EUROPEAN UNION

TRADE SUMMARY

The U.S. goods trade deficit with European Union (25) was $122.4 billion in 2005, an increase of $13.1 billion from $109.3 billion in 2004. U.S. goods exports in 2005 were $186.3 billion, up 7.9 percent from the previous year. Corresponding U.S. imports from European Union (25) were $308.8 billion, up 9.5 percent. European Union (25) countries, together, would rank 2nd behind Canada as an export market for the United States in 2005.

U.S. exports of private commercial services (i.e., excluding military and government) to European Union (25) were $114.8 billion in 2004 (latest data available), and U.S. imports were $96.3 million. Sales of services in European Union (25) by majority U.S.-owned affiliates were $238.7 billion in 2003 (latest data available), while sales of services in the United States by majority European Union (25)-owned firms were $226.6 billion.

The stock of U.S. foreign direct investment (FDI) in European Union (25) in 2004 was $965.2 billion, up from $873.1 billion in 2003. U.S. FDI in European Union is concentrated largely in the manufacturing, finance, and wholesale sectors.

OVERVIEW

In most respects, the enormous U.S.-EU trade and investment relationship operates smoothly and to the great benefit of companies, workers, and consumers on both sides of the Atlantic. In recognition of this fact, leaders of the United States and the European Union agreed, in the context of the June 2005 U.S.-EU Summit, to pursue additional Transatlantic economic integration through a series of cooperative initiatives in areas such as regulatory cooperation, intellectual property rights enforcement, innovation, and trade and security, among other issues.

Despite the broadly positive nature of the U.S.-EU trade and investment relationship, U.S. exporters in some sectors continue to face chronic barriers to entering the EU market. A number of these barriers have been highlighted in this report for many years, despite repeated efforts to resolve them through bilateral consultations or, in some cases, the dispute settlement provisions of the WTO.

Over the course of the past year, U.S. concerns mounted regarding the EU's longstanding policy of subsidizing the development, production, and marketing of large civil aircraft. In general, barriers to access for U.S. agricultural exports continue to be a source of frustration for the United States. Even where formal EU agricultural tariff barriers may be relatively low, U.S. exports of leading commodities such as corn, beef, poultry, and

pork are significantly restricted or excluded altogether due to restrictive non-tariff barriers or regulatory approaches that often do not reflect a sound assessment of actual risks posed by the goods in question and/or that rely on ill-defined concepts of precaution. In addition, the trade-distorting effects of various EU Member State policies governing pharmaceuticals and health care products are generating concerns related both to market access and to health care innovation. This year's report also outlines concerns of U.S. exporters with respect to a number of emerging EU policies that may threaten to disrupt trade in the future, such as the proposed new EU chemicals regulation.

IMPORT POLICIES

Customs Administration EU customs law is set forth principally in the Community Customs Code CCC, the CCC Implementing Regulation, and the Common Customs Tariff, as well as in other implementing regulations promulgated by the Council and the Commission. Notwithstanding the existence of this body of EU customs law, the EU does not operate as a single customs administration. Rather, there is a separate agency responsible for the administration of EU customs law in each of the EU's 25 Member States. The 25 separate agencies do not administer EU customs law in a uniform manner. No EU institutions or procedures ensure that EU rules on classification, valuation, origin, and customs procedures are applied in a way that remains the same from Member State to Member State. Moreover, no EU rules require the customs agency in one Member State to follow the decisions of the customs agency in another Member State with respect to materially identical issues. Additionally, differences between Member States exist in areas such as the type of automated systems used, risk criteria used by administrations to determine when to examine goods, VAT levels, and licenses required for food products, as well as disparities in certificate of origin requirements and treatment of express shipments. These differences are exacerbated by the absence of EU-wide administrative management of customs operations.

On some questions, where the customs agencies in different Member States administer EU law differently, the matter may be referred to the Customs Code Committee. The Committee is an entity established by the Community Customs Code to assist the Commission. It consists of representatives of the Member States and is chaired by a representative of the Commission. The Committee is sub-divided into 14 sections (e.g., Customs Valuation Section, Tariff and Statistical Nomenclature Section, Origin Section, etc.) While, in theory, the Committee exists to help reconcile differences and thereby help to achieve uniformity of administration, in practice its success in this regard has been limited. Only a Member State or the Commission may refer a matter to the Committee; a private party does not have the right to have a matter put on the Committee's agenda. Moreover, even once a matter is put on the Committee's agenda, interested parties have no right to present their views to the Committee. Private parties may present views only at the Committee's invitation. Even when a question is raised at the Committee, achieving consensus among the Member States on particular issues is time-consuming, and there is no guarantee that the Committee will address all elements of the question.

Not only is the Committee an ineffective tool for achieving the uniform administration of EU customs law, but the EU also lacks tribunals or procedures for the prompt review and EU-wide correction of administrative actions relating to customs matters, as is required by Article X:3(b) of the GATT 1994. Instead, review is provided separately by each Member State's tribunals. Thus, a trader encountering non-uniform administration of EU customs law in multiple Member States must bring a separate appeal in each member state whose agency rendered an adverse decision. Different Member States have different rules governing the review process. Some require a party to seek administrative review first before seeking court review. Others permit a party to proceed immediately to a court for review of administrative action. The number of layers of review and time for review also varies significantly between Member States.

Ultimately, a question of interpretation of EU law may be referred to the Court of Justice of the European Union (ECJ). The judgments of the ECJ have effect throughout the EU. However, referral of questions to the ECJ generally is discretionary. Only a court from which there is no recourse (a court of last resort) is ordinarily (though not always) required to refer a question of EU law to the ECJ. Obtaining corrections with EU-wide effect for administrative actions relating to customs matters may take years. The concern also has taken on new prominence in light of the focus of the Doha Development Agenda on trade facilitation.

Given the growing negative consequences of deficiencies in the EU's customs administration and review procedures, the United States in September 2004 initiated WTO consultations on these matters. Subsequently, in March 2005, a dispute settlement panel was formed to consider U.S. complaints. The panel's report is expected in spring 2006.

Poland: U.S. companies have requested that the Polish government issue an executive order or pass legislation allowing bonded warehouses in Poland. Prior to Poland's EU accession, transactions within bonded warehouses were not taxed. Post-accession, bonded warehouses are considered to be in the territory of Poland and are taxed – although there is a provision in EU law that provides an exemption for bonded warehouses. Bonded warehouses or free zones are currently allowed in a number of other EU Member States. The existence of a bonded warehouse in Poland would assist U.S. companies that are switching to just-in-time inventory systems. This would allow changes in inventory ownership to take place without tax consequences until the goods leave the warehouse.

EU Enlargement

The 10 EU member states that acceded in 2004 -- Estonia, Latvia, Lithuania, Poland, Slovakia, the Czech Republic, Slovenia, Hungary, Cyprus and Malta -- were required to change their tariff schedules to conform to the EU's common external tariff schedule, resulting in increased tariffs on certain imported products. Under General Agreement on Tariffs and Trade 1994 (GATT 1994) Articles XXIV:6 and XXVIII, the United States is entitled to compensation from the EU to offset some of these changes. The expansion of EU quotas to account for the addition of 10 new countries and more than 75 million new EU consumers was another key element of the negotiations.

On November 30, 2005, the United States and the European Commission initialed a bilateral enlargement compensation agreement. As part of the agreement, the EU will permanently reduce tariffs on protein concentrates, fish (hake, Alaska Pollack, surimi), chemicals (polyvinyl butyral), aluminum tube, and molybdenuym wire. The EU also will open country-specific tariff-rate quotas for U.S. exports of boneless ham, poultry, and corn gluten meal. Finally, the EU will expand existing global tariff rate quotas for beef, poultry, pork, rice, barley, wheat, maize, sugar, fructose, preserved fruits, fruit juices, pasta, chocolate, food preparations, petfood, live bovine animals and sheep, and various cheeses and vegetables. The United States and European Commission signed the agreement on March 22, 2006.

As part of broader discussions on EU enlargement, the EU had earlier agreed to expand the maximum quantities allowed in licensing applications for imports into the EU of pork. This measure went into force in March 2005.

Restrictions Affecting U.S. Wine Exports

Since the mid-1980s, U.S. wines have been permitted entry to the EU market through temporary exemptions from certain EU wine regulations governing permissible wine-making practices. The temporary nature of these derogations created continuous uncertainty for U.S. wine exporters. In 2002, the EU adopted a new wine labeling regulation (Commission Regulation No. 753/2002). The United States, along with a number of other WTO Members, raised serious concerns about the lack of clarity in the new regulation and its WTO-consistency and urged the EU to withdraw the regulation. The regulation appeared to be more trade restrictive than necessary to meet any

legitimate objective, as it would prohibit the presentation on imported wine of information important for the marketing of wine unless certain conditions are met (e.g., the marketing information used must be regulated in the producing country). In addition, the EU imposed restrictions on the use of traditional terms listed in the regulation, in some instances granting exclusive use of a term to an EU wine in a manner akin to treating it like intellectual property. Traditional terms are, for the most part, terms used with certain other expressions (often geographical indications) to describe wine or liqueur, and in many cases the terms are merely descriptive (e.g., "ruby" and "tawny"). The United States does not recognize the concept of traditional terms as a form of intellectual property, nor is this a form of intellectual property recognized by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

On March 10, 2006, the European Union and the United States signed an agreement on certain aspects of wine trade, as a first phase to a broader agreement on trade in wine. This agreement is intended to eliminate the uncertainties caused by the previous temporary exemptions and to provide more stable market conditions for the wine sector. The pact will simplify export procedures for American wine-makers hoping to increase their share of a trade currently worth around $2.8 billion annually. It provides for mutual acceptance of current wine-making practices and sets up a consultative process for accepting new wine-making practices. It also addresses some of the concerns raised by the EC's wine labeling regulation, including a provision for the use of certain EC-regulated terms on U.S. wine. The two sides have also undertaken to build on the agreement by starting to negotiate a second-phase accord 90 days after the entry into force of this initial pact.

