



Doing Business in the European Union: 2013

Country Commercial Guide for U.S. Companies

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Chapter 1: Doing Business in the European Union

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Market Overview

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The United States and the European Union (EU), with its soon to be 28 member states¹, enjoy a mature economic relationship that is characterized by \$3.6 trillion in two-way investment as well as a massive two-way merchandise trade of \$650 billion in 2012 - up 68% from \$387 billion in 2000. U.S. exports of goods and services to the EU-27 in 2012 reached approximately \$265 billion and imports from the EU, \$380 billion. It is estimated that transatlantic commerce generates more than 15 million jobs.

Recognizing that the U.S.-EU economic relationship is already the world's largest, accounting for one-third of total trade in goods and services and nearly half of global economic output, President Obama, in his State of the Union address on February 12, 2013, announced the Administration's plans to notify Congress of its intent to launch negotiations on a Transatlantic Trade and Investment Partnership (TTIP) with the EU. Congress was formally notified on March 20, 2013. The Administration intends to begin negotiations on the new agreement in summer 2013.

The President's decision to launch TTIP negotiations with the EU follows discussions that began at the November 2011 U.S.-EU Summit. There, the [U.S.-EU High Level Working Group on Jobs and Growth](#) was tasked with identifying policies and measures to increase U.S.-EU trade and investment to support mutually beneficial job creation, economic growth and international competitiveness.

The TTIP is envisioned as an ambitious and comprehensive trade and investment agreement that will promote U.S. international competitiveness, jobs and growth. The TTIP will aim to address non-tariff barriers that impede trade in goods and services and seek to promote greater compatibility, transparency and cooperation in the regulatory and standards arenas.

According to forecasts by the European Commission (EC)², full-year real GDP growth for 2013 is projected to contract for both the EU as a whole (-0.1%) and the eurozone³ (-

¹ Croatia will formally join the EU in July 2013 becoming its 28th member.

² May 3, 2013 Spring Forecast

³ These figures compare the entire real GDP generated in 2013 with that of 2012. The eurozone is an economic and monetary union (EMU) of 17 EU member states that have adopted the euro as their common currency and sole legal tender. The eurozone consists of Austria, Belgium, Cyprus, Estonia, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, the Netherlands, Portugal, Slovakia, Slovenia, and Spain.

0.4%). Stronger growth is projected for 2014 at 1.4% for the eurozone and the overall EU. The EC anticipates a gradual return of confidence and a strengthening global economy over 2013, both of which should help Europe rebound. Ongoing restructuring in many of the EU's most vulnerable economies is expected to contribute to faster growth in 2014. Risks are considered to be more balanced throughout 2013 with threats to eurozone integrity receding to some extent. According to the EC:

- The EU country with the strongest growth in 2013 will be Latvia (3.8%); the weakest growth will be Cyprus (-8.7%);
- Eight eurozone countries, including Cyprus, will be in recession in 2013 (France with -0.1%, the Netherlands -0.8%, Italy -1.3%, Spain -1.5%, Portugal -2.3%, Slovenia -2.0% and Greece -4.2%);
- Outside the eurozone, only the Czech Republic (-0.4%) is projected to contract in 2013;
- All countries, except Slovenia and Cyprus, are expected to return to positive growth in 2014;
- 12.1% unemployment is forecast for 2014 in the eurozone and 11.1% in the entire EU. Unemployment figures are expected to run from 4.7% in Austria to 26.4% in Spain in 2014. Youth unemployment is substantially higher in countries with negative growth.

Market Challenges

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Europe continues to navigate a challenging path of fiscal and financial reforms. The European Central Bank (ECB) and eurozone governments have joined together to support a strategy to ensure that countries undertaking reforms retain access to market financing and that banks have access to liquidity and hold 'credible' capital. The ECB's commitment to Outright Monetary Transactions and the pooling of fiscal resources through the European Stability Mechanism provide important financial tools to protect reforms and limit the spread of the crisis. It is thought that a single supervisory mechanism and banking union will be paramount in bringing Europe back on the path to growth. Continuing to build on the stability European leaders have achieved thus far, while addressing rising unemployment, will remain critical to reinvigorate demand-led growth and facilitate internal rebalancing in the eurozone.

While the EU continues to move in the direction of a Single Market, the reality today is that U.S. exporters in some sectors continue to face barriers to entry and other challenges in the EU market. In several industries such as pharmaceuticals, telecommunications, legal services, and government procurement, some of these barriers are still pronounced in specific member states.

EU legislation generally takes two forms. "Regulations" have mandatory language and are directly applicable in Member States when implemented. "Directives" provide a general framework and must be "transposed" into national legislation at the Member State level. Differences in how directives are transposed in Member States are common, which complicates compliance for U.S. companies doing business in the EU.

Industry has periodically raised concerns over perceived onerous regulations and high compliance costs.

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

Additionally, while the EU Community Customs Code establishes a standard legal framework for basic customs procedures, it is currently being modernized and the EU as yet does not operate as a single customs administration. The implementation of a modernized customs code that should bring the EU closer to a single authority on customs is currently scheduled to come into force by June 2013.

Discussions on a range of existing and proposed trade irritants are ongoing, including transparency in developing regulatory procedures and standards. To ensure that U.S. companies get the full benefits of the trade agreements the United States has negotiated, the U.S. Government has developed a trade compliance initiative that includes the establishment of the [Interagency Trade Enforcement Center \(ITEC\)](#). U.S. trade agencies work closely and diligently with the business community to ensure that the EU and its member states comply with their bilateral and multilateral trade obligations, and to minimize market access problems affecting U.S. firms.

Market Opportunities

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U.S. businesses may benefit from several recent developments in the EU:

- Transatlantic Trade and Investment Partnership (TTIP): A successfully negotiated agreement could boost economic growth in the United States and Europe by further opening markets and strengthening rules-based investment to grow the world's largest such relationship.
- Enlargement of the EU continues with Croatia having signed its accession treaty. It is scheduled to become a full member as of July 1, 2013, once all 27 members have ratified the treaty. This will add an estimated 4.5 million individuals to the already existing population of 502.5 million people in the single market. The EU is currently negotiating with Iceland and is in discussions with Serbia and other Balkan states as well as Turkey.
- The border free EU Schengen area now covers 26 countries, including some non-EU members⁴, and greatly eases the movement of goods and people across air, land, and sea borders. Two more countries are expected to join the Schengen area (Romania and Bulgaria), as soon as approval is received from the existing members.
- Historically, U.S. exporters and investors have faced relatively low barriers to doing business in the EU. Nonetheless, issues exist as would be expected given the breadth and depth of the commercial relationship.

⁴ Twenty-two EU member states and four European Free Trade Association (EFTA) member states participate in the Schengen Area. Of the five EU members which do not form part of the Schengen Area three – Bulgaria, Cyprus and Romania – are legally obliged to join the area, while the other two – Ireland and the United Kingdom – maintain opt-outs. Four non-EU members – Iceland, Liechtenstein, Norway, and Switzerland – participate in the Schengen Area.

- The EU is also one of the biggest international donors and its budget generates sizeable public procurement opportunities in all sectors, in addition to the domestic market of its Member States. The EU annually allocates over 150 billion euros (nearly \$200 billion) for regional and infrastructure development alone.

U.S. firms doing business in Europe should be aware that there are several organizations in Brussels focused on representing U.S. business interests and engaging with EU institutions including the European Commission, European Parliament and the Council. See [chapter 9](#) for further details and contact information.

Market Entry Strategy

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The European Union market is a differentiated one, with specific supply and demand needs varying from Member State to Member State. While a pan-European business strategy is critical, individual market entry plans must be developed on a country-by-country basis. For details of these tactics, please consult the Commerce Department's Country Commercial Guides of the soon to be 28 EU member states found at the following website: [EU Member States' Country Commercial Guides](#).

To conduct a more thorough search for reports on specific industries and sectors within EU member states please consult the Commerce Department's Market Research Library: <http://www.export.gov/mrktresearch/index.asp>

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Chapter 2: Political and Economic Environment

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

<http://www.state.gov/r/pa/ei/bgn/index.htm>

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Using an Agent or Distributor

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Companies wishing to use distribution, franchising and agency arrangements need to ensure that the agreements they put into place are in accordance with EU 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. In essence, 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, including the notice to be given and indemnity or compensation to be paid to the agent. U.S. companies should be particularly aware that the Directive states that parties may not derogate 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:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31986L0653:EN:HTML>

The European Commission's Directorate General for Competition enforces legislation concerned with the effects on competition in the internal market of "vertical agreements." U.S. small- and medium-sized companies (SMEs) are exempt from these regulations because their agreements likely would qualify as "agreements of minor importance," meaning they are considered incapable of affecting competition at the EU level but useful for cooperation between SMEs. Generally speaking, companies with fewer than 250 employees and an annual turnover of less than €50 million are considered small- and medium-sized undertakings. The EU has additionally indicated that agreements that

affect less than 10% of a particular market are generally exempted as well (Commission Notice 2001/C 368/07).

Key Link:

http://eurlex.europa.eu/LexUriServ/site/en/oj/2001/c_368/c_36820011222en00130015.pdf

The EU also looks to combat payment delays. The new Directive 2011/7/EU, which replaced the current law in March 2013, 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 8% 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:

<http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:048:0001:0010:EN:PDF>

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:

<http://www.ombudsman.europa.eu/home/en/default.htm>

http://ec.europa.eu/solvit/site/about/index_en.htm

Data Privacy and Protection

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Current Situation

The EU's general data protection Directive (95/46/EC) spells out strict rules concerning the processing of personal data. Businesses must tell consumers that they are collecting data, what they intend to use it for, and to whom it will be disclosed. Data subjects must be given the opportunity to object to the processing of their personal details and to opt-out of having them used for direct marketing purposes. This opt-out should be available at the time of collection and at any point thereafter.

Transferring Customer Data to Countries outside the EU

The EU's current general data protection Directive provides for the free flow of personal data within the EU but also for its protection when it leaves the region's borders. Personal data can only be transferred outside the EU if adequate protection is provided

for it or if the unambiguous consent of the data subject is secured. The European Commission has decided that a handful of countries have regulatory frameworks in place that guarantee the adequate protection of data transferred to them – the United States is NOT one of these.

As a result, in 2000 the Department of Commerce and the European Commission negotiated the Safe Harbor agreement to provide U.S. companies with simple, streamlined means of complying with the adequacy requirement. It allows those U.S. companies that commit to a series of data protection principles (based on the current Directive), and by publicly stating that commitment by "self-certifying" on a dedicated website, to continue to receive personal data from the EU. Signing up is voluntary but the rules are binding on those who do. The ultimate means of enforcing Safe Harbor is that failure to fulfill the commitments will be actionable as an unfair and deceptive practice under Section 5 of the FTC Act or under a concurrent Department of Transportation statute for air carriers and ticket agents. While the United States as a whole does not enjoy an adequacy finding, transfers that are covered by the Safe Harbor program do. Companies whose activities are not regulated by the FTC or DoT (e.g. banks, credit unions, savings and loan institutions, securities dealers, insurance companies, not-for-profit organizations, meat packing facilities, or telecommunications carriers) are not eligible to sign up for the Safe Harbor.

Key links: U.S.-EU Safe Harbor Overviews

http://export.gov/safeharbor/eu/eg_main_018476.asp
http://export.gov/static/Safe%20Harbor%20and%20Cloud%20Computing%20Clarification_April%2012%202013_Latest_eg_main_060351.pdf

EU based exporters or U.S. based importers of personal data can also satisfy the adequacy requirement by including data privacy clauses in the contracts they sign with each other. The Data Protection Authority in the EU country from where the data is being exported must approve these contracts. To fast track this procedure the European Commission has approved sets of model clauses for personal data transfers that can be inserted into contracts between data importers and exporters. The most recent were published at the beginning of 2005, and were complemented in 2010 by contractual clauses on "sub-processing" (outsourcing by an EU based exporter of its processing activities to other sub-processors outside the EU). Most transfers using contracts based on these model clauses do not require prior approval. Companies must bear in mind that the transfer of personal data to third countries is a processing operation that is subject to the general data protection Directive regardless of any Safe Harbor, contractual or consent arrangements.

EU countries' Data Protection Authorities (DPAs) and large multinational companies have also developed a third major approach to compliance with EU rules on transfers of personal data to countries outside the EU. This is based on country-by-country DPA approval of "binding corporate rules" (BCRs). A BCR is the international code of practice that a multinational corporation follows for transfers of personal data between the companies belonging to that corporation (worldwide intra-group transfer). BCRs are suitable for closely-knit, highly hierarchically structured multinational companies but not for loose conglomerates. Companies that set up BCRs that satisfy European DPAs are able to use the presumption of conformity that these approvals provide to transfer personal data from the EU to any location in the world – not just the United States. BCRs

can be a tool for compliance with privacy rules on a global scale. The process of negotiation and approval of the BCRs is currently lengthy and complex, and has not been attempted by small or medium-sized companies.

Proposed New Regulation

The EU's current data privacy legislation is undergoing review. A new commercial data protection regulation was proposed by DG Justice in January 2012 and is now being revised in the European Parliament and EU Council of Ministers. Ireland was able to make good progress while holding the rotating Presidency of the EU Council during the first six months of 2013. Lithuania will take on the Presidency as of July 2013, and its Ministry of Justice has indicated its intent to prioritize the revision of the proposed legislation. The Commission has pushed for adoption of the proposed regulation in 2014 before the European Parliament's general elections in June of that year.

If the December 2012 version of the regulation is adopted, it will impose significant requirements on European and U.S. businesses and on the way they are able to gather and utilize user data. It will also introduce substantial fines for offending companies (up to 2% of global revenue). For over two years, industry representatives have voiced their concerns to EU Institutions and Member State officials. In a Position Paper published in July 2012, the American Chamber of Commerce to the EU identified 10 key concerns with the proposed regulation:

- data breach notification
- consent
- definition of personal data, a child, and of public interest
- technical feasibility of the "right to be forgotten" provision
- extraterritoriality element that would hamper international data transfers

The implications of this proposed regulation go well beyond its immediate scope; in particular data privacy is an integral part of other current EU regulatory initiatives in ICT sectors such as cloud computing and cyber-security.

Key Links:

European Commission's Justice Directorate-General:

http://ec.europa.eu/justice_home/fsj/privacy/index_en.htm

http://ec.europa.eu/justice/data-protection/document/international-transfers/transfer/index_en.htm

http://ec.europa.eu/justice/data-protection/document/international-transfers/binding-corporate-rules/index_en.htm

AmChamEU position paper on the proposed regulation:

http://www.amchameu.eu/DesktopModules/Bring2mind/DMX/Download.aspx?TabId=165&Command=Core_Download&EntryId=7914&PortalId=0&TabId=165

Franchising

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U.S. businesses looking to franchise within the European Union will likely find that the market is quite robust and friendly to franchise systems in general. There are a number of laws that govern the operation of franchises within the EU, but these laws are fairly

broad and generally, do not constrain the competitive position of U.S. businesses. The potential franchiser should take care to look not only at the EU regulations, but also at the local laws concerning franchising. More information on specific legislation can be found on the website of the European Franchise Federation: <http://www.eff-franchise.com/spip.php?rubrique21>

Direct Marketing

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There is a wide range of EU legislation that impacts the direct marketing sector. Compliance requirements are stiffest for marketing and sales to private consumers. Companies need to focus, in particular, on the clarity and completeness of the information they provide to consumers prior to purchase and on their approaches to collecting and using customer data. The following gives a brief overview of the most important provisions flowing from EU-wide rules on distance-selling and on-line commerce.

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 privacy section above.

Distance Selling Rules

The EU's Directive on Distance Selling to Consumers (97/7/EC and amendments) sets out a number of obligations for companies doing business at a distance with consumers.

It can read like a set of onerous "do's" and "don'ts," but in many ways, it represents nothing more than a customer relations good practice guide with legal effect. Direct marketers must provide clear information on the identity of themselves as well as their supplier, full details on prices including delivery costs, and the period for which an offer remains valid – all of this, of course, before a contract is concluded. Customers generally have the right to return goods without any required explanation within seven days, and retain the right to compensation for faulty goods thereafter. Similar in nature is the Doorstep Selling Directive (85/577/EEC) which is designed to protect consumers from sales occurring outside of a normal business premises (e.g., door-to-door sales) and essentially assure the fairness of resulting contracts.

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 will apply to contracts concluded after June 13, 2014, and will replace current EU rules on distance selling to consumers and doorstep selling along with unfair contract terms and consumer goods and associated guarantees. The Directive contains provisions on core information to be provided by traders prior to the conclusion of consumer contracts, regulates the right of withdrawal, includes rules on the costs for the use of means of payment and bans pre-ticked boxes. Companies are advised to consult the information available via the hyper-links, to check the relevant sections of national Country Commercial Guides, and to contact the Commercial Service at the U.S. Mission to the European Union for more specific guidance.

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 will set up an EU-wide online platform to handle consumer disputes that arise from online transactions. The platform will be operational at the end of 2015.

Key Links:

Consumer Affairs Homepage:

http://ec.europa.eu/consumers/index_en.htm

Consumer Rights:

http://ec.europa.eu/justice/consumer-marketing/rights-contracts/directive/index_en.htm

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:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0065:EN:NOT>

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 easily accessible and clear. 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).

Key Link: http://ec.europa.eu/internal_market/e-commerce/index_en.htm

Joint Ventures/Licensing

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#)

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports.

Selling to the Government

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The EU public procurement market, including EU institutions and member states, totals approximately EUR 1.6 billion. This market is regulated by three Directives:

- Directive 2004/18 on Coordination of Procedures for the Award of Public Works, Services and Supplies Contracts;
- Directive 2004/17 on Coordination of Procedures of Entities Operating in the Utilities Sector, which covers the following sectors: water, energy, transport and postal services; and
- Directive 2009/81 on Coordination of Procedures for the Award of Certain Works, Supply and Service Contracts by contracting authorities in the fields of defense and security.

Remedy directives cover legal means for companies who face discriminatory public procurement practices. These directives are implemented in the national procurement legislation of the EU member states.

