



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

# U.S. Country Commercial Guides



Germany  
2020

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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 (24.7%) of the European Union's GDP in 2019. Germany is also the United States' largest European trading partner and the fifth-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, the Hannover Fair, Automechanika, and the ITB Tourism Show, although it should be noted that most trade fairs for 2020 have been canceled or rescheduled due to the COVID-19 pandemic. 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, Germany weathered the COVID-19 pandemic's devastating economic effects better than any of its EU neighbors thanks in large part to its fiscal austerity, a record-breaking current account surplus (almost \$300 billion in 2019), and its ability to implement flexible short-term work schemes that kept unemployment at only 4.5% in July 2020. The GDP drop of 10.1% in Q2 2020 was the sharpest decrease since 1970 and more than twice the drop during the 2008/2009 financial crisis.

Demographic changes and resulting labor bottlenecks, regulation of the labor market, 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 competitiveness. Experts also fear that international trade tensions and the COVID pandemic global economic impact might substantially hurt the export-oriented German economy.

### **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. Zealous application of safety and environmental standards can 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 (although upward-trending in recent years). 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 the lowest food prices in Europe, and German citizens spend only about 12 % 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 U.S.) and presents good prospects for exporters of organic products (for more information, please see the GAIN report: [US Organic Food Exports will more than double in 2019](#)).
- Ageing 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 view 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 are willing to pay for quality increases.
- COVID-19 related lock-down measures fueled home cooking. The Ministry of Agriculture recently published a nutrition report indicating that 30 percent of Germans are cooking more than before the crisis. It remains to be seen if this trend persists once the pandemic is over.

## 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	2017	2018	2019	2020 (Estimated)
Total Local Production	0	0	0	0
Total Exports	1,194	1,282	1,262	1,500
Total Imports	3,261	3,246	3,218	3,500
Imports from the US	660	730	751	900
Total Market Size	2,067	1,964	1,956	2,000

Source: Trade Data Monitor query dated June 23, 2020

### 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, hake, cod, dogfish, shrimps, crabs, caviar substitutes, cuttlefish and squid, sea urchin, catfish, lobster and scallops. The two most important U.S. fishery export products to Germany are Alaska Pollock and salmon by value.

in million USD	2017	2018	2019	2020 (Estimated)
Total Local Production	2,400	2,534	2,513	2,600
Total Exports	2,571	2,629	2,391	2,400
Total Imports	5,653	5,875	5,647	5,800
Imports from the US	211	188	222	240
Total Market Size	5,482	5,780	5,769	6,000

Source: Trade Data Monitor query dated June 19, 2020

### Wine

Germany is the world's largest importer of wine by volume and third largest by value. In 2019, 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 78%. U.S. wines, together with other “new-world” wines, have developed an increasingly good reputation for quality in the German market. In 2019, the value of Germany's imports of U.S. wines totaled USD 49 million.

in million liters	2017	2018	2019	2020 (Estimated)
Total Local Production	746	1027	822	900
Total Exports	383	374	383	370
Total Imports	1,520	1,467	1,470	1,450
Imports from the US	36	25	30	32
Total Market Size	1883	2,120	1,909	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 June 23, 2020

## 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 foods are produced domestically and the EU requires pet foods 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	2017	2018	2019	2020 (Estimated)
Total Local Production	3,391	3,490	3,563	3,660
Total Exports	1,607	1,764	1,814	1,750
Total Imports	1,328	1,446	1,477	1,400
Imports from the U.S.	3	4	4	5
Total Market Size	3,670	3,790	3,900	4,010

Source: Trade Data Monitor query dated June 19, 2020

## Resources

### *Agricultural Attaché Reports*

Attaché reports provide information on market opportunities, crop conditions, new policy developments and information on the German 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 <https://gain.fas.usda.gov/#/search>. 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*



A number of U.S. agricultural commodity and other trade associations conduct market development programs in Germany. In some cases, these associations maintain field offices in Germany, while others may have a trade representative or public relations company representing their interests. Others may cover Germany from elsewhere in Europe or from offices in the U.S. The USDA-operated Market Access Program (MAP) and Foreign Market Development program (FMD) provide a portion of the funding for these association's 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 (<http://fas-europe.org/countries/germany/>).

#### *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 3-5, 2021

[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 17-20, 2021

[Prowein](#) – the leading wine show in Germany. It is held on an annual basis in Dusseldorf. Next show: March 21-23, 2021

[Interzoo](#) – the world leading pet industry exhibition. It is held every two years in Nuremberg. Next show: June 1-4, 2021

[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 9-13, 2021

[Fish International](#) – the leading fish and seafood show in Germany. It is held every two years in Bremen. Next show: February 13-15, 2022

## 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.)

	2017	2018	2019	2020 estimate
Local Production	45,188	47,240	45,899	30,381
Total Exports	33,439	35,902	35,432	22,786
Total Imports	18,824	18,621	21,139	12,500
Total Market Size	30,573	29,959	31,696	20,095
US Imports = US Market Share	6,860	8,917	10,147	6,596
EUR-USD Exchange Rate	1.1297	1.1810	1.1195	1.14 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 2019 U.S. aerospace exports to Germany amounted to \$10.15 billion. The trade surplus was USD 7.94 billion, representing a 209 percent increase over 2017 (USD 3.8 billion). These figures are in stark contrast to the European statistics stating exports of USD 3 billion. This is due to a different approach in assessing the sale of sub-systems and components. Aerospace & defense is complemented by homeland security & public safety, an industry spanning across 16 vertical markets with a projected global turnover of more than USD 400 billion in 2019. Both industries are grappling with the impact of the coronavirus pandemic. Commercial aviation is feeling it a lot stronger than defense and security segments though. In June 2020, domestic air traffic at Germany's airports was down by 91 percent, European traffic was down by 93.9 percent, and intercontinental traffic was down by 96%. Aerospace manufacturing is expected to decrease by 35 percent in 2020. Revenues in the security segment will shrink by 20 to 25 percent. During the rebound, U.S. manufacturers should be well-positioned to benefit from gradual market growth in Western Europe, especially Germany.

Germany 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), making it an ideal platform for U.S. companies to meet with their global partners and buyers. The major safety & security shows that are relevant for the German market are held in Essen (Security Essen), but also in London (DSEI) and Paris (Milipol).

### Leading Sub-Sectors

Germany has the third-largest aerospace & defense market in Europe, with 2019 revenues at USD 45.9 billion, following the UK at GBP 79 or USD 100.8 billion (including land defense systems) and France at USD 83.2 billion. Some three quarters or USD 35.4 billion of the German production are exported. France received a third of the exports with USD 12.4 billion. In large part, these exports are attributable to Airbus intra-company trade as part of their geographically dispersed production model with several major sites in Germany and France. The German homeland security & public safety market amounted to USD 20.3 billion in 2017.

This figure was published at the "Security Essen" trade show in August 2018. Updated figures are not available at the time of this writing. It is safe to assume that the industry saw modest but steady growth until 2020, mostly due to ongoing upgrades of the German internal security and migration enforcement infrastructure and an increased need for security services. The security services market makes up 50 percent of the overall market and grew by 4.3 percent from EUR 8.76 or USD 10.34 billion to EUR 9.14 USD 10.23 billion in 2019.