Bananas

Acting against the backdrop of agreements that in 2001 resolved the long-running U.S.-EU dispute regarding trade in bananas, the EU instituted a new banana import regime on January 1, 2006. The EU has stated its new regime has been designed to replace the pre-2006 system of tariffs and license-based quota arrangements with a WTO-consistent system.

In the fall of 2005, the EU made two proposals for a new tariff rate for bananas. Both of these proposals were subject to review by a WTO arbitrator, which found that both proposals failed to satisfy the EU's obligation to at least maintain total market access for non-preferential suppliers of bananas to the EU market. EU consultations and negotiations with a number of Latin American banana exporting countries throughout 2005 yielded no agreement on the shape of the EU's post-January 1, 2006 regime. The EU ultimately put in place a regime that combined a 176 euro/metric ton most-favored nation (MFN) tariff level with a continued zero duty tariff-rate quota for bananas originating in Africa, Pacific and Caribbean (ACP) countries, with whom the EU maintains a preferential trading relationship. However, in the face of objections and some emerging WTO legal challenges against its new regime from various Latin countries, (the continued existence of a preferential TRQ for ACP suppliers calls into

question the WTO-compatibility of the new arrangement), the EU has vowed to continue negotiating with its trading partners in hopes of finding a mutually satisfactory resolution. The United States is concerned that the EU's import regime must uphold the EU's multilateral commitment to put in place a WTO-compatible structure that at least maintains total market access for non-preferential banana suppliers. While the United States does not directly export bananas to the EU, this is an issue of considerable importance to U.S. companies involved in the production, distribution, and marketing of bananas.

Market Access Restrictions for U.S. Pharmaceuticals

U.S. pharmaceutical companies encounter persistent market access problems throughout countries of the European Union due to the price, volume, and access controls placed on medicines by national governments. In most cases, Member State governments administer medicine reimbursement programs as part of their healthcare programs, which cover a significant segment of the market. The procedures for getting a product on the reimbursement list and the price controls maintained for those products that are on the list have a strong impact on U.S. exports. These price controls limit patient access to innovative products and may diminish EU expenditures on pharmaceuticals research and development.

While the EU's single market ensures that pharmaceuticals, like other goods, can move freely within the EU, Member States' controlled prices vary greatly from one country to another. This situation permits intermediaries to buy medicines, often in bulk quantities, in EU countries where the government-determined price is lower and sell them in other EU countries where the price is set at a higher level.

Austria: Austria maintains an overly bureaucratic pharmaceutical approval process that limits market access for innovative products. A pharmaceutical firm seeking to include a product on the list of reimbursable drugs without prior authorization must first obtain the approval of the umbrella organization of social insurance funds (Hauptverband/HVB). Almost all new innovative pharmaceuticals must be approved by HVB physicians, who remain reluctant to prescribe them. A reform of the reimbursement system came into effect January 1, 2005, but the situation has not improved. U.S. companies operating in Austria report cumulative losses between $25 million and $100 million due to these practices.

Belgium: Pharmaceutical companies consider Belgium among the most inhospitable markets in Europe. Taxes, pricing policies, and patient access problems discourage investment in research and development. Despite Belgian government statements to industry in 2003 that pharmaceutical price controls would be lifted, prices on pharmaceuticals reimbursed through the Belgian healthcare system remain at well below European averages. There is also strong government pressure on doctors not to prescribe drugs under patent. Further, in addition to the turnover and profit taxes applied exclusively in this sector, pharmaceutical companies are required to fund most of the chronic gaps between budgeted and actual government spending on pharmaceuticals.

In combination, these tax measures amount to a 10 percent to 11 percent additional levy on the sector. Draft legislation that offers lower sales tax rates to firms with higher numbers of employees in Belgium appears discriminatory and not a fair way of providing incentives for local investment.

Cyprus: The Cypriot pharmaceuticals market suffers from several distortions that have resulted in unnecessary barriers to trade and retail shortages of many pharmaceuticals. Of the 3,300 drugs sold in Cyprus prior to May 1, 2004, only 1,629 were available in October 2005. Of these, only around 1,000 were registered.

Since acceding to the EU on May 1, 2004, the Government of Cyprus (GoC) imposed retail price cuts for pharmaceuticals of around 25 percent. The mechanism used by the GOC to set pharmaceutical retail prices involves using a basket of prices of the same drug in eight other EU countries (identified as two high price, four medium price, and two low price countries). However, local representatives of pharmaceutical companies believe the selected countries are not representative, pushing the benchmark price downward.

Cyprus (like other EU countries) requires re-registration of pharmaceuticals every five years. However, Cypriot requirements for re-registration are much more onerous than in other EU countries. Specifically, the GoC requires older pharmaceuticals to conform to the same test documentation requirements (including toxicological and clinical studies) as newer drugs. This causes additional expenses since more extensive testing is required today than a few years ago. Furthermore, the additional documentation is often unavailable for many older drugs. In practice, most other EU countries accept documentation available at the time when the drug was originally patented. The result is that many companies do not bother to re-register older drugs in Cyprus because it is not worth the expense.

Czech Republic: U.S. and European pharmaceutical companies complain that the process of setting reference prices for reimbursement of medicines prescribed by the national health insurance system in the Czech Republic lacks transparency and limits market access for patented medicines. Reimbursement levels are set at the price of the lowest-priced medicine in each therapeutic category, which is usually a generic and is often a domestically produced product. In many cases, the entry of a generic drug (oftentimes manufactured by a Czech company) onto the market immediately results in a sharply reduced reimbursement price. Low-priced pharmaceuticals from the Czech Republic are beginning to be sold in other EU Member States, affecting pharmaceutical companies' sales in those countries. In October 2005, the European Commission sent a letter to the Czech cabinet, claiming that Czech law does not correctly implement the EU regulation on setting rules for pharmaceutical costs, and giving the Czechs two months to respond to the complaint.

Denmark: The Danish government has failed to provide reimbursement for new innovative medicines or has delayed reimbursement for long periods. Within the context of the Danish socialized health system, this has the practical effect of preventing the sale

and use of such medicines. The government, which continues to press for further decreases in prices and sales of innovative pharmaceutical products, introduced a new reimbursement system on April 1, 2005. Under the new rules, reimbursements are determined on the basis of the cheapest generic medicinal product in each category, which means that the patient's own contribution increases if the cheapest product is not chosen. Generally, the pharmaceutical industry complains that the Danish reimbursement standards lack objective and verifiable criteria and do not meet even minimal standards of transparency. If these barriers were lifted, U.S. exports would increase by up to $10 million based on current export levels. However, not all of the medicines affected by the policy are produced in the United States. Thus, an additional benefit of an improved reimbursement policy would be higher revenue to subsidiaries of U.S. firms.

Estonia: There has been some discussion within the Government of Estonia, which is dealing with the country's increasing HIV/AIDS burden, on establishing price controls for anti-retroviral drugs and on the possibilities of introducing generic anti-retroviral medications into the Estonian marketplace. This issue merits on-going monitoring.

Finland: Innovative pharmaceutical companies in Finland have raised concerns that government regulations have resulted in an uncompetitive environment marked by pricing policies that place low ceilings on pharmaceutical prices and limit the price differentials allowed between generic and innovative products. Further, industry claims that it takes more than three years for a pharmaceutical product to be approved for full reimbursement under the national insurance scheme.

In early 2004, Finland's Ministry of Social Affairs and Health (MoSAH) began preparing legislation that would extend the time that brand name drugs are protected from competition by generic alternatives. Research-based pharmaceutical companies, legislators and civil servants at MoSAH and Ministry of Trade and Industry worked closely together and produced a report to the Minister of Social Affairs and Health. Parliament approved an amendment to the Finnish Medicine Act in late 2005 that prevents the inclusion of patent-infringing generic pharmaceuticals on national mandatory generic substitution lists. This amendment entered into effect on January 1, 2006.

France: The French government is implementing a reorganization of its health care system, which should allow the government's pricing committee to enjoy greater independence. For the most innovative products, the new fast track procedure implemented in 2004 has led to positive results, with faster access to the market and prices set at levels comparable to other European countries. The industry, however, still faces tax increases. The government is also aggressively promoting increased use of generics.

Germany: As part of a broader health-care reform package, Germany introduced a reference pricing scheme on generic and patented pharmaceuticals on January 1, 2005. U.S. firms contend that they bear the brunt of cost-containment by virtue of their dominance (25 percent) of the German market. U.S. pharmaceutical companies have

raised serious concerns about the transparency and fairness of the decision-making process related to the new reference pricing scheme, which does not provide a fair rate of return for patented, innovative medicines. Additional cost constraint measures were imposed through the combining of patented, innovative products with generic products, known as "jumbo groups". Both reference pricing and its variant, jumbo groups, are strongly opposed by U.S. pharmaceutical companies. The U.S. Government has raised this issue repeatedly with the German government, including during the visits of interagency U.S. health policy delegations to Berlin in June 2005 and February 2006.

Hungary: The Hungarian government and various pharmaceutical companies signed a contract in June 2004 that ended a price freeze and returned prices to the March 2004 levels (before the last price cut). The government promised no more price freezes until December 31, 2006. In exchange, producers agreed to make payments into a subsidy fund that were matched by funds from the government. While the government originally agreed, as part of this contract, to annual increases in its health budget by only five percent in 2005 and 2006, the actual figures will reflect much higher increases. In October 2005, the government agreed to a cap on company payments to the health budget, while discussions with the pharmaceutical companies continue on how to address future shortfalls.

In addition to this, as part of the government's "100 steps" program, a generic drug program was started in June 2005. Under this framework, the Ministry encourages doctors to prescribe the cheaper generic alternatives of an active compound. As a result of further negotiations with the pharmaceutical producers, a new support scheme entered into force, locally termed "fixing."

Italy: U.S. companies have raised concerns about Italian government measures that they believe will have a deleterious impact on their business. Among these are: (i) an across-the-board decrease in reimbursement prices for almost 300 drugs now on the reimbursement list; (ii) an increase in the amount that industry must "pay back" to the central government for regions' annualized overspending on pharmaceuticals; and (iii) additional discounts on certain classes of drugs that will disproportionately disadvantage U.S. research-based companies. U.S. companies are seeking a dialogue with the Italian government to improve transparency in Italy's cost-containment measures and to factor in the impact of those measures on U.S. industry.

