application date, May 26, 2022, remains unaffected.

- On April 3, 2020, the EU Commission announced temporary suspension of custom duties and VAT for medical equipment to aid EU Member States in receiving necessary protective equipment and medical devices, including masks, protective gear, testing kits, ventilators. On April 19, 2021, the European Commission agreed to extend this suspension until December 31, 2021, with a possibility of further provisions depending on the development of the pandemic in the EU.

- The EU Commission has published guidance to outline temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions to ensure the availability of safe medical devices and to prevent shortages.

- Medical and non-medtech related enterprises have redirected production to meet the surging demand for personal protective equipment and vaccines. These efforts led the Health Ministry to announce the removal of the vaccine priority system on June 7, 2021, making it possible for every person above 12 years of age to receive protection.

- Automotive and general industrial manufacturers; general textile manufacturers; and online platform providers such as Amazon, Apple and Alibaba, entering the health technology markets with COVID-19 products and solutions and set to stay in the healthcare arena, disrupted the previously rather consolidated market with new business models.

- Despite the improvement of pandemic-related parameters, trade show responses have been mixed with some major trade shows such as MEDICA and the IDS-International Dental Show planning to hold hybrid

events with in-person attendance in 2021, while others canceled or postponed their trade shows. Some organizers decided to offer virtual conferences such as the T4M ("Technology for Medical Devices") in Stuttgart.

The rising demand for medical equipment has boosted this sector's economic growth and has incentivized the German government to further increase its investment in innovative medical technology. For example, the Federal Ministry of Education and Research announced on April 7, 2021, that it will increase its medical technology funding by further EUR 20 million (USD 23.7 million) to adequately address the needs of COVID-19 patients and to modernize the healthcare system. This additional funding should support medical technology manufacturers, hospitals, research facilities and SMEs. Besides increased funding, the market experienced other changes. German medical association SPECTARIS in cooperation with Roland Berger conducted a survey to identify recent and future market trends. Those include greater digital distribution and services, new business models for a digital environment, pressure on prices due to reduced revenues by health insurance companies and that in-vitro diagnostics, robotics/automation and smart wearables will benefit the most in this market.

The pandemic has illustrated how complex the supply chains and production networks are in this industry; uncertainty continues to disrupt normal operations as countries have become more protectionist. These political interventions have led to more difficult investment environments, export reductions and capacity constraints. Some branches of the industry recorded revenue reductions of up to 40 percent. According to a survey conducted by German medical industry association, BVMed, firms deem an increasing regulatory framework, such as the introduction of the Medical Device Regulation (MDR), as a main growth barrier. The MDR even led some highly specialized firms to discontinue operations as the additional cost of compliance exceeds possible revenues, creating a shortage of certain equipment for hospitals.

The pharmaceutical industry has seen a shift of resources towards the development of coronavirus drugs and treatments at the expense of new drug introductions in traditional segments. Disrupted supply chains resulted in a medicine shortage in Germany in 2020, when suddenly up to 68 percent of necessary drugs were unavailable. The German Federal Institute for Drugs and Pharmaceuticals (BfArM) created a list of 22 key substances, such as insulin and antibiotics, whose production should be reintroduced in the EU. Specific supply of critical drugs, and the establishment of local production facilities, prove to be possible avenues of investment in the EU and particularly Germany. Those critical products already constituted sales of approximately USD 7.1 billion in 2020. Securing local production requires constant innovation, as exemplified by Pfizer's green factory in Freiburg, whose energy consumption is covered by 90 percent green energy. The EU acknowledges this innovation potential and paves the way for funding modern, digitalized production facilities. At the same time, cooperation has become a central element during the pandemic as 15 pharmaceutical and biotechnological companies have agreed to share their research data in a common database, highlighting that continued challenges provide further transatlantic commercial and research opportunities.

The pandemic has also boosted the collaboration between startups and large corporates. A prime example of exponentially successful cooperation is the BioNTech-Pfizer venture. The boost is seen in large increases in funding, on the stock market and capital market. Positive market developments require a growth-promoting regulatory framework, which allows for easier capital inflow, access to capital and tax incentives. Here, Germany has room for improvement and is also still highly conservative. Fear of selling out German industry experience and knowledge, as well as the goal to secure the medical ingredient supply chain has resulted in greater regulatory hurdles. Still, optimism remains high as investors recognize this sector's strong growth potential. The listing of CureVac and Immatics on the stock market in 2020 and BioNTech's continued success on the stock market is proof of interest surge in promising biotech companies among investors.

COVID-19 also requires a new approach towards patients. Already before the pandemic, a growing interest among consumers in a healthy lifestyle and its optimization could be witnessed. The pandemic amplified the willingness to use health apps for health-related information and monitoring. Connected with this is a growing demand to receive tailored medical treatment based on collected data. Either specialized or holistic medical applications are readily sought after. Lockdowns have quickly established remote consultation as a main method of medical communication. In 2019, only 583 doctor's appointments were conducted via video call or phone, while between March-June 2020, this number rose to 1.2 million, showing that the expansion of the digital infrastructure is indispensable.

Market Entry and Best Practices

The German market for medical devices is regulated by German and EU directives, standards, and safety regulations. After a one-year delay of the start date of the EU Medical Device Regulation (MDR), which introduced increased testing, certification and compliance requirements, this regulatory framework has come into full effect on May 26, 2021. The complementary In Vitro Diagnostic Regulation will be enacted from May 2022. U.S. exporters are well-advised to become informed about MDR and obtain public or private sector counseling and assistance of the possible impact of their market entry plans into Germany. Companies seeking market entry should also carefully map their distribution strategy depending on their target group(s). CE marking is mandatory for selling into Europe. Entry strategies to be considered are top-down or bottom-up marketing, picking the right partners and ensuring patient- and customer-centric system solutions and support. Most medical equipment imported into Germany is either sold directly through a local subsidiary with a field sales force, through medical distributors with an established distribution network (often on a regional/territorial basis) or through appointed agents or manufacturer representatives. Local representation or market presence is essential when considering differing standards and certifications, warehousing costs, maintenance, accessibility, and local marketing/sales preferences/discussions. An agency agreement is often a cost-effective mechanism to enter the market, but under German law – even if the agent's performance is not satisfactory – it can be difficult and costly to terminate an exclusive arrangement. A representation or distributorship agreement may be more difficult to arrange, but the German associate will, in fact, purchase the product to be sold, thus sharing the market risk. Licensing, partnering with large corporate partners or buying a local firm provide alternatives in times where traditional distributors are bought up by corporates and the market increasingly consolidates. Further information is available in Commerce's Global Markets Healthcare Team's annual Healthcare Technologies Resource Guide.

Germany hosts the world's largest annual HCT trade show, MEDICA, making it a premier marketplace for U.S. companies to reach their global partners and buyers. The U.S. HCT industry, represented by 500+ U.S. exhibitors, converges every year for the 4-day long MEDICA trade show to sell to Europe and the rest of the world. We are pleased to inform you that, due to the improvement of the pandemic in Germany, its organizer has scheduled an in-person event for the 2021 MEDICA, which will be complemented with additional digital material and conference streaming.

The German Medical Equipment Market 2019-2022 (USD billion)

	2019	2020	2021 (proj.)	2022 (proj.)
Market Size	35.0	36.7	39.2	41.9
Local Production	37.6	40.5	43.3	46.2
Imports	20.2	22.7	24.2	25.9
Exports	22.8	26.5	28.3	30.2
Imports from the U.S.	4.9	6.8	7.3	7.8

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

Data Sources: Spectaris Trade Association; BVMED Trade Association; Medtech Europe; Statista (German Federal Statistics Office); Fitch Solutions

General statistics on Germany is available by the German Federal Statistics Office.

Leading Sub-Sectors

Leading HCT sectors include Health IT, pharmaceuticals, dental products, and biotechnology.

Health IT: The German Health Ministry and its agency, Health Innovation Hub, are ambitiously implementing the Digital Care Act and digital health solutions, called "DiGA". DiGA Fast Track is Germany's path for digital health solutions to get access to the German statutory health system, reaching over 75 million German citizens insured under the mandatory health insurance. The German Health Ministry's subordinate agency, the Federal Institute for Drugs and Pharmaceuticals, BfArM (German equivalent to the FDA) is taking online applications for DiGAs, and once approved as a medical app, DiGAs can be prescribed by any German physician. DiGA providers will be reimbursed by German insurance funds. Likewise, the telematics infrastructure, including 5G rollout, is being developed at a dramatic pace, and the electronic medical record (in German, ePA) is taking shape. From January 1, 2021 German health insurers are mandated to provide their insured with the ePA; and from July 1, 2021 all statutory health insurance accredited physicians and psychotherapists must be able to read and fill in the ePA. This law also facilitates easier access to patient data for research purposes as healthcare providers transmit their patient records to a centralized government-owned server.

The Hospital Future Act and its funding allow German hospitals to speed digitalization and remain competitive globally. So far, there has been an innovation gap in the German hospital sector because of lacking focus for digitalization among the German health policy makers and hospital management for years and there is still an insufficient number of dedicated digital solution providers. Thus, this market is especially penetrable for U.S.

digital solution providers. E-medication is also on its way, with the new paragraph 360 of Germany's SGB V social law, relating to the Patient Data Protection Act (PDSG). It mandates doctors and dentists to issue prescriptions in digital format from January 1, 2022. The law also makes it clear that even with digital prescriptions, the free choice of pharmacy of the insured remains, and neither health insurance funds nor contract physicians have a right to assign or influence. On July 1, 2021, an app for digital prescriptions was launched on all major mobile device app stores by the government-controlled firm, Gematik. Concurrently, pilot projects began in Berlin and Brandenburg, involving 50 doctor's offices and 120 pharmacies testing the new format. Testing will be expanded to all of Germany on October 1, 2021. These steps will be decisive for Germany to catch up to its EU neighbors and will present excellent opportunities for U.S. HealthIT providers. HealthIT applications currently represent more than USD 450 million, with numerous projects throughout Germany and a University Hospital excellency network, which drives innovation in treating key diseases such as stroke, Alzheimer's, cancer, and diabetes. An aging society (with a significant share of chronic disease), the rollout of e-health patient portals by public health plan providers, high internet and mobile phone penetration make Germany a strong HealthIT market and offer valuable potential to specialty solution providers. The digital health ecosystem in Germany will be driven by cloud computing solutions, artificial intelligence (AI), robotics, smart wearables, big data analytics, and the Internet of Medical Things (IoMT). The German Ministry of Health maintains a website on digitalization in healthcare; the German Ministry of Education and Research maintains a website on the medical informatics initiative. As of January 1, 2021, Germany's BfArM-German Federal Institute for Drugs and Medical Devices is a member of SNOMED International, global standards organization for health terms. With full membership, all German institutions and specialist groups in the healthcare sector wishing to use SNOMED CT in their applications can apply for a free license from BfArM. More information can be found on the SNOMED website.

Germany has an excellent base for HealthIT, with over 80 percent of its workforce holding a degree, and a startup-friendly environment. This makes it a very strong market for m-health and e-health products and services. The strong German medical technology clusters develop telehealth and telemedicine solutions and form excellency clusters for oncology, neurological disorders, and chronic disease management in cooperation with hospitals and industry. The German government's medical informatics initiative aims at improving medical R&D and patient care through innovative IT solutions for specific applications and integrated health data centers. This multi-million-dollar funding resource should pose excellent opportunities for U.S. solutions providers. E-procurement and e-commerce, Machine-to-Machine communication (M2M), mHealth/apps and big data applications are areas of digitalization, in addition to telehealth and telemedicine, with windows of opportunity for U.S. suppliers.

It is strongly recommended to open an office in Germany or work with a knowledgeable partner to enter the German HealthIT market, which is dominated by some large players in the various segments, i.e. Compugroup, Deutsche Telekom Healthcare, Siemens Healthineers, i-Solutions, Nexus, Visus, to name a few.

Pharmaceuticals: The German pharmaceutical market was valued at USD 76 billion in 2020 and remains one of the most attractive worldwide over the coming years. It accounted for 15.6 percent of total health expenditures and 2 percent of GDP. Annual per capita spending is above average at USD 907, with prescription medication contributing 87.6 percent (from 69 percent, but this was the number for patented drugs) to the total. According to market analysts, the German pharmaceutical market is expected to grow by an average of 4.2 percent in euro-terms, and 6.1 percent in USD-terms annually until 2025. Major growth drivers are the aging population and chronic diseases. Germany counts over 520 pharmaceutical companies; many global U.S. corporations such as Pfizer, Eli Lilly, Abbott, and others have production facilities in Germany. Germany is regarded as a test market for other EU countries for pricing and distribution and it is a good location for API

(active pharmaceutical ingredients) production. In 2019, the German pharmaceutical industry manufactured products worth USD 37 billion, a decrease of 13.7 percent over the previous year. For the same year, exports of pharmaceuticals decreased by 6 percent, generating sales of USD 86.3 billion, while imports grew by 2.4 percent, amounting to USD 55 billion. For 2020, exports of pharmaceuticals increased by 6.4 percent, generating sales of USD 91.8 billion, while imports grew by 8.7 percent, amounting to USD 59.8 billion.

Biopharmaceuticals: Sales of biopharmaceuticals in 2020 (pharmacies and hospital market) grew by 14 percent to USD 17.6 billion (EUR 14.6 billion) compared to 2019. The market share in the total pharmaceutical market rose from 29 percent to 30.8 percent. Growth was seen in nearly all fields of application. Among current focus areas are ATMPs (Advanced Therapy Medicinal Products), such as gene therapy products, cell therapy products, and tissue engineered products. Compared to classical medicines, where the active substance consists of a chemical molecule or protein, ATMPs are nucleic acids (such as genes) or can be whole cells or tissues. While classical medicines for the treatment of hereditary diseases usually require life-long use, ATMPs could achieve long-lasting therapeutic efficacy, possibly even a cure, after one use. The German term for ATMPs translates to 'novel therapies' and emphasizes the innovation aspect, which is reflected in their development, production, approval and market access, and reimbursement process.