The U.S. and the EU are signatories to the World Trade Organization's (WTO) Government Procurement Agreement (GPA), which grants access to most public supplies and services and some work contracts published by national procurement authorities of the countries that are parties to the Agreement. In practice, this means that U.S.-based companies are eligible to bid on supplies and services contracts from European public contracting authorities above the agreed thresholds.

However, there are restrictions for U.S. suppliers in the EU utilities sector both in the EU Utilities Directive and in the EU coverage of the GPA. The Utilities Directive allows EU contracting authorities in these sectors to either reject non-EU bids where the proportion of goods originating in non-EU countries exceeds 50% of the total value of the goods constituting the tender, or is entitled to apply a 3% price difference to non-EU bids in order to give preference to the EU bid. These restrictions are applied when no reciprocal access for EU companies in the U.S. market is offered. Those restrictions, however, were waived for the electricity sector.

For more information, please visit the U.S. Commercial Service at the U.S. Mission to the European Union website dedicated to EU public procurement.

Key Link:

<http://export.gov/europeanunion/grantstendersandfinancing/eu-fundedprogramsgrants/index.asp>

Distribution and Sales Channels

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#).

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports.

Selling Factors/Techniques

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Electronic Commerce

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The Electronic Commerce Directive (2000/31/EC) mentioned in the direct marketing section above provides rules for online services in the EU. It requires providers to abide by rules in the country where they are established (country of origin). Online providers must respect consumer protection rules such as indicating contact details on their website, clearly identifying advertising and protecting against spam. The Directive also grants exemptions to liability for intermediaries that transmit illegal content by third parties and for unknowingly hosting content. The European Commission released a work plan in 2012 in order to facilitate cross-border online services and reduce barriers and released a [report](#) on implementation of the action plan in 2013.

Key Link: http://ec.europa.eu/internal_market/e-commerce/directive_en.htm

In July 2003, the EU started applying 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. European Council Directive 2002/38/EC further developed the EU rules for charging Value Added Tax. These rules were indefinitely extended following adoption of Directive 2008/8/EC.

U.S. businesses mainly affected by the 2003 rule change are those that are U.S. based and selling ESS to EU based, non-business customers or those businesses that are EU based and selling ESS to customers outside the EU who no longer need to charge VAT on these transactions. There are a number of compliance options for businesses. The Directive created a special scheme that simplifies registering with each member state. The Directive allows companies to register with a single VAT authority of their choice. Companies have to charge different rates of VAT according to where their customers are located, but VAT reports and returns are submitted to just one authority. The VAT authority responsible for providing the single point of registration service is then responsible for reallocating the collected revenue among the other EU VAT authorities.

Key Link: http://ec.europa.eu/taxation_customs/taxation/vat/how_vat_works/e-services/index_en.htm

General Legislation

Laws against misleading advertisements differ widely from member state to member state within the EU. To respond to this imperfection 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 by a competitor." member states can, and in some cases have, restricted misleading or comparative advertising.

The EU's Audiovisual Media Services Directive lays down legislation on broadcasting activities allowed within the EU. Since 2009, the rules allowing for U.S.-style product placement on television and the three-hour/day maximum of advertising have been lifted. However, a 12-minute/hour maximum remains. Child programming will be subject to a code of conduct that will include a limit of junk food advertising to children. Following the adoption of the 1999 Council Directive on the Sale of Consumer Goods and Associated Guarantees, product specifications, as laid down in advertising, are considered as legally binding on the seller. (For additional information on Council Directive 1999/44/EC on the Sale of Consumer Goods and Associated Guarantees, see the legal warranties and after-sales service section below, though this Directive will be incorporated into the Consumer Rights Directive mentioned above by June 2014.)

The EU adopted Directive 2005/29/EC concerning fair business practices in a further attempt to tighten up 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

Link: http://ec.europa.eu/comm/consumers/cons_int/safe_shop/fair_bus_pract/index_en.htm

http://ec.europa.eu/avpolicy/reg/avms/index_en.htm

Medicines

The advertising of medicinal products for human use is regulated by Council Directive 2001/83/EC as amended by Directive 2004/27/EC. Generally speaking, the advertising of medicinal products is forbidden if market authorization has not yet been granted or if the product in question is a prescription drug. Mentioning therapeutic indications where self-medication is not suitable is not permitted, nor is the distribution of free samples to the general public. The text of the advertisement should be compatible with the

characteristics listed on the product label, and should encourage rational use of the product. The advertising of medicinal products destined for professionals should contain essential characteristics of the product as well as its classification. Inducements to prescribe or supply a particular medicinal product are prohibited and the supply of free samples is restricted.

The Commission presented a new proposal for a framework for information to patients on medicines in 2008 which would allow industry to produce non-promotional information about its medicines while complying with strictly defined rules and would be subject to an effective system of control and quality assurance. The debate on the framework however is currently blocked in the member states and therefore, current varying systems at national level are in force.

Key Link:

http://ec.europa.eu/health/human-use/information-to-patient/index_en.htm

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) are allowed to carry claims. Nutrition and health claims are only allowed on food labels if they are included in one of the EU 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 on information to consumers mentioned below.

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 simplified authorization procedure has been established.

The development of nutrient profiles, originally scheduled for January 2009, has been delayed. Nutrition claims 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.

Key Link: <http://ec.europa.eu/nuhclaims/>

Food Information to Consumers

In 2011, the EU adopted a new regulation on the provision of food information to consumers (1169/2011). The new EU labeling requirements will apply from December 13, 2014 except for the mandatory nutrition declaration which will apply from December 13, 2016.

Key link: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:304:0018:0063:EN:PDF>

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 November 2009. A positive list of substances other than vitamins and minerals has not been established yet, although it is being developed. Until then, member state laws will govern the use of these substances.

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

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. The EU proposed a revision to the Tobacco Products Directive in 2012 with proposals to include bigger, double-sided health pictorial warnings on cigarette packages and plain packaging along with health warnings, tracking systems.

Key link: <http://ec.europa.eu/health/tobacco/products/revision/>

Pricing

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#).

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports.

Sales Service/Customer Support

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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:

<http://ec.europa.eu/enterprise/policies/single-market-goods/product-liability/>

Product Safety

The 1992 General Product Safety Directive introduces a general safety requirement at the EU level to ensure that manufacturers only place safe products on the market. It was revised in 2001 to include an obligation on the producer and distributor to notify the Commission in case of a problem with a given product, provisions for its recall, the creation of a European Product Safety Network, and a ban on exports of products to third countries that are not deemed safe in the EU. The legislation is still undergoing review.

Key link: http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm

Legal Warranties and After-sales Service

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

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

As of June 2014, Directive 1999/44/EC will be incorporated into the new Consumer Rights Directive previously mentioned.

Key link: http://ec.europa.eu/consumers/rights/gen_rights_en.htm

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 Chapter 5 of this report.

Protecting Your Intellectual Property

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Protecting Your Intellectual Property in the EU:

Several general principles are important for effective management of intellectual property ("IP") rights in the EU. First, it is important to have an overall strategy to protect your IP. Second, IP is protected differently in the EU than in the United States. Third, rights must be registered and enforced in the EU under local laws. Your U.S. trademark and patent registrations will not protect you in the EU. There is no such thing as an "international copyright" that will automatically protect an author's writings throughout the entire world. Protection against unauthorized use in a particular country depends on the

national laws of that country. However, most countries do offer copyright protection to foreign works under certain conditions, and these conditions have been greatly simplified by international copyright treaties and conventions.

Registration of patents and trademarks is on a first-in-time, first-in-right basis, so you should consider applying for trademark and patent protection even before selling your products or services in the EU market. It is vital that companies understand that intellectual property is primarily a private right and that the US government generally, cannot enforce rights for private individuals in EU. It is the responsibility of the rights' holders to register, protect, and enforce their rights where relevant, retaining their own counsel and advisors. Companies may wish to seek advice from local attorneys or IP consultants who are experts in EU law. The U.S. Commercial Service can provide a list of local lawyers upon request.

While the U.S. Government stands ready to assist, there is little we can do if the rights holders have not taken these fundamental steps necessary to securing and enforcing their IP in a timely fashion. Moreover, in many countries, rights holders who delay enforcing their rights on a mistaken belief that the USG 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 seen as a substitute for the obligation of a rights holder to promptly pursue its case.

It is always advisable to conduct due diligence on potential partners. Negotiate from the position of your partner and give your partner clear incentives to honor the contract. 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 EU laws to create a solid contract that includes non-compete clauses, and confidentiality/non-disclosure provisions.

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

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

IP Resources

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

- For information about patent, trademark, or copyright issues -- including enforcement issues in the US and other countries -- call the STOP! Hotline: **1-866-999-HALT** or register at www.StopFakes.gov.
- For more information about registering trademarks and patents (both in the U.S. as well as in foreign countries), contact the US Patent and Trademark Office (USPTO) at: **1-800-786-9199**.
- For more information about registering for copyright protection in the US, contact the US 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, a free online training program is available at www.stopfakes.gov.
- For US small and medium-size companies, the Department of Commerce offers a "SME IP Advisory Program" available through the American Bar Association that provides one hour of free IP legal advice for companies with concerns in Brazil, China, Egypt, India, Russia, and . For details and to register, visit: http://www.abanet.org/intlaw/intlproj/iprprogram_consultation.html
- For information on obtaining and enforcing intellectual property rights and market-specific IP Toolkits visit: www.StopFakes.gov This site is linked to the USPTO website for registering trademarks and patents (both in the U.S. as well as in foreign countries), the U.S. Customs & Border Protection website to record registered trademarks and copyrighted works (to assist customs in blocking imports of IP-infringing products) and allows you to register for Webinars on protecting IP.
- The U.S. Commerce Department has positioned IP attachés in key markets around the world. For contact information, please see: http://www.uspto.gov/ip/global/attache/Attache_Contacts_2012-08.doc

Due Diligence

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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.

Local Professional Services

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Local service providers focusing on EU law, consulting, and business development can be viewed on the website maintained by the Commercial Service at the U.S. Mission to the European Union
at: <http://export.gov/europeanunion/businessserviceproviders/index.asp>.

For information on professional services located within each of the EU member states, please see EU Member State Country Commercial Guides which can be found at the following website [EU Member States' Country Commercial Guides](#).

Web Resources

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EU websites:

Coordination of the laws of the member states relating to self-employed commercial agents (Council Directive 86/653/EEC):

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31986L0653:EN:HTML>

Agreements of Minor importance which do not appreciably restrict Competition under Article 81(1) of the Treaty establishing the European Community:

http://eurlex.europa.eu/LexUriServ/site/en/oj/2001/c_368/c_36820011222en00130015.pdf

Directive on Late Payment:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:048:0001:0010:EN:PDF>

European Ombudsman:

<http://www.ombudsman.europa.eu/home/en/default.htm>

EU's General Data Protection Directive (95/46/EC):

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1995:281:0031:0050:EN:PDF>

Safe Harbor:

http://export.gov/safeharbor/eu/eg_main_018476.asp

Information on contracts for transferring data outside the EU:

http://ec.europa.eu/justice/data-protection/document/international-transfers/transfer/index_en.htm

EU Data Protection Homepage :

http://ec.europa.eu/justice_home/fsj/privacy/index_en.htm

Distance Selling Rules:

http://ec.europa.eu/consumers/cons_int/safe_shop/dist_sell/index_en.htm

Distance Selling of Financial Services:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:271:0016:0024:EN:PDF>

E-commerce Directive (2000/31/EC):

http://ec.europa.eu/internal_market/e-commerce/index_en.htm

VAT on Electronic Service:

http://ec.europa.eu/taxation_customs/taxation/vat/how_vat_works/e-services/index_en.htm

The Unfair Commercial Practices Directive:

<http://ec.europa.eu/consumers/rights/>

Information to Patients - Major developments:

http://ec.europa.eu/health/human-use/information-to-patient/legislative-developments_en.htm

Nutrition and health claims made on foods - Regulation 1924/2006

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:012:0003:0018:EN:PDF>

Regulation on Food Information to Consumers:

[Regulation 1169/2011](#)

EU-27 FAIRS EU Country Report on Food and Labeling requirements:

http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Food%20and%20Agricultural%20Import%20Regulations%20and%20Standards%20-%20Narrative_Brussels%20USEU_EU-27_12-27-2012.pdf

Guidance document on how companies can apply for health claim authorizations:

Summary document from

EFSA http://www.efsa.europa.eu/cs/BlobServer/Scientific_Opinion/nda_op_ej530_guidance_summary_en.pdf?ssbinary=true

Health & Nutrition

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

Tobacco

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

Product Liability:

http://europa.eu/legislation_summaries/consumers/consumer_safety/l32012_en.htm

Product Safety

http://ec.europa.eu/consumers/safety/prod_legis/index_en.htm

Legal Warranties and After-Sales Service:

http://ec.europa.eu/consumers/rights/gen_rights_en.htm

Copyright: http://ec.europa.eu/internal_market/copyright/documents/documents_en.htm

Harmonization of certain aspects of Copyright and related rights in the Information Society - Copyright Directive (2001/29/EC):

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0029:EN:HTML>

Industrial Property

http://ec.europa.eu/internal_market/indprop/index_en.htm

Trademark

http://ec.europa.eu/internal_market/indprop/tm/index_en.htm

European Patent Office (EPO)

<http://www.european-patent-office.org/>

Office for Harmonization in the Internal Market (OHIM)

<http://oami.europa.eu/>

World Intellectual Property Organization (WIPO) Madrid

<http://www.wipo.int/madrid/en>

U.S. websites:

IPR Toolkit: http://www.stopfakes.gov/sites/default/files/europeanunion_toolkit.pdf

EU Public

Procurement: <http://export.gov/europeanunion/marketresearch/eufundingandgovernmentprocurementsectors/index.asp>

Local Professional

Services: <http://export.gov/europeanunion/businessserviceproviders/index.asp>

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Chapter 4: Leading Sectors for U.S. Export and Investment

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Commercial Sectors

In his 2010 State of the Union address, President Obama announced the National Export Initiative (NEI) to renew and revitalize U.S. efforts to promote American exports abroad. The Obama Administration made it a top priority to improve the conditions that directly affect the private sector's ability to export – working to remove trade barriers abroad, helping firms to overcome hurdles in market entry and assisting with financing.

The Department of Commerce and the Commercial Service continue to be a major force in this effort. To contribute to NEI efforts within the European Union, Commercial Service EU has focused its work on: 1) avoiding the creation of unnecessary regulatory and standards barriers to transatlantic trade and investment in key emerging sectors; 2) working with the EU to remove common market access barriers in third countries and enforcing and protecting intellectual property rights; and 3) promoting entrepreneurship and innovation in support of SME development, job creation and economic growth.

U.S. Government engagement in such sectors as automotive (e-vehicles), chemicals, energy and environment (smart grids, renewables), health and medical technologies, and information and communications technology will continue to contribute towards meeting the goals of the NEI.

Overview

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	2012	2013
GDP (nominal)	16,573.0	17,285.9
Total EU Exports to the world	2,168.1	2,260.9
Total EU Imports from the world	2,304.1	2,280.1
Imports from the U.S.	265.1	284.77
Exports to the U.S.	380.8	422.8
2011 Exchange Rate (Euro Zone): 1 USD	.7783	.7623

Unit: USD billions

Data Sources:

2012: DOC/MAC/Country Fact Sheet;
2013: Eurostat exchange rate

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European Commission, Directorate-General for Trade, EU-U.S. trade factsheet:
http://trade.ec.europa.eu/doclib/docs/2006/september/tradoc_113465.pdf

Despite frequent disputes, bilateral agricultural trade between the United States and the EU-27 totaled \$29.9 billion in 2012. The EU is the fifth largest export market for U.S. agricultural products after China, Canada, Mexico and Japan. For the eleventh year in a row, the trade balance in agricultural, forestry, and fishery goods continued in the EU's favor (\$17.8 billion vs. \$12.1 billion). U.S. imports from the EU included wine and beer, essential oils, cheese, and processed fruits and vegetables.

The main U.S. products exported to the EU by value were tree nuts, soybeans, processed fruits and vegetables and wine and beer. Increases were seen in U.S. exports of soybeans and soybean meal, vegetable oils, processed fruits and vegetables, tree nuts, and wine and beer. Tree nuts reached their highest EU export sales since 1970.

Global branding and further integration of European markets is continuing to produce a more homogeneous food and drink market in Europe, but significant national differences in consumption remain. Nevertheless, certain common trends are evident throughout the EU: demand for greater convenience, more openness to non-traditional foods, and a growing interest in health foods, organics and niche markets. For a thorough analysis of what commodities and products offer the best opportunities, access www.usda-eu.org and consult Brussels' and the individual member states' Food and Agricultural Import Regulations and Standards (FAIRS) Reports (<http://www.usda-eu.org/trade-with-the-eu/eu-import-rules/fairs-reports>).

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Chapter 5: Trade Regulations, Customs and Standards

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- [Trade Barriers](#)
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Import Tariffs

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The Integrated Tariff of the Community, referred to as TARIC (Tarif Intégré de la Communauté), is designed to show the various rules which apply to specific products being imported into the customs territory of the EU or, in some cases, exported from it. 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: http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/customs_tariff/index_en.htm

Trade Barriers

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For information on existing trade barriers, please see the National Trade Estimate Report on Foreign Trade Barriers, published by USTR and available through the following website: <http://www.ustr.gov/sites/default/files/2013%20NTE%20European%20Union%20Final.pdf>

Information on agricultural trade barriers can be found at the following website: <http://www.fas.usda.gov/posthome/useu/>

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

The TARIC (Tarif Intégré de la Communauté), described above, is available to help determine if a license is required for a particular product.

Many EU member states maintain their own list of goods subject to import licensing. For example, Germany's "Import List" (Einfuhrliste) includes goods for which licenses are required, their code numbers, any applicable restrictions, and the agency that will issue the relevant license. The Import List also indicates whether the license is required under German or EU law. For information relevant to member state import licenses, please consult the relevant member state Country Commercial Guide: [EU Member States' Country Commercial Guides](#) or conduct a search on the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp>.