Lithuania: Some pharmaceutical products in Lithuania are sold at very low prices to consumers. The government reimburses pharmaceutical manufacturers the difference between this price and a price set by the health insurance law. The Lithuanian government amended this law on July 5, 2005, to change the formula used to calculate this price. The new formula yields a price that is five percent less than the average price of the drug in six Central and Eastern European countries. Pharmaceutical manufacturers are not required to participate in this system, and outside of this system, they are free to market their products and charge a price of their choosing.

The Netherlands: The Dutch Ministry of Health views pharmaceuticals as a prime target for savings in its national healthcare budget. Industry asserts that the Ministry does not fully recognize the added value of incremental innovation. Various measures are in force, or planned, which delay the reimbursement of new compounds or favor generic drugs. The current multi-party agreement between the Ministry of Health, insurers, pharmacists, and generic manufacturers was extended for another year in 2005. Nefarma, the association representing the innovative industry, joined the agreement on January 1, 2005. Under the current agreement, Nefarma members will reduce their prices of multi-source brands (out-of-patent products for which there are generics available) by an average of 40 percent. This reduction affects older products, while new, innovative products are protected. Discussions among the same stakeholders now have the objective of extending the multi-party agreement to the end of 2006.

Poland: For several years, the Polish government has alleged that foreign pharmaceutical companies charged excessive margins for drugs and owe hundreds of millions of dollars in fines under a 2000-2002 ordinance related to pharmaceutical pricing. Although this ordinance was subsequently struck down by Polish courts, the issue remains unsettled and subject to potential legal action by both the National Health Fund and Finance Ministry. Poland has thus far ignored requests for EU arbitration of this issue. The uncertainty and amount of the potential fines threaten not only future investment, but also the existing investments of foreign innovative pharmaceutical firms in Poland.

Portugal: U.S. pharmaceuticals companies face a host of systemic problems in Portugal, including: 1) a slow government system to approve drugs for inclusion on reimbursement lists; and 2) a substantial delays in the government payment of debts to the healthcare sector (approaching $1 billion). Industry is very concerned about several new government austerity measures or proposals that could limit expenditures, increase claw-back amounts, penalize new product entry, and mandate that Portugal have the lowest reference prices in Europe. U.S. pharmaceutical firms are also concerned about a proposal that would require them to contribute to the total cost of new hospital construction, not just related pharmaceutical costs.

Spain: A pharmaceutical must go through a lengthy and costly approval and registration process with the Spanish Ministry of Health unless it was previously registered in another EU Member State or with the European Medicines Agency. This process delays the entry of innovative pharmaceuticals into the Spanish market. Further delays are caused by a lengthy administrative pricing process, coupled with onerous government reimbursement procedures. Industry argues that effective patent protection for some older U.S. pharmaceuticals sold in Spain is limited as they are protected under the former pharmaceutical process patent regime. Legislative revisions to Spanish medicines and patent laws now under consideration may pose new challenges in 2006.

A July 2002 regulation requires consumers to obtain special approval from a state inspector before pharmacies can fill prescriptions for two specific drugs produced by U.S. pharmaceutical manufacturers under the "visado" system. This measure resulted in sharply decreased sales for both drugs. In 2003, the regional government of Andalucia

followed suit and imposed a special approval requirement on all anti-psychotic drugs, which affected several U.S. pharmaceutical companies. In October 2005, the European Commission issued a reasoned opinion relating to the visado system, seeking more transparent decision-making procedures for the reimbursement of drugs.

Slovenia: Innovative U.S. drug manufacturers continue to face pricing issues in Slovenia, with the government setting price limitations based on a percentage of "European average prices", thereby inhibiting Slovenian consumers' access to new drugs. Slovenian regulations require health professionals to prescribe drugs with the lowest price in their group as stated on the Interchangeable Drug List (IDL). Drugs on the IDL are the only one that are fully reimbursed under the state insurance plan. This regulation directly and unfairly benefits the two Slovenian manufacturers of pharmaceutical products.

Slovakia: U.S. and European pharmaceutical companies complain that a recent Slovakian Ministry of Health decree (No. 723/2004), which was published in July and went into effect on October 15, 2005, further reduces the transparency of government decisions regarding the pricing and reimbursement decisions for medicines prescribed by national health insurance. The decree specifies the rules to be applied in determining the price of the medicinal product and level of reimbursement. The original decree provided detailed rules for calculation of the price and level of reimbursement. However, recent amendment of the decree cancelled the detailed rules for determination of the reimbursement amount and, instead, provided the Ministry of Health, as the deciding authority, with a wide scope of discretion to decide on the amount of reimbursement without setting a clear set of guidelines for such decisions.

Uranium Imports

The United States is concerned that EU policies may restrict the import into the EU of enriched uranium, and possibly downstream goods such as nuclear fuel, nuclear rods, and assemblies. Since 1992, the EU has maintained strict quantitative restrictions on imports of enriched uranium to protect its domestic producers. Since 1994, these restrictions have been applied in accordance with the terms of the Corfu Declaration, a joint European Council and European Commission policy statement that has never been made public or notified to the WTO. The Corfu Declaration appears to impose explicit quotas on imports of enriched uranium, limiting imports to only about 20 percent of the European market. The United States has raised concerns about the import quotas and the non-transparent nature of the Corfu Declaration and its application. Further, the United States is closely monitoring whether any future EU agreements with Russia under negotiation in the nuclear area will follow WTO rules on import quotas and transparency.

STANDARDS, TESTING, LABELING, AND CERTIFICATION

Overview

With the decline of traditional trans-Atlantic trade barriers, EU regulatory measures are increasingly viewed as impediments for U.S. exporters of manufactured and agricultural products. Compliance with divergent technical regulations and standards for products sold in the United States and the EU imposes additional costs on U.S. exporters (e.g., duplicative testing, product redesign) and increases the time required to bring a product to market. Such costs for U.S. exporters are compounded by a lack of transparency in the development of EU regulations and a lack of meaningful opportunity for non-EU stakeholders to provide input on draft EU regulations and standards. To address these systemic concerns, the United States continues to promote greater U.S.-EU regulatory cooperation and enhanced transparency in the EU regulatory system.

Despite often sharing similar regulatory objectives, U.S.-EU dialogue frequently is unable to promptly resolve regulatory-based trade problems. In particular, many U.S. exporters view the EU's growing use of a so-called "precautionary principle" to restrict or prohibit trade in certain products, in the absence of full scientific justification for doing so, as a pretext for market protection. Further, EU regulatory barriers are often compounded by multiple and/or overlapping measures affecting particular products. Poultry, Agricultural Biotechnology Products, and wine are examples of products that confront multiple layers of restrictive regulation in the EU marketplace. To illustrate:

- U.S. efforts to reopen the EU to U.S. poultry exports have been hindered by multiple obstacles. As a result, resolution of any one obstacle (e.g., the EU allowing the use of alternative antimicrobial treatments on poultry meat) would not necessarily result in reopening of trade due to the existence of other obstacles (such as requirements regarding on-farm practices for raising poultry).

- U.S. exporters of Agricultural Biotechnology Products have been harmed not only by the *de facto* moratorium on approving new products, but also by the existence of certain Member State prohibitions on products already approved for marketing within the European Community.

- Despite the recent conclusion of a U.S.-EU agreement on wine trade, U.S. wine exporters are still confronted not only by the uncertainty surrounding the EU**'**s restrictions on geographical indicators and labeling practices, but also by high tariffs and heavy subsidization of EU wine producers.

Standardization

Given the massive U.S.-EU trade relationship and the volume of EU standardization work in regulated market segments, European standards activities are of considerable importance to U.S. exporters. A number of problems continue to impede U.S. exports, including a general inability to participate in the formation of EU standards and the

occasional reliance on design-based, rather than performance-based, standards. Disparities between the practices of some European conformity assessment bodies add to the frustration and cost for American exporters. In addition, there are concerns related to the respective procedures, responsibilities (e.g., accountability, redress), and lack of transparency in the Member States, the European Commission, and the European standards bodies that require careful monitoring. In the case of some sectors, European directives and their relevant standards pose a significant barrier to American exports.

Pressure Equipment: In May 2002, the EU Pressure Equipment Directive (PED) entered into force, imposing new requirements on manufacturers of such equipment. Previously, pressure equipment manufacturers could demonstrate conformity based on standards for material specifications, including the U.S. ASME Code. Manufacturers using the ASME Code may now be excluded from the EU market because the European standards incorporate material specifications slightly different from those found in the ASME Code. In the absence of a full set of harmonized EU standards, the PED permits manufacturers to file for an EAM (European Approval of Materials); however, few requests for EAMs have been approved so far. Another option, the Particular Material Appraisal (PMA), is a costly process for which there are no clearly defined procedures in the PED. In light of these factors, U.S. manufacturers seek continued acceptance of materials that meet the ASME code that have been widely used in Europe for decades prior to the PED. In an effort to bring the two sides closer together, U.S. and EU officials and stakeholders agreed to a pilot project to eliminate redundant testing requirements for materials. The two sides are working on the beginnings of technical cooperation, starting with an attempt to harmonize several testing standards.

Care Labeling Standard: The U.S. apparel industry continues to raise concerns about care labeling requirements for textile and apparel products sold within the EU. While there is no harmonized EU legislation that requires care labeling when exporting to the EU, individual EU Member States may have specific requirements. However, if a care label is attached it should incorporate care symbols, which are published in the European standard EN 23758 (1994). These symbols are trademarked and their use is regulated by GINETEX, a European-based association. Requirements for the use of the GINETEX care symbols differ by Member State, and in some countries may require a membership fee or royalty payment. The fees associated with the use of the GINETEX care symbols can be costly to U.S. firms and the differing use requirements in Member States can be confusing and burdensome. At the same time, the use of care labels on textile and apparel products is recommended because the manufacturer can be held liable under the EU Product Liability Directive if a problem occurs.