Medical Biotechnology: Germany is Europe's largest biotechnology market. In 2020, 710 dedicated [1] biotechnology companies (+1 percent to 2019) generated sales of USD 7.7 billion, a 36 percent growth over 2019. The number of employees in the biotech industry increased to 37,415, up 10 percent. This significant market growth is largely attributable to the key players listed on the stock exchange: Among Germany's dedicated biotech firms, the 23 listed companies generated roughly 49.3 percent (+43 percent compared to 2019 due to a pandemic-related demand surge) of overall industry sales. Of these major players QIAGEN, Evotec, and BioNTech alone contributed 44 percent to the market sales total. It is especially noteworthy that during this year, Morphosys registered a 357 percent growth, BioNTech a 344 percent growth rate and the COVID-19 diagnostics firm CENTOGENE a 59 percent increase. R&D spending stood at USD 2.9 billion, an increase of 37 percent over 2019. Growth in spending was again attributable to the small number of listed companies, whose expenditure amounted to approximately USD 1.67 billion, or 58 percent of all R&D expenditures (+66 percent), privately held firms recorded a substantial increase in R&D of 11 percent. Growth sectors in Germany's biotech industry continue to focus on new drug development and diagnostics, such as early disease detection, infectious diseases, and rare diseases. The pandemic has especially created a financial incentive to expand the development and sales of vaccines. In-vitro diagnostics (IVDs) are an important growth driver in the market, since two-thirds of all clinical diagnoses are made through IVDs. With more than USD 3.2 billion (+27 percent compared to 2019) in annual sales, Germany represents the largest IVD market in Europe and second worldwide behind the USA. Germany's biotech clusters are Europe's leading research and development hubs, and important partners for industry/academic R&D and technology transfer. Biotech is strong in Bavaria; North Rhine-Westphalia; Baden-Wuerttemberg; and the Berlin-Brandenburg region. Some of the largest and most reputed clusters are in the Rhine-Neckar Triangle (Heidelberg), Cologne/Dusseldorf, Berlin/Brandenburg and Munich. Biotech is a priority for EU and German governments and is central to Germany's innovation and high-tech policies. Biotech action plans focus on diagnostics, therapy and preventive medicine in bio-medical research and care, and research-based bio-medical technologies in specialized clusters. Germany's participation at the BioEurope trade show, and in the world's leading annual biotech event,

[1] is defined as a biotechnology active firm whose predominant activity involves the application of biotechnology techniques to produce goods or services and/or the performance of biotechnology R&D

BIO Convention, in the United States, with an official Germany Pavilion, shows the commitment and close transatlantic ties in this health tech subsector.

Dental products: Germany is Europe's largest market for dental equipment valued at USD 2.48 billion in 2019. For the first time since 2015, total sales of dental products from 207 mostly medium-sized member companies of the Association of German Dental Industry (VDDI) decreased to USD 5.7 billion in 2020 (-13.1 percent compared to 2019) and an export share of 60.6 percent with USD 3.5 billion (-16.5 percent compared to 2019). These firms represent 85-90 percent of the German dental market and employ more than 21,290 people. Even though VDDI's numbers constitute a market contraction, the firms that participated in their annually conducted market survey, remain optimistic. 59 percent of the survey firms expect exports to increase in 2021 compared to 2020, while 32 percent expect similar numbers and only 9 percent have negative expectations. A similar pattern can be seen with their evaluation of the German market. 51 percent expect sales to increase, while 42 percent anticipate similar sales and only 7 percent think their revenue will decrease. The Federal Dentists Chamber, BZAEK, expects the workforce in the dental industry to increase by 18.6 percent in the period 2010-2030, from 410,000 to 486,000 employees. This includes dentists' offices, dental labs, and the trade with dental products. Estimates by Fitch Solutions reveal a forecasted CAGR of 7.6 percent in euro-terms and 9.3 percent in USD-terms for this industry.

Digitization with advanced 3D imaging and printing, the use of CAD/CAM systems and robotics as well as innovation in dental materials and minimally invasive techniques have a major impact on market development. Another key factor contributing to Germany's dental market growth is the increasing dental health awareness among its population and an increasing willingness and ability to pay for preventative and corrective treatments.

U.S. exports to Germany amounted to USD 126 million for dental equipment and supplies, and USD 55.2 million for dental laboratory products in 2020. Over 200 U.S. companies are actively exporting, with heavyweights Henry Schein, Danaher Corporation and Dentsply Sirona holding a direct presence and major market share. The major U.S. dental technology supplier Henry Schein is one of the largest distributors in Germany's dental market, with annual sales of more than USD 126 million and an estimated 5 percent market share in 2020.

Severe impairment of the dental industry by the corona crisis

National and even global lockdowns and curfews have restricted the social mobility of people to reduce the risk of infection. This has resulted in a sharp drop in demand from patients for dental care which was exacerbated by a lack of PPE for dental practice staff. A sharp rise in worldwide demand quickly led to bottlenecks in supplies, and dentists saw their obligation to treat patients endangered. Stockpiling by market players from outside the industry led to temporary bottlenecks for disinfectants and anesthetics, and suppliers of basic materials were unable to deliver the usual amounts. Suppliers of materials and containers were no longer able to deliver, and well-established supply chains collapsed.

The United States is a technology leader and is competing with Germany in large markets such as China and India. Both the U.S. and Germany have branded for top quality products and innovative technologies and have strong trade ties. Traditionally the leading global trade fair for the dental community, the IDS-International Dental Show in Cologne proves to be an arena where both the U.S. and Germany demonstrate strength and forge further ties in R&D and trade, in view of increasing Chinese competition. Staged biennially, the U.S. dental industry is represented by 200+ U.S. exhibitors in two USA Pavilions and independent exhibits; this number has remained solid over the past ten years with 15-20 percent newcomers at every show, except for the 2020-21 pandemic years.

Policy Objectives and Challenges

The Commercial Service is working to evaluate the broad impact of the EU Council's respective health policy goals, as follows:

- Europe to find ways to re-shore the manufacture of essential medicinal products and medical devices (such as face masks) to Europe and build a European stockpile.

- Europe to become more attractive for research. This requires data. Europe to drive the creation of a European health data space and a respective code of conduct for dealing with patient data.

- European public health organizations such as ECDC and EMA to be strengthened to allow them to work on equal terms with their U.S. counterparts.

We collaborate with the local German MED clusters and their members on EU and German trade policies such as the MDR, IVDR, the SPC-Supplementary Protection Certificate for manufacturing pharma, IP and cybersecurity issues, with a focus on SMEs and countering malign third-country influence. We also report major procurement deals and opportunities to U.S. businesses and encourage a positive outlook on transatlantic trade among industry contacts we meet at events and in the context of partner search outreach.

A short overview of the state-of-play of joint assessments of notified bodies in the medical device sector is available now from the European Commission's webpage "Medical Devices - Sector - New Regulations - Implementing measures for Regulations".

We are following the latest healthcare policy developments and discussions in Germany, and work with U.S. associations, such as the Advanced Medical Technology Association and PhRMA-Pharmaceutical Research-based Manufacturers Association based in Washington to ensure fair access, standards interoperability, and IP protection for U.S. firms to and in the German and European markets.

Opportunities

Germany's healthcare market offers more than just agents and distributors; it has various opportunities along the value supply chain route: Design and research and development collaboration; strategic partnerships; equity partner and investor engagements; mergers and acquisitions; project collaboration, and other types of opportunities for SMEs to grow business and expand in the market. For example, the U.S. National Institutes of Health (NIH) plans to promote clinical study capabilities and resources to innovative German and European life science startups and SMEs during BioEurope, a road show, and virtual events in 2022. Combining the resources of NIH and the networks of the German life science clusters, we will see a unique and powerful partnership that will bring the most innovative and brightest solutions to the U.S. market, and help both economies to grow and create jobs. In addition, we will assist major U.S. players in the Healthcare Cybersecurity arena, such as Palo Alto, Tanium and InterSystems, gain further visibility and brand awareness in Germany and German-speaking Europe with seminars around cybersecurity and ransomware attacks in hospitals and other medical facilities. Likewise, the U.S. German Digital Health Forum initiated by the U.S. Commercial Service in partnership with a major German digital health platform continues to expand and opens the door to innovative U.S. digital health solution providers and allows them to forge relationships with university hospitals in Germany.

The German government's health informatics funding initiative and the German states' initiatives on healthcare digitization offer prime opportunities for U.S. firms to engage in Germany. An example would be a procurement for North Rhine-Westphalia's Public Hospitals to re-organize their system and reconstruct and upgrade existing facilities. In a four-year span, U.S. companies will have the opportunity to participate in consortia or as sub-contractors.

The German government's "Medical Informatics" funding scheme as part of the Health Research Framework Program offers an aging society where diseases like cancer, dementia and various cardiovascular, metabolic, and muscular ailments will become more prevalent, to improve the exchange of data across different institutions and locations. The aim is that faster diagnoses and treatments will help to cut costs and help individuals receive faster and more precise care.

For more information on procurements you can get involved in, please contact us via our website to be added to a regular email of tender opportunities, or visit Tenders Electronic Daily by the EU.

Resources

Trade Events

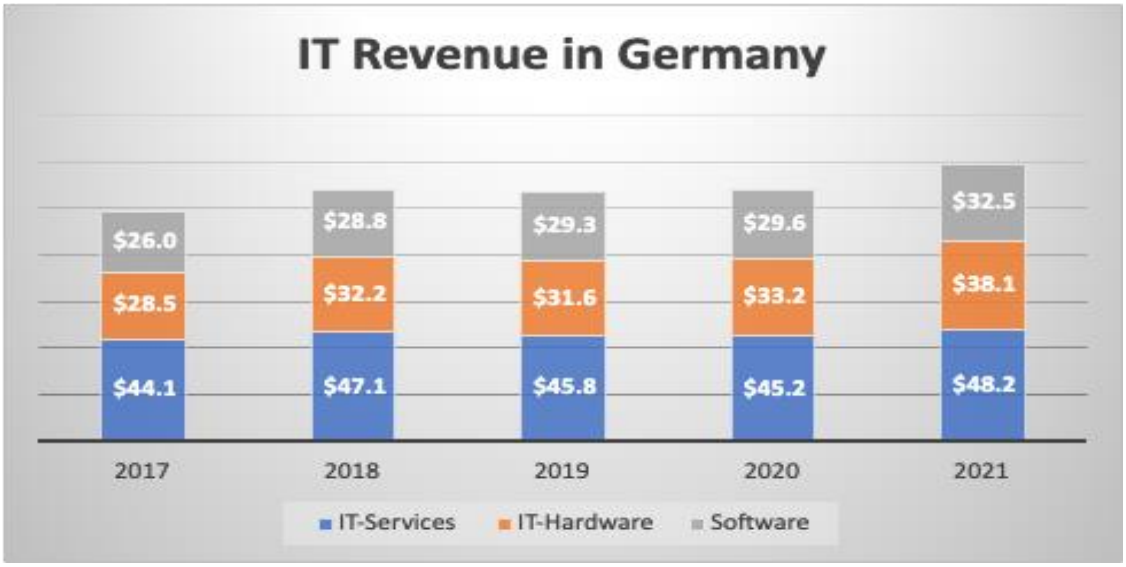
- Medica, Dusseldorf, November 15-18, 2021
- Greater New York Dental Meeting, New York, November 28 – December 1, 2021
- DMEA, Berlin, April 26-28, 2022
- HIMSS 22 – Health 2.0, Helsinki, June 14-16, 2022
- Analytica, Munich, June 21-24, 2022
- American Hospital Association Leadership Summit, San Diego, July 17-19, 2022
- American Association for Clinical Chemistry: AACC Annual Meeting, Chicago, July 24-28, 2022
- Rehacare, Dusseldorf, September 14-17, 2022
- Expopharm, Munich, September 14-17, 2022
- The MEDTECH Conference, Boston, October 5-7, 2022
- Bio-Europe, Leipzig, October 24-26, 2022
- International Dental Show (IDS), Cologne, March 14-18, 2023

Government Links

- Federal Institute for Drugs and Medical Devices (Competent Authority)
- Healthcare Procurement and Tenders

ICT

Overview



*in Billion USD

Figure 1. IT Revenue in Germany. Adapted from "ITK-Marktzahlen," by Bitkom; EITO, 2021

Germany has one of the largest ICT markets in the world and the single largest software market in Europe with 94.301 IT companies (software and hardware, as of 2018) and an estimate of 1.03 million employees in 2021. There is a strong demand for U.S. products and services across all segments. Key players such as Microsoft, Apple, Dell, Adobe, IBM, Oracle, and SAP have large market shares. There are also many highly specialized SMEs in the market. In 2021 revenue in the different IT subsectors consisted of USD 48.2 billion in IT-Services, USD 38.1 billion in IT-Hardware and USD 32.5 billion in the software subsector. Since 2007 total revenue in the IT sector has increased from USD 76.4 billion to an estimated USD 112.6 billion in 2021.

Germany hosts several key ICT trade shows, making it a premier marketplace for U.S. companies to reach global partners and buyers. U.S. exhibitors have frequently found buyers from Europe, Middle East, Africa, Asia and Latin America at the Hannover Messe, IFA Berlin, IT-SA, Gamescom or Embedded World. In 2021, several trade shows have been canceled, postponed, or will take place as a hybrid event because of the ongoing health crisis.

Policy Objectives and Challenges

ICT is a priority sector for the German government. Germany's economic and innovation policy is outlined in the Digital Agenda of the BMWi (Federal Ministry for Economics and Energy). It focuses on digital infrastructure, digital economy, digital workplaces, innovative public administration, digital environments in society, education, research, science, culture and media, security, protection and confidence for society and business.

Policy objectives include cybersecurity, the digitization of the German economy and the expansion of the German broadband network. Challenges include the impact of the EU Digital Single Market, the General Data

Protection Regulation (GDPR), the E-privacy Regulation on ICT companies, and the latest cybersecurity policy developments.

The U.S. Commercial Service follows these developments and continues to work with associations and multipliers such as BMWi, Bitkom (Association for Information Technology), BDI (Federation of German Industries), GTAI (Germany Trade and Investment) and AmCham (American Chamber of Commerce) to unearth opportunities and flag policy concerns.