Aerospace is a German Government priority. 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 “2018 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, especially with regards to climate, noise and environmental protection. Moreover, BMWi has initiated the 6<sup>th</sup> iteration of the Aerospace Research Program (LuFo)—a grant program for aerospace research and technology projects—in the fall of 2018. In May 2020, the German government agreed a EUR 9 billion (USD 10,26 billion) bailout package for German flag carrier Lufthansa, turning the German government into the single largest shareholder in Europe’s second-largest airline. This measure mainly helps to stabilize the German air transport industry. Aerospace manufacturing relies on the recovery of the global air transport industry. 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 Bundeswehr’s Federal Office of Equipment, Information Technology and In-Service Support (BAAINBw) in Koblenz, and following the latest aerospace, defense and security policy developments and discussions in Germany. On an international level, we will gain insight 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 a number of 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; anti-submarine warfare (ASW) / anti-surface warfare (ASuW) helicopters for the German Navy; exo-atmospheric engagement systems for German F124 frigates; Search and Rescue (SAR) helicopters for the German Federal Armed Forces (Bundeswehr); heavy lift helicopters for the German Army; 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; integrated air and missile defense system (TLVS) for the Bundeswehr; large twin-engine transport helicopters for the German Federal Police.

#### **Web Resources**

##### *Trade Events*

- [Aviation Forum](#), Hamburg, November 17-18, 2020
- [Aircraft Interiors Expo](#), Hamburg, April 13-15, 2021
- [AERO](#), Friedrichshafen, April 21-24, 2021
- [DSEI](#), London, September 14-17, 2021
- [inter airport Europe](#), Munich, November 9-12, 2021
- [ILA Berlin](#), Berlin, May 11-15, 2022
- [Security Essen](#), Essen, September 20-23, 2022

*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)

[German Helicopter Association](#) (DHV)

## 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 in need of federal German investment.

The [OPC Foundation](#) (Open Platform Communications) is cooperating with the key German Association, the [VDMA](#) (German Mechanical Engineering Industry Association). In June 2016, these two parties signed an MOU to build an international standards structure 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 has been set up. UMATI means (universal machine technology interface). 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 Industrie 4.0, agreed to collaborate for the benefit of interoperability of systems from the different domains. In Germany, the relevant association, 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 the discussions.

### Leading Sub-Sectors

Advanced Manufacturing is believed to provide the best export potential for industries such as Machine Tools/General Industrial Equipment, Robotics, Information and Communication Technology, Process Control Instrumentation and Electronics Industry Production Equipment, Additive Manufacturing and Advanced Materials for the next five to ten years. Through 2025, 84 percent of German manufacturers plan to invest EUR 10 billion per year into smart manufacturing technologies, i.e. the automotive industry about 1.2 bn per year, machinery & equipment and plant engineering and construction 1.5 bn, electronics and microelectronics industry about 817 million per year, or the metal working industry 424m per year. Today, 75% of the German companies in most industries have implemented digital solutions, and 15 million people are directly and indirectly employed in the advanced manufacturing industries in Germany.

### Robotics and Automation

Germany is the fifth largest robot market in the world with about 20,000 industrial robots utilized in various industries each year. In 2018 the number of installations reached a new peak with 26,723 units being installed, accounting for an increase of 26 percent compared to 2017. The main industries are automotive, electrical and electronics, metal working, chemical rubber and plastics, logistics, medical, and the food industry. Please note that the 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 EUR 15.1 billion in 2018. Sales in all three segments accumulated are expected to decline by 5 percent in 2019 to EUR 14.3 billion, followed by an additional decrease of 10 percent in 2020 with a forecast turnover of EUR 12.8 billion. Robotics is currently forecasting a decrease of 3 percent. However, experts predict an average increase of 12 percent annually between 2020 and 2022, when the economic situation has overcome the COVID-19 crisis. New data will be available in September 2020.

Considering the robot density (robots' utilization per 10,000 worker) Germany ranks 3<sup>rd</sup> in the world with 322 in 2018, behind Korea (710) and, Singapore (658). The USA ranks 7<sup>th</sup> with 200, China is 21<sup>st</sup> (97 estimated).

Future topics 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.

## **Additive Manufacturing and Advanced Materials**

Germany is home to Europe's largest advanced materials market. As of right now the growth rates are hampered by COVID19. It is expected that the sectors will gain momentum instantly as soon as the pandemic is contained by a vaccine. The strong growth of Germany's high-tech industries requires appropriate materials. Depending on the material, growth rates can amount to 10 -15 percent annually. Among the materials sectors with the strongest market potential are composites and particularly additive manufacturing. Formnext, the major European additive manufacturing trade fair, reached a new floor space and visitor record for their show in November 2019. This year, Formnext is scheduled to take place in Frankfurt, November 10-13, 2020. It is planned as a hybrid event consisting of an exhibit as well as virtual events. The German chemicals and pharmaceutical industry achieved annual sales of EUR 198.2 billion in 2019 which would be a decrease of 2.3% compared to 202.9 bn in 2018. (Source: Destatis, VCI). In 2021, the Germany/DACH country focused Fakuma plastics show will take place in Friedrichshafen, October 12-16.

## **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 17 billion in 2019 (\$ 9.4 billion). Imports from the USA have been about EUR 134.9 million (\$153.8 million) for machines and equipment. The capacity utilization was at about 88.5 percent in 2019, according the German machine tool association. The German market consumption is about EUR 10.7 billion (\$12.3 billion).

Germany's best 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 German precision tools industry - whose most important partner is the USA with more than EUR 655 million imports - are similar with a generated increase of 7 percent in 2018 up to EUR 11.6 billion and expected production of EUR 11.7 billion in 2019.

Trends are high-performance processes, Industrie 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.

### **Sensors and Measuring Technology:**

Sensors and measurement technology are another growth subsector. In 2019, the annual turnover of all market players was estimated of EUR 35 billion. 2,300 companies and institutes employed about 250,000 people. In 2017 and 2018, we have seen growth rates of 9% and 10%, whereas the market in 2019 stagnated by -1%. The export quota is 70%. 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. The German industry expects further growth opportunity 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.

## Resources

### *Trade Events*

- [Formnext](#), Frankfurt, November 10-13, 2020
- [SPS](#), Nuremberg, November 24-26, 2020
- [Automatica](#), Munich, December 8-11, 2020
- [Hannover Fair](#), April 12-16, 2021
- [Sensor & Test](#), Nuremberg, May 4-6, 2021
- [Laser World of Photonics](#), Munich, June 21-24, 2021
- [Motek](#), Stuttgart, October 5-8, 2021
- [productronica](#), Munich, November 16-19, 2021
- [EMO](#), Hannover, September 16-21, 2023

### *German Organizations:*

- [Bitkom](#)
- [Federation of German Scientists](#)
- [Verein Deutscher Werkzeugmaschinenfabriken \(VDW\)](#)
- [VDMA](#)
- [ZVEI](#)
- [AMA Association for Sensors and Measurement](#)

### *U.S. Associations:*

- [AIA – Advancing Vision + Imaging](#)
- [Association for Advancing Automation \(A3\)](#)
- [Association for Motorizing Technology \(AMT\)](#)
- [International Federation of Robotics \(IFR\)](#)
- [Industrial Internet Consortium \(IIC\)](#)
- [Motion Control & Motor Association \(MCMA\)](#)
- [National Tooling And Machining Association \(NTMA\)](#)
- [OPC Foundation](#)
- [Robotic Industries Association \(RIA\)](#)

## Healthcare and Medical Technology

### Overview

Germany has a very robust and well-established medical equipment market. Brands such as Siemens, Carl Zeiss and Draegerwerk were founded at the end of the 19<sup>th</sup> 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 ranked no. 1 in Commerce's [Medical Device Top Market Report](#) and still is one of the most lucrative healthcare markets worldwide.

