

Doing Business in the European Union: 2008 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 27 Member States, enjoy a mature economic relationship that is characterized by massive two-way trade and an extensive investment relationship. In 2006, the numbers continued to grow with U.S. exports of goods and services to the EU-25 (prior to Romania and Bulgaria joining in 2007) valued at \$245 billion and imports from the EU-25 valued at \$330 billion. Meanwhile, the transatlantic economy employs more 14 million people in various insourced jobs.

After a few years of slow GDP growth in Europe, 2007 saw a slight drop from 2.7% to 2.2%. However, the Euro remains strong and unemployment in the Euro zone is declining (down to 7.1% from 7.7% in 2006).

Market Challenges

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While the European Union 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 in the EU market. EU legislation in the form of Regulations is mandatory whereas EU Directives are interpreted and implemented differently by each Member State. 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.

Market Opportunities

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U.S. businesses benefit from several recent developments in the European Union:

 Enlargement in 2007 added two new Member States (Romania and Bulgaria) for a total of 27 countries that adhere to EU law and comprise a single market for US goods and services.

- An increase in the size of the Euro zone (with the addition of Cyprus and Malta) in January 2008 brings the total to 15 countries using the currency. Businesses face lower business transaction costs and more transparent pricing throughout the Euro area compared to the challenges and costs of dealing in multiple currencies prior to the Euro's introduction. (Slovakia is expected to join in January 2009.)
- The Schengen area was also enlarged at the end of 2007. It now totals 24 countries easing the movement of goods and people across air, land, and sea borders. The newest members include: the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia.
- The United States and the EU signed the Framework for Advancing Transatlantic Economic Integration at the 2007 U.S.-EU Summit. Action areas include regulatory cooperation, intellectual property rights, trade and security, investment, financial markets, and innovation and technology development.

Historically, U.S. exporters and investors have faced relatively low barriers to doing business in the EU. Nonetheless, the United States has a number of ongoing disputes with the EU, a situation to be expected given the breadth and depth of the commercial relationship. Discussions on a range of existing and potential trade irritants are ongoing, including such issues as EU restrictions on genetically modified organisms, biotechnology, different approaches to transparency in regulatory procedures, and different approaches to the role of standards and their development. 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. U.S. trade agencies work closely and diligently with the business community to ensure that the European Union and its Member States comply with their bilateral and multilateral trade obligations, and to help keep market access problems affecting U.S. firms to a minimum.

U.S. firms doing business in Europe should also be aware of the business facilitating activities of the Transatlantic Business Dialogue (TABD). The TABD is a forum for U.S. and European businesses that provides voluntary input to the U.S. Government and the European Commission on impediments to transatlantic business. For more information on TABD initiatives visit the TABD website: http://www.tabd.com/. Similar transatlantic dialogues are also held between governments and labor, as well as environmental and consumer constituencies.

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, exact market entry strategies must be considered on a country-by-country basis. For details of these tactics, please consult the Commerce Department's Country Commercial Guides of the 27 EU Member States found at the following website: http://www.export.gov/mrktresearch/index.asp under Country and Industry Market Reports.

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Chapter 2: Political and Economic Environment

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

https://www.cia.gov/cia/publications/factbook/

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Chapter 3: Selling U.S. Products and Services

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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 European Union (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 such "vertical agreements." Most U.S. exporters are small- and medium-sized companies (SMEs) and are therefore exempt from the 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 percent of a particular market are generally exempted as well (Commission Notice 2001/C 368/07).

Key Link:

http://eur-

lex.europa.eu/LexUriServ/site/en/oj/2001/c_368/c_36820011222en00130015.pdf

The EU also looks to combat payment delays with Directive 2000/35/EC. This 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. In sum, the Directive entitles a seller who does not receive payment for goods/services within 30-60 days of the payment deadline to collect interest (at a rate of 7 percent above the European Central Bank rate) as compensation. 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://ec.europa.eu/comm/enterprise/regulation/late_payments/

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

Key Link: http://www.ombudsman.europa.eu

Data Privacy

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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 optout of having them used for direct marketing purposes. This opt-out should be available at the time of collection and at any point thereafter. This general legislation is supplemented by specific rules set out in the "Directive on the processing of personal data and the protection of privacy in the electronic communications sector" (2002/58/EC). This requires companies to secure the prior consent of consumers before sending them marketing emails. The only exception to this opt-in provision is if the marketer has already obtained the intended recipient's contact details in the context of a previous sale and wishes to send them information on similar products and services.

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

Transferring Customer Data to Countries Outside the EU

The EU's 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.

The Department of Commerce and the European Commission negotiated the Safe Harbor agreement to provide U.S. companies with a simple, streamlined means of complying with the adequacy requirement. It allows those U.S. companies that commit themselves to a series of data protection principles (based on the Directive), and which publicly state that commitment by "self-certifying" on a dedicated website, to receive personal data from the EU. Signing up is voluntary but the rules are binding on those that do so. 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, companies that sign up to the Safe Harbor scheme will. 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 to the Safe Harbor agreement.

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. 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 are also developing 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 approval of "binding corporate rules" (BCRs). Companies that set up BCRs that satisfy European DPAs will be 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.

Key Links: http://www.export.gov/safeharbor/ http://ec.europa.eu/justice_home/fsj/privacy/modelcontracts/index_en.htm http://ec.europa.eu/justice_home/fsj/privacy/workinggroup/wpdocs/2007_en.htm

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US 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 US businesses. The

potential franchiser should take care to look not only at the EU regulations, but also at the local laws concerning franchising.

Direct Marketing

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There is a wide range of EU legislation that affects 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. Companies are advised to consult the information available via the hyperlinks, 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.

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

Distance and Door-to-Door sales

The EU's Directive on distance selling to consumers (97/7/EC) 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 Directive (85/577/EEC) which is designed to protect consumers from sales occurring outside of a normal business premises (e.g., doorto-door sales) and essentially assure the fairness of resulting contracts.

Key Link: http://ec.europa.eu/consumers/cons int/safe shop/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 amends 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.

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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Please see EU Member State Country Commercial Guides that can be found at the following website: 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 around EUR 1,600 billion. This market is regulated by two Directives:

- Directive 2004/18 on Coordination of procedures for the award of public works, services and supplies contracts, and
- 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.

Remedies directives cover legal means for companies who face discriminatory public procurement practices. These directives are implemented in the national procurement legislation of the 27 EU Member States.

The US and the EU are signatories of the World Trade Organization's (WTO) Government Procurement Agreement (GPA), which grants access to most public supplies and some services and works contracts published by national procuring 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 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 Government Procurement Agreement (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 are 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. This site also has a database of all European public procurement tenders that are open to U.S.-based firms by virtue of the Government Procurement Agreement. Access is free of charge.

Key Link: http://www.buyusa.gov/europeanunion/eu tenders.html

Distribution and Sales Channels

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Please see EU Member State Country Commercial Guides that can be found at the following website: http://www.export.gov/mrktresearch/index.asp under Country and Industry Market Reports.

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Please see EU Member State Country Commercial Guides that can be found at the following website: http://www.export.gov/mrktresearch/index.asp under Country and Industry Market Reports.

Electronic Commerce

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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 are currently set to expire at the end of 2008.

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 based 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/eservices/index_en.htm

Trade Promotion and Advertising

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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 Television without Frontiers Directive lays down legislation on broadcasting activities allowed within the EU. From 2009 the rules will allow for US-style product placement on television and the three-hour/day maximum of advertising will be lifted. However, a 12-minute/hour maximum will remain. 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 now 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.)

The EU adopted Directive 2005/29/EC concerning fair business practices in a further attempt to tighten up consumer protection rules. These new rules will 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

Medicine

The advertising of medicinal products for human use is regulated by Council Directive

2001/83/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 plans to present a new framework for information to patients on medicines in 2008. The framework would allow industry to produce non-promotional information about their medicines while complying with strictly defined rules and would be subject to an effective system of control and quality assurance.

Key Link:

http://ec.europa.eu/eur-lex/pri/en/oj/dat/2001/I_311/I_31120011128en00670128.pdf

Food

Regulation 1924/2006, applicable as of July 1, 2007, sets new EU rules on nutrition and health claims. The annex to Regulation 1924/2006 lists the nutrition claims such as "low fat" and "light" that will be allowed throughout the EU and the conditions for using them. An EU positive list of health claims, based on generally accepted scientific advice such as "X is good for your bones," is yet to be established. The EU positive list will include health claims based on generally accepted science and well understood by the consumer, not those based on emerging science. New health claims and disease reduction claims will have to be assessed by the European Food Safety Authority (EFSA) and approved by the Commission.

Key Links: http://ec.europa.eu/food/food/labellingnutrition/claims/index_en.htm http://useu.usmission.gov/agri/claims.html

Food Supplements

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 and sets criteria for establishing minimum and maximum levels.

Key Link: http://useu.usmission.gov/agri/foodsupplements.html

Exporter Guide

The "Food and Agricultural Import Standards & Regulations" report provides a complete overview of EU food laws currently in force in the EU-27. The report can be downloaded from http://useu.usmission.gov/agri/fairs.html.

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 TV Without Frontiers Directive.

Key link: http://ec.europa.eu/health/ph determinants/life style/Tobacco/tobacco en.htm

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Please see EU Member State Country Commercial Guides that can be found at the following website: 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/regulation/goods/liability_en.htm

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.

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.

Key link:

http://ec.europa.eu/comm/consumers/cons_int/safe_shop/guarantees/index_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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Several general principles are important for effective management of intellectual property rights in the European Union (EU). First, it is important to have an overall strategy to protect IPR. Second, IPR is protected differently in the EU than in the U.S. Third, rights must be registered and enforced *in* the EU under local laws. Companies may wish to seek advice from local attorneys or IP consultants. The U.S. Commercial Service can often provide a list of local lawyers upon request.