The Netherlands: The Dutch Parliament is considering an amendment to the Environmental Management Act affecting (sustainably produced wood) that could have a significant impact on U.S. exports because it requires assessment criteria to be equivalent to one particular certification program (the Forest Stewardship Council - FSC) to the exclusion of others. FSC is only one of a number of internationally–recognized certification programs for sustainable forest management. The three certification programs that are widely used in the United States – the Sustainable Forestry Initiative,

the American Tree Farm System, and FSC – cover certification of over 76 million acres (about 10 percent) of U.S. forestland. However, less than two percent was FSC-certified in 2004. Thus, a significant portion of the $34.5 million of wood products that the U.S. producers exported to the Netherlands in 2004, could potentially be affected by this legislation. The proposed legislation would also require that any person who places wood on the market in the Netherlands, provide a declaration noting where the wood is produced, and accompanied by an auditor's report confirming delivery to the person placing the wood products on the market. This would be overly burdensome for both producers and governments and would be extremely difficult, if not impossible, for manufacturers of panel products and other further processed wood products.

Agricultural Biotechnology Products

Since 1998, the European Council has not managed to assemble a qualified majority of EU Member States in support of agricultural biotechnology product approvals, despite the lack of any legitimate health or safety reason to reject them. While the European Commission has recently granted approval for a limited number of biotechnology products under its legislative authority, the U.S. considers that the EU continues to lack a predictable, workable process for approving these products in a way that reflects scientific, rather than political, factors. At the level of the EU Council, it is clear that a moratorium policy continues to exist.

In May 2003, the United States initiated a WTO dispute settlement process related to the EU's *de facto* moratorium on approvals of biotechnology products and on the existence of individual Member State marketing prohibitions on previously approved biotechnology products. The panel hearing this dispute delivered its interim report in February 2006.

Several Member States have imposed marketing bans (safeguard measures) on some biotechnology products that had been previously approved at the EU level. On June 24, 2005, the Environment Council rejected by a qualified majority the eight Commission proposals to lift safeguard measures imposed by five Member States against biotechnology maize. On October 5, 2005, the European Court of Justice ruled against Upper Austria's effective ban on growing biotechnology crops since there was no scientific evidence to back up this ban. In addition, there has been a recent movement within the Environment Council, largely led by Luxembourg, to review the present decision-making process on biotechnology approvals, apparently with a view to limiting the European Commission's authority to act on approvals in the absence of a qualified majority among EU Member States.

Co-existence: In accordance with the European Commission's guidance document on the co-existence of biotechnology and conventional crops, which recommends a regional approach to co-existence issues, a number of Member States (including Spain, Denmark, Germany, Italy, the Netherlands and most regions in Austria) have drafted new co-existence laws, or have chosen to provide industry guidance. While the decrees/laws

vary substantially from country-to-country, they generally require extensive control, monitoring and reporting of biotechnology crops.

The European Commission may initiate infringement proceedings against a Member State's co-existence law if it is judged to be incompatible with EU law. However, there is no time limit on how quickly the Commission must act.

Traceability and Labeling: In April 2004, EC Regulations 1829/2003 and 1830/2003 governing the approval, traceability and labeling of biotechnology food and feed became effective. The regulations include mandatory traceability and labeling for all biotechnology and downstream products. Among the traceability rules are requirements that information that a product contains or consists of biotechnology products must be transmitted to each operator throughout the entire supply chain. Operators must have a standardized system in place to keep information about biotechnology products and to identify the operator by whom and to whom it was transferred for a period of five years from each transaction.

The requirements include an obligation to label appropriate products and to indicate if the food is different from its conventional counterpart in composition, nutritional value, intended use or health implications.

In some cases, these burdensome directives have already severely restricted market access for U.S. food suppliers, because food producers have reformulated their products to eliminate the use of biotechnology products. Food producers have indicated concern about needing to find expensive or limited alternatives. The Directives generally are anticipated to have a negative impact on a wide range of U.S. exports, including processed food exports.

Austria: Recent amendments to the Austrian Biotechnology Law allow, in principle, the planting of biotechnology crops. However, strict and complicated rules on liability and compensation still represent a *de facto* barrier against all EU-approved biotechnology crops. Under current Austrian rules, unapproved biotechnology events must not be detected in conventional seeds ("zero tolerance"), but EU-approved events may be present in conventional and organic seeds up to 0.1 percent.

Driven by political rather than scientific factors, the Government of Austria has effectively banned most agricultural biotechnology applications apart from research. All major Austrian supermarket chains have banned biotechnology products, even those labeled according to EC regulations, from their shelves.

Cyprus: Cyprus has adopted increasingly tough standards for biotechnology products, which in some cases exceed minimum EU requirements. For example, (a) GOC application requirements for new agricultural biotechnology crops are more arduous than in other EU countries, (b) permits for such crops must be renewed every five years, and (c) the GOC has declared as "GMO-free" areas under the Natura 2000 project (corresponding to 14 percent of Cyprus territory). Biotechnology products that are

already licensed in the EU may circulate in Cyprus freely. However, biotechnology organisms must be approved, even if they are already licensed in other EU countries.

France: France has implemented EU regulations on agricultural biotechnology, notably those covering traceability and labeling. In France, a majority of imported products that are labeled "biotechnology" are soybeans and soybean meal from the United States, Brazil, and Argentina. There are almost no food products labeled as derived from biotechnology available on the market, due partly to a generalized hostility and pressure from anti-biotechnology activists and consumer organizations.

The government has drafted a Biotechnology Law, including the transposition of EU directive 2001/18, national rules on co-existence, and a new evaluation procedure for biotechnology products. However, the text has been under review at the inter-ministerial level because no agreement was found on co-existence. A vote on the bill is expected in early 2006. If the EU directive 2001/18 is not transposed into French law by October 2006, France will have to pay penalties set by the European Court of Justice.

Germany: Germany has suspended the approvals for planting certain biotechnology crops. In November 2004, Germany passed its new version of the genetech law, which went into effect on February 4, 2005. This law contains strict regulations for liability and requires the creation of co-existence regulations. The new law is expected to hinder the importation, use, and development of Agricultural Biotechnology Products. Some biotechnology companies have already decided to stop their agricultural research efforts in Germany.

Greece: Greece has not been responsive to applications to introduce biotechnology seeds for field tests, despite support for such tests by Greek farmers and Greece's agricultural science community.

Hungary: Extensive biotechnology research is taking place in Hungary, and the Hungarian government has allowed field tests for herbicide resistant corn, wheat and other crops. Although Hungary is mandated to adopt all relevant EU biotechnology legislation, Hungary has not yet prepared the national application rules for the EU biotechnology regulations on food and feed and traceability and labeling. In January 2005, the Government of Hungary (GoH) introduced a moratorium on corn varieties containing the Mon 810 event by invoking a "safeguard clause". The temporary measure bans the production, use, distribution, and import of hybrids deriving from the MON 810 maize lines. The ban applies to seed producers and distributors as well as farmers. The moratorium is being addressed in the context of the co-existence legislation, a draft of which is expected by the end of the year. Hungary shares with other EU countries a relatively high level of public resistance to introduction of biotechnology food stocks, which has delayed the introduction of these products.

Italy: There are varying positions on Agricultural Biotechnology Products among Italy's Ministries of Health, Agriculture, and Environment. The Ministry of Agriculture is trying to minimize the risk of adventitious presence by imposing rigorous thresholds for

seed purity, which have hurt U.S. conventional corn and soybean seed exports, which fell from $27 million in 2000 to $1 million in 2004. Current regulations permit only the minimum detectable 0.05 percent of biotechnology seeds to be present. In the case of soybeans used for animal feed, the Ministry of Agriculture allows the use of imported biotechnology beans, as the Ministry is unable to meet Italian feed demand from non-biotechnology sources. On November 29, 2004, the Regional Administrative Tribunal (TAR) of Lazio (which includes Rome) annulled the decree banning the commercialization of four EU-approved biotechnology corn varieties (BT11, MON 810, MON 809, and T25). On January 25, 2005, the Senate passed a law, which criminalizes biotechnology cultivation in Italy through July 28, 2006, by which time each of Italy's regions must devise regional plans for the co-existence of biotechnology, non-biotechnology, and organic crops. Under the law, farmers and/or seed companies may be liable for fines between 5,000 and 50,000 euros ($6,000 - $60,000) or imprisonment of up to two years for "biotechnology" contaminating.

Luxembourg: Luxembourg continues both to ban marketing or growing of biotechnology crops in the country, and to be unsupportive of approving new biotechnology products for EU use. Luxembourg acknowledges that their ban is a problem for the EU with regard to WTO obligations, but the issue remains politically explosive with a "vocal minority" that vehemently opposes biotechnology products. Despite the EU Commission's continued efforts in 2005 requesting Luxembourg to withdraw its national ban, the law remained in effect. Luxembourg continued throughout 2005 to defend its national ban and also is encouraging an EU-wide discussion about decision-making on these products. Legislation which would regulate growing of biotechnology crops in Luxembourg remained in a parliamentary committee at year's end.

Portugal: The EU's (de facto) moratorium on new biotechnology-approvals led to U.S. losses in the Portuguese corn market of $56 million in 2004. The EU Traceability and Labeling Regulation (1830/03) and the EU Food and Feed Regulation (1829/03) resulted in the immediate decline of Portuguese demand for U.S. soybeans and led to $21 million in losses in 2004. The Ministry of Agriculture's 1999 suspension of two biotechnology-corn seeds' inclusion in the National Seed Catalogue led to U.S. losses of $688,000 in 2004. Only after the EU "unfroze" the EU seed catalogue this year, could Portuguese farmers plant biotechnology-seeds. In total, EU actions cost the United States an estimated $78 million in lost revenue in 2004.

Spain: The Spanish inter-ministerial biotechnology commission (composed of the Ministries of Environment, Agriculture, Health, Education and Science, and Industry, Tourism and Trade) continues to accept new applications to permit biotechnology seed cultivation in Spain, most recently in July 2005, with the acceptance of the NK603 Roundup Ready corn variety. In addition, the Ministry of Agriculture was given the authority to approve new varieties derived from MON810. The inter-ministerial commission will likely continue case-by-case decisions with respect to future Spanish votes on EC biotechnology proposals.