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 scheduled to launch on Jan. 1, 2021, also has a focus on health and health sector related R&D and innovation. Projects will focus on conquering cancer; smart health and 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. On the downside, the German healthcare system, because of its decentralized and self-governing structure, is somewhat 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 a number of 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 16 million medical-related jobs, with about \$2.7 trillion in profits annually, according to U.S. Bureau of Labor Statistics. Roughly 90 percent of the over 7,000 medical device manufacturers are often export-ready SMEs, and many of the world's largest medical device manufacturers such as GE Healthcare, Medtronic, 3M, Abbott, Thermo Fisher are U.S.-based. Germany is Europe's largest market for medical devices, accounting for roughly \$37 billion annually, or 27.1 percent of the European market total. 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 a commitment to a high-quality health system. Within the EU, Germany is the largest importer as well as exporter of medical devices (source: Medtech Europe, Facts & Figures 2020). All major U.S. suppliers, such as GE Healthcare, Johnson & Johnson; Becton Dickinson; Abbott; Abbvie; ThermoFisher Scientific; Stryker; Zimmer; 3M; McKesson; Cardinal Health; Henry Schein; and Medline, to name a few, have subsidiaries in Germany. U.S. medical device exporters continue to hold a 35-40 percent share of the German import market.

Germany has a strong healthcare system, especially with regards to infrastructure, hospital beds and trained staff. In 2018, there were 498,400 beds in 1,925 hospitals (around 552 public hospitals, 652 non-profit and 721 private hospitals); 1,142 rehabilitation centers; and 19,075 pharmacies (source: [www.statista.de](http://www.statista.de)). Well-established infrastructure makes the healthcare industry the largest employer in Germany with currently 5.6 million employees (source: [Health Ministry](#)), or under a broader definition of the [German Economics Ministry](#), 7.6 million, 16.6% of the labor market total. One out of six jobs in Germany is linked to the healthcare sector, which generates an economic footprint of \$775 billion (\$429 billion attributed direct), or roughly 12 percent of Germany's gross natural product; and with \$150 billion, contributes 8.4 percent to Germany's export total (source: BMWi). The German medical device market grew by 4.1 percent in 2018, and 4.0 percent in 2019, and is expected to continue with 4-6 percent growth rates through 2021 (BVMed estimate), as the health economy is digitalized and the double digit investment backlog in the hospital market is attacked. Business Monitor analysts even estimate the German medical devices market to grow a CAGR of 7.1% between 2018-2023.

### Response to Covid-19

The unforeseeable coronavirus outbreak, COVID-19, has affected the medtech industry in Germany in multiple ways, particularly as listed below.

- The start date of the Medical Device Regulation has been postponed by 12 months to May 26, 2021. Note, the In-Vitro Medical Devices Regulation application date, May 26, 2022 to date remains unaffected.



- On April 3, 2020, the EU Commission announced temporary suspension of custom duties and VAT for medical equipment in order to aid EU Member States in receiving necessary protective equipment and medical devices including masks, protective gear, testing kits, ventilators, and other medical equipment. Tariffs will be waived for four months with a possibility for further extension.
- The EU Commission has published guidance in order 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 the prevention of shortages.
- Medical and non-medtech related enterprises have redirected productions to meet the surging demand for personal protective equipment and vaccines.
- The market saw new cross-tech market entrants, such as automotive and general industrial manufacturers, general textile manufacturers and general online platform providers such as Amazon and Alibaba, entering the health technology markets with Covid-19 products and solutions and set to stay in the healthcare arena, disrupting the previously rather consolidated market with new players and business models.
- Major medical/digital health/biotech trade shows have been postponed, converted into virtual format or cancelled.

### Market Entry and Best Practices

The German market for medical devices is regulated by German and European Union (EU) directives, standards, and safety regulations. The EU Medical Device Regulation (MDR), with increased testing, certification and compliance requirements, has been postponed by a year to take effect on May 26, 2021, as a result of the Covid-19 pandemic and industry pressure. The complementary In Vitro Diagnostic Regulation will come into effect in 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 Resource Guide](#).

Germany hosts the world's largest annual HCT trade show, MEDICA, making Germany 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, converge every year for the 4-day long MEDICA trade show to sell to Europe and the rest of the world.

*The German Medical Equipment Market 2018-2021 (USD billion)*

	2018	2019	2020 (proj.)	2021 (proj.)
Market Size	33.2	35.0	36.9	39.0
Local Production	34.9	37.6	40.5	43.6
Imports	19.9	20.2	20.5	20.8
Exports	21.6	22.8	24.1	25.4
Imports from the U.S.	4.3	4.9	5	5.1

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)

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: Under the current German EU Council presidency, July 1-December 31, 2020**, the German Health Ministry and its agency, Health Innovation Hub ([www.hih-2025.de/en/](http://www.hih-2025.de/en/)), are ambitiously implementing the digital care law 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 talking online applications for DiGAs and once approved, 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 and a mandatory right of every citizen as of January 1, 2021. 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 here. These developments 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 \$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 ageing society (with significant share of chronic disease), rollout of e-health patient portals by public health plan providers and high Internet and mobile phone penetration, make Germany a strong HealthIT market and offers valuable potential to specialty solution providers. The digital health ecosystem in Germany will be driven by: Cloud computing solutions; Artificial Intelligence (AI), Robotics, Sensors, 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. Costs associated with the purchase of the SNOMED CT license will amount to approximately 1.6 million Euros in 2021, which will be administered by the Federal Institute for Drugs and Medical Devices (BfArM).

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, Cerner, Siemens Healthineers, to name a few.

**Pharmaceuticals:** The German pharmaceutical market was valued at USD 69.7 billion in 2019 and remains one of the most attractive worldwide over the coming years. It accounted for 15.5 percent of total health expenditures and 1.8 percent of GDP. Annual per capita spending is above average at \$835, with prescription medication contributing 69 percent to the total. According to market analysts, the German pharmaceutical market is expected to grow to by an average of 4.6 percent annually until 2022. 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 2018, the German pharmaceutical industry manufactured products worth \$41.9 billion, an increase of 18% over the previous year. Exports of pharmaceuticals increased by 10.3 percent, generating sales of \$96.5 billion, while imports were up by 8.1 percent to \$66 billion in the same period.

**Biopharmaceuticals:** Sales of biopharmaceuticals in 2019 (pharmacies and hospital market) increased by 13 percent to \$14.3 billion compared to 2018. The market share in the total pharmaceutical market rose from 27.1 percent to 28.7 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 2019, 686 dedicated\* biotechnology companies (+3 percent to 2018) generated sales of \$5.5 billion, a 10 percent growth over 2018. The number of employees in the biotech industry increased to 33,706, up 16 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 46% of overall industry sales. Of these, major players QIAGEN, Evotec, and BioNTech alone contributed 40 percent to the market sales total. R&D spending registered \$2 billion, an increase of 21 percent over 2018. Growth in spending was again attributable to the small number of listed companies (up 58 percent), while privately held firms recorded a minimal increase in R&D of 1 percent. Growth sectors in Germany’s biotech industry continue to focus on new drug development and diagnostics, such as early disease detection. In-vitro diagnostics are an important growth driver in the market, with more than two-thirds of all clinical diagnoses being made through IVDs. With more than \$2.3 billion 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-Westfalen; 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, BIO Convention, in the United States, with an official Germany pavilion, shows the commitment and close transatlantic ties in this health tech subsector.

(\*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.)

**Dental products:** Germany is Europe’s largest market for dental equipment valued at \$13.5 billion in 2019. Total sales of dental products from 200 mostly medium-sized member companies of the Association of German Dental Industry (VDDI) amounted to \$5.6 billion in 2019 (up 4.1 percent over 2018) and an export share of 63 percent with \$3.3 billion. These firms represent 85-90 percent of the German dental market and employ more than 21,300 people. 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. The 2018-2023 CAGR market growth is estimated at 6.0 percent by BMI analysts.