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 the EU. It is the responsibility of the rights' holders to register, protect, and enforce their rights where relevant, retaining their own counsel and advisors. While the U.S. Government is willing to assist, there is little it can do if the rights holders have not taken these fundamental steps necessary to securing and enforcing their IPR 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 doctrines such as statutes of limitations, laches, estoppel, or unreasonable delay in prosecuting a law suit. In no instance should USG 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 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. 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 local 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 IPR and stop counterfeiting. There are a number of these organizations, both EU- and U.S.-based. These include:

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

IPR Resources

A wealth of information on protecting IPR 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 US small and medium-size companies, the Department of Commerce offers a "SME IPR Advisory Program" available through the American Bar Association that provides one hour of free IPR legal advice for companies with concerns in Brazil, China, Egypt, India, Russia, and Thailand. 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 IPR-infringing products) and allows you to register for Webinars on protecting IPR.

Copyright

The EU's legislative framework for copyright protection consists of a series of Directives covering areas such as the legal protection of computer programs, the duration of protection of authors' rights and neighboring rights, and the legal protection of databases. Almost all Member States have fully implemented the rules into national law; and the Commission is now focusing on ensuring that the framework is enforced accurately and consistently across the EU.

The on-line copyright Directive (2001/29/EC) addresses the problem of protecting rights holders in the online environment while protecting the interests of users, ISPs and hardware manufacturers. It guarantees authors' exclusive reproduction rights with a single mandatory exception for technical copies (to allow caching), and an exhaustive list of other exceptions that individual Member States can select and include in national legislation. This list is meant to reflect different cultural and legal traditions, and includes private copying "on condition right holders receive fair compensation."

Patents

EU countries have a "first to file" approach to patent applications, as compared to the "first to invent" system currently followed in the United States. This makes early filing a top priority for innovative companies. Unfortunately, it is not yet possible to file for a single EU-wide patent that would be administered and enforced like the Community Trademark (see below). For the moment, the most effective way for a company to secure a patent across a range of EU national markets is to use the services of the European Patent Office (EPO) in Munich. It offers a one-stop-shop that enables rights holders to get a bundle of national patents using a single application. However, these national patents have to be validated, maintained and litigated separately in each Member State.

Key Links: http://ec.europa.eu/internal_market/indprop/index_en.htm http://www.european-patent-office.org/

Trademarks

The EU-wide Community Trademark (CTM) can be obtained via a single language application to the Office of Harmonization in the Internal Market (OHIM) in Alicante, Spain. It lasts ten years and is renewable indefinitely. For companies looking to protect trademarks in three or more EU countries the CTM is a more cost effective option than registering separate national trademarks.

On October 1, 2004, the European Commission (EC) acceded to the World Intellectual Property Organization (WIPO) Madrid Protocol. The accession of the EC to the Madrid Protocol establishes a link between the Madrid Protocol system, administered by WIPO, and the Community Trademark system, administered by OHIM. As of October 1, 2004, Community Trademark applicants and holders are 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 will be entitled to apply for protection of their trademarks under the Community Trademark system.

Key Links: http://oami.europa.eu/en/default.htm http://www.wipo.int/madrid/en

Designs

The EU adopted 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 and the unregistered Community design. Under the registered Community design system, holders of eligible designs can use an inexpensive procedure to register them with the EU's Office for Harmonization in the Internal Market (OHIM), based in Alicante, Spain. They 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.

Key Link: http://oami.europa.eu/en/default.htm

Trademark Exhaustion

Within the EU, the rights conferred on trademark holders are subject to the principle of "exhaustion." Exhaustion means that once trademark holders have placed their product on the market in one Member State, they lose the right to prevent the resale of that product in another EU country. This has led to an increase in the practice of so called "parallel importing" whereby goods bought in one Member State are sold in another by third parties unaffiliated to the manufacturer. Parallel trade is particularly problematic for the research-based pharmaceutical industry where drug prices vary from country to country due to national price Regulation.

Community wide exhaustion is spelled out in the Directive on harmonizing trademark laws. In a paper published in 2003, the Commission indicated that it had no plans to propose changes to existing legal provisions.

Key Link: http://ec.europa.eu/internal market/indprop/tm/index en.htm

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: www.buyusa.gov/europeanunion/services.html

For information on professional services located within each of the EU member states, please see EU Member State Country Commercial Guides that can be found at the following website: http://www.export.gov/mrktresearch/index.asp under the Market Research Library.

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Council Directive on the Coordination of the Laws of the Member States relating to Selfemployed Commercial Agents

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

Guidelines on "Vertical Agreements"

http://eur-

lex.europa.eu/LexUriServ/site/en/oj/2001/c_368/c_36820011222en00130015.pdf

EC Directive on Late Payments

http://ec.europa.eu/comm/enterprise/regulation/late_payments/

The European Ombudsman

http://www.ombudsman.europa.eu

EC on Data Protection

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

Safe Harbor

http://www.export.gov/safeharbor/

Model Contracts for the Transfer of Personal Data

http://ec.europa.eu/justice home/fsj/privacy/modelcontracts/index en.htm

Documents adopted by the Data Protection Working Group

http://ec.europa.eu/justice_home/fsj/privacy/workinggroup/wpdocs/2007_en.htm

Ensuring Safe Shopping across the EU

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

Electronic Commerce

http://ec.europa.eu/internal market/e-commerce/index en.htm

Market Research

http://www.export.gov/mrktresearch/index.asp

EU-Funded Programs: Grants

http://www.buyusa.gov/europeanunion/eu_tenders.html

VAT on Electronic Services

http://ec.europa.eu/taxation_customs/taxation/vat/how_vat_works/eservices/index_en.htm

The Unfair Commercial Practices Directive

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

Community Code relating to Medicinal Products for Human use

http://ec.europa.eu/eur-lex/pri/en/oj/dat/2001/I_311/I_31120011128en00670128.pdf

Regulation on Health and Nutrition Claims

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

Nutrition and Health Claims

http://useu.usmission.gov/agri/claims.html

Fortified Foods and Food Supplements

http://useu.usmission.gov/agri/foodsupplements.html

Food and Agricultural Import Regulations and Standards (FAIRS) Reports http://useu.usmission.gov/agri/fairs.html

Tobacco

http://ec.europa.eu/health/ph determinants/life style/Tobacco/tobacco en.htm

Product Liability

http://ec.europa.eu/enterprise/regulation/goods/liability_en.htm

General Product Safety Directive

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

Sale of Goods and Guarantees

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

Copyright and Neighboring Rights

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

Industrial Property

http://ec.europa.eu/internal market/indprop/index en.htm

European Patent Office

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

Office for Harmonization in the Internal Market

http://oami.europa.eu/en/default.htm

WIPO Madrid System for the International Registration of Marks

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

Trade Marks including Community Trade Mark

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

Business Service Providers

www.buyusa.gov/europeanunion/services.html

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

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Commercial Sectors

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Overall, U.S. companies generally find their best prospects in the EU at the upper-end of the technology scale. U.S. goods are well regarded and demand is driven more by quality and performance than by price.

However, the market of the European Union is a differentiated one, with each Member State market having supply, distribution, demand, cultural and legal characteristics that merit individual attention. Thus, while a pan-European business strategy, as outlined in the Commerce Department's Showcase Europe initiative (see below), is a must, specific tactics for market entry or expansion should be considered for each country. Readers should consult the Country Commercial Guides produced by U.S. embassies in the 27 Member States of the EU for information about export "Best Prospects," the investment climate, and other economic, political and commercial information for the country or countries of interest. These CCGs can be found at the following website: http://www.export.gov/mrktresearch/index.asp under Country and Industry Market Reports.

The Showcase Europe program run by the U.S. Department of Commerce's offices throughout Europe provides U.S. exporters a broader perspective on the European market. It is organized around eight leading sectors (listed alphabetically): aerospace & defense, automotive, energy, environmental, information & communications technologies, medical & pharmaceutical, safety & security and travel & tourism. For more information on how to receive an assessment of your company's product potential in Europe, please visit: http://www.buyusa.gov/quicktake.

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Despite frequent disputes, bilateral agricultural trade between the United States and the EU-27 totaled \$27.1 billion in FY 2007. The EU is the fourth largest export market for U.S. agricultural products after Canada, Mexico and Japan. For the eighth year in a row, the agricultural trade balance continued in the EU's favor (\$16.7 billion vs. \$10.4 billion). U.S demand for European wine, beer, dairy products, olive oil, essential oils and other processed products was again strong. U.S. exports in FY 2007 were up 11 percent from levels seen one year ago, reflecting increased demand for soybeans, wine and beer, processed fruit and vegetables, and vegetable oils (excluding soybean oil). Soybean exports increased by 87 percent. This represents a recovery from the previous year's

low levels that resulted from increased EU imports from Brazil. Exports of vegetable oils (excluding soybean oil), other intermediate products, and wine and beer reached their highest levels since FY 1970.

The main U.S products imported by the EU (by value) are tree nuts, soybeans, seafood, intermediate products and tobacco. Consistent with the global trend, the overall market for high value consumer-oriented food products is the most promising growth area, with U.S. exports of these products to the EU reaching \$3.7 billion in FY 2007, the highest export level 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 http://useu.usmission.gov/agri/ and consult the individual Member States' exporter guides.

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Chapter 5: Trade Regulations and Standards

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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/Document_Library/Reports_Publications/2007/2007_NTE_Report/S ection Index.html?ht=.

Information on agricultural trade barriers can be found at the following website: http://useu.usmission.gov/agri/

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://www.buyusa.gov/europeanunion.

Import Requirements and Documentation

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The Integrated Tariff of the Community, referred to as TARIC (Tarif Intégré de la Communauté), 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 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.

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.