Import Documentation

The Single Administrative Document

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

The Summary Declaration is filed by:

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

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

European Free Trade Association (EFTA) countries including Norway, Iceland, Switzerland, and Liechtenstein also use the SAD. Information on import/export forms is contained in Council Regulation (EEC) No. 2454/93, which lays down provisions for the implementation of the Community Customs Code (Articles 205 through 221). Articles 222 through 224 provide for computerized customs declarations and Articles 225 through 229 provide for oral declarations.

More information on the SAD can be found

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

Non-EU goods presented to customs must be assigned a customs-approved treatment or use authorized for such non-Community goods. Where goods are covered by a

summary declaration, the formalities for them to be assigned a customs-approved treatment or use must be carried out:

- 45 days from the date on which the summary declaration is lodged in the case of goods carried by sea;
- 20 days from the date on which the summary declaration is lodged in the case of goods carried other than by sea.

Where circumstances so warrant, the customs authorities may set a shorter period or authorize an extension.

The Modernized Customs Code (MCC) of the European Union is expected to be fully in place by June 2013. Some facets of the MCC have already been implemented including EU wide Economic Operators Registration and Identification (EORI) numbers. The MCC replaces existing Regulation 2913/92 and simplifies various procedures such as introducing a paperless environment, centralized clearance, and more. Check the EU's Customs website periodically for updates: http://ec.europa.eu/taxation_customs/customs/procedural_aspects/general_community_code/index_en.htm

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

Since 1997, the U.S. and the EU have had an [agreement](#) on customs cooperation and mutual assistance in customs matters. For additional information, please see http://ec.europa.eu/taxation_customs/customs/policy_issues/international_customs_agreements/usa/index_en.htm

In 2012, the U.S. and the EU signed a new Mutual Recognition Arrangement (MRA) aimed at matching procedures to associate one another's customs identification numbers. The MCC introduced the Authorized Economic Operator (AEO) program (known as the "security amendment"). This is similar to the U.S.' voluntary Customs-Trade Partnership Against Terrorism (C-TPAT) program in which participants receive certification as a "trusted" trader. AEO certification issued by a national customs authority is recognized by all member state's customs agencies. An AEO is entitled to two different types of authorization: "customs simplification" or "security and safety". The former allows for an AEO to benefit from simplifications 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.

The U.S. 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 mutual recognition will result in lower costs, simplified procedures and greater predictability for transatlantic business activities. The newly signed arrangement officially recognizes the compatibility of AEO and C-TPAT programs, thereby facilitating faster and more secure trade between U.S. and EU operators. The agreement is being implemented in two phases. The first commenced in July 2012 with the U.S. customs authorities placing shipments coming from EU AEO members into a lower risk category. The second phase will take place in 2013, with the EU re-classifying shipments coming from C-TPAT members into a lower

risk category. The U.S. customs identification numbers (MID) are therefore recognized by customs authorities in the EU, as per Implementing Regulation 58/2013 (which amends EU Regulation 2454/93 cited above): http://ec.europa.eu/taxation_customs/resources/documents/customs/procedural_aspects/general/implementing_regulation_58_2013_en.pdf

Additional information on the MRA can be found at:

http://www.cbp.gov/linkhandler/cgov/trade/cargo_security/ctpat/ctpat_program_information/international_efforts/eu_faq.ctt/eu_faq.pdf

Batteries

EU battery rules changed in September 2006 following the publication of the Directive on batteries and accumulators and waste batteries and accumulators (Directive 2006/66). This Directive replaces the original Battery Directive of 1991 (Directive 91/157). The 2006 Directive applies to all batteries and accumulators placed on the EU market including automotive, industrial and portable batteries. It aims to protect the environment by restricting the sale of batteries and accumulators that contain mercury or cadmium (with an exemption for emergency and alarm systems, medical equipment and cordless power tools) and by promoting a high level of collection and recycling. It places the responsibility on producers to finance the costs associated with the collection, treatment, and recycling of used batteries and accumulators. The Directive also includes provisions on the labeling of batteries and their removability from equipment. For more information, see our market research report: http://www.buyusainfo.net/docs/x_4062262.pdf

REACH

REACH, "Registration, Evaluation and Authorization and Restriction of Chemicals", is the system for controlling chemicals in the EU and it came into force in 2007 (Regulation 1907/2006). Virtually every industrial sector, from automobiles to textiles, is affected by this policy. REACH requires chemicals produced or imported into the EU in volumes above 1 ton per year to be registered with a central database handled by the European Chemicals Agency (ECHA). Information on a chemical's properties, its uses and safe ways of handling are part of the registration process. The next registration deadline is **May 31, 2013**: <http://echa.europa.eu/web/guest/reach-2013>. U.S. companies without a presence in Europe cannot register directly and must have their chemicals registered through their importer or EU-based 'Only Representative of non-EU manufacturer'. A list of Only Representatives (ORs) can be found on the website of the U.S. Mission to the EU: <http://export.gov/europeanunion/reachclp/index.asp>

Material Safety Data Sheets (MSDS) must be updated to be REACH compliant. For more information, see the guidance on the compilation of safety data sheets: http://echa.europa.eu/documents/10162/17235/sds_en.pdf

U.S. exporters to the EU should carefully consider the REACH 'Candidate List' of Substances of Very High Concern (SVHCs) and the Authorization List. Substances on the Candidate List are subject to communication requirements. Companies seeking to export products containing substances on the Authorization List will require an authorization. The Candidate List can be found at: <http://echa.europa.eu/web/guest/candidate-list-table>. The Authorization List is available at <http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>

WEEE Directive

EU rules on Waste Electrical and Electronic Equipment (WEEE), while not requiring specific customs or import paperwork, may entail a financial obligation for U.S. exporters. The Directive requires U.S. exporters to register the products with a national WEEE authority or arrange for this to be done by a local partner. The WEEE Directive was revised on July 4, 2012. The revised WEEE Directive expands the scope of products covered to include all electrical and electronic equipment. The expanded scope will apply from August 14, 2018. U.S. exporters seeking more information on the WEEE Directive should visit: <http://export.gov/europeanunion/weerohs/index.asp>

RoHS

The ROHS Directive imposes restrictions on the use of certain chemicals in electrical and electronic equipment. It does not require specific customs or import paperwork however, manufacturers must self-certify that their products are compliant. The Directive was revised in 2011 and entered into force on January 2, 2013. One important change with immediate effect is that RoHS is now a CE marking Directive. The revised Directive expands the scope of products covered during a transition period which ends on July 22, 2019. Once this transition period ends, the Directive will apply to medical devices, monitoring and control equipment in addition to all other electrical and electronic equipment. U.S. exporters seeking more information on the RoHS Directive should visit: <http://export.gov/europeanunion/weerohs/index.asp>

Cosmetics Regulation

On November 30, 2009, the EU adopted a new regulation on cosmetic products which will apply from July 11, 2013. The new law introduces an EU-wide system for the notification of cosmetic products and a requirement that companies without a physical presence in the EU appoint an EU-based responsible person.

In addition, on March 11, 2013, the EU imposed a ban on the placement on the market of cosmetics products that contain ingredients that have been subject to animal testing. This ban does not apply retroactively but does capture new ingredients. Of note, in March 2013, the Commission published a Communication stating that this ban would not apply to ingredients where safety data was obtained from testing required under other EU legislation that did not have a cosmetic purpose. For more information on animal testing, see: <http://ec.europa.eu/consumers/sectors/cosmetics/animal-testing>

For more general information, see:

http://export.gov/europeanunion/accessingeumarketsinkeyindustrysectors/eg_eu_044318.asp

Agricultural Documentation

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

Sanitary Certificates: For commodities composed of animal products or by-products, EU countries require that shipments be accompanied by a certificate issued by the competent authority of the exporting country. This applies regardless of whether the product is for human consumption, for pharmaceutical use, or strictly for non-human use (e.g., veterinary biologicals, animal feeds, fertilizers, research). The vast majority of these certificates are uniform throughout the EU, but the harmonization process is not

complete. During this transition period, certain member state import requirements continue to apply. In addition to the legally required EU health certificates, a number of other certificates are used in international trade. These certificates, which may also be harmonized in EU legislation, certify origin for customs purposes and certain quality attributes. Up-to-date information on harmonized import requirements can be found at the following website: <http://www.fas.usda.gov/posthome/Useu/certificates-overview.html>

Sanitary Certificates (Fisheries)

In April 2006, the European Union declared the U.S. seafood inspection system as equivalent to the European one. Consequently, a specific public health certificate must accompany U.S. seafood shipments. Commission Decision 2006/199/EC lays down specific conditions on imports of fishery products from the U.S. Unlike for fishery products, the U.S. shellfish sanitation system is not equivalent to that of the EU's. The EU and the U.S. are currently negotiating a veterinary equivalency agreement on shellfish. In the meantime, the EU still has a ban in place (since July 1, 2010), that prohibits the import of U.S. bivalve mollusks, in whatever form, into EU territory. This ban does not apply to wild roe-off scallops.

With the implementation of the second Hygiene Package, aquaculture products coming from the United States must be accompanied by a public health certificate according to Commission Decision 2006/199/EC and the animal health attestation included in the new fishery products certificate, covered by Regulation (EC) 1012/2012. This animal health attestation is not required in the case of live bivalve mollusks intended for immediate human consumption (retail).

Since June 2009, the unique U.S. competent authority for issuing sanitary certificates for fishery and aquaculture products is the U.S. Department of Commerce, National Marine Fisheries Service (NOAA-NMFS).

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

For detailed information on import documentation for seafood, please contact the NOAA Fisheries office at the U.S. Mission to the EU (stephane.vrignaud@trade.gov) or visit the following NOAA dedicated web site: http://www.seafood.nmfs.noaa.gov/EU_Export.html

The U.S. Department of Commerce's Bureau of Industry and Security (BIS) is responsible for implementing and enforcing the Export Administration Regulations (EAR), which regulate the export and re-export of some commercial items, including "production" and "development" technology.

The items that BIS regulates are often referred to as "dual use" since they have both commercial and military applications. Further information on export controls is available at: <http://www.bis.doc.gov/licensing/exportingbasics.htm>

BIS has developed a list of "red flags," or warning signs, intended to discover possible violations of the EAR. These are posted at: <http://www.bis.doc.gov/enforcement/redflags.htm>

Also, BIS has "Know Your Customer" guidance at: <http://www.bis.doc.gov/Enforcement/knowcust.htm>

If there is reason to believe a violation is taking place or has occurred, report it to the Department of Commerce by calling the 24-hour hotline at 1(800) 424-2980, or via the confidential lead page at: <https://www.bis.doc.gov/forms/eeleadsntips.html>

The EAR does not control all goods, services, and technologies. Other U.S. government agencies regulate more specialized exports. For example, the U.S. Department of State has authority over defense articles and services. A list of other agencies involved in export control can be found on the BIS web.

It is important to note that in August 2009, the President directed a broad-based interagency review of the U.S. export control system, with the goal of strengthening national security and the competitiveness of key U.S. manufacturing and technology sectors by focusing on current threats, as well as adapting to the changing economic and technological landscape. As a result, the Administration launched the Export Control Reform Initiative (ECR Initiative) which is designed to enhance U.S. national security and strengthen the United States' ability to counter threats such as the proliferation of weapons of mass destruction.

The Administration is implementing the reform in three phases. Phases I and II reconcile various definitions, regulations, and policies for export controls, all the while building toward Phase III, which will create a single control list, single licensing agency, unified information technology system, and enforcement coordination center.

For additional information on ECR see: <http://export.gov/ecr/index.asp>

BIS provides a variety of training sessions to U.S. exporters throughout the year. These sessions range from one to two day seminars and focus on the basics of exporting as well as more advanced topics. A list of upcoming seminars can be found at: <https://www.bis.doc.gov/seminarsandtraining/index.htm>

For further details about the Bureau of Industry and Security and its programs, please visit the BIS website at: <http://www.bis.doc.gov/>

Temporary Entry

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#)

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports.

Labeling and Marking Requirements

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An overview of EU mandatory and voluntary labeling and marking requirements has been compiled in a market research report that is available at: http://buyusainfo.net/docs/x_366090.pdf

Prohibited and Restricted Imports

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The 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 above.

Key

Link: http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/customs_tariff/index_en.htm

Customs Regulations and Contact Information

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

Electronic Customs Initiative – This initiative deals with EU Customs modernization developments to improve and facilitate trade in the EU member states. The electronic customs initiative is based on the following three pieces of legislation:

- The [Security and Safety Amendment to the Customs Code](#), which provides for full computerization of all procedures related to security and safety;
- The Decision on the paperless environment for customs and trade ([Electronic Customs Decision](#)) which sets the basic framework and major deadlines for the electronic customs projects;

- The [Modernized Community Customs Code](#) which provides for the completion of the computerization of customs.

Key

Link: http://ec.europa.eu/taxation_customs/customs/policy_issues/electronic_customs_initiative/electronic_customs_legislation/index_en.htm

Homepage of Customs and Taxation Union Directorate (TAXUD) Website

Key Link: http://ec.europa.eu/taxation_customs/customs/index_en.htm

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.

The EU imports in excess of 2 trillion euro worth of goods. It is important that the value of such commerce is accurately measured for the purposes of:

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

These objectives are met using a single instrument - the rules on customs value. The EU applies an internationally accepted concept of '[customs value](#)'.

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

Key

Link: http://ec.europa.eu/taxation_customs/customs/customs_duties/declared_goods/index_en.htm

Standards

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Overview

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Products tested and certified in the United States to American standards are likely to have to be retested and re-certified to EU requirements as a result of the EU's different approach to the protection of the health and safety of consumers and the environment. Where products are not regulated by specific EU technical legislation, they are always subject to the EU's General Product Safety Directive as well as to possible additional national requirements.

European Union legislation and standards created under the New Approach are harmonized across the member states and European Economic Area countries to allow for the free flow of goods. A feature of the New Approach is CE marking. For a list of new approach legislation, go to <http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.main>.

The concept of new approach legislation is likely to disappear as the New Legislative Framework (NLF), which entered into force in January 2010, was put in place to serve as a blueprint for existing and future CE marking legislation. Since 2010/2011 existing legislation has been reviewed to bring them in line with the NLF concepts.

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.

Agricultural Standards

The establishment of harmonized EU rules and standards in the food sector has been ongoing for several decades, but it took until January 2002 for the publication of a general food law establishing the general principles of EU food law. This Regulation introduced mandatory traceability throughout the feed and food chain as of Jan 1, 2005. For specific information on agricultural standards, please refer to the Foreign Agricultural Service's website at: <http://www.fas.usda.gov/posthome/useu/about.html>

There are also export guides to import regulations and standards available on the Foreign Agricultural Service's website: <http://www.fas.usda.gov/posthome/useu/about.html>

Standards Organizations

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

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

1. CENELEC, European Committee for Electrotechnical Standardization (<http://www.cenelec.eu/>)

2. ETSI, European Telecommunications Standards Institute (<http://www.etsi.org/>)
3. CEN, European Committee for Standardization, handling all other standards (<http://www.cen.eu/cen/pages/default.aspx>)

Standards are created or modified by experts in Technical Committees or Working Groups. The members of CEN and CENELEC are the national standards bodies of the member states, which have "mirror committees" that monitor and participate in ongoing European standardization. CEN and CENELEC standards are sold by the individual member states standards bodies. ETSI is different in that it allows direct participation in its technical committees from non-EU companies that have interests in Europe and gives away some of its individual standards at no charge on its website. In addition to the three standards developing organizations, the European Commission plays an important role in standardization through its funding of the participation in the standardization process of small- and medium-sized companies and non-governmental organizations, such as environmental and consumer groups. The Commission also provides money to the standards bodies when it mandates standards development to the European Standards Organization for harmonized standards that will be linked to EU technical legislation. Mandates – or requests for standards - can be checked on line at: http://ec.europa.eu/enterprise/policies/european-standards/standardisation-requests/index_en.htm

Given the EU's vigorous promotion of its regulatory and standards system as well as its generous funding for its development, the EU's standards regime is wide and deep - extending well beyond the EU's political borders to include affiliate members (countries which are hopeful of becoming full members in the future) such as Albania, Belarus, Israel, and Morocco among others. Another category, called "partner standardization body" includes the standards organization of Mongolia, Kyrgyzstan and Australia, which are not likely to become a CEN member or affiliate for political and geographical reasons.

To know what CEN and CENELEC have in the pipeline for future standardization, it is best to visit their websites. Other than their respective annual work plans, CEN's "sectors" page provides an overview by sector and/or technical committee whereas CENELEC offers the possibility to search its database. ETSI's portal (http://portal.etsi.org/Portal_Common/home.asp) leads to ongoing activities.

With the need to adapt more quickly to market needs, European standards organizations have been looking for "new deliverables" which are standard-like products delivered in a shorter timeframe. While few of these "new deliverables" have been linked to EU legislation, expectations are that they will eventually serve as the basis for EU-wide standards.

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

The European Standardization system and strategy was reviewed in 2011 and 2012. The new standards regulation, adopted in November 2012, clarifies the relationship between regulations and standards and confirms the role of the three European standards bodies in developing EN harmonized standards. The emphasis is also on referencing international standards where possible. For information, communication and technology (ICT) products, the importance of interoperability standards has been

recognized. Through a newly established mechanism, a “Platform Committee” reporting to the European Commission will decide which deliverables from fora and consortia might be acceptable for public procurement specifications. The European standards bodies have been encouraged to improve efficiency in terms of delivery and to look for ways to include more societal stakeholders in European standardization.

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

Conformity Assessment

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Conformity Assessment is a mandatory step for the manufacturer in the process of complying with specific EU legislation. The purpose of conformity assessment is to ensure consistency of compliance during all stages, from design to production, to facilitate acceptance of the final product. EU product legislation gives manufacturers some choice regarding conformity assessment, depending on the level of risk involved in the use of their product. These range from self-certification, type examination and production quality control system, to full quality assurance system. Conformity assessment bodies in individual member states are listed in NANDO, the European Commission’s website.