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 the upswing of Germany’s dental market is the growing 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 \$115 million for dental equipment and supplies, and \$50.5 million for dental laboratory products in 2019. Over 200 U.S. companies are actively exporting, with heavyweights Henry Schein, Danaher Corp. 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 \$124 million and an estimated 11 percent market share in 2019.

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) 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.

### **Policy Objectives and Challenges**

The Commercial Service is working to evaluate the broad impact of the German EU Council presidency 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 MED cluster 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. An International Patient Day event in 2021 will raise awareness for innovation-based U.S. patient care solutions.

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": [https://lnkd.in/eg\\_NiQK](https://lnkd.in/eg_NiQK)

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 Cancer Institute plans to promote the NIH's Cancer Institute's clinical study capabilities and resources to innovative German life science startups during a road show and virtual events in 2021. 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. Likewise, the formation of a U.S. Digital Health Forum by the U.S. Commercial Service in partnership with a major German digital health platform has opened the door to a number of U.S. digital health solution providers, who have forged 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 NRW 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 [www.trade.gov/germany](http://www.trade.gov/germany) to be added to a regular email of tender opportunities, or visit <http://ted.europa.eu/TED/main/HomePage.do>

## Resources

### *Trade Events*

[BIO International Convention](#), Boston, June 14-17, 2021

[HIMSS 20 – Health 2.0, Digital](#), September 7-11, 2020

[American Hospital Association Leadership Summit](#), Virtual Conference, September 14-16, 2020

[American Association for Clinical Chemistry: AACC Annual Meeting](#), Chicago, December 13-17, 2020

[Rehacare](#), Dusseldorf, October 6-9, 2021

[Expopharm](#), Dusseldorf, September 22-25, 2021

[The virtual MEDTECH Conference, On Demand](#): Sep 8-Oct 23, 2020; Livestream: Oct 5-7, 2020

[Bio-Europe](#), Digital, October 26-29, 2020

[Medica](#), Dusseldorf, November 16-19, 2020

[Analytica](#), Munich, October 19-22, 2020

[Greater New York Dental Meeting](#), New York, November 27 – December 2, 2020

[International Dental Show \(IDS\)](#), Cologne, March 9-13, 2021

[DMEA](#), Berlin, April 13-15, 2021

## Local Associations

[BVMED](#)

[ZVEI Health Pages](#)

[Spectaris](#)

[DKGEV](#)

[BVITG](#)

[BiM](#)

## Government Links

- [Federal Ministry of Health](#)
- [Federal Ministry of Education and Research](#)
- [Federal Institute for Drugs and Medical Devices \(Competent Authority\)](#)
- [Healthcare Procurement](#) and [Tenders](#)

[Private provider for tender information](#)

Government Health Plans:

[International Federation of Health Plans](#)

[Association of Public Health Plan Providers](#)

## ICT

### Overview

	2016	2017	2018	2019	2020 (Estimated)
Total Local Production	174.6	182.2	196.4	192.8	181.6
Total Exports	39.4	43.0	43.0	n/a	n/a
Total Imports	64.5	71.8	68.8	n/a	n/a
Imports from the U.S.	2.2	2.4	2.4	n/a	n/a
Total Market Size	199.7	211.0	221.8	n/a	n/a
Exchange Rates	1.1069	1.1297	1.1810	1.140	1.1104

(in Billion USD | total market size = (total local production + imports) – exports)

Germany has one of the largest ICT markets in the world and the single largest software market in Europe with 90,331 IT companies and 990,000 employees in 2019. 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 SME's in the market. According to the German Association for Information Technology, Bitkom, the subsector market sizes in 2019 (in USD billion) were: IT-hardware 29.9, software 29.8, IT-services 44.1, consumer electronics 10.0, telecommunication devices 12.8 and telecommunication infrastructure 8.0. Bitkom expects a decrease in the total local production in 2020 as a result of the ongoing worldwide health crisis across all ICT sectors.

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 IFA Berlin, IT-SA, Gamescom or Embedded World. In 2020, several trade shows have been canceled, postponed or will take place as a virtual only event as a result 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 (German Federal Economics Ministry), 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, 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
- Health IT
- Artificial Intelligence
- Smart Social Business Platforms
- Big Data (hardware, infrastructure, services, database and analytics technologies)
- Enterprise Resource Planning (industry-specific ERP solutions)

## **Resources**

### **Trade events**

#### [Gamescom](#)

Interactive games and entertainment

Digital only in 2020, Cologne, August 27-30, 2020

#### [IFA Berlin](#)

Consumer electronics and home appliances

Digital with smaller physical live events in 2020, Berlin, September 3 – 5, 2020

#### [it-sa](#)

IT security: cloud, mobile & cyber security, data & network security

Nuremberg, October 12-14, 2021

#### [ISE-Europe](#)

AV and integrated system

Barcelona, February 2-5, 2021

#### [InfoSecurity Europe](#)

Information security

London, June 8-10, 2021

#### [Embedded Word](#)

Embedded Systems

Nuremberg, March 2-4, 2021

#### [AngaCom](#)

Telecommunications

Cologne, June 8-10, 2021

### **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

[German Regulatory Authority](#), Ensures compliance with the Telecommunications Act (TKG), Postal Act (PostG) and Energy Act (EnWG) and their respective ordinances

**Trade Publications**

[Computer Woche](#), Weekly newspaper for CIOs and IT-Managers about computers and information technology

[CRN](#), Computer Reseller News magazine, Channel Partner, Portal for Technology trends, Channel-News and strategic advice for computer retailers, ICT dealers and distributors

[EITO](#), The European IT Observatory, offering reports on the ICT and Consumer Electronics markets in Europe and Internationally



## 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.

Digital transformation offers opportunities for moving towards sustainability and promotes resource-friendly, needs-based solutions for meeting the key challenges of integrated urban development and sustainability.

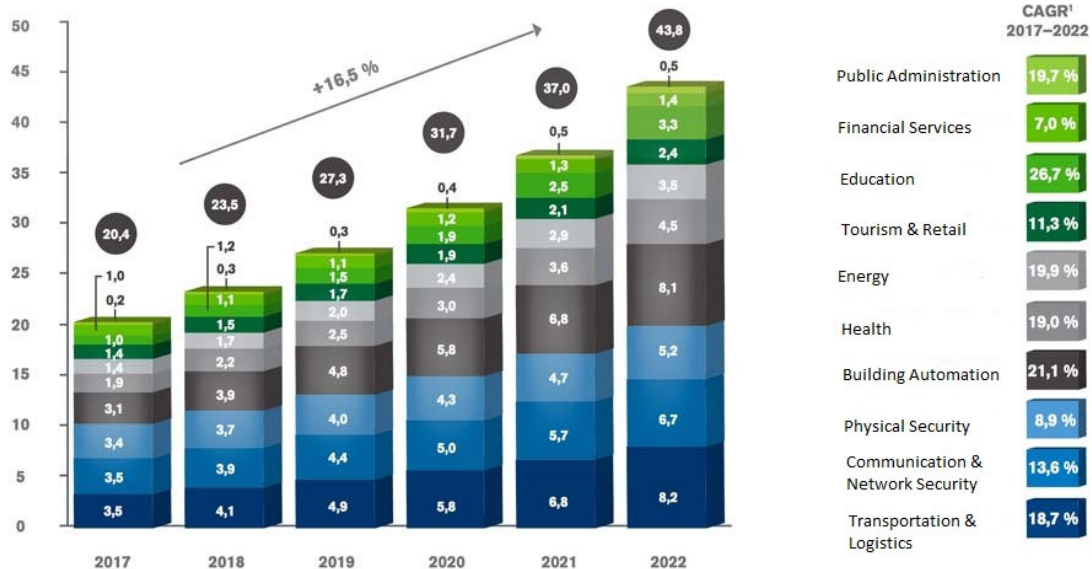
Germany is actively positioning itself as a lead provider of complete smart technology solutions and supported by the government, local authorities are launching their own smart city projects jointly with the private sector, utility companies and universities. To establish guidelines for future German city development, the German Federal Institute for Research on Building, Urban Affairs and Spatial Development (BBSR) published a Smart City Charta on how to make digital transformation at the local level more sustainable.