Key Link: http://ec.europa.eu/taxation_customs/common/databases/taric/index_en.htm

Import Documentation, Non-agricultural Documentation

The official model for written declarations to customs is the Single Administrative Document (SAD). European Free Trade Association (EFTA) countries including Norway, Iceland, Switzerland, and Liechtenstein also use the SAD. However, other forms may be used for this purpose. Information on import/export forms is contained in Title VII, of Council Regulation (EEC) No. 2454/93, which lays down provisions for the implementation of Council Regulation (EEC) No. 2913/92 establishing 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.

Additional information on import/export documentation can be found in Title III, of Council Regulation (EEC) No. 2913/92 of October 12, 1992, establishing the Community Customs Code (Articles 37 through 57). Goods brought into the customs territory of the Community are, from the time of their entry, subject to customs supervision until customs formalities are completed.

Goods presented to customs are covered by a summary declaration, which is lodged once the goods have been presented to customs. The customs authorities may, however, allow a period for lodging 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 can be made on a form corresponding to the model prescribed by the customs authorities. However, the customs authorities may permit the use, as a summary declaration, of any commercial or official document that contains the particulars necessary for identification of the goods. It is encouraged that the summary declaration be made in computerized form.

The summary declaration is to be lodged 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.

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 of the period.

The Modernized Customs Code (MCC) of the European Union is expected to be passed into law in the first half of 2008. The MCC will replace the existing Regulation 2913/92 and simplify 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_c ode/index en.htm.

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 updated Directive applies to all batteries and accumulators put 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. EU Member States must implement the EU Directive into their national law by September 26, 2008. For more information, see our market research report:

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

REACH

REACH is a major reform of EU chemicals policy that was adopted in December 2006 and became national law in the 27 EU Member States in June 2007. Virtually every industrial sector, from automobiles to textiles, could be affected by the new policy. REACH stands for the "Registration, Evaluation and Authorization of Chemicals." As of June 1 2008, REACH will require all chemicals produced or imported into the EU in volumes above 1 ton per year to be registered with a central European Chemicals Agency (ECHA), including information on their properties, uses and safe ways of handling them. Most chemicals currently imported into the EU are eligible for preregistration which provides ECHA with basic information on the substance and allows the continued imports until a later registration deadline. ECHA will accept preregistrations from 1 June 2008 until 1 December 2008. US companies should take advantage of the pre-registration period if possible. The full registration period for chemicals which are pre-registered ranges from three to eleven years depending on the volume of the substance and its hazard properties. Substances not pre-registered must be registered to stay on the market. Chemicals of very high concern, like carcinogens, will need an authorization for use in the EU. U.S. exporters to Europe should carefully consider this piece of EU environmental legislation. For more information, see the CSEU REACH webpage at: http://www.buyusa.gov/europeanunion/reach.html.

WEEE & RoHS

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. They require U.S. exporters to register the products with a national WEEE authority, or arrange for this to be done by a local partner. Similarly, related rules for EEE restricting the use of the hazardous substances (RoHS) lead, cadmium, mercury, hexavalent chromium, PBBs, and PBDEs, do not entail customs or importation paperwork. However, U.S. exporters may be asked by a European RoHS enforcement authority or by a customer to provide evidence of due diligence in compliance with the substance bans on a case-by-case basis. U.S. exporters seeking more information on WEEE and RoHS regulations should visit:

http://www.buyusa.gov/europeanunion/weee.html

Import Documentation, 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). Many of these certificates are uniform throughout the EU, but the harmonization process has not been finalized yet. 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://useu.usmission.gov/agri/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 places specific conditions on imports of fishery products from the U.S. Sanitary certificates for live shellfish are covered by Commission Regulation (EC) 1664/2006 and must be used for gastropods, bivalve mollusks, tunicates and echinoderms. The two competent Authorities for issuing sanitary certificates are the FDA and the U.S. Department of Commerce, National Marine Fisheries Service (NMFS/NOAA/USDC).

Since May 1, 2007, 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) 1664/2006. This animal health attestation is not required in the case of live bivalve mollusks intended for immediate human consumption (retail).

For detailed information on import documentation for seafood, please contact the NOAA Fisheries office at the U.S. Mission to the EU (stephane.vrignaud@mail.doc.gov) or visit the following FDA dedicated web site: http://www.cfsan.fda.gov/.

A new EU Hygiene law has been in force since January 1, 2006. This new set of Regulations aims to simplifying existing rules and at guaranteeing safer food. To facilitate the implementation of the revised rules, the Commission recently published implementing measures and transitional arrangements that are also effective as of January 1, 2006.

These guidelines can be found below:

- □ Commission Regulation 2073/2005
- □ Commission Regulation 2074/2005
- □ Commission Regulation 2076/2005

U.S. Export Controls

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Please see EU Member State Country Commercial Guides that can be found at the following website: http://www.export.gov/mrktresearch/index.asp under Country and Industry Market Reports.

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Please see EU Member State Country Commercial Guides that can be found at the following website: http://www.export.gov/mrktresearch/index.asp under Country and Industry Market Reports.

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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://www.buyusainfo.net/docs/x_4171929.pdf.

The subject has been also been covered in the section about standards (see below).

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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 that product 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/common/databases/taric/index_en.htm

Customs Regulations and Contact Information

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Regulation 648/2005 is the "Security Amendment" to the Customs Code (Regulation 2913/92) and outlines the implementing provisions for Authorized Economic Operators, risk management procedures, pre-departure declarations, and improved export controls.

Tariffs and Import Taxes: Information on customs valuation is contained in Title II, Chapter Three, of Council Regulation (EEC) 2913/92, establishing the Community Customs Code, titled, "Value of Goods for Customs Purposes" (Articles 28 through 36). The primary basis for determining customs value set out in Articles 29 is: "... the transaction value, that is, the price actually paid or payable for the goods when sold for export to the customs territory of the Community..." Article 29 lists the following conditions, which must be met in determining customs value:

- There are no restrictions as to the disposal or use of the goods by the buyer, other than restrictions which are imposed or required by a law or by the public authorities in the community, limit the geographical area in which the goods may be resold, or do not substantially affect the value of the goods;
- The sale or price is not subject to some conditional consideration for which a value cannot be determined with respect to the goods being valued;
- No part of the proceeds of any subsequent resale disposal or use of the goods by the buyer will accrue directly or indirectly to the seller, unless an appropriate adjustment can be made in accordance with Article 32; and
- The buyer and seller are not related, or, where the buyer and seller are related, that the transaction value is acceptable for customs purposes.

The "price actually paid or payable" in Article 29 refers to the price for the imported goods. Thus the flow of dividends or other payments from the buyer to the seller that do not relate to the imported goods are not part of the customs value.

Articles 32 and 33 provide for adjustments to the value for customs purposes. Article 32 lists charges that are added to the customs value, such as, commissions and brokerage, costs of containers, packing, royalties and license fees, and the value of goods and services supplied directly or indirectly by the buyer in connection with the production and sale for export of the imported goods. Article 33 lists charges that are not included in the customs value, such as, charges for transport, charges incurred after importation, charges for interest under a financing arrangement for the purchase of the goods, charges for the right to reproduce imported goods in the Community, and buying commissions.

Effective July 1, 1995, the Commission amended Article 147(1) of Regulation 2454/93 of the Customs Code which affects valuation in the case of successive sales. This amendment "defaults" valuation to the last sale, but allows the value of an earlier sale if it can be demonstrated that such a sale took place for export to the EU. The evidentiary requirements to support the bona fides of any earlier sales will be based upon

commercial documents such as purchase orders, sales contracts, commercial invoices, and shipping documents.

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

For contact information at national customs authorities, please visit: http://ec.europa.eu/taxation_customs/common/links/customs/index_en.htm

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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 standards created under the New Approach are harmonized across the 27 EU Member States and European Economic Area countries to allow for the free flow of goods. A feature of the New Approach is CE marking. While harmonization of EU legislation can facilitate access to the EU Single Market, manufacturers should be aware that Regulations and technical standards might also function as barriers to trade if U.S. standards are different from those of the European Union.

The European Union is currently undertaking a major revision of the New Approach that will enhance some aspects, especially in the areas of market surveillance. To follow the revision, please visit:

http://ec.europa.eu/enterprise/regulation/internal_market_package/index_en.htm

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://useu.usmission.gov/agri/usda.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:

- CENELEC, European Committee for Electrotechnical Standardization (http://www.cenelec.org/Cenelec/Homepage.htm)
- ETSI, European Telecommunications Standards Institute (http://www.etsi.org/)
- CEN, European Committee for Standardization, handling all other standards (http://www.cen.eu/cenorm/homepage.htm)

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 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 Regulations. In the last year, the Commission began listing their mandates on line and they can be seen at http://ec.europa.eu/enterprise/standards_policy/mandates/. All the EU harmonized standards, which provide the basis for CE marking, can be found on http://www.newapproach.org/.

Due to the EU's vigorous promotion of its regulatory and standards system as well as its generous funding for its business 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, Croatia, FYR of Macedonia, and Turkey. Another category, called "partner standardization bodies" includes the standards organizations of Bosnia and Herzegovina, Republic of Moldova, Egypt, Serbia, the Russian Federation, Tunisia, the Ukraine, Armenia and Australia, which are not likely to join the EU or CEN any time

soon, but have an interest in participating in specific CEN technical committees. They agree to pay a fee for full participation in certain technical committees and agree to implement the committee's adopted standards as national standards. Many other countries are targets of the EU's extensive technical assistance program, which is aimed at exporting EU standards and technical Regulations to developing countries, especially in the Mediterranean and Balkan countries, Africa, as well as programs for China and Latin America.

To know what CEN and CENELEC have in the pipeline for future standardization, it is best to visit their websites. CEN's "business domain" 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 Regulations, expectations are that they will eventually serve as the basis for EU-wide standards.

Key Link: http://www.cenorm.be/cenorm/workarea/sectorfora/index.asp.