Barriers Affecting Trade In Cattle, Beef, Poultry, And Animal By-Products

A variety of EU measures, outlined below, have the effect of severely restricting U.S. exports of livestock products to the European Union market.

EU Hormone Directive

In 1988, the EU provisionally banned the use of substances that have a hormonal growth-promoting effect in raising food-producing animals. This action effectively banned the export to the EU of beef from cattle raised in the United States. The use of hormone implants is approved by the U.S. Food and Drug Administration and is a common practice in U.S. beef cattle production. The United States launched a formal WTO dispute settlement procedure in May 1996 challenging the EU ban. In 1999, the WTO ruled that the EU's ban is inconsistent with the WTO Agreement on Sanitary and Phytosanitary (SPS) Measures because it is imposed without a risk assessment based on scientific evidence of health risks and authorized the United States to impose sanctions on EU products with an annual trade value of $116.8 million.

In September 2003, the EU announced the entry into force of an amendment (EC Directive 2003/74) to its Hormone Directive (EC Directive 96/22). The new Directive recodified the ban on the use of estradiol for growth promotion purposes and established provisional bans on the five other growth hormones included in the original EU legislation. With enforcement of this new Directive, the EU argued that it was now in compliance with the earlier WTO ruling.

At present, the United States continues to apply 100 percent duties on $116.8 million of U.S. imports from the EU. In November 2004, the EU requested WTO consultations with the United States on this matter, claiming that U.S. sanctions were no longer justified. The United States maintains that the revised EU measure cannot be considered to implement WTO recommendations and rulings related to this matter, and that the U.S. sanctions therefore remain authorized.

Animal By-Products Legislation

In October 2002, the European Commission approved EC Directive 1774/2002, which regulates the importation of animal by-products not fit for human consumption. The regulation went into force in May 2004. During 2003, intensive technical discussions between U.S. and EU officials successfully addressed some issues and prevented trade disruption for a significant portion (at least $300 million) of U.S. exports to the EU of animal by-products. However, it is estimated that with the publication of the final text, about $100 million of U.S. animal by-product exports to the EU remain adversely affected to some degree. In particular, the United States remains concerned about various outstanding issues for which the EU has not provided risk assessments, such as a ban on the use of dead-in-transport poultry in pet food. The U.S. exports remaining most exposed to this regulation are dry pet food, other animal protein products, and some hides and skins. It is unclear as to the regulation’s overall effect on further downstream

products such as certain in vitro diagnostic products that may use animal by-products. In October 2005, the Commission presented a report to the EU Parliament recommending amendments to EC Directive 1774/2002. Any agreed amendments would need to be voted on by the EU Parliament.

Poultry Meat Restrictions

U.S. poultry meat exports to the EU have been banned since April 1, 1997, because U.S. poultry producers currently use washes of low-concentration chlorine as an anti-microbial treatment (AMT) to reduce the level of pathogens in poultry meat production, a practice not permitted by the EU sanitary regime. U.S. concerns with respect to poultry intensified in 2004 as a result of EU enlargement and the application of EU restrictions in new Member States that had previously allowed entry of U.S. poultry meat. In 2004, the United States made significant progress in its work with the EU to address differences between U.S. and EU food safety rules for poultry meat.

The Commission audited a number of U.S. poultry plants that demonstrated the use of AMTs, and the United States developed an action plan to demonstrate the equivalency of U.S. and EU on-farm manufacturing practices.

In 2005, the two sides continued to discuss the final details of a series of steps, including approval by EU Member States of the use of AMTs, aimed at re-opening the EU market to U.S. poultry meat products.

Other Member State Measures

Finland and Sweden: The European Commission has granted both Finland and Sweden extensions of the derogations approved in their EU accession agreements, which allow both countries to continue to enforce stricter salmonella controls and stricter border controls for live animals (quarantine) than those enforced by other EU Member States. These countries also impose strict requirements regarding the importation of fresh (including frozen) meat, ground meat, and meat preparations, (with the exception of heat-treated meat) and table eggs.

Barriers Affecting Vitamins and Health Food Products

Denmark: A Danish statutory order requires companies to conduct tests on nutrition products for content, including on individual ingredients, which is not required in other EU countries. The tests must be analyzed by a Danish Veterinary and Food Administration (DVFA)-accredited laboratory.

France: As of this time, France does not apply the recently issued EU Directive on dietetics and maintains its own restrictive policy and practices with regard to limits in vitamin and mineral composition. However, France was expected to transpose the EU Directive by the end of 2005.

Greece: In implementing the EU Food Supplement Directive, Greece restricted the sale of protein-based meal replacement products to pharmacies and specialized stores, limiting the ability of U.S. companies to sell such products through direct sales.

Spain: Spain has restrictive practices with respect to the use of vitamins and health food products. Since March 2002, Ministry of Health inspectors have raided health food shops and removed 227 different types of health food products from the market. Although the EU passed a new Directive on dietetics, Spain maintains its restrictive policy with regard to limits in vitamin and mineral composition.

EMERGING REGULATORY BARRIERS

In addition to the previously mentioned trade barriers arising from EU policies regarding standards, testing, labeling, and certification, the United States has serious concerns about the ongoing development of new regulations that would appear to have serious adverse consequences for U.S. exporters in the future. The United States is actively engaging the European Union with respect to the issues outlined below.

EU Directive on Wood Packaging Material (WPM)

In February 2005, the EU suspended for one year until (March 1, 2006) its plan to implement a new Directive on wood packaging material (WPM) that could affect up to $80 billion worth of U.S. agricultural and commercial exports to the EU that are shipped on wooden pallets or in wood packaging materials. The Directive, published by the European Commission on October 5, 2004, would place a debarking requirement, in addition to heat treatment fumigation, on WPM from the United States and other countries.

The EU Directive is more restrictive than the international standard established by the International Plant Protection Convention (IPPC), Guidelines for Regulating Wood Packaging Material in International Trade (IPSM-15). IPPC members, including the EU, approved ISPM-15 to harmonize and safeguard WPM requirements in world trade. IPPC members approved specific treatments and the marking of WPM, but did not support a debarking requirement in the absence of a scientific justification. The IPPC continues to assess emerging scientific studies related to this issue. On January 17, 2006, EU Member States approved a further postponement of its unilateral debarking requirement until December 2008, with a review of the issue scheduled for 2007.

Chemicals

In October 2003, the European Commission presented its proposal for a massive overhaul of existing EU chemicals regulation. The proposal, called REACH (Registration, Evaluation, and Authorization of Chemicals), would require all chemicals produced or imported into the EU in volumes above 1 ton per year affecting approximately 30,000 chemicals to be registered, by providing test results and other information on the substances and their uses, in a central database. Chemicals of very high concern would

need an authorization for use in the EU. Virtually every industrial sector, from automobiles to textiles, could be affected by the new policy.

While the United States supports the EU's objectives of protecting human health and the environment, this approach appears to be costly, burdensome and could present significant obstacles to trade and innovation. Many of the EU's trading partners have expressed similar concerns. The European Council and the European Parliament have been examining the proposal under the EU's legislative co-decision process. On November 17, 2005, the European Parliament, in its first reading, adopted an amended proposal that the Council and the Commission will now review. The Council is expected to conclude its first reading in spring 2006. The U.S. Government has provided detailed comments on the REACH proposal and welcomes changes to the original Commission text that would make REACH a more balanced and cost-effective regulation.

Cosmetics

In January 2003, the EU formally adopted the seventh amendment to Directive 76/768/EEC on Cosmetics. EU Member States were required to transpose the Directive into national law by January 1, 2004, at which time a series of amendments came into effect. The amended Directive calls for an EU-wide ban on animal testing within the EU for cosmetic products and an EU-wide ban on the marketing/sale of cosmetic products that have been tested on animals, whether such testing has occurred inside or outside the EU. It will prohibit the sale in the EU of U.S. cosmetics products tested on animals as of 2009 or 2013 (depending on the type of test) or earlier if the European Community has approved an alternative testing method.

To minimize possible trade disruption, the U.S. Government and the European Commission have embarked on a joint project to develop harmonized, alternative, non-animal testing methods. The project involves cooperation between the U.S. Interagency Coordinating Committee on the Validation of Alternative Methods and the European Center for the Validation of Alternative Methods (ECVAM). The aim is to develop agreed alternative testing methods that would be submitted to the OECD process for international validation. The validation of alternative methods is a long and expensive process, taking on average seven years. The EC is actively encouraging ECVAM to pursue alternative methods in the near term.

Waste Management (WEEE and RoHS Directives)

In January 2003, the European Union adopted two Directives in an effort to address environmental concerns regarding the growing volume of waste electrical and electronic equipment. The Waste Electrical and Electronic Equipment (WEEE) Directive focuses on the recycling of electrical and electronic equipment waste. The Restriction of the Use of certain Hazardous Substances (RoHS) Directive addresses restrictions on the use of

certain substances in electrical and electronic equipment, such as lead, mercury, cadmium, and certain flame-retardants.

Under the WEEE Directive, producers are held individually responsible for financing the collection, treatment, and recycling of the waste arising from their new products as of August 2005. Producers have the choice of managing their waste on an individual basis or participating in a collective scheme. Waste from old products is the collective responsibility of existing producers based on their market share.

Member States were required to transpose the WEEE Directive into national law by August 13, 2004, and implement it by August 13, 2005. Some Member States still have not transposed the WEEE Directive and many are behind in their implementation and do not have their national WEEE registration systems in place. By December 31, 2006, the WEEE Directive requires that Member States ensure a target of at least four kilograms of electrical and electronic equipment per inhabitant per year is being collected from private households. The policy is intended to create an incentive for companies to design more environment-friendly products.

Under the RoHS Directive, as of July 1, 2006, the placing on the European market of electrical and electronic equipment containing lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls, and polybrominated diphenyl ethers will be prohibited, with some limited exemptions. The Commission Decision, published on August 18, 2005, established maximum concentration values of 0.1 percent by weight in homogenous materials for lead, mercury, hexavalent chromium, polybrominated biphenyls (PBB), and polybrominated diphenyl ethers (PDBE) and 0.01 percent by weight in homogenous materials for cadmium.