Leading Sub-Sectors

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

Opportunities

- IT Security is the 2nd largest in Europe with a strong growth
- Health IT has experienced strong growth in recent years; experts expect a consolidation process and fundamental changes in the next couple of years
- Artificial Intelligence market is expected to grow significantly
- Smart Social Business Platforms
- Big Data, such as hardware, infrastructure, services, database and analytics technologies, are all key drivers for a fast digitalization of the German economy
- Enterprise Resource Planning (industry-specific ERP solutions)

Resources

Trade events

Gamescom
Interactive games and entertainment
Cologne, August 24-28, 2022

it-sa
IT security: Cloud, mobile & cyber security, data & network security
Nuremberg, October 25-27, 2022

ISE-Europe
AV and integrated system
Barcelona, February 1-4, 2022

Embedded Word
Embedded systems
Nuremberg, March 15-17, 2022

Hannover Messe
Industrial: “Largest industrial trade show in the world. Of interest for U.S. producers of industrial IT solutions”
Hannover, April 25-29, 2022

AngaCom
Telecommunications, broadband & media
Cologne, May 10-12, 2022

IFA Berlin
Consumer electronics and home appliances
Berlin, September 2-6, 2022

Trade Associations

Bitkom, Federal Association for Information Technology, Telecommunication and New Media

Bitmi, Federal Association for Medium-Sized IT Businesses

Teletrust, IT Security Association Germany

ECO, Association of the Internet Industry

NIFIS, National Initiative for Information- and Internet-Security

German Games Industry Association, Organization that represents the German computer and video games industry

VATM, Association of Telecommunication and Value-Added Service Providers

Government Entities

Federal Office for Information Security, National cyber security authority in Germany

Federal Network Agency, Ensures compliance with the Telecommunications Act (TKG), Postal Act (PostG) and Energy Act (EnWG) and their respective ordinances

Smart Cities

Overview

The term "smart cities" refers to the development and use of ICT in almost all areas of local life in order to link municipal infrastructures such as energy, buildings, governance, transportation, water and sewage on the basis of integrated development concepts. Enabled by the Internet of Things (IoT), sensors, networks, and mobile-based technologies are the basis of any smart city concept.

With the 2020 Smart City Model Projects Program, where 32 selected projects (cities, inter-municipal consortiums, and counties) are funded with around EUR 350 million, the German government is helping municipalities by funding the development of integrated smart city strategies and their implementation. The funding program focuses on cross-sectoral initiatives that can be adapted by other German municipalities.

With its coronavirus stimulus package, Germany is making an additional EUR 500 million available for smart city development. In total, Germany is investing EUR 1,250 billion to advance the development and implementation of urban technologies. More details from GTAI.

Cities in Germany and Europe have grown over centuries and digital technologies are now being added and complementing existing infrastructures can be quite a lengthy process. This is in sharp contrast to Asia, where cities are being built from scratch. Many German cities develop all of their smart city ideas under one roof. Hence, establishing a contact to municipalities is important.

With 77 percent of Germans living in cities and towns, the relevance of strategic urban development through digital solutions is widely recognized. The technology disrupting urban living today has the potential to improve quality of life. Innovative solutions and good decision-making are key to success.

Best Prospects for U.S. exports

Building and construction: Energy-efficient buildings and modernization, smart homes

Energy: Expansion of renewable energy generation, smart grids and distribution, and energy storage systems
Environmental technology: New solutions for waste recycling and waste-water treatment
Management: Digital solutions/IoT for the municipal economy, security for critical infrastructure
Transportation/Logistics: Investment in public transport and smart traffic systems, e-mobility, electric vehicle charging infrastructure, autonomous driving
Ports: Fully automated port where all devices are connected via IoT

Challenges

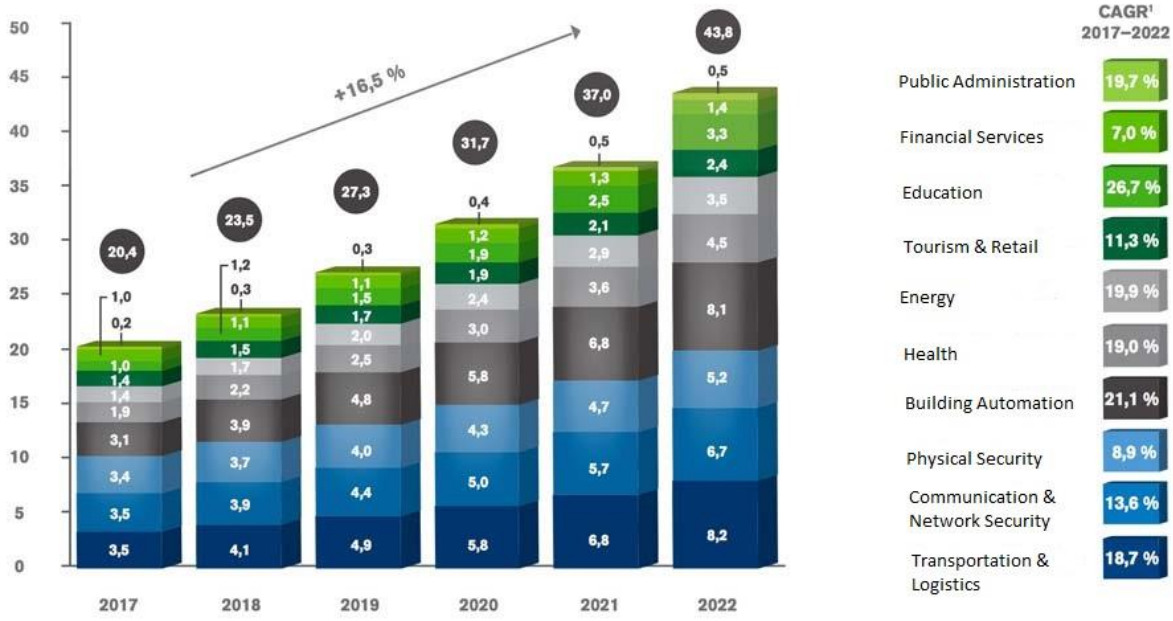
Both the U.S. and Germany are leaders in innovation and early adopters of new technologies rapidly developing ideas into products. Being an innovative technology and solution provider in Germany usually means to compete and do business in a saturated market. It is not an easy undertaking to compete, stand out and even thrive in a saturated market. Having the right approach, careful analysis, and a relentless commitment to providing something unique and of value to customers, will eventually set up for medium and long-term success.

Selected Trade Events

Building and Construction:	Bau Munich, January 09-14, 2023 ISH, Frankfurt, March 13-17, 2023 Chillventa, Nuremberg, October 11-13, 2022
Energy:	E-world of energy and water, Essen, February 8-10, 2022 Energy Storage Europe, Dusseldorf, September 20-22, 2022 Hannover Messe, Hannover, April 25-29, 2022
Environmental technology:	IFAT Munich, Munich, May 30-June 3, 2022
Management:	Intergeo, Essen, October 18-20, 2022
Transportation/Logistics:	IAA Munich, September 5-10, 2023 Innotrans, Berlin, September 20-23, 2022 PolisMOBILITY, Cologne, May 18-21, 2022
Ports:	SMM Hamburg, Hamburg, September 6-9, 2022 (smart ports)

ABB. 2

Revenue and Growth for German Smart-City-Markets 2017-2022 (by billions in Euros)



Quellen: Arthur D. Little, eco

1) CAGR = durchschnittliche jährliche Wachstumsrate (Compound Annual Growth Rate)

Resources

Smart Cities Council
GTAI Germany Trade & Invest
German Renewable Energy Federation
German Partnership for Sustainable Mobility

Customs, Regulations and Standards

Trade Barriers

Germany's regulations and bureaucratic procedures can be a difficult hurdle for companies wishing to enter the market and require close attention by U.S. exporters. Complex safety standards, not normally discriminatory but sometimes rigorously applied, complicate access to the market for many U.S. products. U.S. suppliers are well advised to do their homework thoroughly and make sure they know precisely which standards apply to their product and that they obtain timely testing and certification.

For information on existing trade barriers, please see the National Trade Estimate Report on Foreign Trade Barriers published by USTR. Additional resources: SBA's Office of International Trade and Trade and Development Agency.

Information on agricultural trade barriers can be found at the following website: Foreign Agricultural Service.

To report existing or new trade barriers and get assistance in removing them, contact the Trade Compliance Center. For information on EU retaliatory tariffs on U.S. goods see the list on the Department of Commerce website.

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.S. exporters should consult “The Integrated Tariff of the Community”, referred to as TARIC (Tarif Intégré de la Communauté), to identify the various rules that apply to specific products being imported into the customs territory of the EU. To determine if a license is required for a particular 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 Link: TARIC
Key Link: German Customs import information

Import Requirements and Documentation

The Integrated Tariff is also available to help determine if a license is required for a particular product. The European Commission maintains a link to the EU Trade Helpdesk where information can be found using Harmonized Systems codes to determine, among other information, potential requirements, tariffs, the European Union’s market’s import rules, and taxes. The EU Trade Helpdesk does not provide information for exports from the United States to the European Union. (Using information for a similar North American country, such as exports from Canada, approximates key requirements and may be used as a starting point for your most current Harmonized Systems code.)

Import Documentation

Summary Deceleration and the Single Administrative Document

Goods brought into the European Union customs territory are, from the time of their entry, subject to customs supervision until customs formalities are completed. Such 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 completing the Summary 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 completed by the person who brought the goods into the customs territory of the European Union, 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 Single Administrative Document serves as the European Union importer's declaration. This form describes goods and their movement around the world and is essential for trade outside the European Union or trade of non-EU goods. It encompasses both customs duties and VAT and is valid in all Member States. The declaration is made by whomever is clearing the goods, normally the importer of record or an agent on behalf of the importer.

European Free Trade Association countries, including Norway, Iceland, Switzerland, and Liechtenstein also use the Single Administrative Document. Information on import/export forms is contained in Commission Delegated Regulation (EU) 2015/2446.

The Union Customs Code

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

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

The Union Customs Code also mandates a move to an all-electronic customs system. The system consists of seventeen separated but interconnected components and was originally due to be in place by the end of 2020. While some systems are currently in place or expected to be in place by December 2020, a number of components are lagging due to the complexity of the tasks, and timeframes have been extended for some provisions until 2022 and others until 2025.

Economic Operator Registration and Identification

Since July 1, 2009, all companies established outside of the European Union are required to have an Economic Operator Identification and Registration (EORI) number if they wish to lodge a customs declaration or a Summary Declaration. All U.S. companies should use the EORI number for their customs clearances, which must be formally requested from the customs authorities of the specific Member State to which the company first exports. Member State customs authorities may request additional documents to be submitted alongside a formal request for an EORI number. Once a company has received an EORI number, it can use it for exports to any Member States. There is no single format for the EORI number. Once an operator holds an EORI number, they can request an Authorized Economic Operator (AEO), which can give quicker access to certain simplified customs procedures.

U.S.-EU Customs Cooperation

Since 1997, the United States and the European Union have a Customs Mutual Assistance Agreement. In 2012, the United States and the European Union signed a decision recognizing the compatibility of AEO and Customs-Trade Partnership Against Terrorism (C-TPAT) programs, thereby facilitating faster and more secure trade between transatlantic operators. AEO certification is issued by a national customs authority and is recognized by all Member States' customs agencies. 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, with benefits such as expedited processing of shipments, reduced thefts and losses, reduced data requirements, lower inspection costs, and enhanced loyalty and recognition. Under the revised Union Customs Code, in order for an operator to make use of certain customs simplifications, the authorization of AEO becomes mandatory.

Since 2012, the United States and the European Union have recognized each other's security certified operators and will take the respective membership status of certified trusted traders favorably into account. Furthermore, Customers and Border Protection identification numbers for foreign manufacturers are therefore recognized by customs authorities in the European Union.

Environmental and Related Regulations

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

European Green Deal, Circular Economy Action Plan II, and the Chemicals Strategy for Sustainability

New legislative initiatives published by the European Commission are regularly made available for public consultation on the EU "Welcome to Have your say" website. U.S. companies, civil society organizations and individuals can all participate in these consultations.

On December 11, 2019, the EU Commission presented the European Green Deal as a flagship policy program to transform Europe into a climate neutral society by 2050. The European Green Deal affects all aspects of the European economy including agriculture, fisheries, construction, finance, and manufacturing. To implement the European Green Deal, the Commission has drafted and updated several high-level policy agendas that identify areas in need of new legislative and other actions to deliver on the European Union's climate ambitions.

For example, the 2020 Circular Economy Action Plan II (CEAP) is an iteration of the 2014 Action plan, which takes the circular economy concept as its starting point to propose a general shift in the European Union's product policies. The fundamental idea is that raw materials, products, and services can and should be used several times – not only for the initial intended purpose, but for other purposes through reuse and recycling. This involves placing a larger emphasis on sharing-economy models, leasing, reusing, repairing, refurbishing, and recycling existing materials and products for as long as possible in an effort to extend their life cycle.

The Circular Economy Action Plan sets out a sustainable product policy framework with three main building blocks: Actions on product design, on empowering consumers, and on more sustainable production processes. To translate this framework into law, the Commission proposed modifying the scope of the Eco-Design Directive, which establishes a framework for mandatory ecological requirements for energy-related products in the EU; modifying consumer protection laws to give more power and access to information to consumers, including establishing an EU-wide "right to repair" framework; and mainstreaming this circular production concept into the European Union's industrial policies and industrial emissions legislation.

Further legislative initiatives are expected for products that have a significant impact on EU-wide emissions, including concerning electronics, information and communication technologies, batteries, vehicles, packaging, plastics, textiles, construction and buildings, food waste, and nutrients; for waste reduction goals to meet European Union-wide targets; and for raw materials to prevent the export of waste to countries outside the European Union. Through CEAP, the Commission is positioning the European Union as a global leader on the shift towards a more circular economy, including identifying the advancement of global discussions on plastics and negotiating an international agreement on the management of natural resources as two international priorities.