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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 of the production process to facilitate acceptance of the final product. EU product legislation gives manufacturers some choice with regard to 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. You can find conformity assessment bodies in individual Member State country in this list by the European Commission.

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 the European Standard Agreement Group. CENELEC has its own initiative. ETSI does not offer conformity assessment services.

Product Certification

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To sell products on the EU market of 27 Member States as well as 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 published 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. Although CE marking is intended primarily for inspection purposes by Member State inspectors, the consumer may well perceive it as a quality mark.

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 authorized representative established in the EU. This detailed information should not appear next to the CE marking, but rather on the declaration of conformity, the certificate 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.

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Independent certification bodies, known as notified bodies, have been officially accredited by competent authorities to test and certify to EU requirements. However, under U.S.-EU Mutual Recognition Agreements (MRAs), notified bodies based in the United States and referred to as conformity assessment bodies, are allowed to test in the United States to EU specifications, and vice versa. The costs are significantly lower which results in U.S. products becoming more competitive. At this time, the U.S.-EU MRAs cover the following sectors: EMC (in force), RTTE (in force), medical devices (in transition), pharmaceutical (on hold), recreational craft (in force) and marine equipment (in force). The U.S. Department of Commerce, National Institute of Standards and Technology (NIST), has a link on its website to American and European Conformity Assessment bodies operating under a mutual recognition agreement.

Key Link: http://ts.nist.gov/Standards/Global/mra.cfm

Accreditation is handled at Member State level. "European Accreditation" (http://www.european-accreditation.org/default_flash.htm) 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 gazette of the European Union. It is published daily on the Internet and consists of two series covering draft and adopted legislation as well as case law, questions from the European Parliament, studies by committees, and more (http://europa.eu.int/eur-lex/lex/JOIndex.do?ihmlang=en). It lists the standards reference numbers linked to legislation (http://www.newapproach.org/Directives/DirectiveList.asp). National technical Regulations are published on the Commission's website http://ec.europa.eu/comm/enterprise/tris/ to allow other countries and interested parties to comment.

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://tsapps.nist.gov/notifyus/data/index/index.cfm

Labeling and Marking

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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 until end of December 2009. 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 language of the country of consumption.

The EU has mandated that certain products be sold in standardized quantities. Council Directive 2007/45/EC, to replace 80/232/EC in April 2009, 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/prepack/packsize/packsiz_en.htm

The Eco-label

EU legislation in 1992, revised in 2000, distinguishes environmentally friendly products and services through a voluntary labeling scheme called the Eco-label. Currently, the scheme applies to 28 product types in 7 categories: cleaning products, appliances, paper products, clothing, lubricants, home and garden products and tourism services. The symbol, a green flower, is a voluntary mark. The Eco-label is awarded to producers who can show that their product is less harmful to the environment than similar products. This "green label" also aims to encourage consumers to buy green products. However, the scheme does not establish ecological standards that all manufacturers are required to meet to place product on the market. Products without the EU Eco-label can still enter the EU as long as they meet the existing health, safety, and environmental standards and Regulations.

The EU Eco-label is a costly scheme (up to EUR 1,300 for registration and up to EUR 25,000/year for the use of the label, with a reduction of 25% for SMEs) and has therefore not been widely used so far. However, the Eco-label can be a good marketing tool and, given the growing demand for green products in Europe, it is likely that the Eco-label will become more and more a reference for green consumers.

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

http://ec.europa.eu/comm/environment/ecolabel/index_en.htm

http://www.eco-label.com/

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 Return to top

Office of the U.S. Trade Representative - 2007 National Trade Estimate Report on Foreign Trade Barriers

http://www.ustr.gov/Document_Library/Reports_Publications/2007/2007_NTE_Report/S ection Index.html?ht

Foreign Agricultural Service Website, U.S. Mission to the European Union http://useu.usmission.gov/agri/

Trade Compliance Center http://www.trade.gov/tcc

Foreign Commercial Service - U.S. Mission to the European Union http://www.buyusa.gov/europeanunion

EC's TARIC – Online Customs Tariff Database
http://ec.europa.eu/taxation customs/common/databases/taric/index en.htm

European Commission – Taxation and Customs Union

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

European Union – The New EU Battery Directive http://www.buyusainfo.net/docs/x_8086174.pdf

The Latest on REACH

http://www.buyusa.gov/europeanunion/reach.html

WEEE and RoHS in the European Union

http://www.buyusa.gov/europeanunion/weee.html

Overview of EU Certificates

http://useu.usmission.gov/agri/certificates-overview.html

USDA Center for Food Safety and Applied Nutrition

http://www.cfsan.fda.gov/

EU Hygiene Guidelines - Commission Regulation 2073/2005

http://europa.eu.int/eur-

lex/lex/LexUriServ/site/en/oj/2005/I_338/I_33820051222en00010026.pdf

EU Hygiene Guidelines - Commission Regulation 2074/2005

http://eur-

lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:338:0027:0059:EN:PDF

EU Hygiene Guidelines - Commission Regulation 2076/2005

http://eur-

lex.europa.eu/LexUriServ/site/en/oj/2005/I_338/I_33820051222en00600082.pdf

Market Research

http://www.export.gov/mrktresearch/index.asp

European Union: European Marking, Labeling and Packaging - An Overview

http://www.buyusainfo.net/docs/x_4171929.pdf

Online Customs Tariff Database (TARIC)

http://ec.europa.eu/taxation_customs/common/databases/taric/index_en.htm

Taxation and Customs Union

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

Taxation and Customs Union – Member States

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

Review of the New Approach

http://ec.europa.eu/enterprise/regulation/internal market package/index en.htm

Foreign Agriculture Service, U.S. Mission to the European Union

http://useu.usmission.gov/agri/usda.html

CENELEC, European Committee for Electrotechnical Standardization http://www.cenelec.org/Cenelec/Homepage.htm

ETSI, European Telecommunications Standards Institute http://www.etsi.org/

CEN, European Committee for Standardization, handling all other standards http://www.cen.eu/cenorm/homepage.htm

Standardization

http://ec.europa.eu/enterprise/standards_policy/mandates/

New Approach Standardization in the Internal Market http://www.newapproach.org/

Portal Etsi e-Standardization http://portal.etsi.org/Portal_Common/home.asp

CEN – European Committee for Standardization – Sector Fora http://www.cenorm.be/cenorm/workarea/sectorfora/index.asp

Nando (New Approach Notified and Designated Organizations) Information System http://ec.europa.eu/enterprise/newapproach/nando/

NIST – Mutual Recognition Agreements (MRAs) http://ts.nist.gov/Standards/Global/mra.cfm

European Co-operation for Accreditation http://www.european-accreditation.org/default_flash.htm

Official Journal for the European Union http://europa.eu.int/eur-lex/lex/JOIndex.do?ihmlang=en

New Approach Standardization in the Internal Market http://www.newapproach.org/Directives/DirectiveList.asp

Technical Regulations Information System (TRIS) http://ec.europa.eu/comm/enterprise/tris/

National Center for Standards and Certification Information http://tsapps.nist.gov/notifyus/data/index/index.cfm

Metrology Pre-Packaging http://ec.europa.eu/enterprise/prepack/packsize/packsiz_en.htm

The European Union Eco Label http://buyusainfo.net/docs/x_4284752.pdf

DG Environment European Union Eco-Label Homepage

http://ec.europa.eu/comm/environment/ecolabel/index_en.htm

Eco-Label Catalogue http://www.eco-label.com/

TCC 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 perhaps one of the most hospitable climates for U.S. investment in the world. This reflects, in part, the process of European integration. The 1957 Treaty of Rome (now known as the EU Treaty) established the European Community (now Union). EU Treaty Article 43 requires EU Member States to provide national treatment to investors from other Member States regarding the establishment and conduct of business. In addition, the EU Treaty creates "four freedoms" (free movement of capital, labor, goods and persons) within the European Union. The free movement of capital in particular benefits all potential investors, regardless of whether they originate from an EU Member State or not. The EU Treaty also grants investors national treatment and protection from expropriation. Finally, any violation of these rights can be adjudicated by the European Court of Justice, which may hear cases related to violations of Treaty rights directly, or overturn national court decisions found inconsistent with the Treaty. This was a remarkable achievement, given that the six original signatories to the Treaty had been at war with one another a decade previously.

The 1986 Single European Act further reduced barriers to intra-EU investment and even created opportunities for companies from one Member State to receive better than national treatment in another Member State. For example, in the financial services sector, German universal banks can conduct securities business freely in other Member States, even if local banks are not allowed to offer these services domestically by their local licensing authority.

Prior to the 1992 Treaty on the European Union, the Community itself had virtually no role in determining the conditions that would affect the entry of investors from third countries into the territories of the Member States. While the Member States were compelled by the Treaty to grant national treatment to investors from other EU countries, they could erect and maintain barriers to investors from non-EU countries, consistent with their international obligations. These obligations include the Treaties of Friendship, Commerce and Navigation (FCNs) 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, as mandated under Article 43 of the EU Treaty.

The EU's ability to regulate Member State treatment of incoming foreign investment increased considerably in 1993. In that year, an EU Treaty revision abolished all restrictions on the movement of capital (including direct investment operations), both between EU Member States and between Member States and third countries (Article 56). However, EU Member State measures in force on December 31, 1993 denying national treatment to third-country investors were grandfathered. The Treaty (Article 57) now expressly provides for the adoption of common regimes in these areas: "The Council may, acting by a qualified majority on a proposal from the Commission, adopt measures on the movement of capital to or from third countries involving direct investment establishment, the provision of financial services or the admission of securities to capital markets."

In June 1997, the European Commission issued an interpretative communication clarifying the scope of EU Treaty provisions on capital movements and the right of establishment. The Commission was reacting to limits that certain Member States had imposed on the number of voting shares that 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 EU Treaty. Nationals 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 in a Member State for its own nationals.