Key Link: <http://ec.europa.eu/enterprise/newapproach/nando/>

To promote market acceptance of the final product, there are a number of voluntary conformity assessment programs. CEN’s certification systems are the Keymark, the CENCER mark, and CEN workshop agreements (CWA) Certification Rules. CENELEC has its own initiative. ETSI does not offer conformity assessment services.

Product Certification

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To sell products in the EU market of 27 member states – soon 28 - as well as in Norway, Liechtenstein and Iceland, U.S. exporters are required to apply CE marking whenever their product is covered by specific product legislation. CE marking product legislation offers manufacturers a number of choices and requires decisions to determine which safety/health concerns need to be addressed, which conformity assessment module is best suited to the manufacturing process, and whether or not to use EU-wide harmonized standards. There is no easy way for U.S. exporters to understand and go through the process of CE marking, but hopefully this section provides some background and clarification.

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

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

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

Accreditation

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

"European Accreditation" (<http://www.european-accreditation.org>) is an organization representing nationally recognized accreditation bodies. Membership is open to nationally recognized accreditation bodies in countries in the European geographical area that can demonstrate that they operate an accreditation system compatible with EN45003 or ISO/IEC Guide 58.

Publication of Technical Regulations

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The Official Journal is the official publication of the European Union. It is published daily on the internet and consists of two series covering adopted legislation as well as case law, studies by committees, and more (<http://eur-lex.europa.eu/JOIndex.do?ihmlang=en>). It lists the standards reference numbers linked to legislation (http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm).

National technical Regulations are published on the Commission's website http://ec.europa.eu/enterprise/tris/index_en.htm to allow other countries and interested parties to comment.

NIST Notify U.S. Service

Member countries of the World Trade Organization (WTO) are required under the Agreement on Technical Barriers to Trade (TBT Agreement) to report to the WTO all proposed technical regulations that could affect trade with other Member countries. **Notify U.S.** is a free, web-based e-mail subscription service that offers an opportunity to review and comment on proposed foreign technical regulations that can affect your access to international markets. Register online at Internet URL: <http://www.nist.gov/notifyus/>

Manufacturers should be mindful that, in addition to the EU's mandatory and voluntary schemes, national voluntary labeling schemes might still apply. These schemes may be highly appreciated by consumers, and thus, become unavoidable for marketing purposes.

Manufacturers are advised to take note that all labels require metric units although dual labeling is also acceptable. The use of language on labels has been the subject of a Commission Communication, which encourages multilingual information, while preserving the right of member states to require the use of the language of the country of consumption.

The EU has mandated that certain products be sold in standardized quantities. Council Directive 2007/45/EC harmonizes packaging of wine and spirits throughout the EU. Existing national sizes will be abolished with a few exceptions for domestic producers. Key Link: http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/prepacked-products/index_en.htm

The Eco-label

The EU eco-label is a voluntary label which U.S. exporters can display on products that meet high standards of environmental awareness. The eco-label is intended to be a marketing tool to encourage consumers to purchase environmentally-friendly products. The criteria for displaying the eco-label are strict, covering the entire lifespan of the product from its manufacture, use, and disposal. These criteria are reviewed every three to five years to take into account advances in manufacturing procedures. There are currently 30 different product groups, and approximately 1300 licenses have been awarded for several hundred products.

Applications to display the eco-label should be directed to the competency body of the member state in which the product is sold. The application fee will be somewhere between €300 and €1300 depending on the tests required to verify if the product is eligible. The eco-label also carries an annual fee equal to 0.15% of the annual volume of sales of the product range within the European community. However, the minimum annual fee is currently set at €500 and maximum €25,000.

There are plans to significantly reform the eco-label in the near future, reducing the application and annual fees and expanding the product ranges significantly. It is also possible that future eligibility criteria may take into account carbon emissions.

Key Links:

[Eco-label Home Page](#)

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National Institute of Standards & Technology

Mr. George W. Arnold
Director
Standards Coordination Office
100 Bureau Dr.
Mail Stop 2100
Gaithersburg, Maryland 20899
Tel: (301) 975-5627
Website: <http://ts.nist.gov/Standards/Global/about.cfm>

CEN – European Committee for Standardization

Avenue Marnix 17
B – 1000 Brussels, Belgium
Tel: 32.2.550.08.11
Fax: 32.2.550.08.19
Website: <http://www.cen.eu/>

CENELEC – European Committee for Electrotechnical Standardization

Avenue Marnix 17
B – 1000 Brussels, Belgium
Tel: 32.2.519.68.71
Fax: 32.2.519.69.19
Website: <http://www.cenelec.eu/>

ETSI - European Telecommunications Standards Institute

Route des Lucioles 650
F – 06921 Sophia Antipolis Cedex, France
Tel: 33.4.92.94.42.00
Fax: 33.4.93.65.47.16
Website: <http://www.etsi.org/>

NORMAPME – European Office of Crafts Trades and Small and Medium-Sized Enterprises for Standardization

Rue Jacques de Lalaing 4
B – 1040 Brussels, Belgium
Tel: 32.2.282.05.30
Fax: 32.2.282.05.35
Website: <http://www.normapme.com/>

ANEC - European Association for the Co-ordination of Consumer Representation in Standardization

Avenue de Tervuren 32, Box 27
B – 1040 Brussels, Belgium
Tel: 32.2.743.24.70
Fax: 32.2.706.54.30
Website: <http://www.anec.org>

ECOS – European Environmental Citizens Organization for Standardization

Rue d'Edimbourg 26
B – 1050 Brussels, Belgium

Tel: 32.2.894.46.55
Fax: 32.2.894.46.10
Website: <http://www.ecostandard.org/>

EOTA – European Organization for Technical Approvals (for construction products)

Avenue des Arts 40
B – 1040 Brussels, Belgium
Tel: 32.2.502.69.00
Fax: 32.2.502.38.14
Website: <http://www.eota.be/>

Trade Agreements

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For a list of trade agreements with the EU and its member states, as well as concise explanations, please see http://tcc.export.gov/Trade_Agreements/index.asp

Web Resources

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EU websites:

Online customs tariff database (TARIC):

http://ec.europa.eu/taxation_customs/customs/customs_duties/tariff_aspects/customs_tariff/index_en.htm

The Modernized Community Customs Code MCCC):

http://europa.eu/legislation_summaries/customs/do0001_en.htm

ECHA: <http://echa.europa.eu>

Taxation and Customs Union:

http://ec.europa.eu/taxation_customs/customs/index_en.htm

Security and Safety Amendment to the Customs Code - Regulation (EC) 648/2005:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:117:0013:0019:en:PDF>

Electronic Customs Initiative: Decision N° 70/2008/EC

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:023:0021:0026:EN:PDF>

Modernized Community Customs Code Regulation (EC) 450/2008):

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:145:0001:0064:EN:PDF>

Legislation related to the Electronic Customs Initiative:

http://ec.europa.eu/taxation_customs/customs/policy_issues/electronic_customs_initiative/electronic_customs_legislation/index_en.htm

Export Help Desk

http://exporthelp.europa.eu/thdapp/index_en.html

International Level:

What is Customs Valuation?:

http://ec.europa.eu/taxation_customs/customs/customs_duties/declared_goods/european/index_en.htm

Customs and Security: Two communications and a proposal for amending the Community Customs Code:

http://ec.europa.eu/taxation_customs/customs/policy_issues/customs_security/index_en.htm

Establishing the Community Customs Code: Regulation (EC) n° 648/2005 of 13 April 2005

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:117:0013:0019:en:PDF>

Pre Arrival/Pre Departure Declarations:

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

AEO: Authorized Economic Operator:

http://ec.europa.eu/taxation_customs/customs/policy_issues/customs_security/aeo/index_en.htm

Contact Information at National Customs Authorities:

http://ec.europa.eu/taxation_customs/taxation/personal_tax/savings_tax/contact_points/index_en.htm

New Approach

Legislation: <http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.main>

Cenelec, European Committee for Electrotechnical Standardization:

<http://www.cenelec.eu/>

ETSI, European Telecommunications Standards Institute:

<http://www.etsi.org/>

CEN, European Committee for Standardization, handling all other standards:

<http://www.cen.eu/cen/Pages/default.aspx>

Standardisation – Mandates:

http://ec.europa.eu/enterprise/policies/european-standards/standardisation-requests/index_en.htm

ETSI – Portal – E-Standardisation :

http://portal.etsi.org/Portal_Common/home.asp

CEN – Sector:

<http://www.cen.eu/cenorm/sectors/index.asp>

CEN - Standard Search:

<http://esearch.cen.eu/esearch/>

Nando (New Approach Notified and Designated Organizations) Information System:

<http://ec.europa.eu/enterprise/newapproach/nando/>

Mutual Recognition Agreements (MRAs):

<http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=mra.main>

European Co-operation for Accreditation:

<http://www.european-accreditation.org/home>

Eur-Lex – Access to European Union Law:

<http://eur-lex.europa.eu/en/index.htm>

Standards Reference Numbers linked to Legislation:

http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm

What's New:

http://ec.europa.eu/enterprise/news/index_en.htm

National technical Regulations:

http://ec.europa.eu/enterprise/tris/index_en.htm

NIST - Notify U.S.:

<http://www.nist.gov/notifyus/>

Metrology, Pre-Packaging – Pack Size:

http://ec.europa.eu/enterprise/sectors/legal-metrology-and-prepack/prepacked-products/index_en.htm

European Union Eco-label Homepage:

<http://ec.europa.eu/environment/ecolabel/>

U.S. websites:

National Trade Estimate Report on Foreign Trade Barriers:

<http://www.ustr.gov/about-us/press-office/reports-and-publications/2012-1>

Agricultural Trade Barriers:

<http://www.fas.usda.gov/posthome/Useu/>

Trade Compliance Center:

<http://tcc.export.gov/>

U.S. Mission to the European Union:

<http://useu.usmission.gov/>

The New EU Battery Directive:

http://www.buyusainfo.net/docs/x_8086174.pdf

The Latest on REACH:

<http://export.gov/europeanunion/reachclp/index.asp>

WEEE and RoHS in the EU:

<http://export.gov/europeanunion/weeerohs/index.asp>

Overview of EU Certificates:

www.fas.usda.gov/gainfiles/200605/146187632.doc

Center for Food Safety and Applied Nutrition:

<http://www.fda.gov/Food/default.htm>

EU Marking, Labeling and Packaging – An Overview

http://buyusainfo.net/docs/x_366090.pdf

The European Union Eco-Label:

http://buyusainfo.net/docs/x_4284752.pdf

Trade Agreements:

http://tcc.export.gov/Trade_Agreements/index.asp

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Chapter 6: Investment Climate

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Openness to Foreign Investment

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EU Treaty Provisions Governing Investment/Historical Background

The European Union has one of the most hospitable climates for U.S. investment in the world, with the historical book value of U.S. investment in the EU member states at just over \$2 trillion. This is a result, in part, of the ongoing process of European integration. The European Union now consists of 27 countries covering virtually all the territory of Europe, soon to be 28 with the entry of Croatia in 2013. It is governed by the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU), which collectively constitute the Treaty of Lisbon.

The EU is founded on the “four freedoms” (free movement of capital, labor, goods and persons) within the European Union. Free movement of capital is required by Article 49 TFEU, which requires EU “Member States” to provide national treatment to investors from other Member States regarding the establishment and conduct of business. Any violation of EU law ultimately can be adjudicated by the European Court of Justice.

Prior to the 1992 Treaty on the European Union (popularly known as the “Maastricht” Treaty), the Community had virtually no role in determining conditions that would affect the entry of investors from third countries into the territories of the Member States. Member States were compelled by the Treaty to grant national treatment to investors from other EU countries (including subsidiaries owned by third countries), but could erect and maintain barriers to investors coming directly from non-EU countries, consistent with their international obligations. These obligations include the Treaties of Friendship,

Commerce and Navigation (FCNs) and Bilateral Investment Treaties (BITs) which the United States has with most EU countries, as well as obligations under the OECD codes on capital movements and invisible transactions. The only role Community law played was to ensure that a foreign-owned company that was established in one Member State received non-discriminatory treatment in other Member States.

EU power to regulate Member State treatment of incoming foreign investment increased considerably in 1993. A Treaty revision that year abolished all restrictions on the movement of capital, both between EU Member States and between Member States and third countries (Article 56). However, Member State measures in force on December 31, 1992 denying national treatment to third-country investors were grandfathered. The generally accepted interpretation of the revision was that EU law governed the treatment of incoming investments (excepted where grandfathered provisions existed) and their treatment after establishment, while the Member States were responsible for ensuring the fair treatment of their own investors outside the territory of the EU.

In June 1997, the European Commission issued a Communication clarifying the scope of EU Treaty provisions on capital movement and the right of establishment. The Commission was reacting to limits that some Member States had imposed on the number of voting shares investors from other Member States could acquire during privatization. The Commission stressed that free movement of capital and freedom of establishment constitute fundamental and directly applicable freedoms established by the Treaty. Nationals and companies of other Member States should, therefore, be free to acquire controlling stakes, exercise the voting rights attached to these stakes and manage domestic companies under the same conditions laid down by a Member State for its own nationals. The European Court of Justice ruled in three precedent-setting cases in 2002 against so-called “golden shares” – shares that can outvote other shareholders in certain circumstances – in France, Belgium and Portugal, triggering several infringement actions by the Commission. The Court subsequently ruled against golden share cases in other Member States.

Lisbon Treaty Impact

The entry into force in December 2009 of the Lisbon Treaty changed EU jurisdiction over direct investment issues in major respects. Article 207 of the Lisbon Treaty now brings foreign direct investment within the scope of the EU common commercial policy, making it an exclusive EU competence. The EU gains the ability to negotiate bilateral investment treaties (BITs) or investment chapters of Free Trade Agreements. Also, the Lisbon Treaty requires the consent of the European Parliament for new EU investment agreements.

In July 2010, the Commission issued a communication aimed at defining a comprehensive EU international investment policy as well as a legislative proposal establishing transitional arrangements for investment agreements between Member States and third countries. The Council and the Parliament reached an agreement in late 2012 on the legislation and the final text with amendments will become law in early 2013 (see: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:351:0040:0046:En:PDF>)

Under the new rules, the more than 1,200 BITs concluded by Member States, including some with the United States, are presumed to remain valid under EU law unless

subsequently found to be incompatible with the EU's common commercial policy. One prior example of incompatibility was a 2006 ECJ ruling against several EU member state BITs with the United States on grounds that their free capital transfers provisions were inconsistent with the balance of payments exception in EU law. The United States will monitor the impact of the new legislation on U.S. BITs with the Member States.

U.S.-EU Efforts to Promote Open Investment

In August 2011, the Transatlantic Economic Council (TEC), a U.S.-EU body coordinating economic cooperation, established a High Level Working Group on Investment, affirming the importance of open investment policies as drivers of global economic growth, both in our bilateral relationship and in our economic engagement with third countries. In April 2012, the United States and the European Union (EU), under the auspices of the Transatlantic Economic Council, announced an agreement on Shared Principles for International Investment, which reaffirmed a commitment to open, transparent, and non-discriminatory international investment policies. (See: http://www.ustr.gov/webfm_send/3337.) The Working Group continues to meet periodically to discuss both bilateral investment issues and cooperation with third countries.

Ownership Restrictions and Reciprocity Provisions

TFEU Article 49 (establishment) and 63/64 (capital movements) helped the EU to create one of the most hospitable legal frameworks for U.S. and other foreign investment in the world. However, restrictions on foreign direct investment do exist. Under EU law, the right to provide aviation transport services within the EU is reserved to firms majority-owned and controlled by EU nationals. The right to provide maritime transport services within certain EU Member States is also restricted. Currently, EU banking, insurance and investment services directives include reciprocal national treatment clauses, under which financial services firms from a third country may be denied the right to establish a new business in the EU if the EU determines that the investor's home country denies national treatment to EU service providers. In addition, as with the United States, a number of EU regulatory measures, particularly in the financial sector, are also subject to prudential exceptions and thus are not guaranteed national and most favored nation treatment under the EU's GATS and other international commitments.

In March 2004, the EU adopted a Directive on takeover bids ("Takeover Directive"), which sought to protect shareholders, improve transparency, and create favorable regulatory conditions for takeovers in order to boost corporate restructuring within the EU. The Takeover Directive authorizes Member States to ban corporate defensive measures (e.g., "poison pills" or multiple voting rights) against hostile takeovers. However, a reciprocity provision allows Member States to exempt companies from those restrictions if the potential suitor operates in a jurisdiction that permits takeover defenses. Article 12.3 of the text is ambiguous as to whether the reciprocity principle applies to non-EU firms. However, the preamble states that application of the optional measures is without prejudice to international agreements to which the Community is a party. For example, French companies may suspend implementation of a takeover if they are targeted by a foreign company that does not apply reciprocal rules. In June 2012, the Commission issued a report based on an external study that reviewed the application of the Takeover Directive. The report concluded that most stakeholders were satisfied with the Directive and that it was functioning satisfactorily, although it listed

several rules that could use clarification in order to improve legal certainty for the parties concerned and the effective exercise of minority shareholder rights. The June 2012 report can be found

here: http://ec.europa.eu/internal_market/company/docs/takeoverbids/COM2012_347_en.pdf

Energy Sector Liberalization

On June 25, 2009, after passage by the European Parliament, the European Union officially adopted the Third Energy Package, legislation consisting of two directives and three regulations designed to promote internal energy market integration and to enhance EU energy security. Specifically, the legislation mandates the separation of energy production and supply from transmission through the unbundling of European energy firms. The objective is to create a level playing field by preventing companies engaged in the generation and distribution of gas and electricity from using their privileged position to prevent access to transmission systems or limit connectivity of transmission networks. Energy firms that operate within the European market have three options: 1) full ownership unbundling; 2) an Independent System Operator (ISO); and 3) an Independent Transmission Operator (ITO).

Additionally, the package includes a "Third Country Clause" that requires all non-EU companies to comply with the same unbundling requirements as EU companies before they are certified to own and/or operate transmission networks in the EU. Moreover, the clause permits Member States to refuse a foreign company certification/permission to acquire or operate a transmission network – even if it meets other requirements – if it is deemed to have a potential negative impact on the security of energy supply of an individual Member State or the EU as a whole.