Batteries

The EU Battery Directive (2006/66/EC) was adopted in 2006. It applies to all batteries and accumulators placed on the EU market, including 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 of those batteries. It places the responsibility on producers to finance the costs associated with the collection, treatment, and recycling of used batteries and accumulators. The Directive includes provisions on the labeling of batteries and their removability from equipment. The European Commission has published a frequently asked questions document to assist interested parties in interpreting its provisions, and an April 2019 report was published to evaluate the Directive.

As a part of CEAP, the Commission published a legislative proposal in December 2020 that would replace the 2006 Directive with a new batteries-related regulation. The new law would dramatically expand the scope of the current legal framework to promote a transition to a more circular economy. The regulation would create carbon footprint performance classes and maximum life-cycle footprint thresholds, introduce minimum recycled content requirements, and create a battery passport to enable economic operators to access information about the batteries to facilitate their repair and reuse. The completion of such a directive is expected to be concluded by early 2022.

Chemicals

Based on the European Green Deal's objective to reduce pollution and move towards a toxic-free environment, the Communication on the Chemicals Strategy for Sustainability takes stock of the performance of the European

Union's chemicals legislative framework, in place since 2007, which primarily consists of two regulations: The Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation, and the Classification, Labelling and Packaging of Hazardous Substances (CLP) Regulation. Although the Commission considers these two regulations to be successful in protecting human health and the environment, it has identified a number of shortcomings that impede the European Union's chemicals framework from reaching its full potential. In particular, the Commission has acknowledged the need to make the chemicals framework more efficient (e.g., faster procedures covering more chemicals), effective (e.g., reducing discrepancies in applying the rules between Member States), coherent (e.g., there are currently parallel, and at times, contradictory processes for the same substances), and overall, more predictable for companies.

To achieve these objectives, the Commission is likely to introduce a series of new concepts and procedural changes to REACH and CLP. Most notably, it will move away from its current case-by-case chemicals assessment model in favor of a more generic approach whereby it will group chemicals and apply restrictions to these groups. Determining when the use of otherwise restricted chemicals will be allowed will be based on a new "essential use" concept (based on, but not identical to, the Montreal Protocol's definition of "essential use"). The Commission is also looking to streamline parallel substance evaluations and possible conflicts arising from uncoordinated actions by the Commission by introducing stronger internal coordination and planning mechanisms under the motto of "one substance, one assessment". Further actions under the Chemicals Strategy for Sustainability include developing and promoting a "sustainable-by-design approach" to placing chemicals on the market to encourage substitution of certain high-risk chemicals; developing new methodologies to measure the lifecycle impacts of chemicals; taking stronger action against endocrine disrupting substances; introducing a "mixture assessment factor" during the safety assessment of substances; addressing contamination by synthetic per- and polyfluoroalkyl substances; and increasing efforts to ensure compliance.

In addition, the Commission is in the process of conducting a series of studies to weigh options for improving the REACH and CLP Regulations, which will feed into the broader impact assessment process for modifying these regulations, which be made available to the public. The Commission is also set to conduct public consultations for both regulations in late 2021 and early 2022, with final regulatory proposals expected by the end of 2021 for CLP and 2022 for REACH. The regulations will then have to pass through the co-legislative process involving the European Parliament and the Council of the European Union and could take several years.

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

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

In addition to the registration requirement, REACH allows the European Commission to monitor, restrict, or prohibit the use of hazardous substances and products containing such substances. The Authorization List identifies substances that require a company to obtain permission from the European Commission to import into the European Union. In addition, the Restriction List contains a list of substances that are subject to specific controls within the European Union. The Candidate List of Substances of Very High Concern (SVHCs) identifies substances that the European Commission intends to restrict or prohibit. Since January 2021, companies supplying items containing SVHC on the Candidate List in a concentration above 0.1 percent weight by weight

to the European Union are required to submit information on these items to ECHA through the Substances of Concern In Products (SCIP) Database. This information is made available to waste operators and consumers. The SCIP notification requirements impose a legal obligation on those placing items on the EU market, including importers of U.S. products. In most cases, European importers will ask their U.S. partners to verify SVHC content and, if applicable, may ask for additional information necessary to comply with SCIP requirements. There is also an option for U.S. companies to submit notifications in the SCIP database as a foreign user, but this requires reaching an agreement with the European importer.

Classification, Labelling and Packaging of Hazardous Substances

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

Public Activities Coordination Tool for Chemicals

The Public Activities Coordination Tool for Chemicals is a free-to-use tool maintained by ECHA, which provides an overview of activities conducted by European public authorities with respect to chemicals, including data generation and assessment, regulatory management option analysis, and regulatory risk management.

Waste Electrical and Electronic Equipment

EU rules on waste electrical and electronic equipment, while not requiring specific customs or import paperwork, may entail a financial obligation for U.S. exporters. The Waste Electrical and Electronic Equipment (WEEE) Directive requires U.S. exporters to register relevant products with a national authority or arrange for this registration 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 packaging.

Restriction on Hazardous Substances in Electrical and Electronic Equipment

The Restriction on Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive imposes restrictions on the use of certain chemicals in electrical and electronic equipment and applies to nearly all products that require power unless a specific exclusion or exemption applies. U.S. exporters certify a product meets the requirements of this legislation by affixing a CE Mark to their product. The U.S. exporter must retain a product file to support the CE Mark in the event of a control.

Cosmetics

The most controversial element of EU legislation harmonizing the regulation of cosmetics 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 a European Union-established entity may submit such a notification. U.S. exporters must therefore retain a Responsible Person to act on their behalf, rely on the entity responsible for the import of their product into the European Union, or establish a presence in a Member State.

Agricultural Documentation

Phytosanitary Certificates

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

Sanitary Certificates

For commodities composed of animal products or by-products, EU Member States 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, and research). The majority of these certificates are uniform throughout the European Union, but the harmonization process is still ongoing. Most recently, certificates are being harmonized for a series of highly processed products, including chondroitin sulphate, hyaluronic acid, hydrolyzed cartilage products, chitosan, glucosamine, rennet, isinglass, and amino acids. Until harmonization is finalized, Member State import requirements continue to apply. In addition to the legally required EU health certificates, a number of other certificates are used in international trade. These certificates, which may also be harmonized in EU legislation, certify origin for customs purposes and certain quality attributes. Information on Harmonized Import Requirements can be found here.

Sanitary Certificates (Fisheries)

In April 2006, the European Union declared the U.S. seafood inspection system to be equivalent to the European system. 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 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 European Union's system. The European Union and the United States are currently negotiating a veterinary equivalency agreement on shellfish. In the meantime, the European Union has had a ban in place since July 1, 2010, which prohibits the import of U.S. bivalve mollusks, in whatever form, into EU territory. This ban does not apply to wild roe-off scallops.

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

In addition to sanitary certificates, all third countries wishing to export fishery products to the European Union 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 European Union or visit the NOAA website.

Labeling and Marking Requirements

Summary

There is a broad array of EU legislation pertaining to the marking, labeling, and packaging of products in the European Union. The first step in investigating the marking, labeling, and packaging legislation that might apply to a product entering the European Union is to draw a distinction between what is mandatory and what is voluntary. Decisions related to mandatory marking, labeling, or packaging requirements may sometimes be left up to individual Member States. Furthermore, voluntary marks and labels are used as marketing tools in some Member States but not in others. This section 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, or environmental concerns. It also includes a brief overview of a few mandatory packaging requirements, as well as more common voluntary marks 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 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).

Mandatory Marks and Labels

- Automotive
- Cosmetics
- Dangerous substances
- Electrical and electronic equipment
- Energy efficiency
- Explosive atmosphere
- Food related
- Footwear
- Household appliances
- Maritime
- Measuring instruments
- Noise emissions
- Pricing
- Pyrotechnics
- Recycling; separate collection
- Tire labeling
- Textiles
- Units of measurement
- Wood packaging

Voluntary Marks and Labels

- Materials in contact with food
- e-mark
- Eco-label
- The Green Dot
- Recycling marks

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

Mandatory Marks and Labels

CE Marking

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

- Cableway installations
- Civil explosives
- Construction products
- Electrical/electronic products
- Electromagnetic compatibility
- Low voltage
- Restriction of Hazardous Substances (RoHS)
- Energy efficiency
- Equipment and protective systems in potentially explosive atmospheres
- Gas appliances
- Hot water boilers
- Lifts
- Machinery
- Medical devices
- Non-automatic weighing instruments
- Personal protective equipment
- Pressure equipment
- Pyrotechnics
- Radio equipment
- Recreational crafts
- Refrigeration appliances
- Simple pressure vessels
- Toys

Not all products must have the CE Mark. Only products that fall under the regulations or directives for the categories above have the CE Mark. It is forbidden to use the CE mark on other products, such as cosmetics or chemicals. The CE mark is a declaration by the manufacturer that the product meets all EU legal requirements and does not indicate that authorities have approved the product. CE marked products can be sold in all EU countries and the European Economic Area. Exporters should also note that CE markings are routinely falsified by manufacturers outside of the European Union.

Starting on July 16, 2021, all CE marked products will need to have an EU address on the label. This also applies to products sold online. The name and address must appear on the product or the product's packaging so that customs and market surveillance authorities can have a contact person in case the product is suspected to present a risk. If an importer or distributor cannot fulfill that role, an exporter will have to appoint an Authorized Representative in the European Union or use a shipping platform to play that role. The Authorized Representative is responsible for ensuring the availability of the conformity documentation, cooperating with market surveillance authorities, and informing authorities when they have reasons to believe that a product presents a risk. In March 2021, the European Commission published guidelines under Article 4 of the regulation (Regulation (EU) 2019/1020).

For more information on obtaining a CE Mark, please contact the U.S. Mission to the European Union.

Automotive

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

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

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 market entry into the European Union. These include consumer vehicles, low-volume production trucks, light and heavy goods vehicles, trailers, motorcycles, cranes, agriculture and forestry tractors, and special-purpose and off-road vehicles.

(The number is the country number; in this case, E4 refers to the Netherlands.)

Cosmetics

According to the Cosmetics Regulation (1223/2009), containers and packaging in certain cases must include:

- The name, trade name and address, or registered office, of the manufacturer or person responsible for marketing the cosmetic product within the European Union.
- 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 thirty months. In this case, this symbol must be included 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 thirty months as indicated by a symbol representing an open cream jar:

- Particular precautions for use.
- The batch number or product reference for identification.
- The product's function.
- If it is impossible for practical reasons to print all the conditions of use and warnings on the packaging, an enclosed leaflet, label, or tape must be provided, and the following symbol has to be on the packaging:

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 must appear also on the container or packaging. Member States may stipulate that the information on the label is provided in their national or official language(s).

With respect to the labeling of nanomaterials present in cosmetics, the Cosmetics Regulation indicates that "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."

Dangerous Substances

According to the Classification, Labelling and Packaging of Hazardous Substances (CLP) Regulation (Regulation 1272/2008), a label of dangerous substances must indicate the name of the substance; the origin of the substance, specifically, the name and address of the manufacturer or distributor; the danger symbol and an indication of danger involved in the use of the substance; and a reference to the special risks arising from such dangers.

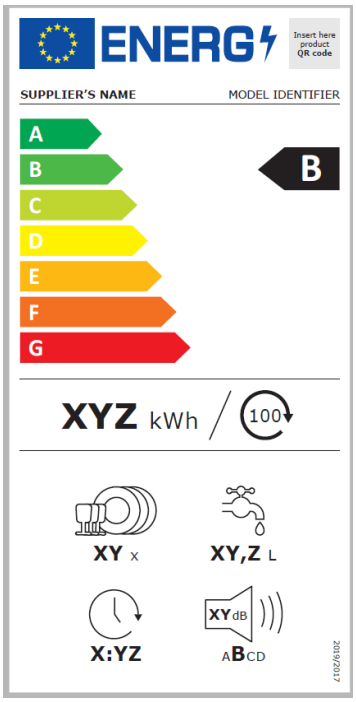
The dimensions of the label must not be less than a standard A8 sheet of paper (52 mm x 74 mm), and each symbol must cover at least one-tenth of the label's surface area. Member States may require their national language(s) to be used in the labeling of dangerous substances. If the packaging is too small,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

Symbols must be employed if the substance can be defined as explosive, oxidizer, flammable, harmful, toxic irritant, corrosive, or harmful to the 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 the CLP Regulation has undergone numerous amendments relating to, for example, the marking and labeling of additional substances, including implementing the classification, labeling, and packaging requirements for chemicals based on the United Nation's Globally Harmonized System.

The Waste Electrical and Electronic Equipment Directive (WEEE)

The WEEE Directive (Directive 2012/19/EU) is designed to tackle the rapidly increasing waste of electrical and electronic equipment and it complements European Union measures on landfills and waste incineration. It also impacts the design of products in order to reduce material use and facilitate reuse and recycling. It sets collection, recycling, and recovery targets for all types of electrical and electronic equipment. Businesses should check requirements for the Member State to which the product will be imported. Depending on the country and quantities placed on the market, the party responsible for placing the product on the market will have to register with the appropriate authorities, join a producer compliance scheme, or set up an individual scheme to meet their take-back and recycling obligations. The wheel bin symbol indicates that the product is not to be discarded with normal household waste. In instances where this symbol cannot be displayed on the equipment itself, it should be included on the packaging.

Energy Labelling



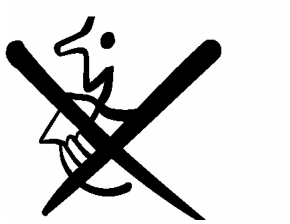
Energy labels, according to Regulation 2017/1369, show how appliances rank on a scale from A (green), the most energy efficient, to G (red), the least energy efficient, according to their energy consumption. These labels apply to different categories of household appliances including air conditioners,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

In addition, since January 1, 2019, manufacturers, importers, and authorized representatives of non-EU manufacturers have to register all products requiring energy labels in the European Product Database for Energy Label and Eco-Design, access to which is available to EU consumers.