In June 2007, a new EU Directive to strengthen investor-voting rights across borders came into force. The Directive bolsters cross-border investment by abolishing shareholder-voting impediments that were then prevalent in several Member States, such as the inability to vote electronically or by proxy. It is too soon to know how the Directive will be implemented by the affected Member States and whether the Commission will need to take legal action to compel implementation.

On November 1, 2007, the EU's Markets in Financial Instruments Directive (MiFID) came into force. The 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. The EU hopes that MiFID could lower EU securities trading costs by 25% within a year.

On November 9, 2007, the U.S. and the European Commission under the umbrella of the Transatlantic Economic Council launched the "U.S. – EU Investment Dialogue" to reduce barriers to transatlantic investment and promote open investment regimes globally. The Dialogue work plan includes: 1) reviewing global investment trends, including sovereign wealth investment; 2) addressing protectionist pressures and barriers to global investment; 3) reducing barriers to transatlantic investment; and 4) facilitating progress on investment issues in the OECD.

Finally, in January 2008, the European Commission proposed to remove barriers to cross-border venture capital investment and fundraising. The Commission proposal would authorize national regulators to recognize venture capital funds operating in other EU Member States in order to help innovative small businesses access risk capital. The Commission invited Member States, when reviewing existing or adopting new legislation, to enable cross-border operations and consider mutual recognition of venture capital funds.

Ownership Restrictions and Reciprocity Provisions

EU Treaty Articles 43 (establishment) and 56/57 (capital movements) have helped the EU to create one of the most hospitable legal frameworks for U.S. investment in the world. However, restrictions on foreign direct investment do exist and others have been proposed.

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. U.S. firms' right to national treatment in this area is reinforced by the EU's GATS commitments. However, a number of regulatory measures, particularly in the financial sector, remain subject to the "prudential carve-out" and thus are not covered by these GATS commitments.

After years of discussion, in March 2004, the Council of Ministers finally approved a directive on takeover bids ("Takeover Directive"). This directive seeks to create favorable regulatory conditions for takeovers and to boost corporate restructuring within the EU. The Directive authorizes Member States and companies to ban corporate defensive measures (e.g. "poison pills" or multiple voting rights) against hostile takeovers. It also includes a "reciprocity" provision to allow companies that otherwise prohibit defensive measures to sue if the potential suitor operates in a jurisdiction that permits takeover defenses. Article 12.3 of the final text is ambiguous as to whether the reciprocity principle would apply to non-EU firms. However, the preamble states that application of the optional measures is without prejudice to international agreements to which the EC is a party. France has already indicated its intent to apply reciprocity to third countries. Some other Member States appear to be leaning in the same direction.

The Takeover Directive was due to be implemented by the Member States by May 20, 2006. However, implementation has been delayed. By February 2007, seventeen

Member States had transposed the Directive or adopted necessary framework rules. Belgium implemented the directive in April 2007 while Cyprus, the Czech Republic, Estonia, Italy, Poland and Spain had not yet fully aligned their legislation with the Directives. The Netherlands implemented the law by October 2007. Other Member states have tabled draft legislation.

The U.S. and the EU continue to discuss the EU's evolving role with respect to foreign investment and the developments noted above in the OECD, the WTO and elsewhere.

In September 2007, the European Commission introduced legislation intended to increase competition and investment in the gas and electricity sectors, featuring controversial plans to separate the production and distribution arms of large integrated energy firms. The proposals would either force large firms to sell off their power transmission and gas storage assets in order to keep these activities fully separate from energy production ('Ownership unbundling'); or allow them to maintain ownership of their transmission assets but transfer their management to an Independent System Operator (ISO) responsible for taking investment and commercial decisions. The legislation includes a potential restriction on third country investment in transmission systems by mandating that third country firms seeking to gain a significant interest in or control over transmission systems within the EU comply with the same unbundling requirements as EU firms. The Commission seeks Council and European Parliamentary approval of the proposals by early 2009 before campaigns start for May 2009 parliamentary elections. The outcome for passage is unclear given strong opposition by some key member states, including Germany and France.

Conversion and Transfer Policies

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Europe's single currency, the Euro, and remaining national EU Member State currencies are freely convertible. The EU, like the United States, places virtually no restrictions on capital movements. Article 56 of the EU Treaty specifically prohibits restrictions on the movement of capital and payments between Member States and between Member States and third countries, with the grandfathered exceptions noted above. The adoption of the Euro in 15 of the 27 EU Member States has shifted currency management and control of monetary policy to the European Central Bank (ECB) and the EU Council of Ministers. Newer EU members Malta and Cyprus adopted the Euro on January 1, 2008; Slovenia adopted the currency a year earlier, on January 1, 2007. The remaining new EU Member States must join the Euro upon meeting specific economic convergence criteria although no time limit is placed for the application process to be completed. Slovakia is considered the next likely Euro-zone member.

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 the EU law - which has been ruled supreme to Member State law, including constitutional law - can be heard in local courts or addressed directly by a foreign investor with a presence in a Member State to the European Court of Justice. 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 in the context of individual bilateral investment treaties. While the EU is not itself a party to ICSID or other such arbitration conventions, it has stated its willingness to have investment disputes subject to international arbitration.

Performance Requirements and Incentives

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As the ten-year anniversary of the implementation of European Economic and Monetary Union on January 1, 1999 approaches, political interest in a coordinated tax policy has grown among some EU officials. However, Charlie McCreevy, the Commissioner for the Internal Market and Services, has flatly rejected legislation to move toward tax harmonization across Member States. A number of key Member States also object to proposals that would create a "common consolidated tax basis" across borders for European countries. European Union grant and subsidy programs are generally available only for nationals and companies in the EU, but usually on a national treatment basis. For more information, see Chapter 7 "Trade and Project Financing" 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 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). 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. On October 23, 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. Despite overall strong support for IPR enforcement, several 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 a Directive on the enforcement of intellectual and industrial property rights such as copyright and related rights, trademarks, designs, or patents. This Directive requires all Member States to apply effective and proportionate remedies and penalties that form a deterrent against those engaged in counterfeiting and piracy. Member States are required to have a similar set of measures, procedures, and remedies available for right holders to defend their IPR. The Directive includes procedures covering evidence and measures such as injunctions and seizures. Remedies available to right holders include the destruction, recall, or permanent removal from the market of illegal goods, as well as financial compensation, injunctions, and damages. There is a right to information allowing judges to order certain persons to reveal the names and addresses of those involved in distributing illegal goods or services, along with details of the quantities and prices involved. Under the Directive, Member States are required to appoint national correspondents to cooperate and exchange information with other Member States and with the Commission. The Directive takes on additional importance because of the expansion through EU enlargement of the EU's borders to the east, which moves them closer to countries such as Russia that have been a persistent source of pirated CDs and DVDs. Member States were supposed to have implemented the Directive by April 2006. At present, about half of them have transposed the legislation.

On October 11, 2005, the European Commission adopted a Communication outlining actions aimed at enhancing the efficiency of EU customs authorities' response to counterfeiting and piracy. Although not a legislative proposal, the Communication puts forth an Action Plan on implementation of current legislation focusing on enhanced partnership with economic operators and the promotion of co-operation with third countries.

On January 3, 2008, the European Commission released a Communication on Creative Content online. The Commission wants to encourage the content industry, telecoms companies and Internet service providers to work together closely to make available more content online while at the same time ensuring a robust protection of intellectual property rights. It identifies legal offers and piracy as one of the four main challenges and suggests the promotion of codes of conduct between all stakeholders could be welcomed.

On January 29, 2008, the European Court of Justice (ECJ) issued an important decision confirming that EU rules do not require countries to disclose names of Internet file sharers in civil cases. The Spanish firm Promusicae and other European rights holders had hoped that the ECJ would rule that Telefonica (a Spanish Internet service provider) had to provide the proper data to protect its property rights. This was the expected finding as the European Advocate General's opinion had said as much in July 2007. The Court, however, said that Member States could require communication of personal data to ensure effective copyright protection in the context of civil proceedings as long as such national laws are not in conflict with the fundamental EU rights of respect for private life and protection of personal data.

Criminal Enforcement

On November 23, 2005, the European Commission adopted a Communication outlining seven current pieces of legislation that needed to be revised to include criminal sanctions in case of infringements. The seven areas affected include money laundering. intellectual property violations, corruption, human trafficking, maritime pollution, Euro counterfeiting, and Internet-related infringements. The Communication has been adopted within the context of a European Court of Justice ruling that the Commission had the right to set criminal sanctions for breaches of legislation in policy areas where the EU law has primacy (i.e. first pillar), which Member States must then enforce. According to the Communication, the Commission will establish criminal penalties that must be enforced by Member States, and those governments not enforcing them will be brought to the EU Court of Justice. In light of the ECJ ruling, the Commission on April 26, 2006, reissued a proposed Directive on criminal measures to enforce IPR. Since the revision, there has been another ECJ case that has strengthened the Commission position regarding its competence to initiate directives on criminal enforcement; however, this newer case also ruled out mandating particular sanction levels. The proposal is currently under consideration by the Council and the European Parliament.

Copyright: In 2001, the EU adopted Directive 2001/29 establishing pan-EU rules on copyright and related rights in the information society. The Directive is meant to provide a secure environment for cross-border trade in copyright-protected goods and services, and to facilitate the development of electronic commerce in the field of new and multimedia products and services. Authors' exclusive reproduction rights are guaranteed with a single mandatory exception for technical copies, and an exhaustive list of exceptions to copyright which are optional for Member States in terms of including them in national law.

In April 2004, Directive 2004/48 on enforcement of IPR covering civil and administrative sanctions entered into force. The Commission also released a proposal on the criminal enforcement of IPR that is now in the legislative process but its discussion is held up as people are waiting for a European Court of Justice ruling that might affect the proposal. The trademark and copyright community would like to see the directive succeed, but not if it were too watered down. The Directive could facilitate cross-border enforcement. 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 entered into force on January 17, 2007.