Member States are required to inform the Commission of their choice of unbundling model and certification has to be carried out with the involvement of the Commission. The Third Package entered into force in March 2011, while the "Third Country Clause" is only applicable from March 2013 onwards. The Commission has also set up a Gas Advisory Council to work with the Russian government and state-owned Gazprom, both of which have extensively criticized the unbundling provisions. In September 2012, the European Commission opened an antitrust investigation into three alleged anti-competitive practices by Gazprom in Central and Eastern European gas markets. First, Gazprom may have divided gas markets by hindering the free flow of gas across Member States. Second, Gazprom may have prevented the diversification of supply of gas. Finally, Gazprom may have imposed unfair prices on its customers by linking the price of gas to oil prices.

Conversion and Transfer Policies

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Europe's single currency, the euro, and the remaining national EU Member State currencies are freely convertible. The EU, like the U.S., places virtually no restrictions on capital movements. Article 63 TFEU specifically prohibits restrictions on the movement of capital and payments between Member States and between Member States and third countries, although article 64 allows for exceptions in certain circumstances, a fact which formed the basis of the ECJ case referenced above under "Lisbon Treaty Impact". The adoption of the euro in 17 of the EU Member States has

shifted currency management and control of monetary policy in those countries to the European Central Bank (ECB).

Expropriation and Compensation

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The European Union does not have the authority to expropriate property; this remains the exclusive competence of the Member States.

Dispute Settlement

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Foreign investors can, and do, take disputes against Member State governments directly to local courts. In addition, any violation of a right guaranteed under EU law - which has supremacy over Member State law, can be heard in local courts or addressed directly to the European Court of Justice by a foreign investor with a presence in a Member State. Further, all EU Member States are members of the World Bank's International Center for the Settlement of Investment Disputes (ICSID), and most have consented to ICSID arbitration of investment disputes arising under individual bilateral investment treaties. While the EU is not itself a party to ICSID or other similar arbitration conventions, it has stated its willingness to have investment disputes subject to international arbitration. Regulation No 1219/2012 of the European Parliament and the Council adopted 12 December 2012 (see link in paragraph eight) foresees that if a Bilateral Investment Treaty (BIT) falls within the scope of that Regulation, the Member State is, under Art 13(c), obliged to "seek the agreement of the Commission before activating any relevant mechanisms for dispute settlement against a third country included in the bilateral investment agreement and shall, where requested by the Commission, activate such mechanisms." The article further states that "those mechanisms shall include consultations with the other party to a bilateral investment agreement and dispute settlement where provided for in the agreement," and that "the Member State and the Commission shall fully cooperate in the conduct of procedures within the relevant mechanisms, which may include, where appropriate, the participation in the relevant procedures by the Commission."

Performance Requirements and Incentives

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European Union grant and subsidy programs are generally available only for nationals and companies based in the EU, but usually on a national treatment basis. For more information, see Chapter 7 "Trade and Project Financing" in the EU Country Commercial Guide as well as individual Country Commercial Guides for Member State practices.

Right to Private Ownership and Establishment

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The right to private ownership is firmly established in EU law, as well as in the law of the individual Member States. See individual country commercial guides for EU Member State practices.

Protection of Property Rights

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The EU and its Member States support strong protection for intellectual property rights (IPR) and other property rights. The EU and/or its Member States adhere to all major intellectual property rights agreements and offer strong IPR protection, including

implementation of the WTO TRIPS provisions. Together, the U.S. and the EU have committed to enforcing IPR in third countries and at our borders in the EU-U.S. Action Strategy endorsed at the June 2006 U.S.-EU Summit.

Despite overall strong support for property rights enforcement, several EU Member States have been identified in the U.S. Special 301 process due to concerns with protection of certain intellectual property rights. The United States continues to be engaged with the EU and individual Member States on these matters.

Enforcement of Intellectual and Industrial Property Rights

In April 2004, the EU adopted the Intellectual Property Enforcement Directive (IPRED) (http://ec.europa.eu/internal_market/iprenforcement/directives_en.htm). This Directive requires Member States to apply effective and proportionate remedies and penalties to form a deterrent against counterfeiting and piracy and harmonizes measures, procedures, and remedies for right holders to defend their IPR within Member States. Remedies available to right holders under IPRED include the destruction, recall, or permanent removal from the market of illegal goods, as well as financial compensation, injunctions, and damages. Commission studies have shown that the Directive has provided a solid basis for the enforcement of IPR but also led to “very diverging interpretations by Member States and their courts.” As a result, the European Commission has been consulting stakeholders since 2010 in order to evaluate the overall functioning of the civil enforcement system for intellectual property rights and ways in which to improve the legal framework in the EU. The current consultation closes in March 2013.

At the second High Level Conference on Counterfeiting and Piracy April 2, 2009, the Commission launched the European Observatory on Counterfeiting and Piracy. The role of the Observatory, which is composed of private industry representatives and designees chosen by Member States, is to serve as the central resource for gathering, monitoring and reporting information related to IPR infringement in the EU. In March 2012 a regulation entrusting the Office for Harmonisation in the Internal Market (OHIM) with the tasks and activities relating to the management of the European Observatory on Counterfeiting and Piracy was adopted. See: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:129:0001:0006:EN:PDF>

Specific Enforcement Measures

Copyright: In 2001, the EU adopted Directive 2001/29 establishing pan-EU rules on copyright and related rights in the information society. In December 2006, the Council and Parliament passed an updated version of the 2001 Copyright Directive modified to clarify terms of copyright protection. This new Directive (2006/116/EC) entered into force in January 2007. Despite these directives aimed at harmonizing certain aspects of copyright and related rights in the information society, there currently isn't a legal instrument specifically addressing the clearing of copyright and related rights for cross-border on-line audiovisual media services. The Commission therefore presented proposals in 2012 to improve the collective management of copyright including by increased transparency and better governance of collecting societies, with the aim of ensuring that collective management evolves and responds to the needs of multi-territorial licensing.

See: http://ec.europa.eu/internal_market/copyright/docs/management/com-2012-3722_en.pdf

In September 2011 the EU amended Directive 2006/116/EC regarding the term of protection of copyright and certain related rights. The agreed text will extend the term of copyright protection for performers and record producers from 50 to 70 years and introduce a 'use-it-or-lose-it' provision that allows performers to recover their rights after 50 years, should the producer fail to market the sound recording, and a so-called 'clean slate' which prevents record producers from making deductions to the royalties they pay to featured performers. The proposal also creates a new claim for session players amounting to 20 percent of record labels' offline and online sales revenue.

On December 14, 2009, the European Union and Member States ratified the World Intellectual Property Organization (WIPO) Copyright Treaty and the WIPO Performances and Phonograms Treaty.

In October 2007, the U.S. and key trading partners announced their intention to negotiate an Anti-Counterfeiting Trade Agreement (ACTA) in order to bolster efforts to combat counterfeiting and piracy by identifying a new, higher benchmark for enforcement that countries can join on a voluntary basis. The United States, Australia, Canada, Korea, Japan, New Zealand, Morocco, and Singapore signed ACTA at a ceremony on October 1, 2011, in Tokyo. The EU and 22 EU Member States signed ACTA on 26 January 2012, also in Tokyo, but the European Parliament did not give its consent and therefore the EU will not be a member of the Agreement for the time being.

Trademarks: Registration of trademarks with the European Union's Office for Harmonization in the Internal Market (OHIM) began in 1996. OHIM issues a single Community Trademark (CTM) that is valid in all EU Member States. In October 2004 the European Community acceded to the World Intellectual Property Organization (WIPO) Madrid Protocol. The accession of the Community to the Madrid Protocol established a link between the Madrid Protocol system, administered by WIPO, and the Community Trademark system, administered by OHIM. Since October 2004 Community Trademark applicants and holders have been allowed to apply for international protection of their trademarks through the filing of an international application under the Madrid Protocol. Conversely, holders of international registrations under the Madrid Protocol are entitled to apply for trademark protection under the Community trademark system. The link between the OHIM and the WIPO registration systems allows firms to profit from the advantages of each while reducing costs and simplifying administrative requirements.

On March 31, 2009, the Commission announced new, lower fees and simplified procedures for EU-wide trademark rights, eliminating registration fees and reducing application fees by 40 percent. The new rates entered into force May 1, 2009, and applications for trademarks can be done online. In 2011 more than 105,900 trade mark applications were filed with more than 99,000 in 2012. In recognition that stakeholders increasingly demand faster, higher quality, and more streamlined trade mark registration systems which are technologically up-to-date, the European Commission is expected to present proposals to revise both the Community Trade Mark Regulation and the Trade Mark Directive in the near future.

Designs: The EU adopted the Community Designs Regulation, a Regulation introducing a single Community system for the protection of designs, in December 2001. The Regulation provides for two types of design protection, directly applicable in each EU Member State: the Registered Community Design (RCD) and the unregistered Community design. Under the Registered Community Design system, holders of eligible designs can use an inexpensive procedure to register them with OHIM, and will then be granted exclusive rights to use the designs anywhere in the EU for up to twenty-five years. Unregistered Community designs that meet the Regulation's requirements are automatically protected for three years from the date of disclosure of the design to the public. Protection for any registered Community design was automatically extended to Romania and Bulgaria when those countries acceded to the European Union on January 1, 2007.

In September 2007 the EU acceded to the Geneva Act of the Hague Agreement concerning international registration of industrial designs. This allows EU companies to obtain protection for designs in any country that belongs to the Geneva Act, reducing costs for international protection. The system became operational for businesses in January 2008. In April 2008 OHIM updated the guidelines for renewal of Registered Community Designs. In February 2009 OHIM announced it would accept priority documents that do not include views of designs, such as German registration certificates. The change has helped accelerate the registration process, and is in line with the practice in most EU member states.

Patents: In 2012, the European Union formally approved the creation of a first unitary patent covering all EU member states except Spain and Italy. The current system requires patents to be registered separately in individual EU Member States making it a lengthy and costly procedure. Under the new system, companies will need to submit applications to the European Patent Office in Munich. EU Patents will be made available in three languages (English, French, and German) but applications can be made in any EU language and free machine translations are available in 28 European languages for information purposes. There will also be a new the Unified Patent Court replacing the need to defend patents in several Member State courts. The historic decision follows more than four decades of negotiations and deadlocks, and legal objections from Spain and Italy. The two countries have chosen not to join the system but are welcome to join at a later stage. The Unitary Patent should enter into force by January 2014 and the first unitary patents are expected to be granted by April 2014. The European Commission estimates that when fully in place, a unitary patent will cost around 5,000 euros, compared to the current 36,000 euros for coverage in all 27 Member States.

Links to new regulations: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:361:0001:0008:EN:PDF>
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:361:0089:0092:EN:PDF>

Until the implementation of the new Community Patent System, the most effective way to secure a patent across EU national markets is to use the services of the European Patent Office (EPO). EPO offers a one-stop-shop enabling right holders to obtain various national patents using a single application. However, these national patents have to be validated, maintained and litigated separately in each Member State. In September 2008 the EPO and the U.S. Patent and Trademark Office (USPTO) launched the Patent Prosecution Highway, a joint trial initiative leveraging fast-track patent

examination procedures already available in both offices to allow applicants to obtain corresponding patents faster and more efficiently. This permits each office to exploit work already done by the other office and reduce duplication. In addition, the two offices, along with the patent offices of Japan, Korea, and China, announced a joint agreement (IP5) in November 2008 to undertake projects to harmonize the environment for work sharing and eliminate unnecessary work duplication.

Geographical Indications: The United States continues to have concerns about the EU's system for the protection of Geographical Indications (GIs). In a WTO dispute launched by the United States, a WTO panel found that the EU regulation on food-related GIs was inconsistent with EU obligations under the TRIPS Agreement and the General Agreement on Tariffs and Trade of 1994. In its report, the panel determined that the EU regulation impermissibly discriminated against non-EU products and persons, and agreed with the United States that the EU could not create broad exceptions to trademark rights guaranteed by the TRIPS Agreement. The panel's report was adopted by the WTO Dispute Settlement Body (DSB) in April 2005. In response to the DSB's recommendations and rulings, the EU published an amended GI regulation, Council Regulation (EC) 510/06, in March 2006 (amended by Council Regulation (EC) 179/2006 and Commission Regulation 417/2008). The United States continues to have some concerns about this amended regulation, about Council Regulation (EC) 479/08, which relates to wines, and about Commission Regulation (EC) 607/09, which relates inter alia, to GIs and traditional terms of wine sector products.

The EU adopted on 10 December 2010 a "Quality Package Regulation" which includes a proposal for a new 'Agricultural Product Quality Schemes Regulation' which reinforces the scheme for protected designations of origin and geographical indications (PDOs and PGIs); overhauling the traditional specialties guaranteed scheme (TSGs), and lays down a new framework for the development of Optional Quality Terms to provide consumers with information such as 'free range' and 'first cold pressing.' It also includes a proposal to streamline adoption of marketing standards by the Commission, including the power to extend place of farming labeling in accordance with the specificity of each agricultural sector and new guidelines on best practices for voluntary certification schemes and on the labeling of products using geographical indications as ingredients. This legislative proposal was sent to the Council and European Parliament for review and possible amendments and was adopted on November 21, 2012, and published in the Official Journal L343 on December 14, 2012. It is Regulation 1151 of 2012. With this regulation, all different quality schemes were combined into one legal instrument; the approval time for GIs was shortened; and, the comment period on applications was also shortened. The United States is carefully monitoring the application of these regulations.

EU international efforts to expand GI protection: The EU continues to campaign to have its geographical indications protected throughout the world without regard to consumer expectation in individual markets, and to expand the negotiations for a registry of geographical indications beyond wines and spirits to other foodstuffs. This has developed into a major EU priority in the context of the Doha Development Agenda negotiations in the WTO, in which a discussion is ongoing concerning the extension of so-called "additional" GI protection to products in addition to wine and spirits. The U.S. and other WTO members continue to oppose the EU's proposals to extend "additional" GI protection, noting that the objective of effective protection of such indications can be accomplished through existing GI obligations.

U.S.-EU coordination on IP counterfeiting and piracy: Since the U.S.-EU summit of June 2005, where leaders agreed to more closely cooperate on IPR enforcement, the U.S. and the EU have intensified customs cooperation and border enforcement, strengthened cooperation with and in third countries, and built public-private partnerships and awareness raising activities together. The U.S.-EU action strategy for the enforcement of intellectual property was launched at the US-EU Summit in June 2006. Since then, U.S. and EU officials have regularly met with stakeholders to identify new areas for cooperation including capacity building, joint messaging, and coordinated border actions.

Transparency of Regulatory System

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The EU is widely recognized as having a generally transparent regulatory regime. The Commission, which has the sole authority to propose EU-level laws and regulations, generally announces an interest in legislating in a certain area, issuing a “green paper” for broad discussion, followed by a “white paper” with more detail on the proposed measure, and eventually a formal legislative proposal. The Member State ministers and experts examine and amend these proposals in Council in tandem with European Parliament consideration of them; Council decisions and EP amendments are publicly available. Informal working documents are not published, but interested parties usually can get fairly detailed information as these processes unfold. All adopted measures are published in 22 languages in the EU’s Official Journal, which is available online.

The EU’s Better Regulation policy, adopted in 2005, aims at simplifying and improving existing regulation and at better designing new regulation. In October, 2010, the Commission announced Smart Regulation, which expands on the Better Regulation policy and emphasizes three points: the continued importance of evaluating existing legislation and conducting impact assessment statements for proposed legislation in order to provide evidence and transparency on the benefits and costs of regulatory policy choices; shared responsibility and commitment between the Commission, European Parliament, the Council and Member States for making legislation clearer and more accessible; and facilitating the ability of citizens and stakeholders to engage policy makers on the impact of existing and proposed regulations.

See: http://ec.europa.eu/governance/better_regulation/index_en.htm

U.S.-EU Regulatory Cooperation

The U.S and EU have worked together to minimize the impact of unnecessary regulatory divergences since at least the December 1997 Agreement on Regulatory Cooperation Principles. Much of this work was subsumed under the High Level Regulatory Cooperation Forum (HLRCF), established in 2005 as a place for regulators to exchange best practices. The HLRCF is co-chaired on the U.S. side by the Administrator of OMB’s Office of Information and Regulatory Affairs (OIRA) and on the EU side by the Director General of Enterprise and Industry. The HLRCF reports to the cabinet-level Transatlantic Economic Council (TEC)- <http://www.state.gov/p/eur/rt/eu/tec/index.htm> While the HLRCF is the principal formal tool for broad regulatory cooperation, significant contacts also exist between individual regulators in the U.S. and in EU.

At the November 28, 2011 meeting of the HLRCF, U.S. and EU officials emphasized a continued shared commitment to streamlining regulation and a joint recognition that improving the compatibility of American and European regulation would lead to economic growth and jobs. Both sides celebrated an agreement to “build bridges”

between the different systems for setting standards in the U.S. and EU and expressed optimism that this agreement will result in comparable standards emerging from the different systems. Both sides agreed in principle on the importance of notifying one another of proposed legislation that might impact trade, and committed to formalizing an understanding to provide such notice, notwithstanding fundamental differences in the way that legislation is formulated in the EU and U.S.

At the November 28, 2011 U.S.-EU Summit, U.S. and EU leaders announced the formation of a High Level Working Group on Jobs and Growth and tasked it to identify policies and measures to increase trade and investment to support mutually beneficial job creation, economic growth, and competitiveness, working closely with public and private sector stakeholder groups, and drawing on existing dialogues and mechanisms, as appropriate. The Working Group issued an interim report in June 2012 which addresses the importance of enhanced U.S.-EU regulatory cooperation. The Working Group has not yet issued its final recommendations to leaders, though a final report is expected in early 2013. If the Working Group recommends that the U.S. and EU pursue a formal, comprehensive trade agreement, such an agreement is likely to have a significant impact on U.S.-EU regulatory cooperation efforts.