Devices for Use in Potentially Explosive Atmospheres (ATEX)

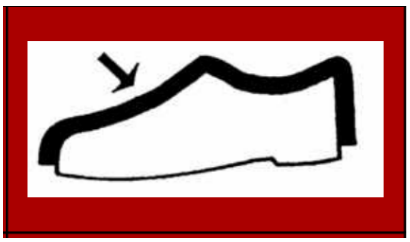
In addition to applying a CE marking for products falling under the ATEX Directive (2014/34/EC), which defines essential health and safety requirements and conformity assessment procedures of equipment or protective systems intended for use in potentially explosive atmospheres (e.g., offshore platforms, mines), it is necessary to display the "Ex" mark, which is a specific marking for hazardous location equipment showing compliance with the ATEX Directive. A symbol designating the product group or category as specified in the directive will be located next to the "Ex" mark.

Do Not Eat



Regulation 450/2009 on active and intelligent materials and articles or parts that come into contact with food, includes labelling for the "Do Not Eat" symbol. To allow identification by the consumer of non-edible parts, active and intelligent materials and articles or parts, if they are perceived as edible, must be labelled with the words "Do Not Eat" and include, when technically possible, the above symbol.

Footwear



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

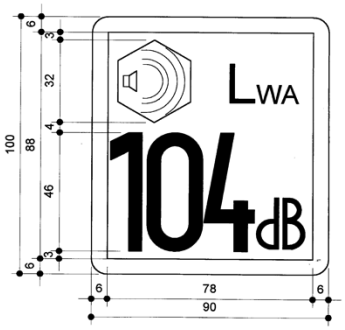
The label must be legible, firmly secured, and accessible, and the manufacturer or the authorized representative established in the European Union is responsible for supplying the label and for the accuracy of the information contained therein. Only the information provided for in the directive needs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

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 ship in the European Union, wherever the ship is situated at the time of construction, and on equipment placed onboard existing ships in the European Union, 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 life-saving appliances, marine pollution prevention, fire protection, navigation equipment, and radio communication equipment. A revised Marine Equipment Directive (2014/90/EC) was adopted in July 2014 and is applicable since September 18, 2016.

Noise Emission of Outdoor Equipment



Machines used outdoors are subject to CE marking requirements in line with the Outdoor Noise Directive (2000/14/EC). Along with the CE mark, products that fall under the directive must also have marking, above, indicating the "guaranteed sound power level."

Packaging Recycling

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

The mobius loop with a number at the center and a letter code indicates the type of plastic the packaging is made from. The above symbol 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, according to Decision 97/129/EC, the following marks are used for the most common types of plastics:

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

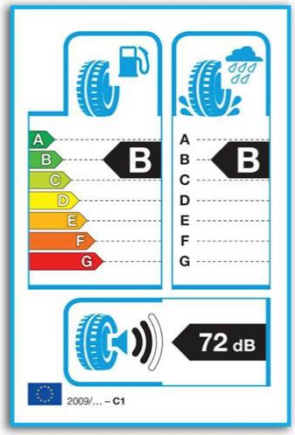
Glass

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 a sample to show recyclability.

Textiles

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

Tire Energy Labelling



Tire label legislation (Directive 1222/2009/EC and Directive 228/2011/EC) requires that tire manufacturers declare fuel efficiency, wet pavement grip, and external rolling noise performance of C1, C2 and C3 tires (i.e., tires mainly fitted on passenger cars, light vehicles, and heavy-duty vehicles). The energy efficiency class ranges from A (most efficient) to G (least efficient). The wet grip class ranges from A (shorter braking distance on wet asphalt) to G (longest). The external noise class ranges from A (less noise outside the vehicle) to B (more noise). The objective of the regulation is to provide beneficial information for the consumer and to contribute to a more energy efficient transport policy.

Units of Measurement

The use of units of measurement in the European Union is set down in the EU Metric Directive (Directive 80/181/EEC). The directive, which went into effect on January 1, 2010, was modified to allow the continuation of both supplemental (e.g., U.S. customary, inch-pound) and metric units for consumer goods sold in the European Union. Similarly, the EU pre-packaging Directive (Directive 76/211/EEC) specifies permissible ranges of nominal quantities, container capacities, and the weights or volumes of prepackaged products. It helps guarantee the net quantity in prepacks and the volume of product in bottles. Manufacturers are advised to take note that all labels require metric units, although dual labeling is also acceptable. The e-mark is referred to as the estimated sign, ⟨℮⟩, which also refers to the e-mark or *quantité estimée* and acts as a metrological "passport" to facilitate the free movement of prepackaged goods. It guarantees that certain liquids and other substances have been packed by weight or volume in accordance with the directives. While compliance is not mandatory, free movement throughout the European Union is guaranteed for prepackaged products that 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 European Union) is responsible for ensuring that the containers meet the directive's requirements.

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 cup/fork symbol above shows compliance with these requirements. It is mandatory to comply with the legislation, but the use of the symbol on products is voluntary.

European 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. Though voluntary, the mark can help create new business opportunities, particularly paired with the expansion of green public procurement in Europe.

The symbol may apply to twenty-five products and services groups, including cleaning products, electronic equipment, household equipment, or gardening. The Eco-label product catalogue provides information on how to apply for the EU Eco-label. Manufacturers should be aware that similar eco-friendly markings are often used nationally, such as the Nordic Swan or the German Blue Angel.

Green Dot

The Green Dot 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 (e.g., 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. Not all Member States have Green Dot organizations. The Green Dot is only mandatory in Spain and Cyprus.

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 and less-sensitive military items through implementation of the Export Administration Regulations (EAR) (15 CFR Parts 730 – 774). The Bureau of Industry and Security (BIS) is comprised of two elements: Export Administration (EA), which is responsible for processing license applications, counselling exporters, and drafting and publishing changes to the EAR, and Export Enforcement (EE), which is responsible for compliance monitoring and 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 of items subject to the EAR comply with the regulations. 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 items subject to the EAR. 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), regardless of whether or not a BIS license was required.

BIS officials rely on EUCs to safeguard items subject to the EAR from diversion to unauthorized end uses/users and destinations. 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 "red flags", or warning signs, and compiled "Know Your Customer" 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 a list of upcoming seminars and webinars or reference BIS provided online training. BIS's Export Control Officers (ECOs) located at U.S. embassies and consulates in seven overseas locations also conduct outreach to raise awareness of reexport control requirements with foreign business communities.

BIS and the EAR regulate transactions involving the export of "dual-use" and less-sensitive military items (commodities, software, and technology) as well as some U.S. person activities. For advice and regulatory requirements on items under the export control jurisdiction of other U.S. government agencies, exporters should consult the other U.S. government agencies. For example, the U.S. Department of State's Directorate of Defense Trade Controls has authority over the defense articles and services that are not subject to the EAR. A list of other agencies involved in export control can be found on the BIS website and in Supplement No. 3 to Part 730 of the EAR. The EAR is available on the BIS website and on the e-CFR (Electronic Code of Federal Regulations) and is updated as needed.

The Consolidated Screening List (CSL) is a list of parties for which the United States government maintains restrictions on certain exports, reexports or transfers of items. The CSL consolidates 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 should determine the export requirements specific to their proposed transaction by classifying their items prior to export, and reviewing the EAR's requirements specific to the item(s) and the proposed end use and end user, as well as consulting the CSL to determine if any parties to the transaction may be subject to specific license requirements.

Assistance is available from BIS by calling one of the following numbers:

(202) 482-4811 – Outreach and Educational Services Division (located in Washington, DC – open Monday-Friday, 8:30am - 5:00pm ET);

(949) 660-0144 – Western Regional Office (located in Irvine, CA – open Monday-Friday, 8:00am - 5:00pm PT); or

(408) 998-8806 – Northern California branch (located in San Jose, CA – open Monday-Friday, 8:00am - 5:00pm PT).

You may also email your inquiry to the Export Counseling Division of the Office of Exporter Services at ECDOEXS@bis.doc.gov.

Contact information for BIS's overseas ECOs can be found at: https://www.bis.doc.gov/index.php/enforcement/oea/eco.

Temporary Entry

The ATA Carnet Customs procedure is 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).

The German customs office provides information on Temporary admission.

Prohibited and Restricted Imports

As described above, 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 European Union, 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

The German customs office provides information on restrictions. For example, the movement or import of weapons and ammunition from a non-EU state into Germany is subject to certain obligations to obtain authorization.

Customs Regulations

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

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

Customs Valuation

Most customs duties and value added tax 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. In addition, the European Union applies an internationally accepted concept of "customs value." The value of imported goods is one of three elements of taxation that provides the basis for assessment of the customs debt, which is the technical term for the amount of duty that has to be paid, the other elements being the origin of the goods and the customs tariff.

Key Link: Customs Procedures
Key Link: German customs

Standards for Trade

Overview

Products tested and certified in the United States by U.S. regulations to U.S. standards are likely to have to be retested and re-certified to EU requirements as a result of the European Union's differing 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 General Product Safety Directive as well as to possible additional national requirements.

While harmonization of EU legislation can facilitate access to the EU Single Market, manufacturers should be aware that regulations, which are mandatory, and technical standards, which are voluntary, might also function as barriers to trade when U.S. standards differ from those of the European Union, which is often the case. For more on how the EU standards and regulatory system function as a barrier to trade, see page 177 in the National Trade Estimate maintained by the Office of the United States Trade Representative.

In general, the harmonization of EU standards has greatly simplified technical regulations amongst EU Member States. Prior to harmonization, each country in the European Union developed its own standards through its national standards body, leading to differing and conflicting standards, laws, and conformity assessment procedures. Thus, it became necessary to create a new, integrated, European system of standardization. The new system provided for three EU standards bodies to create standards on a Europe-wide level: The European Committee for Standardization (CEN), the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI).

CEN activities cover a broad range of areas and CENELEC addresses electrotechnical standards, while ETSI specializes in telecommunications. CEN and CENELEC's principal members are Member State national standards bodies. ETSI's membership has a broader range of interested parties. These three are the only recognized bodies where a Harmonized European Standard (EN) can be developed. When the development of a European Harmonized Standard begins in one of these organizations, development of a national standard must stop. Harmonized Standards are standards that support European legislation. They have been mandated by the European Commission, have been developed by the European Standards Bodies above, address essential health and safety requirements, and notification of their development has been published in the Official Journal of the European Union.

Technically, the use of a Harmonized Standard is voluntary. A manufacturer can elect to use a Harmonized Standard or decide to use a non-Harmonized Standard (e.g., a standard developed by one of the many standards development organizations based in the United States) to meet essential requirements. However, when using a Harmonized Standard, the manufacturer is presumed to be in conformity with the law (Presumption of Conformity). EU harmonized standards that confer presumption of conformity are listed in the directive or regulation usually in Annex Z or ZZ. On the contrary, using a standard that is not a Harmonized Standard will impose additional responsibilities. The use of anything but an EU Harmonized Standard places a burden of proof upon the manufacturer that the product meets the essential requirements. This proof may be provided by the manufacturer's technical file, by the employment of a third party (e.g., consultant or testing house), or by a combination of the two.

In addition to the three EU standards developing organizations, the European Commission funds the participation of small- and medium-sized EU companies and non-governmental EU organizations, such as environmental, labor and consumer groups, in the standardization process. The Commission also provides

money to the European standards bodies when it mandates standards development for harmonized standards that will be linked to EU legislation. The Commission requests CEN/CENELEC or TSI to develop standards.

There are also several European Standards (ENs) developed by CEN, CENELEC, and ETSI that are not mandated by the Commission and that do not necessarily define essential requirements. In theory, their use is voluntary. They may define other characteristics, such as durability, appearance, quality levels, or even cultural preferences. They may be test methods or measurement guides. These European Standards often have the advantage of recognition in the European marketplace. A standard that does not emanate from one of the European standards bodies is not always recognized by insurers, lending institutions, retailers, developers, market surveillance organizations, conformity assessment bodies, and consumers, and may hinder acceptance of the product in the marketplace, particularly when a well-known European Standard already exists for the same product.

Finally, given the European Union's vigorous promotion of its regulatory and standards system, as well as its generous funding for its development, the European Union's standards regime extends well beyond the European Union's borders to include affiliate members (countries which are hopeful of becoming full members in the future). Another category, called "companion standardization body" includes the standards organization of Morocco, Israel, Kazakhstan, and Australia, among others, which are not likely to become a CEN member or affiliate for political and geographical reasons.

(Future standardization activities can be viewed on the CEN and CENELEC's work plan. 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 webpage links to ongoing activities.)

Testing, Inspection and Certification

Conformity Assessment

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

Modules vary in complexity. For example, Module A permits the manufacturer to assume total responsibility for conformity assessment. If the product is manufactured to Harmonized Standards, and if the risk is not unusually high (as in most machinery, for example), the manufacturer may rely on internal manufacturing checks. The manufacturer would compile a technical file, issue a Declaration of Conformity to the appropriate directives, and if appropriate, apply the CE marking, and places the product on the market. Modules for higher

risk products, for example, a medical device, could call for a type examination of the product and a production quality assurance system that conforms to the standard or a complete quality management system and conforms to accepted standards (e.g., ISO 9001 or EN 29001). These modules may call for the involvement of third-party testing and assessment for a Declaration of Conformity. In the European Union, these third parties are designated by Member States' authorities, accepted by the European Commission, and are called Notified Bodies. Each directive provides the module choices available, but there are no choices beyond the modules specified.

When third party testing is required, that testing must be done by accredited member state organizations called Notified Bodies, which must be domiciled in a Member State. The official list of approved Notified Bodies for each EU harmonized directive or regulation is found on the New Approach Notified and Designated Organizations (NANDO) Information System page on the EU Commission website.

The only exceptions to this EU-domiciled rule are U.S.-based organizations and test labs for products covered under U.S.-EU mutual recognition agreements for certain types of marine equipment, products under the electromagnetic compatibility mutual recognition agreement, and the radio equipment mutual recognition agreement.

In addition, to promote market acceptance for products in the European Union, there are several voluntary conformity assessment programs. CEN and CENELEC's certification system are known as the Keymark. ETSI does not offer conformity assessment services.