However, only about one third of the two hundred largest German cities use smart information and communication technology in their urban development to become *Smart Cities* according to a study of the German Institute for Urban Studies.

With 74% 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.



**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)

### 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. However, a competitive marketplace is a sign that there is demand. 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 11-16, 2021
  - [ISH](#), Frankfurt, March 22-26, 2021
  - [Chillventa](#), Nuremberg, October 11-13, 2022
- Energy:
  - [E-world of energy and water](#), Essen, February 9-11, 2021
  - [Energy Storage Europe](#), March 18-21, 2021
  - [Hannover Messe](#), Hannover, April 12-16, 2021
- Environmental technology:
  - [IFAT Munich](#), Munich, May 30-June 3, 2022
- Management:
  - [9<sup>th</sup> European Conference on sustainable cities & towns](#), September 30-October 2nd, Mannheim, 2020 (virtual event)
  - [Intergeo](#), Stuttgart, October 13-15, 2020 (virtual event)
- Transportation/Logistics
  - [IAA Munich](#), September 7-12, 2021
  - [Innotrans](#), Berlin, April 27-30, 2021
- Ports:
  - [SMM Hamburg](#), Hamburg, February 2-5, 2021 (smart ports, fully automated ports)

### **Resources**

[Federal Ministry of the Interior, Building and Community](#)

[Federal Office for Building and Regional Planning](#)

[Smart Cities Council](#)

[GTAI Germany Trad & 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 zealously 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.

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 Single Administrative Document

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

The Summary Declaration is filed by:

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

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

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

More information on the SAD can be found at:

[Single Administration Document](#)

[EU Customs Code](#)

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

### **Economic Operator Registration and Identification (EORI)**

Since July 1, 2009, all companies established outside of the EU are required to have an EORI number if they wish to lodge a customs declaration or an Entry/Exit Summary declaration. All U.S. companies should use this number for their customs clearances. An EORI number must be formally requested from the customs authorities of the specific member state to which the company first exports. Member state customs authorities may request additional documents to be submitted alongside a formal request for an EORI number. Once a company has received an EORI number, it can use it for exports to any of the 28 EU Member States. There is no single format for the EORI number. Once an operator holds an EORI number s/he can request the Authorized Economic Operator (AEO: see below under “MRA”) status, which can give quicker access to certain simplified customs procedures.

More information about the EORI number can be found at [Economic Operator Identification and Registration](#)

### **U.S. – EU Customs Cooperation**

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

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

and recognition. Under the revised Union Customs Code, in order for an operator to make use of certain customs simplifications, the authorization of AEO becomes mandatory.

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

[Additional Information on the Decision](#)

## **Labeling and Marking Requirements**

### *Summary*

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

### *Introduction*

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

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

Please refer to the Country Commercial Guide for the European Union for more details on labeling and marking.

## **U.S. Export Controls**

The United States imposes export controls to protect national security interests and promote foreign policy objectives related to dual-use goods through implementation of the Export Administration Regulations (EAR). The Bureau of Industry and Security (BIS) is comprised of two elements: Export Administration (EA), which is responsible for processing license applications, counselling exporters, and drafting and publishing changes to the [Export Administration Regulations](#); and Export Enforcement (EE), which is responsible for the enforcement of the EAR. BIS works closely with U.S. embassies, foreign governments, industry, and trade associations to ensure that exports from the United States are secure and comply with the EAR. BIS officials conduct site visits, known as End-Use Checks (EUCs), globally with end-users, consignees, and/or other parties to transactions involving items subject to the EAR to verify compliance.

An EUC is an on-site verification of a non-U.S. party to a transaction to determine whether the party is a reliable recipient of U.S. items. EUCs are conducted as part of BIS's licensing process, as well as its compliance program, to determine if items were exported in accordance with a valid BIS authorization or otherwise consistent with the EAR. Specifically, an EUC verifies the *bona fides* of transactions subject to the EAR, to include: confirming the legitimacy and reliability of the end use and end user; monitoring compliance with license conditions; and ensuring items are used, re-exported or transferred (in-country) in accordance with the EAR. These checks might be completed prior to the export of items pursuant to a BIS export license in the form of a Pre-License Check (PLC), or following an export from the U.S. during a Post-Shipment Verification (PSV).

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

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

The EAR is available on the [BIS website](#) and on the [e-CFR](#) (Electronic Code of Federal Regulations) 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 are encouraged to classify their items prior to export, as well as consult the CSL to determine if any parties to the transaction may be subject to specific license requirements.

Notify

### **Temporary Entry**

Specific information on the [ATA Carnet Customs](#) procedure used for temporary importation, transit and temporary admission of goods designed for specific purposes, duty-free and tax-free (such as professional equipment for presentations or trade fairs) can be found under the ATA Carnet website of the Department of Commerce's International Trade Administration.

The German customs office provides information on [Temporary admission](#).

### **Prohibited and Restricted Imports**

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

*CITES Convention on International Trade of Endangered Species*

*PROHI Import Suspension*

*RSTR Import Restriction*

For information on how to access the TARIC, see the Import Requirements and Documentation Section.

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

The Union Customs Code (UCC) was adopted in 2013 and its substantive provisions apply from May 1, 2016. It replaced 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 the Delegated Regulation (EU) 2015/2446, the Delegated Regulation (EU) 2016/341 and the Implementing Regulation (EU) 2015/2447.

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

Key Link: [Homepage of Customs and Taxation Union Directorate \(TAXUD\) Website](#)

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

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

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

These objectives are met using a single instrument - the rules on customs value.

The EU applies an internationally accepted concept of '[customs value](#)'.

The value of imported goods is one of three 'elements of taxation' that provides the basis for assessment of the customs debt, which is the technical term for the amount of duty that has to be paid, the other ones being the origin of the goods and the customs tariff.

Key Links: [Customs Procedures](#)  
[German customs](#)

## Standards for Trade

Products tested and certified in the United States to U.S. regulations and standards are likely to have to be retested and re-certified to EU requirements as a result of the EU's different approach to the protection of the health and safety of consumers and the environment.

While harmonization of EU legislation can facilitate access to the EU Single Market, manufacturers should be aware that regulations (mandatory) and technical standards (voluntary) might also function as barriers to trade if U.S.

standards are different from those of the European Union which is often the case. For more on how the EU standards and regulatory system functions as a barrier to trade see page 177 in the [National Trade Estimate](#).