Efficient Capital Markets and Portfolio Investment

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The single market project has spurred efforts to establish EU-wide capital markets. The EU has acted to implement the 1999 Financial Services Action Plan (FSAP) to establish legal frameworks for integrated financial services (banking, equity, bond and insurance) markets within the EU. FSAP measures include Directives on: Prospectuses (permitting one approved prospectus to be used throughout the EU), Transparency (detailing reporting requirements for listed firms, including adoption of International Accounting Standards), Markets in Financial Instruments (MiFID - providing framework rules for securities exchanges and investment firms), Takeover Bids (to facilitate cross-border takeovers), and Capital Requirements (implementing the rules developed by the Basel Committee of Banking Supervisors (BCBS)).

Markets in Financial Instruments Directive: In November 2007, the EU's Markets in Financial Instruments Directive (MiFID) came into force. This law seeks to eliminate many barriers to cross-border stock trading by establishing a common framework for European securities markets, increasing competition between market exchanges, raising investor protection and providing investors a broader range of trading venues. It gives EU securities exchanges, multilateral trading facilities and investment firms a "single passport" to operate throughout the EU on the basis of authorization in their home Member States. MiFID is broadly considered a success but came under the Commission's normal review process in 2011.

On October 20, 2011, the Commission issued its proposal for modifying the Markets in Financial Instruments Directive and Regulation (MiFID/MiFIR), which the European Parliament and Council discussed throughout 2012. This proposal implements the G-20 commitment to promote trading of standardized derivatives on exchanges on electronic trading platforms, where appropriate, as well as revised market structure rules, including new rules for trading platforms and high frequency trading. In particular, the MiFID proposal seeks to introduce "organized trading platforms" and central clearing of derivatives trades, end vertical silos between clearing and trading, and establish

equivalence findings for jurisdictions outside the EU. Adoption is expected in 2013, possibly in the first half of the year.

Market Abuse Directive: Connected to the review of MiFID is the revision of the Market Abuse Directive (MAD). In October 2011, the Commission presented its legislative proposals reviewing the Market Abuse Regulation (MAR) and the Market Abuse Directive (MAD). The proposals aim to increase market integrity and investor protection. The new MAR seeks to create a single, directly applicable EU-wide rulebook for market abuse enforced by national administrative sanctions. MAD would require all Member States to introduce criminal sanctions for intentional insider dealing and market manipulation. Following the LIBOR scandal in June 2012, the European Commission amended its MAD/R proposal to make the manipulation of benchmarks a criminal offence. Adoption is expected in 2013.

Solvency II: Solvency II is the new risk-based solvency regime for the EU insurance sector, approved in 2009. It was originally due to come into force in January 2013 but has been pushed back one year. It introduces the concepts of group solvency and group supervision. Third-country insurers will be allowed to operate in the EU if their home country regulatory framework is found to be equivalent to the EU's by a formal Commission decision. Third-country insurers whose home jurisdictions are not found equivalent will likely have to establish a holding company in the EU.

In October 2010, the European Commission (EC) announced that it will include in the first wave of equivalence assessments under Solvency II, the regulatory systems of Bermuda and Switzerland (for Reinsurance, Group solvency and Group supervision), and of Japan (for Reinsurance only). To account for the exclusion of the United States from the first wave of assessments, and even though the Solvency II Directive does not foresee a transitional regime for equivalence, the EC suggested that time-limited transitional measures be developed as secondary legislation, to allow eligible third-countries (including the U.S.) to enjoy the full benefits of equivalence. The eligibility criteria will be specified by the EC in the implementing measures, but will likely require a commitment to converge towards a regime capable of meeting the equivalence criteria at the end of the transitional period. The Omnibus II Directive, which will introduce the necessary legal basis to set up the transitional regime for eligible third-countries, could be approved by the middle of 2013. Meanwhile, its entry into force has been extended to January 2014, to account for the delay in adoption.

Reform of mutual funds: In January 2009 the European Parliament adopted legislation to achieve a less fragmented and more efficient investment fund market in the EU. UCITS IV -- Undertakings for Collective Investment in Transferable Securities -- are investment funds sold under a common set of EU rules for investor protection and cost transparency that also meet basic requirements for organization, management and oversight of funds. UCITS funds manage approximately €6.4 trillion and account for 11.5% of EU household financial assets. The legislation includes a provision for a management "passport," which will make it easier and less expensive for investment funds to operate outside their state of origin. Member States were required to implement the legislation by 2011.

In July 2012, the EC proposed to amend the UCITS IV. The amendment (UCITS V) aims to bring UCITS in line with the Alternative Investment Fund Managers Directive (AIFMD) as regards depositary functions, remuneration policies and sanctions.

Outlook: Adoption is expected in 2013, ahead of a fully-fledged revision of the UCITS framework (so-called UCITS VI) that could be published in the second half of 2013.

Retail Services: The EU has also focused on deepening integration of retail financial services markets, although this has become less of a priority as a result of the financial crisis. The retail investment market is largely dominated by Packaged Retail Investment Products (PRIP). While they provide retail investors with easy access to financial markets, they can also be complex for investors to understand. Sellers can also face conflicts of interest since they are often remunerated by the product manufacturers rather than directly by the retail investors. To address these issues, the Commission has proposed legislation to introduce changes in product transparency (pre-contractual disclosures) and sales rules.

Outlook: Legislation was proposed in July 2012, and aims to raise standards for advice and to tighten rules on investment funds to enhance their safety. While this does not seem to be a priority file, adoption could still be achieved by the end of 2013.

Regulatory Responses to the Financial Crisis

In response to the growing impact of the global financial crisis in Europe, the Commission put forward several legislative proposals that go beyond the measures envisaged by the 1999 Financial Services Action Plan (FSAP) in order to address what was increasingly perceived as an unacceptable degree of deregulation in the financial sector, particularly in the wake of massive injections of public money to rescue weak financial institutions. Concerns about the stability of the eurozone also prompted several far-reaching proposals in 2012.

Banking union: In December 2012, Member States agreed on legislation to create a Single Supervisory Mechanism (SSM) at the European Central Bank. The existence of a single supervisor is the necessary (though not sufficient) prerequisite to allow euro area financial backstops (e.g., the European Stability Mechanism) to be used to directly recapitalize euro area banks in need. The SSM is part of a wider plan to create a Banking Union that includes a proposal to amend the remit and the powers of the European Banking Authority (EBA) and a roadmap towards future proposals for a European deposit guarantee system and bank resolution authority.

According to the December agreement, the SSM would be operational on March 1, 2014 at the earliest. Banks with more than €30bn in assets or representing 20 percent of the member state of establishment's GDP will qualify for direct ECB supervision. Banks with subsidiaries in more than two member states may also be required to fall under ECB supervision (a list of all the banks that will be supervised by the ECB is being prepared). The ECB will be empowered to apply higher capital buffers than required by national authorities (including countercyclical buffers), and apply more stringent measures aimed at addressing systemic or macro-prudential risks at the level of credit institutions.

As of early 2013, work was still ongoing on the proposal to amend the EBA regulation, where the European Parliament as well as the Council must find agreement. Agreement is expected by March 2013.

Crisis management and resolution: In June 2012, the EC unveiled its proposal for a framework for “bank recovery and resolution” that would aim for consistency among member states regimes. The Directive proposes setting up tools for "prevention," "early intervention" and "resolution," with intervention by the authorities becoming more intrusive as the situation deteriorates. Adoption of this directive would provide the EU with a coherent framework for resolving banks (which some EU Member States still lack), and would fulfill the EU's G-20 commitments in this area.

Under the proposal, national authorities will be required to create resolution funds, which will raise contributions from banks proportionate to their liabilities and risk profiles. National resolution funds will be required to interact and borrow from each other. Existing national deposit guarantee schemes (DGS) can provide funding for the protection of retail customers, and even be merged with the resolution funds, as long as they are able to repay depositors in case of failure.

Banks would have to draw up recovery plans for individual firms and at group level and resolution authorities would be required to prepare resolution plans for individual firms and at group level. Authorities could require a bank to modify its legal or operational structures to ensure that it can be resolved with the available tools. The Directive requires the adoption of reforms, at national level, to enable the use of tools such as sale of business, bridge bank and asset separation. The most controversial provision is the ability to use bail-in capital to recapitalize a going concern institution.

In the first half of 2013, the EC is expected to unveil a proposal for a common resolution framework covering euro area banks. While initial proposals by the European Commission envisioned a banking union that would ultimately entail common euro area deposit insurance and resolution & recovery backstops, common deposit insurance no longer appears to be under discussion, with the near-term focus on harmonizing existing national frameworks. Adoption is not expected during 2013.

Credit Rating Agencies (CRAs): The current Regulation on Credit Rating Agencies entered into force in 2009 and introduced an authorization and supervision regime. For ratings issued by third-country CRAs to be used in the EU for regulatory purposes, the Regulation introduced two mechanisms:

Equivalence: Ratings by non-systemically relevant CRAs established outside of the EU can be used in the EU if the CRA's home jurisdiction is deemed equivalent and the home jurisdiction supervisor (e.g. SEC) has concluded a cooperation agreement with ESMA. In May 2010, CESR (now ESMA) found the U.S. regulatory system “broadly equivalent to that of the EU.” After the entry into force of the Dodd-Frank Act, the Commission asked ESMA for an additional analysis of the changes it introduced.

Endorsement: An EU-registered CRA may endorse ratings issued by an unregistered affiliate located outside of the EU. The endorsing CRA must demonstrate that the ratings have been developed following internal standards “at least as stringent as” the EU's, that the affiliate is registered and supervised and that a cooperation agreement between supervisors is in place. As they are likely to be deemed systemically relevant, endorsement will be the only mechanism for ratings issued by Moody's, S&P and Fitch to be used in the EU.

In October 2011, ESMA successfully completed the registration process for DBRS, Fitch Ratings, Moody's Investors Service, and Standard & Poor's (S&P) as Credit Rating Agencies. A year later, the Commission found the U.S. regulatory framework for CRAs equivalent to the EU's. As a consequence, under the second Credit Rating Agencies Regulation (CRA II), U.S.-headquartered CRAs no longer need to have the ratings they produce endorsed by an EU-based affiliate in order for them to be used in Europe.

In December 2012, the European Parliament and the Council agreed on an amendment to the regulation on credit rating agencies (CRA) known as CRA III. The new regulation will enter into force later in 2013, following its publication in the Official Journal, and introduces limitations on the number of sovereign ratings a rating agency can provide in a year as well as a stricter regime for the rating of structured finance products that requires issuers to rotate rating agencies according to a defined calendar. The regulation also introduces a liability regime and seeks to resolve conflicts of interest by establishing rules on ownership of rating agencies and rated entities.

Deposit Guarantees: In December 2008 the Council and Parliament approved a Commission proposal to raise the minimum threshold for deposit insurance to €100,000 in two steps, and to harmonize the time period for repayment of deposits. As a result, minimum deposit guarantees were raised to €50,000 on June 30, 2009, and the payout period shortened from the current three months to 20 days. Coverage applies to all depositors in all Member States, regardless of whether the member state is a member of the euro area. The threshold was raised to €100,000 on January 1, 2010.

In June 2010, the Commission published draft legislation amending the Directive on Deposit Guarantee Schemes. It proposes that:

- Deposit guarantees in all Member States be set to €100,000 for all deposit-taking institutions, even though some Member States currently offer higher levels;
- Deposit Guarantee Schemes (DGS) must hold "1.5% of eligible deposits at hand after a transition period of 10 years";
- Borrowing from other DGS in the EU be allowed if necessary;
- Shorten from 20 to seven days the time-lag for receiving funds after the activation of the guarantees.

Outlook: Work is stalled and adoption in 2013 is unlikely.

Alternative Investment Fund Managers Directive (AIFMD): AIFMD will enter into force mid-2013. EU managers will be allowed EU-wide market access on the basis of a passport. Third-country managers will be eligible for this passport in 2015 at the earliest. National private placement regimes will remain in place at least until 2018. ESMA and third-country competent authorities are currently negotiating the required MoUs on supervisory co-operation agreements.

Capital Requirements Directives: On July 20, 2011 the Commission issued its proposal to implement the Basel III framework in a two-document package that includes the fourth amendment to the Capital Requirements Directives (CRD IV) and the first Capital Requirements Regulation (CRR I). The European Parliament's Economic and Monetary Affairs Committee (ECON) is now reviewing the proposals.

- CRR I contains most of the capital and liquidity rules for banks and investment firms. The decision to use a regulation, rather than a directive, signals the Commission's intention to achieve maximum harmonization in the way the rules are applied across Member States by promoting a "single rulebook." Some Member States – particularly the UK and Sweden – have opposed this approach because it would limit their macro-prudential authorities' ability impose higher standards nationally.
- CRD IV prescribes measures on enhanced corporate governance, supervision, and capital buffers that need to remain within the competence of individual Member States for legal or practical reasons.

The EU proposal is largely consistent with Basel III with a few notable exceptions, including:

- **Minority Interest:** The proposal permits the use of non-standard methods for calculating regulatory capital in conglomerates, in a way that benefits European bank-assurance models. Instead of the Basel III cap of 10 percent on minority interest as a share of core Tier 1 capital, CRR I allows European firms to use methodology specified in the EU's 2002 Financial Conglomerates Directive (FCD) that effectively reduces the deductions from capital related to minority interest.
- **Leverage Ratio:** While Basel III calls for migration of the simple leverage ratio from a transition period to mandatory Pillar I treatment in 2018, CRR I does not include a legal mechanism to ensure the transition from Pillar II to Pillar I. The CRR I text also does not include the 3 percent ratio calibration established in Basel III.
- **Liquidity Coverage Ratio (LCR):** CRR I allows national supervisors an option to apply the LCR at the group level only, while Basel III calls for liquidity standards to apply at the level of legal entities as well. In addition, while CRR I creates a legal vehicle to establish the LCR, it does not provide such a vehicle for the net stable funding ratio.
- **Outlook:** The EC had to delay its planned implementation of the law by January 2013, in keeping with G-20 commitments. Several issues, including a controversial proposal by the European Parliament on remuneration that would cap bonuses at 100 percent of the fixed pay (violating the FSB's principles for sound remuneration), have prevented the two co-legislators from reaching agreement. Adoption is expected in 2013.

Short-selling/Credit Default Swaps Regulation: On November 1, 2012 the regulation on "Short Selling and certain aspects of credit default swaps (CDS)" entered into force. The law bans naked sales of sovereign CDS, as well as naked bond and share sales, unless used to hedge exposures. Investors may continue to buy CDS on sovereign debt only if they own the bond or other assets whose price is correlated to that of the bond, as defined by ESMA and the Commission. National authorities can "opt-out" to protect the functioning of their sovereign debt markets under certain conditions.

Financial Conglomerates Directive: A recent revision of the Financial Conglomerates Directive (FCD) gives national supervisors new powers to better oversee the conglomerates' parent entities. Supervisors are able to apply banking supervision, insurance supervision and supplementary supervision at the same time and to receive better information at an earlier stage.

New Financial Supervisory Architecture

Supervisory authority and enforcement in the fields of banking, securities and insurance remains a Member State competence. However, in late 2008, the European Commission asked former IMF Director General Jacques de Larosière to review the EU's financial supervisory architecture and make recommendations for improvement. The "de Larosière" report, published on February 25, 2009, recommended the creation of a European System of Financial Supervisors (ESFS) and a European Systemic Risk Board (ESRB) and served as the basis for legislative proposals by the Commission seeking to reform the European system of financial supervision at macro and micro prudential levels. Legislation adopted in September 2010 created as of January 1, 2011 three new European Supervisory Authorities (ESAs) - the European Banking Authority (EBA), the European Insurance and Occupational Pensions Authority (EIOPA), and the European Securities and Markets Authority (ESMA) – as well as the European Systemic Risk Board (ESRB).

European System of Financial Supervisors (ESFS): The new European Supervisory Authorities replaced the EU "Level 3" Committees (CESR, CEBS, and CEIOPS). While the Level 3 Committees were only consultative bodies, the ESAs gained limited but real powers to carry out their four primary tasks:

- Develop technical standards to establish a single EU rule book. The ESAs were empowered to develop rules and technical standards. (However, Commission approval is necessary to make them legally binding.) The ESAs continue to provide the Commission with expert technical advice, as the Level 3 Committees did. However, while previously the Commission could modify on its own the advice it received from the Level 3 Committees, the new procedure will require Council and EP approval to modify the ESA's advice. No scrutiny is needed to affirm the ESA's advice.
- Ensure the consistent application of Community rules. In cases of breach of EU law, the ESAs can require national authorities to intervene. In case of refusal of the national supervisor to intervene, the ESAs can directly address individual firms, but only if the breach relates to legislation targeted to firms.
- Act in emergency situations. Once the Council declares a banking emergency (after consulting the Commission and the ESRB), the ESAs can take binding decisions to coordinate national supervisory responses, and to require national supervisors to jointly take specific actions to remedy an emergency situation. However, the ESAs' actions cannot "impinge" on a Member State's fiscal responsibility. If a Member State believes that this is the case, it has three days to notify the ESA that it is challenging its decision, suspending its enforceability. The Council has ten days to decide by simple majority whether to uphold the ESAs' decision. If the Council allows the ten day deadline to lapse without taking action, the ESA's decision is terminated.
- Binding mediation powers: The ESAs have the power to settle disagreements between national supervisors, arbitrating between them in areas where national supervisors are required to cooperate with one another (such as on bank capital, model approval, home/host information sharing, joint inspections). However,

ESA decisions as part of binding mediation can be challenged. To do so, a Member State has one month to notify the ESA of its intention, which suspends its enforceability. After notification, the ESA will have one month to amend or maintain its decision. If the ESA maintains its decision, the Council has two months to vote to uphold it, acting by qualified majority voting (QMV). If the Council allows the two month deadline to lapse without taking action, the ESA's decision is terminated.

In addition, the ESAs have a role (soft powers) in the identification and measurement of systemic risk (in coordination with the ESRB) posed by market participants, and in the protection of consumers. The ESAs are able to adopt non-binding guidelines and recommendations to which the “comply or explain” principle applies.

The main decision-making body of the ESAs is the Board of Supervisors. Decisions are made by a simple majority of its members, which comprise: the Chairperson, the head of each national supervisor, and representatives of the Commission, the ESRB, and of each of the other two ESAs (all non-voting, except national supervisors). The Board of Supervisors names the Chairperson on the basis of a short-list of eligible candidates drawn up by the Commission. The European Parliament confirms the appointment.