Publication of Technical Regulations

The Official Journal of the European Union is the official publication of the European Union. It is published daily on the European Commission's EUR-Lex webpage and consists of two series covering adopted legislation, as well as case law and studies by committees. It also lists the standards reference numbers linked to legislation (known as a Harmonized Standard).

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

Members of the World Trade Organization, such as the European Union, are required under the Agreement on Technical Barriers to Trade to notify the WTO proposed technical regulations and conformity assessment procedures that could affect trade. Notify U.S. is a free registration service that captures and makes available for review and comment key information on draft regulations and conformity assessment procedures. Users receive customized alerts when new notifications are added by a selected country or countries and industry sectors of interest and they can request full texts of regulations.

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

Agricultural Standards

The establishment of harmonized EU rules and standards in the food sector has been ongoing for several decades, and the EU publicized a law establishing the general principles of EU food law in January 2002. This regulation introduced mandatory traceability throughout the feed and food chain as of January 1, 2005. For specific information on agricultural standards, please refer to the Foreign Agricultural Service's website.

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

Trade Agreements

For a list of trade agreements between the European Union and other countries in the world, as well as concise explanations of these agreements, please consult EU Trade Agreements.

United States and European Union Trade Agreement Regarding Tariffs on Certain Products

On August 21, 2020, the United States and the European Union announced a trade agreement regarding reductions on tariffs on certain products of interest to each side. The agreed tariff modifications entered into effect on December 18, 2020, for the European Union, with the publication in the Official Journal of the EU of Regulation 2020/2131 of the European Parliament and of the Council, and on December 22, 2020, for the United States. Under the agreement, the European Union eliminated tariffs on imports of certain live and frozen lobster products on a Most-Favored-Nation (MFN) basis, retroactive to August 1, 2020. European Union tariffs will be eliminated for a period of five years, and the European Commission will initiate procedures aimed at making the tariff elimination permanent. The United States reduced its tariff rates on prepared meals, certain crystal glassware, surface preparations, propellant powders, cigarette lighters, and lighter parts by 50 percent. United States tariff reductions are also on an MFN basis and retroactive to August 1, 2020.

Licensing Requirements for Professional Services

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

If an individual with a foreign qualification was recognized in a Member State but wants to move to another Member State and has worked for at least three years in that Member State, which had recognized the qualification, that individual can apply for professional recognition in another Member State under the rules that apply to professionals who have received their qualification from an EU country.

To prove the necessary experience to exercise a profession, a certificate issued by the Member State that first recognized one's qualifications may be needed. This applies to both EU citizens and non-EU citizens.

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

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

The European Union's "Your Europe" website maintains a webpage dedicated to help citizens identify regulated professions and what documents are needed for their recognition in each Member State.

Selling U.S. Products and Services

Distribution & Sales Channels

Using an Agent or Distributor

Companies wishing to use distribution, franchising, and agency arrangements need to ensure that the agreements they put into place are in accordance with EU law 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 aware that according to the directive, parties may not derogate from certain requirements. Accordingly, the inclusion of a clause specifying an alternate body of law to be applied in the event of a dispute will likely be ruled invalid by European courts.

Key Link: Self Employed Commercial Agents

The European Commission's Directorate General for Competition enforces legislation concerned with the effects on competition in the internal market of "vertical agreements." SMEs in the United States 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 EUR 50 million are considered SMEs. According to Commission Notice 2014/C 291/01, agreements that affect less than 10 percent of a particular market are generally exempted.

Key Link: European Law

European Union authorities also look to combat payment delays. Directive 2011/7/EU covers all commercial transactions within the European Union, 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). This Directive entitles a seller who does not receive payment for goods and/or services within thirty days of the payment deadline to collect interest (at a rate of 8 percent above the European Central Bank rate) as well as forty euro as compensation for recovery of costs. For business-to-business transactions, a sixty-day period may be negotiated subject to conditions. The seller may also retain the title to goods until payment is completed and may claim full compensation for all recovery costs.

Key Link: Late Payments

Companies' agents and distributors can take advantage of the European Ombudsman when being 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 European Union. 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 within the European Union, offers online assistance to citizens and businesses who encounter problems with transactions within the borders of the single market.

Key Link: European Ombudsman
Key Link: EU Solvit

Establishing an Office

Anyone can open an office in Germany – irrespective of nationality or place of residence. There is no specific investment legislation in Germany, nor is there a minimum percentage of German shareholdings required for foreigners. Investors can choose the most suitable legal form; i.e., a corporation, a partnership or conduct business via a German branch office.

Foreign companies with a head office and registered business operations outside of Germany can establish a German branch office. This business form is suitable for a foreign company wishing to establish a presence in Germany for the purpose of initiating business and maintaining contacts with business partners.

For more details see information from Germany Trade and Invest: Establishing a Company.

Franchising

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

German Franchising Market

Key to a successful market entry is finding the right partner to develop the market with. Multi-brand franchising is still relatively unknown in Germany, but according to the German Franchise Association it will become more important in the future. Individuals/companies already in the franchise market have the expertise and financial connections to pave the way. Reaching out to these active players can greatly ease the access into Germany and provide local knowledge of the market. This can be achieved through cooperation with the industry/trade associations, franchise consultants, brokers and media channels reaching out to the appropriate industry audience. Individuals/companies already in the franchise market can also help create brand awareness that minimizes the risk for the potential investor. German business partners prefer to talk directly to the owner, not the manager.

Germany's population and industry are decentralized and there is no one single predominant business center. It is common in Germany for franchisors (and many other business sectors) to divide the country into regions and then appoint area developers to oversee a group of franchisees. Successful market strategies consider regional differences as part of a strong national market presence.

There are many options for advertising on the German market. A selection of franchise focused sites/media include:

Online Platforms:

- Deutsche Unternehmerboerse (in German) – print and online, site advertising investment possibilities

- Franchise Pool International (FPI) (in English and German) – consultant pool with listing of franchises
- FranchisePORTAL (in German) – virtual franchise fair with listing of available franchises

Franchise Trade Events in Germany:

- Franchise Expo Frankfurt – conference and exhibition for the franchise industry
- EXPO REAL in Munich – Europe's largest real estate and investment trade fair

Direct Marketing

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

Processing Customer Data

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

Distance Selling Rules

In 2011, the European Union overhauled its consumer protection legislation and merged several existing rules into a single rulebook, the Consumer Rights Directive, the provisions of which have been in force since 2014. The directive contains provisions on core information to be provided by traders prior to the conclusion of consumer contracts. It also regulates the right of withdrawal, includes rules on the costs for the use of means of payment and bans pre-ticked boxes. There are updates to these rules that will apply from May 2022. For more information, consult the EU Commission's useful tool to learn about consumer rules.

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

More information: Digital Contract Rules

Alternative Dispute Resolution

In 2013, the European Union adopted rules on alternative dispute resolution mechanism, 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. An Online Dispute Resolution Regulation has set up an EU-wide platform to handle consumer disputes that arise from online transactions.

Key Link: Consumer Affairs Homepage
Key Link: Consumer Rights

Distance Selling of Financial Services

Financial services are regulated by a 2002 Directive (2002/65/EC), which was designed to ensure that consumers are appropriately protected with respect to financial transactions taking place where the consumer and the provider are not face-to-face. In addition to prohibiting certain abusive marketing practices, the directive establishes criteria for the presentation of contract information. Given the special nature of financial markets, specifics are also laid out for contractual withdrawal.

Key Link: Distance Marketing

Direct Marketing over the Internet

The e-Commerce Directive (2000/31/EC) imposes certain specific requirements connected to the direct marketing business. Promotional offers must not mislead customers and the terms that must be met to qualify for them must be clear and easily accessible. The e-Commerce Directive stipulates that marketing emails 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; instead, this is a matter for national law. Vendors of electronically supplied services (such as software, which European Union authorities consider a service and not a good) must also collect value added tax.

Germany

Most German companies use direct marketing to sell their products and services. The most frequently used formats are email and online marketing, telephone marketing, and direct mail. It is important to know the pitfalls of using direct marketing as a selling tool in Germany. Data protection and privacy laws are stringent, and consumer protection guidelines and competitive advertising are also highly regulated. Companies should consult with a lawyer before raising, storing, or processing any sort of data in Germany. Other potential challenges regard the laws pertaining to unfair competition and rebates.

Joint Ventures/Licensing

Dealing with joint ventures is challenging under German competition law. In Germany, joint venture legislation falls under the purview of the Federal Cartel Office (Bundeskartellamt). The law requires that a joint venture must exercise “genuine entrepreneurial” activities. Under German law, this means:

- Organizations which merely carry out auxiliary functions such as purchasing or distribution on behalf of the parents are not considered joint ventures; and
- JVs must have at their disposal sufficient assets and personnel to carry out their activities.

The Bundeskartellamt is required to prohibit a merger if it is "expected to create or strengthen a dominant position." Market dominance is defined as an undertaking which either has no competitors or is not exposed to any substantial competition or has a paramount market position in relation to its competitors.

Licensing

German antitrust law does not, in the absence of a dominant market position, restrict the owner's freedom to use her/his industrial property rights, including the exploitation of a patented innovation.

Express Delivery

Most international express delivery companies are active in Germany. Large players include DHL and Hermes (both headquartered in Germany), FedEx and UPS. These companies ship domestically and internationally, provide a wide range of delivery options and prices and have grown significantly because of e-commerce. The German express delivery industry shipped more 4.05 billion packages in 2020. An increasing number of companies incl. Amazon, Gorillas, Flink and Decathlon (sporting goods retailer) offer same day deliveries in large metropolitan areas.

Due Diligence

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

Companies interested in taking over German firms should always conduct their own due diligence before entering business ventures. One of the U.S. Commercial Service's programs, the International Company Profile, has been designed to support due diligence processes. All major consulting companies offer due diligence services, and most large U.S. accounting or consulting firms have subsidiaries in Germany.

e-Commerce in Germany

Germany has one of the largest e-commerce markets in Europe. The number of e-commerce consumers, internet penetration and average amount spent per year is above the European average. In 2020, total sales amounted to USD 83.1 billion, which is a 23 percent growth compared to 2019. It is expected that the online population in Germany will increase from 62.4 million in 2020 up to 68.4 million in 2025. This will likely lead to an e-commerce penetration of 74 percent in the German market. As a result of the strict lockdown measures throughout March and April 2020, caused by the global healthcare crisis, many German consumers have increased their online purchases and bought goods like groceries and sanitary items online for the very first time.

German consumers are rather risk-averse and expect high quality products. Websites and online stores are expected to be in German language.

The most popular products purchased online include clothing, electronics, household appliances and furniture. It is further expected that toys and "Do it Yourself" (DIY) products as well as food and drugstore products will

play an increasingly crucial role by 2025. The smartphone penetration in Germany lies at 80 percent with a social media penetration of 53 percent. The role of social media platforms such as Facebook, YouTube or Instagram continues to be of high importance.

Popular e-Commerce Sites

The most popular online retailers in Germany in 2020 were amazon.de (revenue of USD 16.2 billion), otto.de (USD 5.4 billion), zalando.de (USD 2.3 billion), mediamarkt.de (USD 1.8 billion), and lidl.de (USD 1.2 billion).

Online Payment

Most German online stores accept PayPal and credit cards as payment methods. Many websites also accept bank transfers or invoice/buy now, pay later. Online customers have the right to cancel orders and return goods or services within 14 days, for any reason and with no justification. As a result, Germany is known for its high return rate, particularly in the fashion industry.

Mobile e-Commerce

The strong e-commerce market in Germany can be attributed to the considerable proportion of the population who owns smartphones (80 percent). In 2020, 54 percent of online purchases were made via smartphone. This growth is likely to continue as retailers improve their mobile websites and provide more convenient ways of shopping on mobile devices.

Selling Factors & Techniques

Overview

Success in the German market, as elsewhere around the world, requires long-term commitment to market development and sales backup, especially if U.S. companies are to overcome the geographic handicap with respect to European competitors. Germans at times perceive U.S. suppliers as tending to process a U.S. domestic order before taking care of an export sale or being quick to bypass a local distributor to deal directly with its customer. Some German entrepreneurs with selective experience with U.S. companies are skeptical about their long-term commitment and after-sales support. U.S. firms entering Germany today are generally aware of the factors that make for a successful export relationship and are ready to establish a credible support network. However, U.S. firms should be ready to address any lingering doubts from prospective German clients/partners.

Trade Promotion and Advertising

Trade Fairs

Few countries in the world can match Germany when it comes to leading international trade fairs. Such a reputation should be no surprise given that the trade fair concept was born in Germany during the Middle Ages. Today, Germany hosts a major world-class trade event in virtually every industry sector, attracting buyers from around the world. Trade fairs thrive in Germany because they are true business events where contracts are negotiated, and deals are consummated. U.S. exhibitors at German fairs should be prepared to take full advantage of the business opportunities presented at these events. While U.S. exhibitors and visitors can conclude transactions, all attendees can use major German trade fairs to conduct market research, see what

their worldwide competition is doing, and test pricing strategies. Finally, German fairs attract buyers from throughout the world, allowing U.S. exhibitors to conduct business here with buyers from across Europe, Asia, Africa, Latin America, the Middle East, as well as with other U.S. companies.

German trade fairs, in general, attract impressive numbers of visitors and exhibitors. This reality confirms the conviction that there is no other venue where an American company can get so much product exposure for its marketing dollar. Trade fairs also provide a U.S. company interested in entering Germany with the opportunity to research its market and the potential of its product properly before making a business decision.

Many German Trade Fairs have been cancelled or postponed in 2020 and 2021 because of the COVID pandemic. While trade fair organizers are determined to return to business as usual or hybrid concepts as soon as they can, continued cancelations are possible and U.S. firms interested in exhibiting or attending shows in Germany should monitor trade show websites closely for any updates.

Advertising

In addition to exhibiting at major German trade fairs, advertising plays a central role in most companies' broad-based marketing programs. Regulation of advertising in Germany is a mix between basic rules and voluntary guidelines developed by the major industry associations. The "Law Against Unfair Competition" established legal rules at the beginning of the 20th Century. Although it has been modified over time, this law continues to be valid today. The law allows suits to be brought if advertising "violates accepted mores."