The January 2008 Commission Communication on creative content online also discusses some aspects of legal offers and piracy.

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. On October 1, 2004, the EC acceded to the World Intellectual Property Organization (WIPO) Madrid Protocol. The accession of the EC to the Madrid Protocol establishes a link between the Madrid Protocol system, administered by WIPO, and the Community Trademark system, administered by OHIM. As of October 2004, Community Trademark applicants and holders are 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 protection of

their trademarks under the Community trademark system. The link between the OHIM and the WIPO registration systems allows firms to profit simultaneously from the advantages of each, while also reducing costs and simplifying the administrative aspects.

On November 1, 2005, the European Commission reduced the prices for trademark protection across the EU. Application fees were cut by about 25% and renewal fees by 40% along with further reductions for e-filing. The Commission is required to balance its budget through fees; however, not to make a profit. The fees were originally decided based on lower projections of annual applications. The reductions are based on improved efficiencies and economies of scale. The cuts save companies about 40 million Euros annually. For the price of four or five national European trademarks, companies can get protection in all EU Member States.

Designs: The EU adopted 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 the EU's Office for Harmonization in the Internal Market (OHIM) based in Alicante, Spain. They 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 on January 1, 2007. As of January 1, 2008, all fees for registering designs must be paid electronically to OHIM. In September 2007, the EU acceded to the Geneva Act of the Hague Agreement concerning the 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 on January 1, 2008. OHIM plans to update in 2008 the guidelines for renewal of Registered Community Designs.

Patents: It is not yet possible to file for a single EU-wide patent that would be administered and enforced in all EU member states. The most effective way to secure a patent across a range of EU national markets is to use the services of the European Patent Office (EPO). EPO offers a one-stop-shop that enables 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. Although the European Commission came out with a proposed regulation in 2000 (COM 412) on the institutional framework regarding the establishment of a community patent, the Council (Member States) has repeatedly failed to reach agreement on the dossier. The main outstanding issues relate to the translation of patent claims and litigation options. The Union has so far also failed to set up a streamlined system for the resolution of patent disputes. The Council rejected a Commission request for a mandate to negotiate an EU patent litigation agreement in December 2006. In March 2007, the Commission released a Communication (COM 2007/165) restating the Commission's position that it would not abandon the Community patent and European Patent Litigation Agreement (EPLA).

Geographical Indications: The United States has long had concerns that the EU's system for the protection of geographical indications, reflected in Community Regulation 1493/99 for wines and spirits and in previous Regulation 2081/92 for certain other agricultural products and foodstuffs, appears to fall short of what is required under the TRIPS Agreement. As a result of a WTO dispute launched by the United States, the WTO Dispute Settlement Body ruled on April 20, 2005, that the EC's regulation on foodrelated geographical indications (GIs) was inconsistent with the EC's obligations under the TRIPS Agreement and the GATT 1994. In its report, the DSB agreed that the EC's GI regulation impermissibly discriminated against non-EC products and persons, and agreed with the United States that the regulation could not create broad exceptions to trademark rights guaranteed by the TRIPS Agreement. In response, the EC published an amended GI regulation in April 2006 that is intended to implement the DSB's recommendations and rulings. The United States continues to have some concerns about this amended regulation and is carefully monitoring its application. In addition, as it appears that the amended regulation is serving as a model for geographical indication regulations in the areas of wines and spirits (which have not yet been amended to incorporate national treatment obligations), the United States will be carefully monitoring developments in those areas as well.

EU International Efforts to expand GI protection: The EU continues to press forward with its campaign to have geographical indications protected throughout the world and to expand the negotiations for a registry of geographical indications beyond wines and spirits to other foodstuffs. This has developed as 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 GI protections beyond wine and spirits. The U.S. and other WTO members continue to oppose the EU's proposals to extend GI protection, noting that the objective of effective protection of such indications can be accomplished through existing obligations.

U.S.-EU efforts to coordinate 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 been intensifying customs cooperation and border enforcement, strengthening cooperation with and in third countries, and building public-private partnerships and awareness raising activities together. The US-EU action strategy for the enforcement of intellectual property was launched at the US-EU Summit in June 2006. Since then, there have been bi-annual meetings between officials and between officials and rights holders to continue 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 regulatory system can be considered generally transparent in that all laws and regulations are published in the Official Journal of the European Communities. However, the process by which regulations (and related technical standards) are developed is not as operationally transparent as U.S. firms are generally accustomed to (such as the provisions of U.S. Administrative Procedures Act). The problems for U.S. stakeholders have revolved around access, accountability and redress. In 2002, the Commission released two sets of documents comprising a "Better Regulation Action Plan." The most important components of the plan include commitments to: engage in

more comprehensive consultations with interested stakeholders, including a minimum eight week period for public comments; full impact assessments of proposed legislation/regulation; and consideration of alternatives to traditional regulation. The Better Regulation Action Plan and follow-up communications demonstrate a high level commitment to move toward increased transparency and potentially more efficient EU-wide regulation as a key way to achieve the goals of the renewed Lisbon Strategy. The success of this initiative will vary depending on the willingness of the different institutions to accept these changes.

In December 2003, all three EU legislative bodies (the Council, Commission and Parliament) signed an "Inter-Institutional Agreement on Better Lawmaking," which aims to improve coordination between the institutions during the legislative process. This clarifies the use of alternative methods of lawmaking such as co-regulation (by EU and Member States) and self-regulation. The Agreement also states that the transposition by Member States of EU laws should never take more than two years. However, Member State implementation of EU directives remains neither consistent nor fully effective.

On January 26, 2004, Ireland, the Netherlands, Luxembourg and the U.K issued the Joint Initiative on Regulatory Reform. The European Commission submitted written comments supporting better monitoring of implementation of regulation, incorporation of impact assessments in law-making, simplification of legislation, greater use of review clauses, and the importance of a pro-active competition policy to foster competitiveness of the EU's industry. The Commission also underscored the importance of improving regulation at the national level. The four countries stressed that this is a long-term project, which "needs to be sustained by all future EU presidencies." Both the Austrian and Finnish EU Presidencies continued work on the initiative, and the German Presidency made Better Regulation and regulatory cooperation key priorities during its term (January-June 2007).

The EU's Better Regulation policy aims at simplifying and improving existing regulation, to better design new regulation and to reinforce the respect and the effectiveness of the rules, while respecting the EU proportionality principle. In March 2005, a Better Regulation package focused on reducing red tape, strengthening the extended impact assessment system, accelerating simplification, using outside expertise to improve quality and methodology of impact assessments. This package requested annual reports from Member States on impact assessments.

In October 2005, the Commission adopted a three-year action plan for simplifying existing EU legislation. Over a thousand legal acts across nearly all policy areas are being eliminated or modified. EU Enterprise Commissioner, Gunter Verheugen, stressed the changes thought to make legislation less burdensome in order to stimulate growth, not to weaken their effect. The initiative covers most policy sectors, but the most heavily regulated sectors (such as waste, cars, construction) are being tackled first, followed by the pharmaceutical, engineering and information technology sectors.

In November 2005, the European Commission adopted a Communication launching a European Transparency initiative (ET). The initiative focuses on four main issues: availability of data as regards end-recipients of EU subsidies; ethics of public office holders; transparency of lobbying activities; and access to documents. On EU subsidies, the Commission established a central web portal, providing links to

information on end-recipients. In December 2007 it released a comparative study of codes of conduct for public-office holders. On lobbying transparency, the European Commission decided in March 2007, based on the input of its May 2006 Green Paper on transparency, to set up a voluntary public register and will in addition release a common code of conduct for all lobbyists in early 2008. On access to documents, the Commission will take into account the input of its spring 2007 consultation when drafting the proposals for amendment of the current Regulation.

In May 2006, the Commission released its BEST Report on Streamlining and Simplification of Environment-Related Regulation Requirements for Companies. It provided 76 examples of such activities, including examples of decreased administrative burdens and increased innovation. It also provided 26 good or best practices found in Member States. The report recommends how to use the results to simplify legislation and/or decrease administrative burdens.

In November 2006, the European Commission presented its strategic review of better regulation in the European Union that, among other things, established an impact assessment board to improve the quality and consistency of EC impact assessments. This was a welcome step that had often been discussed in the transatlantic regulatory dialogues. The impact assessment board has completed over sixty opinions on draft impact assessments. In April 2007, the Commission sponsored evaluation of Commission's impact assessment system was completed, and the results will be used for a further revision of impact assessment guidelines.

In January 2007, the Commission presented an action program to measure administrative costs and reduce administrative burdens of existing EU legislation by 25% by 2012 using the EU Standard Cost Model, ultimately increasing annual GDP by about 1.5% or around 150 billion. On November 19, 2007, the Commission set up a high level expert group on the reduction of administrative burdens to advise it on the implementation of this program.

Rolling simplification program: The EC started reviewing 100 initiatives affecting about 220 basic legislative acts, to be completed by the end of 2008, and identified 43 additional initiatives to be reviewed from 2006-2009.

U.S.-EU Regulatory Cooperation

At the June 2005 U.S.-EU summit, the U.S. and the EU agreed to a Roadmap for Regulatory Cooperation that outlines a work plan for joint horizontal and sectoral efforts. Many of the bilateral economic issues between the U.S. and the EU relate to divergent regulatory approaches. The U.S. and the EU have agreed that more dialogue is needed to promote transatlantic regulatory cooperation. The initiative covers fifteen sectoral dialogues and the establishment of the EC-OMB Dialogue. The first EC-OMB dialogue took place in Washington, DC, in September 2005, and a second one in Brussels in January 2006. Since that time, there have been numerous discussions by phone and in person. The EC and OMB completed a joint draft report reviewing the application of EU and US regulatory impact assessment guidelines on the analysis of impacts on international trade and investment. Three high-level regulatory cooperation fora have taken place in Brussels in January on "good regulatory practices" and in Washington, DC in May on "best cooperative practices" and in November 2007, in Washington, DC.