Some U.S. companies seeking to comply with the RoHS Directive claim to face significant commercial uncertainties. Firms assert that they lack sufficient, clear, and legally binding guidance from the European Commission on product scope and, in cases where technically viable alternatives do not exist, businesses face a lengthy, uncertain, and non-transparent exemption process. As of late 2005, the European Commission was considering additional RoHS exemption requests. Some exporters claim that the uncertainty about RoHS provisions is having an adverse impact on companies as they must make practical design, production, and commercial decisions without adequate information.

Given the substantial impacts of RoHS substance bans on international trade, the United States has urged the European Commission to provide sufficiently detailed, legally binding guidance to give companies seeking to comply with RoHS commercial certainty. The United States has also urged the Commission to make the exemption process more efficient and transparent so that companies can have definitive answers more promptly on whether and how the Directive will apply to their products. As an additional concern, the

U.S. testing industry argues that the EU has not yet developed test methods for use in conformity assessment of the products covered by these directives.

Battery Directive

In 2003, the European Commission proposed a revised version of the 1991 EU Battery Directive. The aim of the new Directive is to collect and recycle all waste batteries and to prevent their incineration and disposal. Producers must finance the collection, treatment, and recycling of waste batteries. On the issue of nickel cadmium (NiCd), the Commission proposes to set high collection targets rather than a ban. The impact assessment carried out by the Commission identifies this approach for dealing with NiCd batteries as the best option from the environment and economic points of view.

In April 2004, the European Parliament rejected the Commission's approach and voted for a ban on nickel cadmium batteries, with a list of exemptions for some industrial and automotive batteries. In the common position of July 2005, the Council agreed upon a partial ban on the use of cadmium in portable batteries.

Emergency and alarm systems, medical equipment and power tools are exempt from the ban. The second reading in Parliament started in September 2005, with final adoption of the text expected in 2006.

Energy Using Products (EUP)

The EU framework directive promoting eco-design for energy-using products (EUP) became law on August 11, 2005, and EU Member States have until August 11, 2007, to transpose it into national law. Through this directive, the EU means to regulate the integration of environmental considerations at the design phase of a product with the objective of cutting energy use. Once in place for a product or a product feature, design requirements will become legally binding for all products put on the EU market, regardless of where they are designed or produced. The legislation commits the European Commission to draw up a three year working plan of "implementing measures" that will identify products and set specific standards by July 2007. Although there will be impact studies that will slow the implementation, the directive contains a list of products that are likely to be the first targets which includes: lighting, office equipment, heating equipment, domestic appliances, air conditioning, and consumer electronics, and the feature of stand-by energy losses, for which implementing measures may be issued even before July 2007. The directive sets out CE marking requirements for the items covered by implementing measures. The electronics industry in particular has raised concerns with EuP, noting producers already face other extensive new regulations. Industry is most concerned about the possible need for a complete product life cycle analysis, and fears adverse impacts on design flexibility, new product development and introduction, as well as increased administrative burdens.

Acceleration of the Phase-Outs of Ozone-Depleting Substances and Greenhouse Gases

As part of a wider climate change program to reduce emissions of greenhouse gases to meet its Kyoto Protocol objectives, the European Commission put forward a proposal in October 2003 to regulate the emission of fluorinated gases (f-gases). The aim of the proposal is to improve the containment of f-gases and introduces specific restrictions on their marketing and use in specific applications. During the first reading in fall 2004, EU environment ministers decided to split the proposal into two packages, one includes a Regulation on f-gases used in stationary applications and the other a Directive on fluorinated hydrocarbons (HFCs) in vehicle air conditioning. The first measure (the "stationary" Regulation) will impact U.S. manufacturers of stationary air conditioning and refrigeration equipment and the companies that produce the chemicals used within them. The second will impact U.S. car and parts manufacturers by phasing-out HFC 134a in vehicle air conditioning beginning in 2011 with a complete ban by 2017.

The "stationary" Regulation seeks to improve containment of f-gases by setting minimum standards for inspection and recovery, and, where containment is not feasible, proposes to ban marketing and use of certain applications. Examples of applications using f-gases the Regulation seeks to ban include vehicle tires, non-refillable containers, windows, footwear, one-component foams, self-chilling drinking cans, novelty aerosols and fire extinguishers. Despite the Environment Committee of the European Parliament (EP) voting to ban the use of HFCs in a range of appliances including small domestic refrigerators, commercial and industrial refrigerators, and stationary air-conditioning units, the EP Plenary did not adopt these bans in the October 2005 second reading. Nonetheless, the EP did adopt an amendment allowing Member States to maintain or introduce stricter protective measures in order to reach Kyoto targets. The United States will continue to closely monitor the remaining phases of EU consideration of this legislation by the Council of Ministers.

Other Member State Measures

Some EU Member States have their own national practices regarding standards, testing, labeling, and certification. A brief discussion of the additional national practices of concern to the United States follows:

Austria: Austria became the second EU country after Denmark to ban a range of uses of the three fluorinated gases controlled under the Kyoto protocol on climate change. An ordinance that took effect on November 22, 2002, prohibits the use in new sprays, solvents, and fire extinguishers of hydrofluorocarbons (HFCs), perfluorocarbons, and sulphur hexafluoride. The ordinance phases out their use in foams between mid-2003 and the end of 2007. It bans their use in new refrigeration and air-conditioning equipment by the end of 2007. The ban appears to exempt production of HFCs in Austria for the export market. If the upcoming EU f-gases regulation focuses on containment instead of bans, the government of Austria has indicated it will try to retain its own national HFC bans.

Finland: A ban on the importation and sale of new appliances containing hydrochlorofluorocarbons (HCFCs) was imposed on January 1, 2000, and remains in place. The importation of the chemical HCFC is allowed when used for maintenance of old appliances using HCFC. New HCFC compounds used for maintenance of refrigeration equipment will be banned as of 2010 and use of all HCFC compounds, including recycled compounds, will be banned as of 2015.

GOVERNMENT PROCUREMENT

In an effort to open government procurement markets within the Member States, the EU in 2004 adopted a revised Utilities Directive (2004/17), covering purchases in the water, transportation, energy, and postal services sectors. Member States were mandated to implement the new Utilities Directive by the end of January 2006.

This Directive requires open, objective bidding procedures but still discriminates against bids with less than 50 percent EU content that are not covered by an international or reciprocal bilateral agreement. The EU-content requirement applies to U.S suppliers of goods and services in the following sectors: water (production, transport, and distribution of drinking water), energy (gas and heat), urban transport (urban railway, automated systems, tramway, bus, trolley bus, and cable), and postal services. The Directive excludes the telecommunications sector, which means that the EU content requirement does not apply to procurement of telecommunications equipment from U.S. suppliers. This was a significant improvement over earlier versions of the Utilities Directive, which had included the telecommunications sector within its scope. The United States had imposed retaliatory sanctions in 1993 in connection with then-existing discrimination against U.S. firms in the EU telecommunications equipment market brought about by the 1993 Utilities Directive. That Directive's discriminatory provisions were waived for heavy electrical equipment manufactured in the United States under the May 1995 Memorandum of Understanding (MOU) on government procurement between the United States and the EU.

Following a review of the impact of the new 2004 Directive on access to the telecommunications market, USTR determined to terminate the 1993 sanctions imposed on certain EU Member States, effective March 1, 2006. This determination was based on assurances from the European Communities that EU telecommunications operators are no longer subject to the discriminatory requirements of the Utilities Directive, and that purchasing by EU telecommunications operators is now based solely on commercial considerations. In a reciprocal move, the EC lifted its counter-measures on March 1, 2006.

Other Member State Measures

Member States have their own national practices regarding government procurement. In some cases, they require offsets, or obligations that require companies to provide services, create jobs, or purchase local goods as a condition for the contract's award. A brief discussion of some of the national practices of particular concern to the United States follows.

Austria: U.S. firms continue to report a strong pro-EU bias and pro-Austrian bias in government contract awards and some privatization decisions. In major defense purchases, most government procurement regulations do not apply, offset requirements up to 200 percent of the value of the contract are common, political considerations remain important, and transparency remains limited. Austria's largest military procurement to date, the $2 billion purchase of fighter jets in 2002, continues to be a source of concern regarding its lack of transparency, an apparent bias against a U.S. proposal, and flawed offset deals related to the purchase.

Czech Republic: U.S. and other foreign companies express great concern about the transparency of the public procurement process. Many U.S. bidders report that Czech (or other European) bidders are favored and usually win contract awards despite their higher bids and questions regarding those companies' ability to deliver on the terms of the tender. This has been a problem particularly in construction and the purchase of military equipment, as well as in the sale of state-owned industries. A draft law aimed at improving the process of government procurement is in the Parliament, but whether it is enacted and has a positive impact remains to be seen.

France: France has a strong and extremely competitive aerospace and defense manufacturing base. Having allowed only limited privatization in the sector; the French government continues to maintain shares in several major prime contractors. The French defense market remains generally closed to non-European competition. Even in the case of European competition, French companies are often selected as prime contractors. Nevertheless, U.S. firms do enjoy success as component and systems suppliers, if not as prime contractors. The Defense Ministry, which handles around 70 percent of the equipment budget, has a tendency to select non-American contractors, even if it costs more and takes longer to market. These factors have made it difficult for U.S. defense firms to take part in French/European programs.

Greece: Greece has the worst ranking in Western Europe for corruption and lack of transparency in relation to procurement decisions, according to Transparency International. However, the government is taking steps to improve the civil service and tackle corruption, although progress has been slow. For example, the Armaments Director in the Ministry of Defense put all pending contracts on hold until they can be reviewed. While this review of pending procurement has led to delays in payment and awarding of contracts - and in some cases cancellation of contracts - these steps to introduce greater transparency should ultimately improve the future climate for U.S. businesses.

Greece continues to insist on offset arrangements as a condition for the purchase of defense items. Although there is evidence that some decision-makers hold a bias against American products, on balance Greece is receptive to U.S. companies, technology, equipment, and services.