Many advertising practices that are common in the United States, such as offering premiums, are not allowed in Germany. Any planned advertising campaigns should be discussed with a potential business partner or an advertising agency in Germany.

General EU Legislation

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

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

The EU's Audiovisual Media Services Directive (AVMS) lays down legislation on broadcasting activities allowed within the EU. Since 2009, the rules allowing for U.S.-style product placement on television with exceptions. The AVMS was revised recently to extend the scope of the directive to video-sharing platforms and social media. In some circumstances Children's programming is subject to a code of conduct that includes a limit on junk food advertising to children, but organizations subject to the AVMS Directive are encouraged to do more to

protect children. Following the adoption of the 1999 Council Directive on the Sale of Consumer Goods and Associated Guarantees, product specifications, as laid down in advertising, are considered as legally binding on the seller.

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

Key Links

Audiovisual Media Services Directive
Misleading Advertising
Unfair Commercial Practices Directive

Medicines

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

Nutrition and Health Claims

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

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

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 were 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 and in the USDA Food and Agricultural Import Regulations and Standards EU 28 2017.

Key Link: EU Register of Nutrition and Health Claims

Food Information to Consumers

In 2015, the EU adopted a new regulation on novel foods (2015/2283) amending the provision of food information to consumers (1169/2011). Novel foods and food ingredients must not present a danger for the consumer or mislead the consumer and should not differ from the ingredients that they are intended to replace to such an extent that normal consumption would represent a nutritional disadvantage for the consumer. It is important to mention that the European Commission may decide, on its own initiative or upon a request by a Member State, by means of implementing acts (a sort of decree), whether or not a particular food falls within the definition of novel food. More information can be found on the Commission's website. Most provisions of this new Novel Foods Regulation became applicable on January 1, 2018. The Common Organization of the Markets establishes the specific information that must accompany fishery and aquaculture products sold to consumers and mass caterers. These requirements compliment the general EU rules on the provision of food information to consumers and contribute to more transparency on the market as they enable consumers to make informed choices on the products they buy. The new rules have become applicable since December 13, 2014. The Commission has published a pocket guide to the EU's new fish and aquaculture consumer labels.

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

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: Labelling Nutrition Supplements

Tobacco

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

Key Link: Tobacco Products

Pricing

German customers are often very price sensitive. Consequently, price is an important competitive factor, but quality, timely delivery and service remain equally important, especially in B2B relations.

Sales Service/Customer Support

Germany

The German commercial customer expects to be able to pick up the telephone, talk to his or her dealer and have replacement parts or service work immediately available. American exporters should avoid appointing distributors with impossibly large geographic areas, without firm commitments regarding parts inventories or service capabilities, and without agreements on dealer mark-ups.

EU Legislation

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

Product Liability

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

Key Link: Liability of Defective Products

Product Safety

The 1992 General Product Safety Directive introduced a general safety requirement at the EU level to ensure that manufacturers only place safe products on the market. It was revised in 2001 to include an obligation on the producer and distributor to notify the Commission in case of a problem with a given product, provisions

for its recall, the creation of a European Product Safety Network, and a ban on exports of products to third countries that are not deemed safe in the EU.

Key Link: Product Safety Legislation

Legal Warranties and After-sales Service

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

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

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

Key Link: Sales and Guarantees

Local Professional Services

Business service providers active in Germany can be viewed on the website maintained by the Commercial Service at the U.S. Embassy in Germany.

Major German Business Associations

Bundesverband der Deutschen Industrie e.V. (BDI)
(Federation of German Industries)
Deutscher Industrie und Handelskammertag (DIHK)
(Federation of German Chambers of Industry and Commerce)
Bundesverband Grosshandel, Aussenhandel, Dienstleistungen e.V.
(Federation of German Wholesale, Foreign Trade and Services)
Verband Deutscher Maschinen- und Anlagenbau e.V. (VDMA)
(German Association of Machinery and Plant Manufacturers)
Centralvereinigung Deutscher Wirtschaftsverbaende fuer Handelsvermittlung und Vertrieb (CDH)
(National Association of German Commercial Agencies and Distributors)

For industry-specific business associations, please visit our leading sectors section, which lists key contacts and resources by industry sector.

Limitations on Selling U.S. Products and Services

We are not aware of any limitations on manufacturing or service sectors that prohibit non-Germans from owning or selling these businesses in Germany.

Trade Financing

Methods of Payment

The majority of import transactions by German customers, especially those involving large German distributors, take place under seller-buyer terms, such as the common 30/60/90-day accounts, or payment against documents. The electronic funds transfer (EFT, equivalent to SWIFT or wire transfers) is the most popular payment mechanism by which German importers remit payment to their U.S. suppliers and is the fastest and cheapest way to transfer funds. Current technology makes online transfers reasonably secure and transparent.

The letter of credit is still used in some industry sectors but now covers a fraction of total imports, largely due to its cost and time requirements as well as the ease in obtaining credit ratings in Germany, which increases transparency and transactional safety. L/C's for payments under USD 5,000 are almost unknown in Germany. U.S. exporters may also encounter Bills of Exchange (Wechsel), usually payable within two or three months, however this antiquated payment mechanism is also passing from the scene. Cash-in-advance is also rare in German import payment.

Both private and public credit insurance are available in Germany. Euler Hermes (German), Coface (French) and Atradius (Dutch) are among the private providers (which also offer ranking and scoring services), and the main public insurer is the Staatliche Kreditversicherung (Hermes-Bürgschaften), which is administered by Euler Hermes and is used to cover German exports to countries with high political and country risk.

Overall, German firms continue to enjoy a relatively good reputation for their payment practices and management of credit. However, default risks in Germany vary from region to region and industry to industry. The U.S. Commercial Service Germany offers the International Company Profile as a tool to help evaluate the creditworthiness of potential customers or partners and recommends that U.S. exporters consider normal, prudent credit practices in Germany in all transactions.

The Export-Import Bank of the United States (Ex-Im Bank) is the official export credit agency of the United States. The Ex-Im Bank's mission is to assist in financing exports of U.S. goods and services to international markets. The Ex-Im Bank enables U.S. companies – large and small – to turn export opportunities into real sales that help to maintain and create U.S. jobs and contribute to a stronger national economy. The Ex-Im Bank does not compete with private-sector lenders but instead provides export-financing products that fill gaps in trade financing. The bank assumes credit and country risks the private sector is unable or unwilling to accept and helps level the playing field for U.S. firms by matching the financing that other governments provide to their exporters. The Ex-Im Bank provides working capital guarantees (pre-export financing), export credit insurance, loan guarantees, and direct loans (buyer financing), primarily focusing on developing markets worldwide. For further information on Ex-Im Bank's objective and programs, please see the website.

For more information about the methods of payment or other trade finance options, please read the Trade Finance Guide.

Banking Systems

Germany has a non-discriminatory, well-developed financial services infrastructure. Although corporate financing via capital markets is on the rise, Germany's financial system remains mostly bank-based, with bank

loans serving as the predominant form of funding for firms, particularly the small- and medium-sized enterprises of Germany's famed Mittelstand.

Germany's universal banking system allows the country's more than 1,679 banks and savings banks and network of 25,800 branches to take deposits and make loans to customers as well as to trade in securities. There are no reports of a shortage of credit in the German economy. Credit is available at market-determined rates to both domestic and foreign investors, and a variety of credit instruments are available. The traditional German system of cross-shareholding among banks and industry, as well as a high rate of bank borrowing relative to equity financing, allowed German banks to exert substantial influence on industry in the past.

Key Link: The German Bankers' Association
Key Link: Federal Financial Supervisory Authority

Germany has a modern banking sector, but it is considered "over-banked," as evidenced by ongoing consolidation and low profit margins. The country's so-called "three-pillar" banking system is made up of private commercial banks, cooperative banks, and public banks (savings banks or Sparkassen, and the regional state-owned banks, or Landesbanken). German banks' profitability is increasingly under pressure given very low interest rates, high-cost structures, growing competition from FinTechs, and increasing compliance costs as a result of new regulation and supervision. German banks have seen their interest margin narrow during the negative interest rate period that began in 2014. Banks are currently discouraging customers by charging negative rates to a growing number of depositors – corporates and private retail clients alike (depending on the bank on deposits exceeding EUR 50,000 or EUR 100,000) – and have substantially increased fees for banking services and accounts to compensate for interest rate earnings losses.

Private banks control roughly 40 percent of the market, while publicly owned savings banks partially linked to state and local governments account for 50 percent of banking transactions, and cooperative banks make up the balance. All three types of banks offer a full range of services to their customers. A state-owned bank, KfW, provides special credit services, including the financing of homeowner mortgages, guarantees to small- and medium-sized businesses, financing for projects in disadvantaged regions in Germany, and export financing for projects in developing countries.

The private bank sector is dominated by the universal banks Deutsche Bank (Germany's largest bank by balance sheet total) and Commerzbank (fourth-largest bank), with balance sheets of EUR 1.3 trillion and EUR 506.9 billion respectively (2020 figures). Commerzbank received EUR 18 billion in financial assistance from the federal government in 2009, for which the government took a 25 percent stake in the bank (now reduced to 15.6 percent). Merger talks between Deutsche Bank and Commerzbank failed in 2019. The second largest of the top ten German banks is DZ Bank, the central institution of the Cooperative Finance Group (after its merger with WGZ Bank in July 2016), followed by KfW, Commerzbank, LBBW, and German branches of large international banks (UniCredit Bank, HVB, or ING-Diba), and regional state-owned banks (LBBW, Bayern LB, Helaba, NordLB). Germany's regional state-owned banks were among the hardest hit by the global financial crisis and continue to face major challenges to their business models. The federal government is still in the process of winding down several so-called "bad banks" composed of toxic assets of failed banks WestLB (now Portigon AG) and Hypo Real Estate. All German banks have weathered the COVID-19 pandemic well thanks to cheap central bank liquidity regulatory easing, and moratoria on corporate insolvency laws.

Most major U.S. banks are represented in the German market, principally but not exclusively in the city of Frankfurt am Main, Germany's main financial center. Following the UK's exit from the EU, many U.S. banks chose Frankfurt as their EU headquarter. A large number of German banks, including some of the partially state-

owned regional banks, similarly maintain subsidiaries, branches, and/or representative offices in the United States.

Practices regarding finance, availability of capital, and schedules of payment are comparable to those that prevail in the United States. There are no restrictions or barriers on the movement of capital, foreign exchange earnings, or dividends.

Foreign Exchange Controls

The German government imposes no forms of controls on the purchase or sale of foreign currencies.

U.S. Banks & Local Correspondent Banks

Bank of America
Neue Mainzer Straße 52, 60311 Frankfurt am Main, Germany
Phone: +49 69 589910

BNY Mellon
Messe Turm, Friedrich-Ebert-Anlage 49, 60308 Frankfurt am Main, Germany
Phone: +49 69 12014 1000

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Goldman Sachs
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Merrill Lynch International
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Phone: +49-69-5899 5000

Morgan Stanley
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Phone: +49-69-2166-0

Silicon Valley Bank
Guiollettstraße 48, 60325 Frankfurt am Main, Germany
Phone: +49-69-7158-950

State Street Bank International GmbH
Solmsstraße 83, 60486 Frankfurt am Main, Germany
Phone: +49 -69-6677-45000

Wells Fargo
An der Hauptwache 7, 60313 Frankfurt am Main, Germany
Phone: +49-69-2980-2700

Project Financing

Germany possesses the financial framework and institutions to support the development of large infrastructure projects. However, the volume of project finance operations has been relatively modest in Germany in comparison to that of other EU countries, particularly the U.K. and France. Although the relatively high debt levels of the German federal government and local authorities would seem to favor this type of financing, difficult economic conditions have also limited anticipated rates of return for potential project finance developers. Other inhibiting factors are Germany's complex juridical and federal frameworks, which make project-financed works harder to structure than in other countries. Low interest rates and returns on savings have contributed to an improved investment climate. One area that has attracted project finance, including that involving a few U.S. developers and investors, is alternative energy production. Clean and renewable energy projects have gained prominence in Germany, particularly since the decision in 2011 to accelerate the phase-out of nuclear energy by 2022 and the decision in June 2020 to end coal power generation in Germany by 2038, at the latest.

The principal German institutions active in facilitating project finance deals are the state-owned KfW Bank Group (which plays a major role in most industries), commercial banks such as Commerzbank, and several of the publicly-owned savings banks controlled by state and local governments and state development banks ("Förderbanken", in German), such as WIBank in Hesse, NRW Bank in North Rhine-Westphalia, LFA Förderbank Bayern, Investitionsbank Berlin (IBB), among others. The KfW Group includes KfW IPEX-Bank, which supports a consortium with German members to design and finance infrastructure projects in Germany and overseas, and KfW Capital, launched in October 2018 to develop the VC and VD funding landscape in Germany and Europe. Another group member, KfW Development Bank, helps municipalities finance infrastructure. German insurers are pressing for regulatory changes to enable them to finance infrastructure projects.

Key Link: European Bank for Reconstruction and Development (EBRD)
Key Link: U.S. Commercial Service Liaison Office to the EBRD

Protecting Intellectual Property

Protecting Your Intellectual Property in Germany:

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

Most copyrighted works created in the United States will be automatically protected in Germany from the moment of creation or publication according to international agreements. However, the extension of protection

will vary according to the laws of Germany and of the EU. Protection against unauthorized use will vary depending on the national laws of each country.

Obtaining a utility patent in EU Member States is based on a first-to-file system, i.e. the first person or entity to register the patent becomes the title holder. Similarly, most trademark and design rights – similar to a design patent – are based on a first-to-file registration system. So, you should consider how to obtain patent, design, or trademark protection before introducing your products or services into the German market. Better yet, you should consider having an IP strategy for the whole world even before making your intellectual property public in any country, to ensure that you do not lose the right outside the United States.