At the June 2006, U.S.-EU Summit, new topics and sectors ripe for regulatory cooperation were added: pharmaceuticals, energy efficiency, tele- and radiocommunications equipment, medical devices, marine equipment and automobile safety.

Efficient Capital Markets and Portfolio Investment

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The EU Treaty specifically prohibits restrictions on capital movements and payments between the Member States and between the Member States and third countries.

The single market project has spurred efforts to establish EU-wide capital markets. In 1999, the EU launched the Financial Services Action Plan (FSAP) to establish legal frameworks for integrated financial services (banking, equity, bond and insurance) markets within the EU. The FSAP aims to increase both market and regulatory efficiency, generate greater growth, and increase coordination among Member State supervisory and regulatory authorities. The plan was nearly completed on schedule. By the deadline of January 1, 2005, the EU had adopted 39 of the 42 measures comprising the FSAP. However, as of January 2007, only 12 of the FSAP directives had been fully implemented by all Member States. The Lamfalussy process (established in 2001 to streamline passage of EU legislation) then was used extensively to speed implementation of the FSAP measures among Member State financial regulators. The result was that Member States had implemented most of the 39 directives by the end of 2007.

These 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) and Takeover Bids (to facilitate cross-border takeovers), and Capital Adequacy (implementing the Basel II Accord). A few FSAP measures, such as MiFID, are still in the process of being implemented fully, and it is unclear whether a high degree of convergence will exist among the Member States' implementing measures.

EU attention now is focused increasingly on deepening integration of retail financial services markets. In November 2005, the Commission issued a new Legal Framework for Cross-Border Payments in the EU. In May 2007, the Commission issued a Green Paper laying out goals and launching a debate on future EU policy on retail financial services. In November 2007, the Commission released a package of initiatives to modernize the EU single market, including initiatives to increase consumer choice of banking services, facilitate switching of banking accounts, complete the development of the Single Euro Payments Area (SEPA), and improve transparency of retail investment products. In December 2007, the Commission also articulated a strategy to increase cross-border supply and funding of mortgage credit. The Commission hopes for concrete progress on these initiatives during 2008.

In July 2007, the Commission proposed a Framework Directive broadening requirements for the financial position and solvency of insurance businesses in the EU (Insurance Solvency II). The Commission hopes for European Parliament and Council approval of

Solvency II in 2009, with adoption of implementing measures to occur in 2010 and transposition into national law completed by 2012. This Directive contains some draft text that restricts rights of insurance companies from third countries if their home country regulatory structure is not deemed "equivalent" to the one created by Solvency II for Europe.

Bank supervision authority and enforcement remains a Member State competence. However, three EU-wide communities of sectoral financial supervisors were created to facilitate efficient and comparable rule making throughout the EU. These are: the Committee of European Bank Supervisors (CEBS), composed of Member State supervisors; CESR, the Committee of European Securities Regulators; and CEIOPS, the Committee of European Insurance and Occupational Pensions Supervisors. Financial market turmoil in the second half of 2007 increased discussion among EU institutions of ways to strengthen mechanisms to coordinate financial supervision across the EU.

In addition, European monetary union gives the European Central Bank limited authority over the banking system in the 15-member Euro zone in certain areas, including the issuance of Euro currency, banking statistics, a smooth payments system, and advising on banking supervision.

Additional information is available at:

http://ec.europa.eu/internal market/finances/actionplan/index en.htm.

Political Violence

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Political violence is not unknown in the European Union, but it is, in general, extremely rare. Such incidents are almost always regional in nature, and individual Country Commercial Guides should be consulted for more details on problems in specific regions.

Corruption Return to top

Per EU Treaty Article 280 (5), the EU and the Member States are jointly responsible for the fight against fraud and corruption affecting the EU's financial interests. A detailed overview of EU and Member State achievements in this regard (e.g., increasing EU capacity to conduct anti-fraud investigations, greater cooperation with international partners) is provided in the EU's Anti-Fraud Office (OLAF) most recent annual report (for Year 2006) on the fight against fraud.

This report is available online at the EU's Anti-Fraud Office website: http://ec.europa.eu/anti_fraud/reports/olaf/2006/report/en.pdf

The report broadly outlines the developments that the Community has taken in terms of protecting its financial interests and addressing fraud. An overview is given of the major developments in 2006, with emphasis on the structural measures, including a reorganization of OLAF, and recovery in the field of direct expenditure.

Bilateral Investment Agreements

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The EU does not yet have any bilateral investment treaties in the traditional sense, although virtually all the Member States have extensive networks of such treaties with third countries. However, the EU's "Europe," "Association" and other such agreements with preferential trading partners often contain provisions directly addressing the treatment of investment, generally providing at least for establishment, and repatriation of capital and profits. In the context of the EU's enlargement negotiations, the U.S. Government has conveyed to the EU its concern that U.S. bilateral investment treaties with accession countries should not be adversely affected.

Other regional or multilateral agreements addressing the admission 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; and,
- c) The GATS, which contains an MFN obligation on all measures affecting the supply of services, including in relation to the mode of commercial presence.

In November 2007, the U.S. and the European Commission formally launched a bilateral investment dialogue to reduce barriers to transatlantic investment and promote open investment regimes globally (see Openness to Foreign Investment above).

OPIC and Other Investment Insurance Programs

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

Labor Return to top

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/dgs/employment social/index en.htm), and on the Eurostat website

(http://epp.eurostat.ec.europa.eu/portal/page?_pageid=1090,30070682,1090_33076576 &_dad=portal&_schema=PORTAL).

In general, the labor force in EU countries is highly skilled and offers virtually any specialty required. The Member States regulate labor-management relations, and employees enjoy strong protection. The EU Member States have among the highest rates of ratification and implementation of ILO conventions in the world.

There is a strong tradition of labor unionism 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 membership in labor unions, many other large Member States, most notably Germany and the United Kingdom, have seen their levels of organization drop nearly to U.S. 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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European Union law provides that Member States may designate parts of the Customs Territory of the Community as free trade zones and free warehouses. 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;
- 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 from Member State to Member State. 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 September 2007 is available online 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 25 then-Member States of the European Union, on a historical-cost basis as of the end of 2006, was just over USD \$1.23 trillion, up from \$948 billion at the end of 2005. The United Kingdom was the major EU host to U.S. foreign direct investment, with \$364 billion, followed by the Netherlands (\$215 billion), Germany (\$99 billion), Ireland (\$84 billion) and Luxembourg (\$83 billion).

For virtually all EU Member States, the largest "foreign" investors are in fact from other Member States. More statistics on U.S. investment abroad are available at: http://www.bea.gov/about/pdf/ITA_USDIA.pdf.

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Internal Market DG – Financial Services Unit http://ec.europa.eu/internal_market/finances/actionplan/index_en.htm

Economic and Financial Affairs DG http://ec.europa.eu/economy_finance/index_en.htm

Employment and Social Affairs DG http://ec.europa.eu/dgs/employment_social/index_en.htm

Office for Harmonization in the Internal Market 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?_pageid=1090,30070682,1090_33076576 & dad=portal& schema=PORTAL

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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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 infrastructure projects in a number of key sectors (e.g., environmental, transportation, energy, telecommunications, tourism, public health). 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 and Turkey, as well as some of the former Soviet republics.

The European Union provides project financing through grants from the European Commission and loans from the European Investment Bank. Grants from the Structural Funds are distributed through the Member States' national and regional authorities, and are only available for projects in the 27 EU Member States. All grants for projects in non-EU countries are managed through the EuropeAid Cooperation agency in conjunction with various European Commission departments, called "Directorates-General."

The CSEU Tenders Database

The U.S. Commercial Service at the U.S. Mission to the European Union offers a tool on its website to help U.S.-based companies identify European public procurement opportunities. The database features all current public procurement tenders issued by all national and regional public authorities in the 27 Member States of the European Union, plus four other European countries, and that are open to U.S.-based firms under the terms of the Government Procurement Agreement (GPA) implemented in 1995. The database is updated twice weekly and is easy to use with a range of search options, including approximately 20 industry sectors. The database also contains tenders for public procurement contracts relating to structural funds. Readers may access the database at http://www.buyusa.gov/europeanunion/eu_tenders.html.

EU Structural Funds

The 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. The EU earmarked EUR 308 billion for projects under the Structural Funds and the Cohesion Fund programs for the 2007-2013 period for the EU-27. 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/fiche_index_en.htm.

For projects financed through the Structural Funds, Member State officials 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 local officials 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. 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 advisable to team up with a local partner. 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 US Mission to the EU: http://www.buyusa.gov/europeanunion/mrr.html

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/funds/cf/index_en.htm

The Trans-European Networks

The European Union also provides financial support to the Trans-European Networks (TENs) to develop infrastructure, strengthen cohesion and increase employment across greater Europe. Launched at the Essen Counsel (Germany) in 1994, the TENs are a series of transport, telecommunications and energy projects that are continually being expanded and upgraded. The TENs are largely financed by private sector and non-EU sources. The EU does, however, provide grants from the Cohesion Fund, loans from the European Investment Bank (and loan guarantees from the European Investment Fund), and partial feasibility study grants for the TENs. There are no overt EU restrictions on the participation of U.S. firms in the TENs.

Key Link: http://ec.europa.eu/ten/transport/index_en.htm

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://europa.eu.int/grants/index_en.htm

External Assistance Grants

The EuropeAid Cooperation Office is the European Commission agency in charge of managing the EU's external aid programs. This Agency is responsible for the management of the entire project cycle, from identification to evaluation, while the Directorates-General in charge of External Relations and Development, are responsible for the drafting of multi-annual programs. The EuropeAid 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 to calls for tender for contracts financed by EuropeAid is reserved for enterprises located in the EU Member States and require that the products used to respond to these projects are manufactured in the EU or in the aid recipient country. European subsidiaries of U.S. firms are eligible to participate in these calls for tender.