Ireland: Government procurements in Ireland generally are tendered under open and transparent procurement regulations. U.S. companies have raised concerns, however, that they have been successful in only a few national and regional government tenders, particularly for infrastructure-related procurements. U.S. firms complain that lengthy budgetary decisions delay procurements and that unsuccessful bidders often have difficulty receiving information on the rationale behind the tender award. Once awarded a contract, companies can experience significant delays in finalizing contracts and commencing work on the contract.

Italy: Italy**'**s government procurement practices have created obstacles for U.S. firms. This is particularly true in the case of the Italian government's procurement of civilian helicopters, which a U.S. company has alleged favors a competing Italian supplier. This procurement has been unsuccessfully challenged in Italian administrative courts and is being pursued at the EU level. Reviews of other Italian procurements by the European Commission has encouraged Italy to increase the transparency of its procurement laws and regulations and update its public procurement laws to be more in line with EU Directives.

CONSIP, an agency of Italy's Finance Ministry, manages procurements of all goods on behalf of public administration entities and issues tenders that stipulate framework agreements for specific products and services. Framework agreements are executed between a supplier and CONSIP, but the eventual business transaction for a specific product or service is between the supplier and the ordering government entity. CONSIP monitors transactions to ensure that they are carried out. U.S. firms have mixed views on the effectiveness and transparency of CONSIP's operations. Reportedly, its role is gradually being diminished.

Lithuania: The public procurement process in Lithuania is not always transparent. Complaints persist that some tenders are so narrowly defined that they appear to be drafted with the intent that only one company can provide the good or service. The Ministry of Defense, for example, recently withdrew a tender for automobiles amid public charges that the tender's drafters specified it in such a way that it favored a particular European automobile manufacturer.

The Lithuanian government adopted a resolution in 2003 requiring offset agreements as a condition for the award of contracts for procurement of military equipment exceeding LTL 5 million (about $1.8 million). The Government of Lithuania (GOL) purchases most U.S. military equipment using U.S. government grant money, which precludes offsets. In a couple of recent cases, however, the GOL requested offsets for purchases it made using its own funds.

In one case, the GOL eventually dropped its request for an offset; in the other, the GOL reached an offset agreement with the provider that allowed the deal to go through. This offset requirement adds a level of complexity to exporting military equipment to Lithuania, but it has not yet scuttled a single U.S. export opportunity.

Portugal: According to U.S. firms, U.S. bidders with technically superior bids and lower prices have been passed over in favor of competitors from other EU Member States. Such cases have cost U.S. industry over $170 million in just the past two years. A lack of transparency in procurement procedures and severe government budgetary problems are also hampering U.S. firms' ability to win procurement awards.

Slovenia: The Slovenian government has said that it intends to improve the transparency of its public procurement process. The Ministry for Public Administration has also said it will create an e-procurement system, although efforts in this area have stalled. American firms, however, continue to express concerns that the public procurement process in Slovenia is non-transparent. Many American bidders report that European firms are favored and usually win the bids in spite of more costly offers and questionable ability to deliver and service their products. This is a problem across the entire range of public procurement, but seems most prevalent in telecommunications and medical equipment procurement. For over one year, a U.S.-based firm has been seeking to participate in a public tender for a digital, hand-held radio network for use by police, military, rescue, and other professional emergency services.

The company, which has built similar networks in several neighboring countries, has expressed concern that it may not even have the chance to participate in a formal bidding process as it is unclear when, or if, a tender for this network will be published.

United Kingdom: There is an ongoing pattern in U.K. military procurements of non-competitive procurements and the overturning of decisions where a U.S. supplier was selected, and the subsequent award of the contract to a domestic supplier.

SUBSIDIES POLICIES

Government Support for Airbus

Over many years, the Governments of France, Germany, Spain, and the United Kingdom have provided subsidies to their respective Airbus member companies to aid in the development, production and marketing of Airbus large civil aircraft. These governments have financed between 33 percent and 100 percent of the development costs for all Airbus aircraft models ("launch aid") and provided other forms of support, including equity infusions, debt forgiveness, debt rollovers, and marketing assistance, including political and economic pressure on purchasing governments. The EU's aeronautics research programs are driven significantly by a policy intended to enhance the international competitiveness of the European civil aeronautics industry. EU governments have spent hundreds of millions of euros to create infrastructure needed for Airbus programs, including 751 million euros from the City of Hamburg to purchase land

that Airbus is using for the Airbus A380 "superjumbo" project and 182 million euros from French authorities to create the AeroConstellation site, which contains the Airbus facilities for the A380. With more than $6 billion in subsidies, the Airbus A380 is the most heavily subsidized aircraft in history. EU governments have also made legally binding commitments of launch aid for the new Airbus A350 aircraft, even though Airbus has not yet repaid any of the financing it received for the A380.

The Airbus Integrated Company - successor to the original Airbus consortium and representing a partnership of the European Aeronautic, Defense, and Space Company (EADS) (80 percent equity share) and BAE Systems (20 percent equity share) - is now the second largest aerospace company in the world. With more than half of worldwide deliveries of new large civil aircraft deliveries over the last few years, Airbus is a mature company that should face the same commercial risks as its global competitors.

In October 2004, following unsuccessful U.S.-initiated efforts to negotiate a new U.S.-EU agreement that would end subsidies for the development and production of large civil aircraft, the United States filed a WTO consultation request with respect to the launch aid and other forms of subsidies that EU governments have provided to Airbus. Concurrent with the U.S. WTO consultation request, the United States also exercised its right to terminate the 1992 U.S.–EU bilateral agreement on large civil aircraft. The consultations failed to resolve the U.S. concerns, however, and a renewed effort to negotiate a solution ended without success in April 2005.

Therefore, on May 31, 2005, the United States filed a WTO panel request. The WTO established the panel on July 20, 2005, and panel proceedings are currently ongoing. U.S. officials have consistently noted their willingness to negotiate a new bilateral agreement on large civil aircraft, even while the WTO litigation proceeds, but have insisted that any such agreement must end launch aid and other direct subsidies for the development and production of such aircraft.

Government Support for Airbus Suppliers

Belgium: The Federal Government of Belgium, in coordination with the three regional governments, subsidizes Belgian aircraft component manufacturers that supply parts to the Airbus Integrated Company. In November 2001, the Belgian federal government reached an agreement with the three regional governments, usually responsible for R&D and investment promotion, on a 195 million euro package for aviation research and development for Airbus A380 components. Belgium claims the program was structured in accordance with the 1992 bilateral agreement, and covers non-recurring costs. According to Belgian industry sources, about 160 million euros of the 195 million euro package remains available, and the costs covered to date have netted orders worth 1.3 billion euros for the A380. On October 14, 2005, the Belgian federal government made a decision in principle to create a program to assist Belgian aviation part producers' work on the Airbus A350.

The program would provide 150 million euros of reimbursable public finance, available for non-recurring development costs. Because this program can only be started after a federal-regional government agreement, this A350 assistance may face significant delays.

France: In addition to the launch aid that the French government provided for the development of the Airbus A380 super-jumbo aircraft in 2005, France will continue to provide reimbursable advances for Airbus programs, engines, helicopters, and on-board equipment. Appropriations in 2006 total 218 million euros, of which 168 million euros are committed to the A380. Overall 2006 appropriations, including 55 million euros in support of research and development by industrialists in the sector, amount to 273 million euros. In 2006, budget authorizations for these items are limited to 284 million euros.

Spain: The recently completed Puerto Real factory in Spain's Andalucia region is responsible for constructing 10 percent of Airbus' A380 aircraft. Spain's Ministry of Science and Technology currently subsidizes A380 construction through its agreement to provide 376 million euros in direct assistance through 2013. Furthermore, the regional government of Andalucia has channeled an additional 13 million euros of State General Administration regional incentive funds and 17.5 million euros of its own funds to subsidize the A380 project. Spain has provided numerous additional grants to Airbus' parent company, EADS.

Government Support for Aircraft Engines

United Kingdom: In February 2001, the U.K. government announced its intention to provide up to 250 million pounds to Rolls-Royce to support development of two additional engine models for large civil aircraft, the Trent 600 and 900.

The U.K. government characterized this engine development aid as an "investment" that would provide a "real rate of return" from future sales of the engines.

The European Commission announced its approval of a 250 million pounds "reimbursable advance" without opening a formal investigation into whether the advance constituted an illegal (under EU law) state aid. According to a European Commission statement, the "advance will be reimbursed by Rolls-Royce to the U.K. government in case of success of the program, based on a levy on engine deliveries and maintenance and support activity." Detailed terms of the approved launch aid were not made public. To date, none of the launch aid for the Trent 600 and 900 has been repaid.

Continuing U.K. government support of Rolls-Royce raises serious concerns about U.K. and EU adherence to the WTO Subsidies and Countervailing Measures Agreement. U.S. engine suppliers have lost sales of engines and claim that they have encountered suppressed prices in the United States and world markets.

France: The French government-owned engine manufacturer SNECMA has merged with technology and communications firm Sagem to form Safran. The government supports the Safran SaM146 propulsive engine program with a reimbursable advance of 140 million euros.

Canned Fruit Subsidies

The EU continues to subsidize shipments of canned peaches as well as the production of apples, prunes, grapes, wine, cherries, and citrus. Although a 1985 U.S.-EU Canned Fruit Agreement brought some discipline to processing subsidies, significant fraud and abuse have undermined the discipline imposed by the Agreement. Growers and producers of peaches receive a range of assistance from producer aid, market withdrawal subsidies, sugar export rebates, producer organization aid, and regional development assistance. The United States will continue to monitor EU subsidies to this sector, evaluate their trade-distorting effects, and monitor other areas of interest to our agricultural sector, for example, horticulture, grains, pork, and beef.

Wood Industry Subsidies

Several EU Member States and regional governments within them provided state aid to pulp, paper, and wood processing projects. Germany, in particular, has given aid in the form of grants, loans, and loan guarantees for pulp and paper and wood processing operations, especially in Eastern Germany. These subsidy programs are part of the overall combined EU/national regional support programs, which are available to any industry. This has added substantial new capacity and has contributed to a substantial drop in U.S. pulp and paper exports to the EU and globally, while fostering a rise in European paper and lumber and wooden panel exports to the United States and third country markets. A combination of factors, namely robust growth in the construction sector and duties put on Canadian softwood lumber, has also increased the competitiveness of German construction lumber in the United States.