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

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

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

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

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

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

Key Link: [Standardization Policy](#)



## Testing, Inspection and Certification

### Conformity Assessment

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

Modules vary in complexity. For example, Module A permits the manufacturer to assume total responsibility for conformity assessment. If the product is manufactured to Harmonized Standards, and if the risk is not unusually high (as in most machinery, for example), the manufacturer may rely on internal manufacturing checks. He or she compiles a Technical File, issues a Declaration of Conformity to the appropriate directives, and if appropriate, standards, applies the CE marking, and places the product on the market. Modules for higher risk products, for example, a medical device, on the other hand, could call for a type examination of the product plus a production quality assurance system that conforms to the standard. Another choice for a medical device manufacturer would be a complete quality assurance program that would conform to ISO 9001 (or EN 29001) for example. These later modules may call for the involvement of third party testing and assessment for a Declaration of Conformity. In Europe, these third parties are designated by member states' authorities, accepted by the European Commission, and are called Notified Bodies. Each directive provides the module choices available, but there are no choices beyond the modules specified.

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

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

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

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

### Publication of technical regulations

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

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

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

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

### **Agricultural Standards**

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

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

Contact Information for Standards

[U.S. Mission to the EU](#)

[Flavie.Guerin@trade.gov](mailto:Flavie.Guerin@trade.gov)

Tel: +32 2 811 4817

[National Institute of Standard & Technology](#)

### **Trade Agreements**

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

U.S. – EU Trade Negotiations

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

[USTR U.S. – EU Trade Negotiations](#)

### **Licensing Requirements for Professional Services**

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

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

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

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

- Recognition of [professional qualifications](#) obtained in one Member State for the purposes of access and pursuit of [regulated professions](#) in another Member State is subject to Directive 2005/36.

- Recognition of qualifications for academic purposes in the higher education sector, including school-leaving certificates is subject to the *Lisbon Recognition Convention*. The ENIC-NARIC network provides advice on (cross-border) recognition of these qualifications.

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

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

## **Selling US Products and Services**

### **Distribution & Sales Channels**

#### **Overview**

Distribution channels are varied and similar to the United States. There are certain restrictions, however, concerning multi-level networking systems, i.e., so-called snowball or pyramid distribution systems. More information can be found [here](#).

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

Key Link: [Self Employed Commercial Agents](#)

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

Key Link: [European Law](#)

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

Key Link: [Late Payments](#)

Companies' agents and distributors can take advantage of the European Ombudsman when victim of inefficient management by an EU institution or body. Complaints can be made to the European Ombudsman only by businesses and other bodies with registered offices in the EU. The Ombudsman can act upon these complaints by investigating cases in which EU institutions fail to act in accordance with the law, fail to respect the principles of good administration, or violate fundamental rights. In addition, SOLVIT, a network of national centers, offers online assistance to citizens and businesses who encounter problems with transactions within the borders of the single market.

Key Links:

[European Ombudsman](#)

[EU Solvit](#)

#### **Establishing 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 EU, but these laws are fairly broad and generally do not constrain the competitive position of U.S. businesses. The potential franchiser should take care to look not only at the EU regulations, but also at the local laws concerning franchising. More information on specific legislation can be found on the website of the [European Franchise Federation](#).

### *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. In Germany, the concept and the market demand for the relevant product and/or service matters.

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:

- [Deutsche Unternehmerboerse](#) (in German) – print and online, advertising investment opportunities
- [Franchise Pool International](#) (FPI) (in English and German) – consultant pool with listing of franchises
- [FranchisePORTAL](#) (in German) – virtual franchise fair
- [Punkt Franchise](#) (in English and 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 EU has yet to adopt legislation harmonizing the direct selling of consumer products. However, there is a wide range of EU legislation that impacts the direct marketing sector. Compliance requirements are elevated for marketing and sales to private consumers. Companies need to focus on the clarity and completeness of the information they provide to consumers prior to purchase and on their approaches to collecting and using customer data. The following gives a brief overview of the most important provisions flowing from EU-wide rules on distance-selling and on-line commerce. In addition, it is important for exporters relying on a direct-selling business model to ensure they comply with member state requirements.

### *Processing Customer Data*

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

### *Distance Selling Rules*

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

The Commission has a [useful tool to learn about consumer rules](#).

More information: [Consumer Rights Directive](#)

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

More information: [Digital Contact Rules](#)

### *Alternative Dispute Resolution*

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

### *Key Links*

[Consumer Affairs Homepage](#)

[Consumer Rights](#)

### *Distance Selling of Financial Services*

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

Key Link: [Distance Marketing](#)

### *Direct Marketing over the Internet*

The e-commerce Directive (2000/31/EC) imposes certain specific requirements connected to the direct marketing business. Promotional offers must not mislead customers and the terms that must be met to qualify for them have to be clear and easily accessible. The Directive stipulates that marketing e-mails must be identified as such to the recipient and requires that companies targeting customers on-line must regularly consult national opt-out registers where they exist. When an order is placed, the service provider must acknowledge receipt quickly and by electronic means, although the Directive does not attribute any legal effect to the placing of an order or its acknowledgment; this is a matter for national law. Vendors of electronically supplied services (such as software, which the EU considers a service and not a good) must also collect value added tax (see Electronic Commerce section below). The European Commission has performed a stakeholder’s consultation and the e-commerce Directive could be revised. Please see the Data Privacy Section.

### *Germany*

Most German enterprises use direct marketing to sell their products and services. The most frequently used formats are email and online marketing, telephone marketing, direct mail and inserts in publications. 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 ranks among the most difficult jobs 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 as a result of e-commerce. The German express delivery industry shipped more 3.6 billion packages in 2019. An increasing number of companies incl. Amazon and Decathlon (sporting goods retailer) also 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.

### **eCommerce in Germany**

Germany has one of the largest e-commerce markets in Europe. The number of e-commerce consumers, internet penetration and average spent per year is above the European average. By the end of 2020, total sales are estimated to have reached USD 105.2 billion, which is a 10% growth compared to 2019. The estimated average spent online per person per year is USD 867. In 2020, Germany had an online population of 60.12 million people who were aged 15 and older. Strict lockdown measures throughout March and April 2020, resulting from the global healthcare crisis, have led many German consumers to increase online purchases, or to buy goods like groceries and drugs online for the very first time.

German consumers are rather risk-averse and expect high quality products. By law, consumers have the right to return online purchases within 14 days without explanation, and there is indeed a high product return rate. Websites and online stores are expected to be in German language.

The most popular products purchased online include clothing, electronics, tickets and books. 87% of the German population uses social media, with Facebook, Youtube and Instagram being the most popular platforms, thereby rendering social media a valuable marketing tool.

## **Popular eCommerce Sites**

The most popular website used in Germany is Amazon.com with 578.80 million monthly visitors. It is followed by eBay (229.32 Million), eBay Kleinanzeigen (148.78 Million), Otto (57.27 Million), Idealo (55.70 Million), MediaMarkt (33.47 Million), Lidl (26.84 Million), Zalando (23.96 Million), Thomann (22.59 Million) and Saturn with 20.59 Million monthly visitors.

## **Online Payment**

Data from the *Ecommerce Foundation* shows that Paypal is the most popular method of online payment in Germany (52 percent of Internet users), followed by invoice (26 percent), debit or credit cards (12 percent), direct debiting (6 percent) and cash on delivery (1 percent). 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 own smartphones (nearly 80 percent). In 2019, retail sales conducted via mobile devices in Germany surpassed 40% of total e-commerce sales, with clothing, books, electronics and tickets being the most commonly purchased items. This growth is likely to continue as retailers improve their mobile websites and provide even 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 & 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.

It should be noted that many German Trade Fairs have been cancelled or postponed in 2020 as a result of the COVID pandemic. While trade fair organizers are determined to return to business as usual as soon as they can, additional cancellations or postponements of shows in 2020 and perhaps 2021 are possible and all US firms interested in exhibiting or attending shows in Germany should monitor the show websites closely for updates on their status.