Day-to-day supervision remains national. The EU may expand the ESAs' pan-European reach by including a role for them in future sectoral legislation. The recent proposals to regulate CRAs, OTC derivatives and short-selling do in fact include a role for ESMA in overseeing and authorizing credit rating agencies, trade repositories, and in coordinating national temporary bans of short-selling practices. ESAs also promote the efficient functioning of the Colleges of Supervisors, assess market developments and interface with the ESRB through the collection of information from national authorities and firms.

The main function of the ESRB is to monitor and collect information relevant to potential threats and risks to financial stability arising from macro-economic developments and the EU financial system. Its tasks include the following:

- Identify and prioritize systemic risks;
- Issue warnings where such systemic risks are deemed to be significant;
- Issue recommendations for remedial action in response to the risks identified including, where appropriate, for legislative initiatives;
- Monitor the follow-up to warnings and recommendations;
- Coordinate with international institutions, as well as the relevant bodies in third countries on matters related to macro-prudential oversight.

Warnings or recommendations may be either of a general or specific nature and can be addressed to the whole EU, to one or more Member States, to one or more of the ESAs, or to one or more national supervisory authorities. The ESRB does not cover monetary policy, fiscal policy, or specific financial institutions. Warnings and recommendations may or may not be made public, at the discretion of the ESRB. Its recommendations do not have legal force, but the addressees are required to communicate the actions undertaken in response to them to the Council and the ESRB and to provide adequate justification in case of inaction (“comply or explain”). The ESRB reports every six months to the Council and the European Parliament.

Political violence is not unknown in the European Union, but is rare. Such incidents are generally regional in nature, and individual Country Commercial Guides should be consulted for details on problems in specific areas.

Corruption

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The Commission has gained the ability through the Lisbon Treaty to propose EU legislation harmonizing criminal law relating to corruption and trafficking in drugs, persons, and weapons across Member States. The Commission recognized in a 2011 paper that, although the nature and extent of corruption vary, it harms all EU Member States and the EU as a whole. In order to support the implementation of a comprehensive anti-corruption policy across the EU, the Commission has managed since 2011 a reporting mechanism for the periodic assessment of anti-corruption efforts (referred to as the 'EU Anti-Corruption Report') that is used to identify trends and best practices, to make general and tailor-made recommendations for adjusting EU policy on preventing and fighting corruption, to help Member States, civil society or other stakeholders identify shortcomings, and to raise awareness and provide training on anti-corruption. Regarding the protection of EU finances, the EU's Anti-Fraud Office (OLAF) publishes an annual report on its activities which can be found online at the EU's Anti-Fraud Office website: http://ec.europa.eu/anti_fraud/index_en.htm.

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

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

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

U.S. Foreign Corrupt Practices Act: In 1977, the United States enacted the Foreign Corrupt Practices Act (FCPA), which makes it unlawful for a U.S. person, and certain foreign issuers of securities, to make a corrupt payment to foreign public officials for the purpose of obtaining or retaining business for or with, or directing business to, any person. The FCPA also applies to foreign firms and persons who take any act in furtherance of such a corrupt payment while in the United States. For more detailed

information on the FCPA, see the FCPA Lay-Person's Guide at: <http://www.justice.gov/criminal/fraud/>

Other Instruments: It is U.S. Government policy to promote good governance, including host country implementation and enforcement of anti-corruption laws and policies pursuant to their obligations under international agreements. Since enactment of the FCPA, the United States has been instrumental to the expansion of the international framework to fight corruption. Several significant components of this framework are the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions (OECD Antibribery Convention), the United Nations Convention against Corruption (UN Convention), the Inter-American Convention against Corruption (OAS Convention), the Council of Europe Criminal and Civil Law Conventions, and a growing list of U.S. free trade agreements. See individual Country Commercial Guides for specific information on Member States and to which agreements they are a party. Generally, however, all countries prohibit the bribery and solicitation of their public officials.

OECD Antibribery Convention: The OECD Antibribery Convention entered into force in February 1999. As of March 2009, there are 38 parties to the Convention including the United States (see <http://www.oecd.org/dataoecd/59/13/40272933.pdf>). Major exporters China, India, and Russia are not parties, although the U.S. Government strongly endorses their eventual accession to the Convention. The Convention obligates the Parties to criminalize bribery of foreign public officials in the conduct of international business. The United States meets its international obligations under the OECD Antibribery Convention through the U.S. FCPA.

UN Convention: The UN Anticorruption Convention entered into force on December 14, 2005, and there are 158 parties to it as of November 2011 (see <http://www.unodc.org/unodc/en/treaties/CAC/signatories.html>). The UN Convention is the first global comprehensive international anticorruption agreement. The UN Convention requires countries to establish criminal and other offences to cover a wide range of acts of corruption. The UN Convention goes beyond previous anticorruption instruments, covering a broad range of issues ranging from basic forms of corruption such as bribery and solicitation, embezzlement, trading in influence to the concealment and laundering of the proceeds of corruption. The Convention contains transnational business bribery provisions that are functionally similar to those in the OECD Antibribery Convention and contains provisions on private sector auditing and books and records requirements. Other provisions address matters such as prevention, international cooperation, and asset recovery.

OAS Convention: In 1996, the Member States of the Organization of American States (OAS) adopted the first international anticorruption legal instrument, the Inter-American Convention against Corruption (OAS Convention), which entered into force in March 1997. The OAS Convention, among other things, establishes a set of preventive measures against corruption, provides for the criminalization of certain acts of corruption, including transnational bribery and illicit enrichment, and contains a series of provisions to strengthen the cooperation between its States Parties in areas such as mutual legal assistance and technical cooperation. As of December 2009, the OAS Convention has 34 parties (see <http://www.oas.org/juridico/english/Sigs/b-58.html>)

Council of Europe Criminal Law and Civil Law Conventions: Many European countries are parties to either the Council of Europe (CoE) Criminal Law Convention on Corruption, the Civil Law Convention, or both. The Criminal Law Convention requires criminalization of a wide range of national and transnational conduct, including bribery, money-laundering, and account offenses. It also incorporates provisions on liability of legal persons and witness protection. The Civil Law Convention includes provisions on compensation for damage relating to corrupt acts, whistleblower protection, and validity of contracts, inter alia. The Group of States against Corruption (GRECO) was established in 1999 by the CoE to monitor compliance with these and related anti-corruption standards. Currently, GRECO comprises 49 member States (48 European countries and the United States). As of December 2011, the Criminal Law Convention has 43 parties and the Civil Law Convention has 34 (see www.coe.int/greco.)

Free Trade Agreements: While it is U.S. Government policy to include anticorruption provisions in free trade agreements (FTAs) that it negotiates with its trading partners, the anticorruption provisions have evolved over time. The most recent FTAs negotiated now require trading partners to criminalize “active bribery” of public officials (offering bribes to any public official must be made a criminal offense, both domestically and trans-nationally) as well as domestic “passive bribery” (solicitation of a bribe by a domestic official). All U.S. FTAs may be found at the U.S. Trade Representative Website: <http://www.ustr.gov/trade-agreements/free-trade-agreements>. Consult USTR Website for date: <http://www.ustr.gov/trade-agreements/free-trade-agreements>.

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

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

The Departments of Commerce and State provide worldwide support for qualified U.S. companies bidding on foreign government contracts through the Commerce Department’s Advocacy Center and State’s Office of Commercial and Business Affairs. Problems, including alleged corruption by foreign governments or competitors, encountered by U.S. companies in seeking such foreign business opportunities can be brought to the attention of appropriate U.S. government officials, including local embassy personnel and through the Department of Commerce Trade Compliance Center “Report A Trade Barrier” Website at tcc.export.gov/Report_a_Barrier/index.asp.

Guidance on the U.S. FCPA: The Department of Justice’s (DOJ) FCPA Opinion Procedure enables U.S. firms and individuals to request a statement of the Justice Department’s present enforcement intentions under the anti-bribery provisions of the FCPA regarding any proposed business conduct. The details of the opinion procedure are available on DOJ’s Fraud Section Website at www.justice.gov/criminal/fraud/fcpa.

Although the Department of Commerce has no enforcement role with respect to the FCPA, it supplies general guidance to U.S. exporters who have questions about the FCPA and about international developments concerning the FCPA. For further information, see the Office of the Chief Counsel for International Counsel, U.S. Department of Commerce, Website, at http://www.ogc.doc.gov/trans_anti_bribery.html. More general information on the FCPA is available at the Websites listed below.

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

Anti-Corruption Resources

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

- Information about the U.S. Foreign Corrupt Practices Act (FCPA), including a “Lay-Person’s Guide to the FCPA” is available at the U.S. Department of Justice’s Website at: <http://www.justice.gov/criminal/fraud/fcpa>.
- Information about the OECD Anti-bribery Convention including links to national implementing legislation and country monitoring reports is available at: http://www.oecd.org/departement/0,3355,en_2649_34859_1_1_1_1_1,00.html. See also new Antibribery Recommendation and Good Practice Guidance Annex for companies: <http://www.oecd.org/dataoecd/11/40/44176910.pdf>.
- General information about anticorruption initiatives, such as the OECD Convention and the FCPA, including translations of the statute into several languages, is available at the Department of Commerce, Office of the Chief Counsel for International Commerce Website: http://www.ogc.doc.gov/trans_anti_bribery.html.
- Transparency International (TI) publishes an annual Corruption Perceptions Index (CPI). The CPI measures the perceived level of public-sector corruption in 180 countries and territories around the world. The CPI is available at: <http://www.transparency.org/cpi2012/results>. TI also publishes an annual *Global Corruption Report* which provides a systematic evaluation of the state of corruption around the world. It includes an in-depth analysis of a focal theme, a series of country reports that document major corruption related events and developments from all continents and an overview of the latest research findings on anti-corruption diagnostics and tools. See <http://www.transparency.org/publications/gcr>.
- The World Bank Institute publishes Worldwide Governance Indicators (WGI). These indicators assess six dimensions of governance in 213 countries, including Voice and Accountability, Political Stability and Absence of Violence, Government Effectiveness, Regulatory Quality, Rule of Law and Control of Corruption. See <http://info.worldbank.org/governance/wgi/index.asp>. The World Bank Business Environment and Enterprise Performance Surveys may also be of interest and are available at: <http://data.worldbank.org/data-catalog/BEEPS>.

- The World Economic Forum publishes the *Global Enabling Trade Report*, which presents the rankings of the Enabling Trade Index, and includes an assessment of the transparency of border administration (focused on bribe payments and corruption) and a separate segment on corruption and the regulatory environment. See <http://www.weforum.org/s?s=global+enabling+trade+report>.
- Additional country information related to corruption can be found in the U.S. State Department's annual *Human Rights Report* available at <http://www.state.gov/g/drl/rls/hrrpt/>.
- Global Integrity, a nonprofit organization, publishes its annual *Global Integrity Report*, which provides indicators for 106 countries with respect to governance and anti-corruption. The report highlights the strengths and weaknesses of national level anti-corruption systems. The report is available at: <http://report.globalintegrity.org/>.

Bilateral Investment Agreements

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The EU as a whole does not yet have any traditional bilateral investment treaties (BITs), although virtually all the Member States have extensive networks of such treaties with third countries. The EU "Europe", "Association" and other agreements with preferential trading partners have contained provisions directly addressing treatment of investment, generally providing national treatment after establishment and repatriation of capital and profits.

The adoption in December 2009 of the Lisbon Treaty has changed in major respects how the EU treats investment (see Openness to Foreign Investment, above). Since Lisbon makes foreign direct investment an exclusive EU competence, a broad definition of FDI extends EU authority over much of the subject matter hitherto addressed under Member State BITs. The Council has so far granted the Commission authority to negotiate investment chapters in the free trade agreements under negotiation with Canada, India, and Singapore. The Commission has indicated that it does not plan to develop a model investment treaty, preferring instead to establish general objectives and principles.

Other regional or multilateral agreements addressing the admission and treatment of investors to which the Community and/or its Member States have adhered include:

- a) The OECD codes of liberalization, which provide for non-discrimination and standstill for establishment and capital movements, including foreign direct investment;
- b) The Energy Charter Treaty (ECT), which contains a "best efforts" national treatment clause for the making of investments in the energy sector but full protections thereafter; and
- c) The GATS, which contains national treatment, market access, and MFN obligations on measures affecting the supply of services, including in relation to the mode of commercial presence.

OPIC and Other Investment Insurance Programs

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OPIIC programs are not available in the EU as a whole, although individual Member States have benefited from such coverage.

Labor

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Issues such as employment, worker training and social benefits remain primarily the responsibility of EU Member States. However, the Member States are coordinating ever more closely their efforts to increase employment through macroeconomic policy cooperation, guidelines for action, the exchange of best practices, and programmatic support from various EU programs. The best information regarding conditions in individual countries is available through the labor and social ministries of the Member States.

Helpful information from the EU can be found on the websites for the European Commission's Directorate-General for Employment and Social Affairs, <http://ec.europa.eu/social/home.jsp?langId=en>, and on the Eurostat website <http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/>.

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

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

Foreign-Trade Zones/Free Ports

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EU law provides that Member States may designate parts of the Customs Territory of the Community as “free zones” and free warehouses. The EU considers the free zones to be mainly a service for traders to facilitate trading procedures by allowing fewer customs formalities. Information on free trade zones and free warehouses is contained in Title IV, Chapter Three, of Council Regulation (EEC) no. 2913/92 establishing the Community Customs Code, titled, "Free Zones and Free Warehouses" (Articles 166 through 182).

Article 166 states that free zones and free warehouses are part of the Customs Territory of the Community or premises situated in that territory and separated from the rest of it in which:

- a) Community goods are considered, for the purposes of import duties and commercial policy import measures, as not being on Community customs territory, provided they are not released for free circulation or placed under another customs procedure or used or consumed under conditions other than those provided for in customs regulations; and
- b) Community goods for which such provision is made under Community legislation governing specific fields qualify, by virtue of being placed in a free zone or free warehouse, for measures normally attaching to the export of goods.

Articles 167-182 detail the customs control procedures, how goods are placed in or removed from free zones and free warehouses and their operation.

The use of free trade zones varies across Member States. For example, Germany maintains a number of free ports or free zones within a port that are roughly equivalent to U.S. foreign-trade zones, whereas Belgium has none. A full list of EU free trade zones last updated August 2012 is available at: http://ec.europa.eu/taxation_customs/resources/documents/customs/procedural_aspects/imports/free_zones/list_freezones.pdf.

Foreign Direct Investment Statistics

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According to U.S. statistics (the U.S. Bureau of Economic Analysis), the value of U.S. investment in the Member States of the European Union, on a historical-cost basis as of the end of 2011, was \$2.1 trillion. The Netherlands was the largest EU host to U.S. foreign direct investment, with \$595 billion, followed by the United Kingdom (\$549 billion), Luxembourg (\$335 billion), and Ireland (\$188 billion). More statistics on U.S. investment abroad are available at: <http://www.bea.gov/international/di1usdbal.htm> For virtually all EU Member States, the largest "foreign" investors are in fact other Member States.

According to the European Commission's statistics, FDI flows accounted for 2.3% of European GDP in 2010. The biggest investors in the United States include the United Kingdom at \$454 Billion, The Netherlands (\$238 Billion), and Germany (\$218 Billion). http://epp.eurostat.ec.europa.eu/portal/page/portal/product_details/dataset?p_product_code=TEC00046

DG Internal Market and Services

http://ec.europa.eu/dgs/internal_market/index_en.htm

DG Economic and Financial Affairs

http://ec.europa.eu/dgs/economy_finance/index_en.htm

DG Employment and Social Affairs

<http://ec.europa.eu/social/home.jsp?langId=en>

Office for Harmonization in the Internal Market (trademarks and designs)

<http://oami.europa.eu/>

EU Anti-Fraud Office

http://ec.europa.eu/anti_fraud/index_en.html

Eurostat – EU Statistical Office

<http://epp.eurostat.ec.europa.eu/portal/page/portal/eurostat/home/>

U.S. Bureau of Economic Analysis – Department of Commerce

<http://www.bea.gov>

European Patent Office

<http://www.epo.org/index.html>

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Chapter 7: Trade and Project Financing

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- [How Does the Banking System Operate](#)
- [Foreign-Exchange Controls](#)
- [U.S. Banks and Local Correspondent Banks](#)
- [Project Financing](#)
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How Do I Get Paid (Methods of Payment)

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#)

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports

How Does the Banking System Operate

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#)

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports

Foreign-Exchange Controls

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For general information on convertibility of various EU currencies including the Euro, please look at the [Conversion and Transfer Policies](#) in Chapter 6.

For additional information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#).

U.S. Banks and Local Correspondent Banks

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#).

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports.

Project Financing

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EU financial assistance programs provide a wide array of grants, loans, loan guarantees and co-financing for feasibility studies and projects in a number of key sectors (e.g., environmental, transportation, energy, telecommunications, tourism, public health). A number of centralized financing programs are also generating procurement and other opportunities directly with EU institutions. From a commercial perspective, these initiatives create significant market opportunities for U.S. businesses, U.S.-based suppliers, and subcontractors.

The EU supports projects within its member states, as well as EU-wide "economic integration" projects that cross both internal and external EU borders. In addition, the EU provides assistance to accession countries in Eastern and Southern Europe, Iceland and Turkey, as well as some of the former Soviet republics.

The EU provides project financing through grants from the European Commission and loans from the European Investment Bank. Grants from the Structural Funds program are distributed through the member states' national and regional authorities, and are only available for projects in the 27 (soon to be 28) EU member states. All grants for projects in non-EU countries are managed through the Directorate-General EuropeAid in conjunction with various European Commission departments, such as DG Regional Development.