Further, keep in mind that trademark and design titles can be obtained for the whole of the EU, at the European Union Intellectual Property Office – EUIPO. Individual titles for Germany can also be obtained at the corresponding IP office. Similarly, a bundle of patent titles can be obtained for various countries through a simplified process at the European Patent Office; an individual patent title can be directly obtained from the German Patent and Trade Mark Office. There are also other international registration systems like the Patent Cooperation Treaty for patents or the Madrid Protocol for trademarks, that could be useful to facilitate the protection of your IP in many countries of the world, including Germany.

It is vital that companies understand that intellectual property rights are primarily private rights and that the United States government cannot enforce them for private individuals in the EU. It is the responsibility of the rights holders to register, protect, and enforce their rights where relevant, retaining their own counsel and advisors. Companies may wish to seek advice from local legal counsel or IP consultants who are experts in German and EU law. The U.S. Commercial Service can provide a list of local lawyers upon request.

While the United States government stands ready to assist, there is little that can be done if the rights holders have not taken these fundamental steps necessary to secure and enforce their IP in a timely fashion. Moreover, in many countries rights holders who delay enforcement of their rights 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 lawsuit. In no instance should United States government advice be regarded as a substitute for the responsibility of a rights holder to promptly pursue its case.

It is always advisable to conduct due diligence on potential partners. A good partner is an important ally in protecting IP rights. Consider carefully whether to permit your partner to register 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 faith actors. Projects and sales in the EU require constant attention. Work with legal counsel familiar with 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-sized companies understand the importance of working together with trade associations and organizations to support efforts to protect IP and stop counterfeiting. There are a number of these organizations, in both the EU and the U.S., including Local American Chambers of Commerce.

IP Resources

A wealth of information on protecting IP is freely available to United States 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 the website.
- For more information about registering trademarks, obtaining designs or utility patents (both in the United States as well as in foreign countries), contact the U.S. Patent and Trademark Office (USPTO) at: **1-800-786-9199**.
- For more information about registering copyrighted works in the United States, contact the U.S. Copyright Office at: **1-202-707-5959**.
- For more information about how to evaluate, protect, and enforce intellectual property rights and how these rights may be important for businesses, please visit the "Resources" section of the STOPfakes website. For information on obtaining and enforcing intellectual property rights and market-specific IP Toolkits visit: STOPfakes IPR Toolkits. The toolkits contain detailed information on protecting and enforcing IP in specific markets and also contain contact information for local IPR offices abroad and United States government officials available to assist SMEs.
- For more information, please see the webpage on Protecting Intellectual Property.

The Office of the United States Trade Representative (USTR) publishes the Special 301 Report on an annual basis. This report provides a review of IP protection and enforcement for United States trading partners around the world. In the 2021 edition of the Report, USTR highlights the negative market access implications for United States producers due to the EU's protection of geographical indications (GIs) and third-country markets.

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

The U.S. Mission to the European Union (based in Brussels, Belgium)

Serving the EU, EFTA, and UK

World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO)
(based in Geneva, Switzerland)

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

Other Key Links:

IP in the EU and international organizations

Copyright in the EU
European Patent Office (EPO)
Database of laws of the World Intellectual Property Organization (WIPO Lex)

Selling to the Public Sector

Selling to German government entities is not an easy process. German government procurement is formally non-discriminatory and compliant with the WTO Government Procurement Agreement (GPA) and EU-wide legislation under the EU Public Procurement Directives. That said, it is a major challenge to compete head-to-head with major German or other EU suppliers who have established long-term ties with purchasing entities. For information on EU procurement, please refer to the article in the the Country Commercial Guide for European Union at https://www.trade.gov/country-commercial-guides/eu-selling-public-sector.

Business Travel

Business Customs:

- Punctuality is an important part of German business culture. The norm is to arrive about five minutes early to an appointment. If you show up more than five minutes after the appointed time, you would be perceived as late, and more than fifteen minutes are considered impolite. However, if there is a delay, you can always call ahead and explain the situation. Germans generally act and communicate in a direct and structured way; they want things to be done as efficiently as possible. It is not about being rude, but this behavior can include honest and constructive criticism. It also means to them that they value your time as much as theirs.
- Appointments are made for most matters. The usual times for business appointments are between 9:00am - 12:00pm or between 2:00pm - 5:00pm. You should avoid scheduling on Friday afternoons as some offices might already be closed during that time.
- Addressing people: You should respect formal introductions and the use of official titles, for example: Dr., Prof., Ing., among others. Your professionalism will be highly valued. In general, acting in a formal way is important, particularly at first, but following the examples of others is a good rule. After several meetings, they might prefer a more informal interaction, but this varies depending on the people and the company so, it is polite to remain formal in tone unless they invite you to do otherwise.
- Business attire is generally formal and conservative. This means suits (not necessarily with tie) for men and suits or conservative dresses for women.
- First approach: A greeting usually consists of a smile (even when covered by a mouth and nose covering) and 'elbow bumps' or 'fist bumps' which have largely replaced handshakes as hygiene controls came into place due to the pandemic. Do not greet with a hug nor a kiss on the cheek, as in other cultures. Allowing for adequate personal space is important throughout the meeting. The question "Wie geht es Ihnen?" ["How are you?"] is used as a literal question and expects a literal answer. The common English usage of it simply being a formality or greeting feels strange to most Germans. Not replying in the expected way or moving on without waiting for an answer can therefore be considered superficial and impolite.
- Giving compliments is not common and can cause embarrassment. The same can be said about giving gifts, which may even be viewed as inappropriate. Only after negotiations or agreements, a small gift may be acceptable. The gift should not be overly expensive, but of good quality.

Travel Advisory:

There is currently (July 2021) a *global health advisory* in effect advising people not to travel and to avoid international travel due to the global impact of COVID-19. See the Website of the State Department for updates.

The State Department has advised to exercise increased caution in Germany due to *terrorism,* both local and foreign. In the past years, the risk of terror incidents in European countries has increased. Germany's open borders with its European neighbors allow for the possibility of terrorist groups entering and exiting the country with anonymity.

For the latest security information, Americans traveling abroad should regularly monitor the State Department's website, where the current Worldwide Caution Public Announcement, Travel Warnings and Public Announcements can be found.

Up-to-date information on security can also be obtained by calling +1-888-407-4747 toll free in the United States, or, for callers outside the United States and Canada, a regular toll line at +1-317-472-2328. These numbers are available 8:00am - 8:00pm; Eastern Time, Monday through Friday (except U.S. federal holidays).

Read the:

State Department consular information sheet for Germany
Department of State: Travel to Germany
Department of State Visa Website
Center for Disease Control and Prevention
CDC on Germany

Visa requirements

You do not require a visa for tourist or business stays up to 90 days within the Schengen Group of countries as a U.S. citizen. This includes Germany. The time of the visit should not exceed 90 days and the visitor must leave the country after this period. A passport that is valid for at least three months beyond the stay is required.

Further information on entry visa and passport requirements may be obtained from the German Embassy at 4645 Reservoir Road N.W., Washington, D.C. 20007, telephone +1-202-298-4000, or the German Consulates General in Atlanta, Boston, Chicago, Houston, Los Angeles, Miami, New York, or San Francisco and on the Internet.

For inquiries outside the United States, see the list of German Embassies and Consulates on the Federal Foreign Office's website: Bilateral Relations and German missions.

Please review the E.U. travel restrictions which are now in place as a result of the global health crisis. You can find information and updates on the website of the European Commission.

Currency

In Germany and other countries within the Eurozone, the Euro [EUR/€] is the used currency.

Exchange rate from EUR to USD (as of January 1st)

Year	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**

EXR	1.0834	1.0795	1.2420	1.1444	1.1093	1.2136

See the Euro foreign exchange reference rates for continuously updated exchange rates.

- Because of high currency-exchange fees, travelers should consider converting their currency before traveling.
- Banks, credit unions, online bureaus, and currency converters provide convenient and often inexpensive currency exchange services.
- Once on foreign soil, the best means to convert currency is to use a foreign ATM or identify if your bank has ATMs or banking affiliates nearby.
- Many credit and debit card issuers allow users to purchase with no foreign transaction fees.

Unlike in the United States, many restaurants and vendors in Germany do not accept card payment, so remember to always carry some cash. In addition, some credit cards, such as American Express (among others), may not be accepted at certain shops.

Telecommunications/Electronics

Mobile phones are based on GSM 800 and 1600 MHz standards. UMTS/IMT 2000 frequencies are 1900 to 2170 MHz.

Cell or mobile phones ["Handy", in German] are commonly used. Germany and most of Europe use GSM networks, which some U.S. carriers also use. Most U.S. carriers have international travel packages that include texting, calling and data for better rates rather than roaming without a plan.

Internet is widely accessible in Germany, WI-FI is available in most hotels, some public spaces, restaurants, cafes, etc.

Power sockets are "Type F", also known as "Schuko", and types C and E can also be used. This socket is used in most of Europe and parts of Africa, Asia, and South America. The standard voltage is 230V with a standard frequency of 50Hz.

Transportation

Travel by plane, train or car meets international standards, but prices exceed U.S. averages. The number of in-country flights has been picking up and the train stations that dot the country provide sufficient access to nearly all cities. Nevertheless, cars are a very popular means of transportation, and Germany's famous highway system is extensive.

Geographic distances are relatively short when compared to the United States, but as Germany is much more densely populated than its European neighbors, it may take a little longer to travel the same distance in Germany than it may take in France or Scandinavia.

Within cities, public transportation as well as private cars, taxis, e-scooters, shared bikes and services like Uber are used (although not available in every city and at every hour). The public transit system which includes trains, trams and buses is generally very reliable and most locations have extensive connections and routes.

The Deutsche Bahn website is the easiest way to navigate means of public transit as well as long distance trains. Google Maps, and other such search engine maps, often offer public transit options when searching for directions and show where the closest stops/stations are.

Language

German is the official language. In larger towns and cities, many people can communicate in English, particularly in business settings. German is also an official language in the neighboring countries Austria, Belgium, Liechtenstein, Luxembourg, and Switzerland.

Health

Good medical care is widely available. Doctors and hospitals may expect immediate payment in cash for health services from tourists and persons with no permanent address in Germany. Most doctors, hospitals and pharmacies do not accept credit cards.

The Department of State strongly urges Americans to consult with their medical insurance company prior to traveling abroad to confirm whether their policy applies overseas and if it will cover emergency expenses, such as a medical evacuation. U.S. medical insurance plans seldom cover health costs incurred outside the United States unless supplemental coverage is purchased. Therefore, the State Department recommends supplemental insurance to cover any medical issues including evacuation.

The State Department recommends being up to date on all vaccinations recommended by the U.S. Center for Disease Control and Prevention.

If traveling with prescription medication, check with German government regulations if the medication is legal in Germany, as it could cause issues in German customs.

The situation with COVID-19 can change rapidly. Travelers must keep abreast of any Coronavirus Entry Regulations when visiting Germany. You may need to complete a Digital Registration on Entry if you are arriving from a risk area.

Local time, business hours, and holidays:

Central European Time (CET):	UTC/GMT +1 hour
Central European Summer Time (CEST):	UTC/GMT +2 hours

There are many national holidays, some of which fall on different days depending on the year. German school holidays vary by state and year.

Business hours vary, but generally begin around **8am - 9am** and end around **4pm - 5pm**. Most businesses are closed on Sundays including most supermarkets and pharmacies.

Temporary Entry of Materials and Personal Belongings

When bringing professional equipment such as electronic goods, cameras, and musical instruments into Germany, we strongly recommend that you first contact the consulate or embassy in your area for customs

information. You might also want to consider purchasing an ATA Carnet. The ATA Carnet, which allows for the temporary, duty-free entry of goods into over 50 countries, is issued by the United States Council for International Business by appointment of the U.S. Customs Service.

More details on entry and exit restrictions for individuals and businesses can be found on the website of the German customs office.

Investment Climate Statements (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.

As Europe's largest economy, Germany is a major destination for foreign direct investment (FDI) and has accumulated a vast stock of FDI over time. Germany is consistently ranked as one of the most attractive investment destinations based on its stable legal environment, reliable infrastructure, highly skilled workforce, positive social climate, and world-class research and development.

Foreign investment in Germany mainly originates from other European countries, the United States, and Japan, although FDI from emerging economies (and China) has grown over 2015-2018 from low levels. The United States is the leading source of non-European FDI in Germany.

The German government continues to strengthen provisions for national security screening of inward investment in reaction to an increasing number of high-risk acquisitions of German companies by foreign investors in recent years, particularly from China. In 2018, the government lowered the threshold for the screening of investments, allowing authorities to screen acquisitions by foreign entities of at least 10 percent of voting rights of German companies that operate or provide services related to critical infrastructure. The amendment also added media companies to the list of sensitive businesses.

Further amendments enacted in 2020 to implement the 2019 EU FDI Screening Regulation, which Germany strongly supported, include to:

a) facilitate a more pro-active screening based on "prospective impairment" of public order or security by an acquisition, rather than a de facto threat,
b) take into account the impact on other EU member states, and
c) formally suspend transactions during the screening process.

Furthermore, acquisitions by foreign government-owned or -funded entities will now trigger a review, and the healthcare industry will be considered a sensitive sector to which the stricter 10% threshold applies. A further

amendment, in force since May 2021, introduced a list of sensitive sectors and technologies (similar to the current list of critical infrastructure) including artificial intelligence, autonomous vehicles, specialized robots, semiconductors, additive manufacturing and quantum technology, among others. Foreign investors who seek to acquire at least 10% of voting rights of a German company in one of those fields would be required to notify the government and potentially become subject to an investment review.

German legal, regulatory, and accounting systems can be complex but are generally transparent and consistent with developed-market norms. Businesses operate within a well-regulated, albeit relatively high-cost, environment. Foreign and domestic investors are treated equally when it comes to investment incentives or the establishment and protection of real and intellectual property. Foreign investors can rely on the German legal system to enforce laws and contracts; at the same time, this system requires investors to closely track their legal obligations. New investors should ensure they have the necessary legal expertise, either in-house or outside counsel, to meet all national and EU regulations.

German authorities are committed to fighting money laundering and corruption. The government promotes responsible business conduct and German SMEs are aware of the need for due diligence.

Political Environment

The Department of State provides background information on the political and economic environment of Germany.