## **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. The [German association of advertising agencies](#) can be found online.

There are numerous technical or specialized periodicals and websites that deal with all aspects of technology and doing business in Germany. In addition, Germany has a well-developed array of newspapers and magazines which offer the opportunity to gather information and advertise products and services.

## **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 & 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 at [USEU/FAS website](#) and in the [USDA Food and Agricultural Import Regulations and Standards EU 28 2017](#)

**Key Link:** [EU Register of Nutrition and Health Claims](#)

### **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 him and should not differ from the ingredients that they are intended to replace to such an extent that normal consumption would represent a nutritional disadvantage for the consumer. It is important to mention that the European Commission may decide, on its own initiative or upon a request by a Member State, by means of implementing acts (a sort of decree), whether or not a particular food falls within the definition of novel food. More information can be found on the Commission's website. Most provisions of this new Novel Foods Regulation 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](#).

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

### **Principal 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)

Zentralverband Elektrotechnik- und Elektronikindustrie e.V. (ZVEI)

(German Electrical and Electronic Manufacturers Association)

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 US 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. Critical industries for U.S. exporters are construction, furniture, paper and publishing. Default risk is somewhat higher for firms in unevenly performing eastern Germany. 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 available at <https://www.trade.gov/trade-finance-guide-quick-reference-us-exporters>

### **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 36,000 bank 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.

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, and increasing compliance costs as a result of new regulation and supervision.

Private banks control roughly 30% of the market, while publicly owned savings banks partially linked to state and local governments account for 50% 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 €1.3 trillion and €463.6 billion respectively (2019 figures). Commerzbank received €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 WGZBank in July 2016), followed by German branches of large international banks (UniCredit Bank or HVB, ING-Diba), development banks (KfW Group, NRW.Bank), 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 currently 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.

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. 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.

### **US Banks & Local Correspondent Banks**

#### [Bank of America](#)

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

#### [Citigroup Global Markets Germany](#)

Reuterweg 16, 60323 Frankfurt am Main, Germany  
Phone: +49-69-1366 0

#### [JP Morgan AG](#)

TaunusTurm, Taunustor 1, 60310 Frankfurt am Main, Germany  
Phone: +49.69.7124.1601

#### [Goldman Sachs](#)

Friedrich-Ebert-Anlage 49, 60308 Frankfurt am Main, Germany  
Phone: +49-69-7532 1000

#### [Merrill Lynch International](#)

Main Tower, Neue Mainzer Straße 52, 60311 Frankfurt am Main, Germany  
Phone: +49-69-5899 5000

## [Morgan Stanley](#)

Junghofstr. 13-15, 60311 Frankfurt am Main, Germany  
Phone: +49-69-2166-0

### **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 the Commerzbank, and several of the publicly-owned savings banks controlled by state and local governments (Landesbanken) located in northern Germany. The KfW Group includes KfW IPEX-Bank, which supports a consortia 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 (Förderbank), helps municipalities finance infrastructure. German insurers are pressing for regulatory changes to enable them to finance infrastructure projects.

### **Financing Web Resources**

[Trade Finance Guide: A Quick Reference for U.S. Exporters](#), published by the International Trade Administration's Industry & Analysis team

[Export-Import Bank of the United States](#)

[Country Limitation Schedule](#)

[OPIC](#)

[Trade and Development Agency](#)

[SBA's Office of International Trade](#)

[USDA Commodity Credit Corporation](#)

[U.S. Agency for International Development](#)

[European Bank for Reconstruction and Development](#) (EBRD)

[U.S. Commercial Service Liaison Office to the EBRD](#)

[KfW Bank Group](#)

[The German Bankers' Association](#)

[Federal Financial Supervisory Authority](#)

### **Protecting Intellectual Property**

#### **Protecting Your Intellectual Property in the EU:**

Several general principles are important for effective protection of intellectual property ("IP") rights in the EU. First, it is important to have an overall strategy to protect your IP. Second, IP may be protected differently in the EU than

in the United States. Third, rights must be registered and enforced in the EU under local laws. For example, your U.S. trademark, design, and patent registrations will not protect you in the EU without further registrations in the corresponding regional or local level.

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

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

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

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

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

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

## **IP Resources**

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

- For information about patent, trademark, or copyright issues -- including enforcement issues in the United States and other countries -- call the STOP! Hotline: **1-866-999-HALT** or visit [STOP Fakes](#)
- For more information about registering trademarks, designs and patents (both in the United States as well as in foreign countries), contact the [U.S. Patent and Trademark Office](#) (USPTO) at: **1-800-786-9199**
- For more information about registering copyrighted works in the United States, contact the [U.S. Copyright Office](#) at: **1-202-707-5959**.



- For more information about how to evaluate, protect, and enforce intellectual property rights and how these rights may be important for businesses, please visit the “Resources” section of the [STOPfakes website](#).
- For information on obtaining and enforcing intellectual property rights and market-specific IP Toolkits visit: [STOPfakes Business tools](#). The toolkits contain detailed information on protecting and enforcing IP in specific markets (e.g. [EU toolkit](#)) and also contain contact information for local IPR offices abroad and U.S. government officials available to assist SMEs.

For more information, please see the following article on [Protecting Intellectual Property](#), and [Stopfakes.gov](#) or contact contact ITA’s Office of Intellectual Property Rights Director, [Stevan Mitchell](#) at [Stevan.Mitchell@trade.gov](mailto:Stevan.Mitchell@trade.gov).

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

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

**WTO - World Trade Organization (based in Geneva, Switzerland)**

Deborah Lashley-Johnson, [deborah\\_e\\_lashley-johnson@ustr.eop.gov](mailto:deborah_e_lashley-johnson@ustr.eop.gov)

**WIPO - World Intellectual Property Organization (based in Geneva, Switzerland)**

Kristine Schlegelmilch, [SchlegK@state.gov](mailto:SchlegK@state.gov)

**European Union (based in Brussels, Belgium)**

Susan Wilson, [Susan.Wilson@trade.gov](mailto:Susan.Wilson@trade.gov)

For more information, contact ITA’s Office of Standards and Intellectual Property (OSIP) Director, [Stevan Mitchell](#) at [Stevan.Mitchell@trade.gov](mailto:Stevan.Mitchell@trade.gov).

**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.

**EU Legislation**

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

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

- [Directive 2014/24/EU](#) (replacing Directive 2004/18/EC) on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts applies to the general sector.
- [Directive 2014/25/EU](#) (replacing Directive 2004/17/EC) coordinates the procurement procedures of entities operating in the water, energy, transport, and postal services sectors.
- [Directive 2009/81/EC](#) on defense and sensitive security procurement. This Directive sets Community rules for the procurement of arms, munitions and war material (plus related works and services) for defense purposes, but also for the procurement of sensitive supplies, works and services for non-military security purposes.

- [Directive 2014/23/EU](#) on the award of concession contracts. A concession contract (either for the delivery of works or services) is conducted between a public authority and a private enterprise that gives the right to the company to build infrastructure and operate businesses that would normally fall within the jurisdiction of the public authority (e.g. highways).

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

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

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

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

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

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

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

### **Value Added Tax (VAT)**

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

The EU applies Value Added Tax (VAT) to sales by non-EU based companies of Electronically Supplied Services (ESS) to EU-based non-business customers. U.S. companies that are covered by the rule must collect and submit VAT to EU tax authorities. From 1 January 2015, all supplies of telecommunications, broadcasting and electronic services are taxable at the place where the customer resides. In the case of businesses this means either the country

where it is registered or the country where it has fixed premises receiving the service. In the case of consumers, it is where they are registered, have their permanent address, or usually live.