EU Structural Funds

EU Structural Funds, including the European Regional Development Fund, were created in 1975 to assist economically depressed regions of the European Union that required industrial restructuring. From 2007 – 2013, the EU earmarked EUR 308 billion for projects under the Structural Funds and the Cohesion Fund programs. In addition to funding economic development projects proposed by member states or local authorities, EU Structural Funds also support specialized projects promoting EU socioeconomic objectives. Member states negotiate regional and "sectoral" programs with officials from the regional policy Directorate-General at the European Commission. For information on approved programs that will result in future project proposals, please visit: http://ec.europa.eu/regional_policy/atlas2007/index_en.htm

For projects financed through the Structural Funds, member state officials and regional authorities are the key decision-makers. They assess the needs of their country; investigate projects; evaluate bids; and award contracts. To become familiar with available financial support programs in the member states, it is advisable for would-be contractors to meet with DG Regional Development officials and local officials in Member States to discuss local needs.

Tenders issued by member states' public contracting authorities for projects supported by EU grants are subject to EU public procurement legislation if they meet the EU minimum contract value requirement for the eligible sector. Below this threshold, tender

procedures are subject to national procurement legislation and EU Treaty rules. There are no overt prohibitions against the participation of U.S. companies, either as developers or concessionaires of projects supported partially by the Structural Funds, or as bidders on subsequent public tenders related to such projects, but it is highly advisable to team up with a local partner to gain credibility and demonstrate references.. All Structural Fund projects are co-financed by national authorities and most may also qualify for a loan from the European Investment Bank. The private sector is also involved in project financing. For more information on these programs, please see the market research section on the website of the U.S. Mission to the EU: <http://export.gov/europeanunion/marketresearch/index.asp>

The Cohesion Fund

The Cohesion Fund is another instrument of EU structural policy. Its EUR 61.5 billion (2007-2013) budget seeks to improve cohesion within the EU by funding transport infrastructure and environmental projects in Portugal, Spain, Greece and the twelve new (since 2004) EU member states from Central and Eastern Europe. These projects are generally co-financed by national authorities, the European Investment Bank, and the private sector.

Key Link: http://ec.europa.eu/regional_policy/thefunds/cohesion/index_en.cfm

Other EU Grants for Member States

Another set of sector-specific grants offers assistance to EU member states in the fields of science, technology, communications, energy, environmental protection, education, training and research. Tenders related to these grants are posted on the various websites of the directorates-generals of the European Commission. Conditions for participation are strict and participation is usually restricted to EU firms or tied to EU content. Information pertaining to each of these programs can be found on: http://ec.europa.eu/grants/index_en.htm

External Assistance Grants

“Development and Cooperation – EuropeAid” is a new Directorate–General (DG) responsible for designing EU development policies and delivering aid through programs and projects across the world. It incorporates the former Development and EuropeAid DGs. Its website offers extensive information on the range of grant programs, the kind of projects that are eligible, as well as manuals to help interested parties understand the relevant contract law. However, participation in these calls for tender is reserved for enterprises located in the EU member states or in the beneficiary country and requires that the products used to respond to these projects are manufactured in the EU or in the aid recipient country. Consultants of U.S. nationality employed by a European firm are allowed to form part of a bidding team. European subsidiaries of U.S. firms are eligible to participate in these calls for tender.

Key Link:

http://ec.europa.eu/europeaid/index_en.htm

The EU also provides specific Pre-Accession financial assistance to the accession candidate countries that seek to join the EU through the “Instrument for Pre-accession Assistance” (IPA). Also, the European Neighborhood and Partnership Instrument (ENPI) will provide assistance to countries that are the Southern Mediterranean and Eastern neighbors of the EU.

IPA focuses on priorities linked to the adoption of the *acquis communautaire* (the body of European Union law that must be adopted by accession candidate countries as a precondition to accession), i.e., building up the administrative and institutional capacities and financing investments designed to help them comply with European Commission law. IPA will also finance projects destined to countries that are potential candidate countries, especially in the Balkans. The budget of IPA for 2007-2013 is €11.4 billion.

Key Link: http://ec.europa.eu/enlargement/index_en.htm

The European Neighborhood Policy program (ENPI) covers the EU's neighbors to the east and along the southern and eastern shores of the Mediterranean i.e. Algeria, Armenia, Azerbaijan, Belarus, Egypt, Georgia, Israel, Jordan, Lebanon, Libya, Moldova, Morocco, the Palestinian Authority, Syria, Tunisia and Ukraine. ENPI budget is €11.9 billion for 2007-2013.

http://ec.europa.eu/world/enp/index_en.htm

Loans from the European Investment Bank

Headquartered in Luxembourg, the European Investment Bank (EIB) is the financing arm of the European Union. Since its creation in 1958, the EIB has been a key player in building Europe. As the EIB's lending practices evolved over the years, it became highly competent in assessing, reviewing and monitoring projects. As a non-profit banking institution, the EIB offers cost-competitive, long-term lending in Europe. Best known for its project financial and economic analysis, the Bank makes loans to both private and public EU-based borrowers for projects in all sectors of the economy, such as telecommunications, transport, energy infrastructure and environment.

While the EIB mostly funds projects within the EU, it lends outside the EU as well (e.g., in Central, Eastern and Southeastern Europe; Latin America; and Pacific and Caribbean states). In 2012, the EIB lent EUR 52 billion for projects. The EIB also plays a key role in supporting EU enlargement with loans used to finance improvements in infrastructure, research and industrial manufacturing to help those countries prepare for eventual EU membership.

Projects financed by the EIB must contribute to the socioeconomic objectives set out by the European Union, such as fostering the development of less favored regions; improving European transport and telecommunication infrastructure; protecting the environment; supporting the activities of SMEs; assisting urban renewal; and, generally promoting growth, competitiveness and employment in Europe. The EIB created a list of projects to be considered for approval and posted the list on its website. As such, the EIB website is a source of intelligence on upcoming tenders related to EIB-financed projects: <http://www.eib.org/projects/pipeline/index.htm>

The EIB presents attractive business opportunities to U.S. businesses. EIB lending rates are lower than most other commercial rates. Like all EIB customers, however, U.S. firms must apply the loan proceeds to a project that contributes to the European objectives cited above.

EU websites:

The EU regional policies, the EU Structural and Cohesion

Funds: http://ec.europa.eu/regional_policy/index_en.htm

EU Grants and Loans index: http://ec.europa.eu/grants/index_en.htm

EuropeAid Co-operation Office: http://ec.europa.eu/europeaid/index_en.htm

EU tender repository: <http://ted.europa.eu/TED/main/HomePage.do>

The European Investment Bank: <http://www.eib.org>

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

U.S. websites:

Market research section on the website of the U.S. Mission to the

EU: <http://export.gov/mrktresearch/index.asp>

Export-Import Bank of the United States: <http://www.exim.gov>

Country Limitation Schedule: http://www.exim.gov/tools/country/country_limits.html

OPIC: <http://www.opic.gov>

Trade and Development Agency: <http://www.ustda.gov/>

SBA's Office of International Trade

<http://www.sba.gov/about-offices-content/1/2889>

U.S. Agency for International Development: <http://www.usaid.gov>

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Chapter 8: Business Travel

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Business Customs

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#).

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports.

Travel Advisory

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#).

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Visa Requirements

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#).

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports.

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

Visa applicants should go to the following link for additional information:

State Department Visa Website: <http://travel.state.gov/visa/>

Telecommunications

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#).

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports.

Transportation

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#).

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports.

Languages

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Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, Gaelic, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovene, Spanish, Swedish; *note - only official EU languages are listed.*

Health

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For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#).

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports.

Local Time , Business Hours, and Holidays

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The European Institutions generally follow the holidays of the EU member state in which they are located. During the month of August, most EU organizations are staffed with minimum personnel. For information on local holidays in the EU member states, please

see individual member state's Country Commercial Guides. The following is a list of holidays observed by the European Commission in Belgium during calendar year 2013:

January 1	New Year's Day
January 2	The day following New Year's Day
March 28	Maundy/Holy Thursday
March 29	Good Friday
April 1	Easter Monday
May 1	Tuesday, Labor Day
May 9	Wednesday, anniversary of the declaration made by President Robert Schuman in 1950 + Ascension Day
May 10	The day following Ascension Day
May 20	Whit Monday
August 15	Wednesday, Assumption Day
November 1	Thursday, All Saint's Day
November 2	Friday, All Soul's Day (<i>*Belgian holiday but not observed by EC</i>)
December 24	
- January 2, 2014	Christmas/New Year's Holidays

The above-mentioned dates also apply to Luxembourg.

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

Business travelers to the European Union seeking appointments with officials in the U.S. Mission to the European Union in Brussels, Belgium, should contact the Commercial Service in advance. The Commercial Service at the U.S. Mission to the European Union can be reached by telephone at +32-2 811-4817, fax at +32-2 811-5151, or e-mail at Office.BrusselsEC@trade.gov. A current directory of staff and locations worldwide may be accessed on the Commercial Service website <http://www.export.gov/>

Temporary Entry of Materials and Personal Belongings [Return to top](#)

For information on this topic please consult the Commerce Department's Country Commercial Guides on EU member states: [EU Member States' Country Commercial Guides](#).

Alternatively, search the Commerce Department's Market Research Library, available from: <http://www.export.gov/mrktresearch/index.asp> under Country and Industry Market Reports.

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Market Research Library
<http://www.export.gov/mrktresearch/index.asp>

EU Member States' Country Commercial Guides:
[EU Member States' Country Commercial Guides](#)

State Department Visa Website
http://travel.state.gov/visa/visa_1750.html

Commercial Service at the U.S. Mission to the European Union General E-mail Address
brussels.ec.office.box@trade.gov

Current directory of Commercial Service staff and locations worldwide
<http://www.export.gov/>

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Chapter 9: Contacts, Market Research and Trade Events

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- [Trade Events](#)

Contacts

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United States Department of Commerce - Contacts at the U.S. Mission to the EU:

Minister Counselor for Commercial Affairs

Beryl Blecher

Tel: 32.2.811.5374

Beryl.Blecher@trade.gov

Deputy Senior Commercial Officer

Patricia Gonzalez

Tel: 32.2.811.5328

Patricia.Gonzalez@trade.gov

Commercial/Standards Attaché

William Thorn

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William.Thorn@trade.gov

Commercial Attaché

Ilona Shtrom

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ilona.Shtrom@trade.gov

Market Access and Trade Compliance Attaché (*As of Summer 2013*)

Michael Rogers

Tel: 32.2.811.4244

Michael.Rogers@trade.gov

NOAA Fisheries Representative

Stephane Vrignaud

Tel: 32.2.811.5831

Stephane.Vrignaud@trade.gov

U.S. Commercial Service

U.S. Mission to the European Union

Rue Zinner 13

B-1000 Brussels, Belgium

Tel.: 32.2.811.4100

Fax: 32.2.811.5151

E-mail: brussels.ec.office.box@trade.gov
Website: <http://export.gov/europeanunion/>

United States Department of Agriculture - Contacts at the U.S. Mission to the EU:

Office of Agricultural Affairs
U.S. Mission to the European Union
Rue Zinner 13
B-1000 Brussels, Belgium
Tel.: 32.2.811.4247
Fax: 32.2.811.5560
E-mail: AgUSEUBrussels@fas.usda.gov
Website: <http://www.fas.usda.gov/posthome/Useu/>

The European Commission:

European Commission
Rue de la Loi 200 / Wetstraat 200
B-1049 Brussels, Belgium
Tel: 32.2.299.11.11 (switchboard)
Fax: 32.2.295.01.38 (also 295.01.39 and 295.01.40)
Websites: http://ec.europa.eu/index_en.htm (European Commission)
http://eeas.europa.eu/us/index_en.htm (EU-U.S. relations)

For general information about the European Union:

Delegation of the European Commission to the United States
Washington, D.C. 20037
Tel: (202) 862-9500
Fax: (202) 429-1766
Website: <http://www.eurunion.org/>

For Information on Customs-related Matters within the European Union:

Mr. Heinz ZOUREK, Director General
Directorate General Taxation and Customs Union
Rue de la Loi 200
B-1049 Brussels
Tel: 32. 2.299.50.50
Fax: 32.2.296.90.46
Website: http://ec.europa.eu/taxation_customs/index_en.htm

European Commission - Directorate - General Enterprise and Industry

Avenue d'Auderghem 45/Rue Belliard 100
B – 1049 Brussels, Belgium
Tel: 32.2.299.56.72
Fax: 32.2.299.16.75
Website: http://ec.europa.eu/enterprise/standards_policy/index_en.htm

EFTA – European Free Trade Association

Rue Joseph II, 12-16
B – 1000 Brussels
Tel: 32.2.286.17.11
Fax: 32.2.286.17.50
Website: <http://www.efta.int/>

Business Associations:

AmchamEU

53 Avenue des Arts
B-1000 Brussels, Belgium
Tel: 32.2.513.68.92
Fax: 32.2.513.79.28
Website: <http://www.amchameu.eu/>

Business Europe

The Confederation of European Business
Avenue de Cortenbergh 168
1000 Brussels, Belgium
Tel: 32.2.237.65.11
Fax: 32.2.231.14.45
Website: www.businesseurope.eu

Tech America Europe

40 Rue des Drapiers
B-1050 Brussels, Belgium
Tel: 32.2.502.75.60
Fax: 32.2.502.67.34
Website: <http://www.techamerica.org/europe>

The European Institute

1001 Connecticut Avenue, N.W., Suite 220,
Washington DC, 20036-5531
Tel: (202) 895-1670
Website: <http://www.europeaninstitute.org/>

Centre for European Policy Studies (CEPS)

1 Place du Congres
B-1000 Brussels, Belgium
Tel: 32.2.229.39.11
Fax: 32.2.219.41.51
Website: <http://www.ceps.eu/index.php>

The European Policy Centre

Residence Palace
155 Rue de la Loi
1040 Brussels, Belgium
Tel: 32.2.231.03.40
Fax: 32.2.231.07.04
Website: <http://www.epc.eu/>

European Round Table of Industrialists (ERT)

Place des Carabiniers 18a
B-1030 Brussels
Tel: 32 2 534 31 00
Fax: 32 2 534 73 48
Website: <http://www.ert.be/>

The Transatlantic Policy Network

Rue Froissart 115, 1st floor
B-1040 Brussels, Belgium
Tel: 32.2.230.61.49
Fax: 32.2.230.58.96
Website: <http://www.tpnonline.org/>

Transatlantic Business Council

Washington Office
919 18th Street NW, Suite 220
Washington, DC 20006
Tel: 1 202 828 9104
Fax: 1 202 828 9106

Brussels Office

Av. de Cortenbergh 168
B-1000 Brussels
Tel: 32 2 514 05 01
Website: <http://transatlanticbusiness.org/>

The Trans European Policy Studies Association (TEPSA)

11 Rue d'Egmont
B-1000 Brussels, Belgium
Tel: 32.2.511.34.70
Fax: 32.2.511.67.70
Website: <http://www.tepsa.be/>

Key EU-related websites:

For general information on the European Union
The EU's portal website
<http://www.europa.eu/>

Resource for EU news, policy positions and actors
<http://www.euractiv.com/>

A to Z index of European Union websites
<http://www.eurunion.org/infores/euindex.htm>

For information on topics related to doing business in the European Union

EU's "One Stop Internet Shop for Business" (EU funds, technical standards, intellectual property law, and free access to public procurement tender notices via the Tenders Electronic Daily (TED) database):
http://ec.europa.eu/youreurope/business/index_en.htm

EU Member State Chambers of Commerce in the U.S.
<http://www.eurunion.org/states/doingbizweu.htm>

EU market access database (information on tariffs and other trade information)
<http://madb.europa.eu/>

EURLEX – Access to EU law

<http://eur-lex.europa.eu/en/index.htm>

CORDIS – Community Research and Development Information Service (EU research and innovation website)

<http://cordis.europa.eu/>

European Commission Statistical Office (Eurostat)

<http://epp.eurostat.ec.europa.eu/>

EU Office of Official Publications

<http://publications.europa.eu/>

EU official website on the euro

http://ec.europa.eu/euro/index_en.html

European Central Bank, Frankfurt

<http://www.ecb.int/>

European Investment Bank, Luxembourg

<http://www.eib.org/>

Council of the European Union

<http://www.consilium.europa.eu/>

European Commission

http://ec.europa.eu/index_en.htm

European Parliament

<http://www.europarl.europa.eu/>

European Court of Justice

<http://curia.europa.eu/>

EU Who is Who – The Official Directory of the European Union

<http://europa.eu/whoiswho/public/>

Market Research

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To view market research reports produced by the U.S. Commercial Service please go to the following website: <http://www.export.gov/mrktresearch/index.asp> and click on Country and Industry Market Reports.

Please note that these reports are only available to U.S. citizens and U.S. companies. Registration to the site is required and is free.

Trade Events

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Please click on the link below for information on upcoming trade events.

<http://www.export.gov/tradeevents/index.asp>

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Chapter 10: Guide to Our Services

The President's National Export Initiative aims to double exports over five years by marshaling Federal agencies to **prepare U.S. companies to export successfully, connect them with trade opportunities and support them once they do have exporting opportunities.**

The U.S. Commercial Service offers customized solutions to help U.S. exporters, particularly small and medium sized businesses, successfully expand exports to new markets. Our global network of trade specialists will work one-on-one with you through every step of the exporting process, helping you to:

- Target the best markets with our world-class research
- Promote your products and services to qualified buyers
- Meet the best distributors and agents for your products and services
- Overcome potential challenges or trade barriers
- Gain access to the full range of U.S. government trade promotion agencies and their services, including export training and potential trade financing sources

To learn more about the Federal Government's trade promotion resources for new and experienced exporters, please click on the following link: www.export.gov.

For more information on the services the U.S. Commercial Service offers to U.S. exporters, please click on the following link: <http://www.buyusa.gov>.

U.S. exporters seeking general export information/assistance or country-specific commercial information can also contact the **U.S. Department of Commerce's Trade Information Center at (800) USA-TRAD(E).**

To the best of our knowledge, the information contained in this report is accurate as of the date published. However, **The Department of Commerce** does not take responsibility for actions readers may take based on the information contained herein. Readers should always conduct their own due diligence before entering into business ventures or other commercial arrangements. **The Department of Commerce** can assist companies in these endeavors.

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