Key Link: http://europa.eu.int/comm/europeaid/index_en.htm

All tenders related to EU-funded programs outside the territory of the European Union (including the accession countries) are located on the EuropeAid Cooperation Office website: http://europa.eu.int/comm/europeaid/tender/index_en.htm.

Two new sets of programs have been approved for the financing period 2007-2013. As of January 2007, the EU will provide specific Pre-Accession financial assistance to the accession candidate countries that seek to join the EU through a new instrument called 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 replaces the following programs: PHARE (Poland and Hungary Assistance for Restructuring of the Economy), ISPA (Instrument for Structural Pre-Accession financing transport and environment projects), SAPARD (projects in the agriculture sector), CARDS (aid to southern Balkans) and the Turkey Facility Fund. 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 EUR 11.4 billion.

Key Link: http://ec.europa.eu/enlargement/financial assistance/ipa/index en.htm

 ENPI: replaces the former TACIS and MEDA programs. The European Neighborhood Policy program 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.

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 2006, the EIB approved loans for projects worth EUR 53.3 billion, of which around 14% was lent outside the EU. 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. Last year, 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/.

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.

The EIB's i2i (Innovation 2010 Initiative) is designed to highlight projects that support innovative technology in the European Union, in particular by financing broadband and multimedia networks; the physical or virtual infrastructure providing local access to these networks; and research and development infrastructures, especially in the less developed regions of the European Union. i2i will also finance projects to computerize schools and universities and to provide information technology training in conjunction with public authorities.

Key Link: http://www.eib.org/Attachments/thematic/innovation 2010 initiative en.pdf

The US Mission to the European Union in Brussels has developed a database to help US-based companies bid on EIB public procurement contracts in non-EU countries in particular. The EIB-financed contracts that are open to US-based companies are featured in this database. All the tenders in this database are extracted from the EU's Official Journal. The EIB database contains on average 50 to 100 tenders and is updated twice per week.

Key Link: http://www.buyusa.gov/europeanunion/eu_tenders.html

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EU websites:

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

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

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

The EU regional policies, the EU Structural and Cohesion Funds: http://ec.europa.eu/regional_policy/index_en.htm

U.S. websites:

European Union Tenders Database: http://www.buyusa.gov/europeanunion/euopportunities.html

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.tda.gov/

SBA's Office of International Trade: http://www.sba.gov/oit/

USDA Commodity Credit Corporation: http://www.fsa.usda.gov/ccc/default.htm

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

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Business Customs

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Please see EU Member State Country Commercial Guides that can be found at the following website: http://www.export.gov/mrktresearch/index.asp under Country and Industry Market Reports.

Travel Advisory

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Please see EU Member State Country Commercial Guides that can be found at the following, website: http://www.export.gov/mrktresearch/index.asp under Country and Industry Market Reports.

Visa Requirements

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Please see EU Member State Country Commercial Guides that can be found at the following website: 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 options are handled via an interagency process. Visa applicants should go to the following links.

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

United States Visas.gov: http://www.unitedstatesvisas.gov/

Telecommunications

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Please see EU Member State Country Commercial Guides that can be found at the following website: http://www.export.gov/mrktresearch/index.asp under Country and Industry Market Reports.

Transportation

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Please see EU Member State Country Commercial Guides that can be found at the following website: http://www.export.gov/mrktresearch/index.asp under Country and Industry Market Reports.

Language

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Bulgarian, 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 languages are listed.

Health Return to top

Please see EU Member State Country Commercial Guides that can be found at the following website: 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 the European institutions are staffed with minimum personnel. For information on local holidays in the EU Member States, please see their Country Commercial Guides. The following is a list of holidays observed by the European Commission in Belgium during calendar year 2008:

1st January - Tuesday, New Year's Day

2nd January - Wednesday, day following New Year's Day

20th March - Maundy Thursday

21st March - Good Friday

24th March - Easter Monday

1st May - Thursday, Ascension Day

2nd May - Friday, day following Ascension Day

9th May - Friday, Anniversary of the 1950 Declaration made by President Schuman

12th May - Whit Monday

21st July - Monday, Belgian National Holiday

15th August - Friday, Assumption Day

24th December through 31st December - Christmas and end of year

The above-mentioned dates also apply to Luxembourg, except that Monday 21 July is replaced by Monday 23 June, Luxembourg National Holiday. The Commission reserves the right to modify the decisions, should the needs of service so require. 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 +32-2 508-2746, fax at +32-2 513-1228, or e-mail at brussels.ec.office.box@mail.doc.gov. A current directory of staff and locations worldwide may be accessed on the Commercial Service website http://www.buyusa.gov/.

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Temporary Entry of Materials and Personal Belongings

Please see EU Member State Country Commercial Guides that can be found at the following website: http://www.export.gov/mrktresearch/index.asp under Country and Industry Market Reports.

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

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

United States Visas.gov http://www.unitedstatesvisas.gov/

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

Current directory of Commercial Service staff and locations worldwide http://www.buyusa.gov/

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Chapter 9: Contacts, Market Research, and Trade Events

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

Minister Counselor for Commercial Affairs

Jonathan Bensky 32.2.508.27.47 jonathan.bensky@mail.doc.gov

Deputy Senior Commercial Officer

Rosemary Gallant 32.2.508.27.55 rosemary.gallant@mail.doc.gov

Standards Attaché

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Trade Compliance Attaché

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Commercial Attaché

Jennifer Kane 32.2.508.28.40 jennifer.kane@mail.doc.gov

NOAA Fisheries Representative

Stephane Vrignaud 32.2.508.28.42 stephane.vrignaud@mail.doc.gov

U.S. Commercial Service

U.S. Mission to the European Union

Rue Zinner 13

B-1000 Brussels, Belgium Tel.: 32.2.508.22.22 Fax: 32.2.513.12.28

E-mail: brussels.ec.office.box@mail.doc.gov Website: http://www.buyusa.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.: 32.2.508.27.60 Fax: 32.2.511.09.18

E-mail: AgUSEUBrussels@fas.usda.gov Website: http://useu.usmission.gov/agri Org Chart: http://useu.usmission.gov/agri/staff.html

The European Commission:

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

Mr. Robert Verrue, Director General

Directorate General Taxation and Customs Union

Rue de la Loi 200 B-1049 Brussels Tel: 32.2.295.43.76 Fax: 32.2.296.90.46

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

For general information about the European Union:

Delegation of the European Commission to the United States

2300 M Street, N.W. Washington, D.C. 20037 Tel: (202) 862-9500 Fax: (202) 429-1766

Website: http://www.eurunion.org/

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://ec.europa.eu/comm/external_relations/us/intro/index.htm (EU-U.S. relations)

Standards Contacts:

Dr. Carmiña Londono

Chief of the Global Standards and Information Program

National Centers for Standards and Certification Information (NCSCI)

National Institute of Standards & Technology

100 Bureau Dr. Mail Stop 2100

Gaithersburg, Maryland 20899

Tel: (301) 975-2573

Website: http://ts.nist.gov/Standards/Global/about.cfm

CEN – European Committee for Standardization

Rue de Stassart 36

B – 1050 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

Rue de Stassart 35

B – 1050 Brussels, Belgium

Tel: 32.2.519.68.71 Fax: 32.2.519.69.19 Website: http://www.cenelec.org/

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/

European Commission

Directorate - General Enterprise and Industry

Avenue d'Auderghem 45 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/

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 Tervueren 32, Box 27 B – 1040 Brussels, Belgium

Tel: 32.2.743.24.70 Fax: 32.2.706.54.30

Website: http://www.anec.eu

ECOS – European Environmental Citizens Organization for Standardization

Boulevard de Waterloo 34 B – 1000 Brussels, Belgium

Tel: 32.2.289.10.93 Fax: 32.2.289.10.99

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/

Private Sector 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.be/

Business Europe

The Confederation of European Business Avenue de Cortenbergh 168 1000 Brussels

Tel: 32.2.237.65.11 Fax: 32.2.231.14.45

Website: www.businesseurope.eu

European-American Business Council - EU Office

Rue de l'Industrie 26 B-1040 Brussels, Belgium

Tel: 32.2.513.38.72

Website: http://www.eabc.org/

European-American Business Council - US Office

919 18th Street, NW #220 Washington, DC 20006 Tel: (202) 828-9104

Fax: (202) 828-9106

Website: http://www.eabc.org/

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.be/

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 Dialogue – TABD EU Office

Residence Palace 115 Rue de la Loi, 4th floor B-1040 Brussels, Belgium Tel: 32.2. 238.52.40

Fax: 32.2.238.52.42

Website: http://www.tabd.com/

TransAtlantic Business Dialogue - TABD US Office

TABD c/o CSIS 1800 K Street, NW, Suite 400 Washington, DC 20006

Tel: (202) 775 32 51 Fax: (202) 775 31 99

Website: http://www.tabd.com/

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/nav/en/business/index.html#top

EU Member State Chambers of Commerce in the U.S. http://www.eurunion.org/infores/business/chambers.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 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/index.htm

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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/marketresearch.html 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, but free of charge.

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

http://www.export.gov/tradeevents.html

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Chapter 10: Guide to Our Services

The U.S. Commercial Service offers customized solutions to help your business enter and succeed in markets worldwide. 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

For more information on the services the U.S. Commercial Service offers U.S. businesses, please click on the link below.

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U.S. exporters seeking general export information/assistance or country-specific commercial information should consult with their nearest **Export Assistance Center** or the **U.S. Department of Commerce's Trade Information Center** at **(800) USA-TRADE**, or go to the following website: http://www.export.gov

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.