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

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

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

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

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

#### **Further information relating to VAT on ESS:**

[https://ec.europa.eu/taxation\\_customs/business/vat/telecommunications-broadcasting-electronic-services/](https://ec.europa.eu/taxation_customs/business/vat/telecommunications-broadcasting-electronic-services/)

#### *VAT in Germany*

The standard VAT rate in Germany is 19 percent (below the European average and temporary reduced to 16 percent until the end of 2020). A reduced 7 percent VAT (5 percent until the end of 2020) rate applies to some consumer goods and everyday services (food, newspapers, local public transport, hotel stays). Some services (such as bank and health services or community work) are VAT exempt.

Vendors who are not established in the European Union and who make sales that are subject to German VAT must register for tax purposes in Germany. The tax office Bonn-Innenstadt ([Service@FA-5205.fin-nrw.de](mailto:Service@FA-5205.fin-nrw.de)) is responsible for assessing and collecting VAT for U.S. vendors who are not established in Germany.

Under certain conditions international travelers can receive VAT refunds if they are not a resident of the European Union: [Tax-free shopping](#)

#### **Data Privacy and Protection**

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

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

A company that is not established in the Union may have to comply with the Regulation when processing personal data of EU and EEA residents (EEA countries include Norway, Lichtenstein and Iceland) and Switzerland:

- a) If the company offers goods or services to data subjects in the EU; or,
- b) If the company is monitoring data subjects' behavior taking place within the EU.

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

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

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

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

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

For more information:

[Full GDPR text](#)

[Official Press Release](#)

European Commission guidance:

[https://ec.europa.eu/info/law/law-topic/data-protection\\_en](https://ec.europa.eu/info/law/law-topic/data-protection_en)

[https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules\\_en](https://ec.europa.eu/commission/priorities/justice-and-fundamental-rights/data-protection/2018-reform-eu-data-protection-rules_en)

[https://edpb.europa.eu/edpb\\_en](https://edpb.europa.eu/edpb_en)

[https://edpb.europa.eu/our-work-tools/general-guidance/gdpr-guidelines-recommendations-best-practices\\_en](https://edpb.europa.eu/our-work-tools/general-guidance/gdpr-guidelines-recommendations-best-practices_en)

### *Transferring Customer Data to Countries outside the EU*

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

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

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

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

For more information:

[EU data protection authorities’ FAQs on data transfers to the U.S.](#)

*Important note:*

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

### The EU-U.S. Privacy Shield

On July 16, 2020, the Court of Justice of the European Union (CJEU) issued a [judgment](#) declaring as “invalid” the European Commission’s Decision (EU) 2016/1250 of July 12, 2016 on the adequacy of the protection provided by the EU-U.S. Privacy Shield. As a result of that decision, the EU-U.S. Privacy Shield Framework is no longer a valid mechanism to comply with EU data protection requirements when transferring personal data from the European Union to the United States. This decision does not relieve participants in the EU-U.S. Privacy Shield of their obligations under the EU-U.S. Privacy Shield Framework.

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

For more information:

[Commerce FAQs on Privacy Shield following CJEU decision of July 16](#)

[EU-U.S. Privacy Shield](#)

[Other transfer mechanisms](#)

## **Cybersecurity**

### *Network and Information Systems (NIS) Security Directive*

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

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

For more information: [NIS Directive](#)

### *Cybersecurity Act*

The EU adopted the Cybersecurity Act in March 2019 to set up a mechanism to develop voluntary EU certification schemes for ICT security products, processes and services. The Cybersecurity Act does not set out requirements in details but lays out elements that should be in any given scheme to provide assurance on security requirements for all ICT products, services and processes. The areas that would benefit from certification schemes will either be proposed by the European Commission through an annual work program or by stakeholder group. Product manufacturers and service providers are encouraged to monitor the development of these schemes. The EU cybersecurity agency ENISA creates [ad-hoc stakeholder groups](#) to help it create certification schemes, and companies can apply to participate in these groups.

More information:

[EU Cybersecurity Act](#)

[EU Cybersecurity Agency, ENISA](#)

## Business Travel

### Business Customs

*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 as impolite. However, if there is a delay, you can always call ahead and explain the situation. Germans generally might act and communicate in a straightforward and direct way. This is not meant to be rude, but rather to be efficient and can include *honest criticism*.

*Appointments* are made for most matters. The usual times for business appointments are between **10:00am and 1:00pm** or between **3:00pm and 5:00pm**. You should avoid scheduling on Friday afternoons as some offices might already be closed during that time.

You should respect formal *introductions* and the use of *official titles*. 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. That applies to most situations, since companies and people can differ.

*Business dress* is generally formal and conservative. This means suits with ties for men and suits or conservative dresses for women.

A *greeting* usually consists of a firm handshake and nod or polite smile with ‘elbow bumps’ largely replacing handshakes as hygiene controls came into place in 2020. Allowing for adequate *personal space* is important during the introduction, as well as during the whole 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.

Giving *compliments* is not common and can cause embarrassment. The same can be said about giving *gifts*, which can 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 2020) 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 [www.travel.state.gov](http://www.travel.state.gov) for updates.

The State Department has advised to exercise increased caution in Germany due to *terrorism*. 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 from 8:00 a.m. to 8:00 p.m. Eastern Time, Monday through Friday (except U.S. federal holidays).

Read the [State Department consular information sheet for Germany](#)

[Department of State: Travel](#)

[Department of State: Travel to Germany](#)

[Department of State Visa Website](#)

[Center for Disease Control and Prevention](#)

[CDC on Germany](#)

[United States Council for International Business](#)

[U.S. Customs and Border protection](#)

## 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 six 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. Inquiries from outside the United States may be made to the nearest [German embassy](#) or consulate.

**Please review the EU travel restrictions 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

2016	1.1069
2017	1.1297
2018	1.1810
2019	1.1199

2020 1.13 Projected

*ATMs* are as easily found in Germany as they are in North America. They are located at bank branches or in shopping, tourist and other busy areas. Major credit and debit cards, along with all other bank cards carrying the PLUS and NYCE symbols, are universally accepted. When located indoors, you may have to use your card to gain access if the door is locked. The German word for an ATM is “Geldautomat”.

*Credit cards* are not as widely used in Germany as they are in the United States and are not typically used for everyday expenses. However, hotels, stores, train stations and other places regularly frequented by tourists will almost always accept them. There might be exceptions for some restaurants.

## Telecommunications/Electric

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

Cell or mobile phones, or “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.

The internet is widely accessible in Germany. WIFI 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 the most 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 or taxis are used. The public transit system which includes trains, trams and buses are 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 the 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 of 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.

In general, there are no *known health risks* which travelers must be aware of when visiting Germany. However, the situation with COVID-19 can change rapidly and global travel at all should be avoided during the pandemic.

## 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*.

## Temporary Entry of Materials or Personal Belongings

When bringing professional equipment such as electronic goods, cameras and musical instruments into Germany, we strongly recommended 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 from the [German customs office](#) can be found on their [website](#).

Voltage in Germany is 230. Electronic equipment from the United States will require an adaptor.

## **Investment Climate Statement (ICS)**

The U.S. Department of State's [Investment Climate Statements](#), prepared annually by U.S. embassies and diplomatic missions abroad, provide country-specific information and assessments of the investment climate in foreign markets. Topics include: Market barriers, business risk, legal and regulatory system, dispute resolution, corruption, political violence, labor issues, and intellectual property rights. Visit the U.S. Department of State's [Investment Climate Statement website](#).

## **Political Environment**

The Department of State provides background information on the [political and economic environment of Germany](#).