INTELLECTUAL PROPERTY RIGHTS (IPR) PROTECTION

The EU and its Member States support strong protection for intellectual property rights (IPR), and the importance of protecting IPR and US-EU cooperation on IPR enforcement was highlighted at the U.S.-EU summit in June 2005. During 2005, the European Commission issued a communication on strengthening the criminal law framework to combat intellectual property offenses and a communication from the Commission's taxation and customs directorate on improving IPR enforcement.

The United States has raised concerns regarding the IPR practices of several EU Member States, either through the U.S. Special 301 process or through WTO Dispute Settlement procedures concerning their failure to fully implement the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The United States continues to be engaged with the EU and individual Member States on these matters.

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, and 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 rights 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 will have 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, including the ten new Member States, have until April 2006 to implement the Directive.

Copyrights

In April 2001, the EU passed a Directive (known as the Copyright or "Information Society" Directive) to harmonize aspects of the copyright law and implement the World Intellectual Property Organization (WIPO) Internet Treaties. Some Member States, such as Belgium and Spain, have failed to meet the December 2002 deadline to implement the directive. France has announced it will complete the transposition by early 2006. In July 2004, the European Commission published a working paper on the EC's legal framework in the field of copyright and related rights. The European Commission will take into account the results of the consultations on the working paper, which closed in October 2005, in proposing further legislative amendments.

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 designs with the EU's Office for Harmonization in the Internal Market (OHIM). The holders will then be granted exclusive rights to use the designs anywhere in the EU for up to 25 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 the 10 new EU Member States on May 1, 2004.

The European Commission has proposed amending the legal protection of designs Directive (98/71) by removing Member States' option to maintain design protection for "visible" replacement vehicle parts, such as hoods, bumpers, doors, lamps, rear protection panels, windscreens, and wings. The proposal would allow independent part manufacturers, not linked to the producers of finished vehicles, to compete throughout the EU market for visible replacement parts. Neither non-visible parts, like engine or mechanical parts, nor components in new vehicles would be affected by the proposal.

Patents

Patent filing and maintenance fees in the EU and its Member States are significantly higher than in other countries. Fees associated with the filing, issuance, and maintenance of a patent over its life far exceeds those in the United States.

In October 2004, the European Commission proposed a regulation to allow manufacturers of generic pharmaceuticals to produce medicines under patent for export to countries in need that cannot produce sufficient quantities themselves. The regulation would implement within the EU an August 2003 WTO decision, under which national authorities can grant compulsory licenses for such production if certain conditions are fulfilled. One requirement is that the destination country must have notified the WTO that it is seeking the medicine covered by the license. To help ensure that medicines get to the patients who need them and to protect patent holders, customs authorities will be able to prevent the re-importation into the EU of medicines produced under the system. The proposed regulation would set up a system for companies that wish to manufacture medicines for export to apply to national authorities for the grant of a compulsory license from a patent holder that has exclusive rights over the manufacture and sale of the products concerned. Before coming into effect, the proposed regulation would have to be discussed and approved by EU Member States and the European Parliament.

In some countries, such as Slovakia and Portugal, copies of medicines that are still under patent are allowed on the market by the Ministries of Health, which fail to coordinate with their domestic patent offices.

Data Exclusivity

In some of the new Member States in particular, there is a lack of protection for data submitted to obtain marketing approval for pharmaceutical and agricultural chemical products. Article 39.3 of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement requires such protection.

Hungary: Hungary's 2001 ministerial decree on the protection of test data took effect on January 1, 2003. Retroactive protection exists for pharmaceutical products that received first marketing authorization in the EU or Hungary on or after April 12, 2001.

Poland: Although Poland is required to implement the EU data protection regime as part of its entry into the European Union, concerns remain over its request to delay implementation for 15 years. In addition, while the government has signaled that it is considering implementation of a coordination mechanism between the Health Ministry and the patent agency, no concrete actions have been taken to do so.

Portugal: Pharmaceutical firms continue to be adversely affected because there is no crosscheck for pre-existing patents before granting market access for generic versions of patented products. The courts are the only remedy and, due to a significant judicial backlog, legal recourse is time-consuming and expensive. It can take several months to obtain an injunction against continued production of a patented pharmaceutical product knock-off. Final rulings can take years, resulting in high legal fees and lost income for U.S. firms.

Slovakia: U.S. companies continue to have concerns about the weak enforcement of patent rights in Slovakia. The Ministry of Economy, at the urging of the U.S. government, initiated a process in March 2005 to address the outstanding complaints that have led to Slovakia's inclusion on the "Special 301" Watch list. However, insufficient progress has been made to date on the following issues:

- Inadequate storage of sensitive documents and confidential data: The Government of Slovakia (GOS) has stored sensitive registration data on the premises of a competing generic drug producer for years. The GOS claims to have moved some of the data to a neutral storage facility, but some of it still remains under the care of the generic drug producer. The name on the title of the storage facility changed, but the parties involved remain the same. The Minister of Health has indicated it will procure a new, dedicated storage facility for the proprietary registration data by the end of 2005.

- Registration of Generics: In several cases in recent years, the Drug Control Office in the Ministry of Health has approved applications for registration by generic manufacturers for drugs that are still under patent protection because they failed to check the status of the original patent with the Patent Office. Once a registration is granted to a generic manufacturer, it is very difficult for the patent owner to overturn the decision or obtain compensation through the courts. The Drug Control Office and Patent Office are working together to develop a coordinating mechanism to prevent future registrations of unauthorized patent-infringing products.

Patenting of Biotechnology Inventions

A 1998 EU Directive (98/44) on the legal protection of biotechnology inventions harmonizes EU Member State rules on patent protection for biotechnology inventions. Although Member States were required to bring their national laws into compliance with the Directive by July 2000, some had not yet fully met that obligation, and the European Commission has started legal proceedings at the European Court of Justice against them.

France: France brought its national law into compliance with Directive 98/44 in December 2004. The French law allows plant breeders making varietal selections to freely use (protected) plant varieties to create new varieties.

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 that is valid in all 25 EU Member States.

Madrid Protocol

On October 1, 2004, the European Community acceded to the World Intellectual Property Organization (WIPO) Madrid Protocol, establishing a link between the Madrid Protocol system, administered by WIPO, and the Community Trademark system, administered by OHIM. Community Trademark applicants and holders now 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.

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 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 DSB ruled on April 20, 2005, that the EC's regulation on food-related geographical indications (GIs) is 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 discriminates 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. The DSB recommended that the EC amend its GI regulation to come into compliance with its WTO obligations. The EC has indicated intent to comply and, by agreement with the United States, has until April 3, 2006 to do so.

Additional Member State Practices:

Belgium: Domestically pirated and parallel-imported DVDs are a growing problem in Belgium. An industry trade association estimates that 250,000 illegal downloads of DVDs occur daily, and illegal copies on VHS, CD-R and DVD-R media are distributed by specialty stores, retail outlets, and local and international Internet sites. The recording industry estimates that 85 percent of blank digital media sold in Belgium are used for illegal downloads of music or videos. Annual losses to the U.S. motion picture industry through IPR piracy in Belgium are estimated at over 15 million euros. The Belgian Anti-Piracy Foundation (BAF) focuses both on the purchase of hard goods and on combating illegal Internet distribution. In June 2005, the BAF helped broker a Protocol Agreement between the recording industry federation (IFPI) and the Internet Service Providers Association (ISPA) of Belgium to shutdown Internet sites used for illegal downloading of music and videos. Although only two ISPs have signed on to the Agreement, they encompass a majority of Belgian Internet subscribers. Belgium's 1994 Copyright Law provides deterrent penalties for piracy, but national legal procedures are cumbersome and the court system is overburdened, discouraging action to combat IPR fraud. Obtaining a judicial restraining order against Internet piracy, for example, takes two to three months, and judges demand proof of damages to assign more than token fines. Belgian judicial action, however, was helpful in 2005. An Appeals Court upheld a lower court judgment in favor of IFPI and rights collectors and against private copying rights. The Belgian government finally brought into force the EU Copyright/"Information Society" Directive (EC/29/2001) in May 2005.

Cyprus: IPR legislation in Cyprus is, on the whole, modern and comprehensive, although enforcement should be further improved. Cyprus has harmonized its IPR regime with EU requirements as part of its accession to the EU in 2004. According to industry sources, the level of optical media piracy continues at roughly 50 percent. Audio piracy (mainly CDs) is also fairly constant at around 40 percent. Software piracy, largely fueled by small PC assembly and sale operations, has declined to 53 percent but is still significantly above the European average. Piracy of textbooks is a growing concern.

Czech Republic: The Czech Republic is considered to have done an above-average job of implementing EU legislation in the area of IPR, but there remain significant issues when it comes to enforcement of these laws. Court cases on IPR issues can often stretch to five years, and even then the current systems for the calculation and collection of damages favor defendants according to legal experts who work in the field. A new law is being drafted to address some of these issues (specifically the seizure of accounting books from pirating companies and how to calculate the profits of IPR violators), but processing times and a lack of judicial interest in the area suggests change in this area is likely to be slow.

France: Although the French government has significantly stepped up its efforts to fight piracy, video piracy and unauthorized parallel imports continue to impose losses on U.S. industry, and cable piracy and Internet piracy continue to present further problems in this area. In June 2004, the government launched: 1) an ambitious plan to collaborate with

Asian countries on combating piracy; 2) a customs national action plan that strengthens customs training and places French government anti-piracy personnel in embassies abroad; and 3) an interagency "tracking center" called "Tracfin" that gathers information on sales and manufacturing of counterfeit products and their links with organized crime. The French government also is funding a large-scale public anti-piracy and counterfeiting campaign aimed at businesses and consumers.

Germany: Non-retail outlets (Internet, print media, mail order, open-air markets) represent Germany's major piracy problem. Pirated videos, VCDs, and DVDs are sold primarily by residential mail-order dealers who offer the products via the Internet, newspaper advertisements, or directly sell them in flea markets. German copyright legislation allows the making of private copies, which, although it does not include sharing or downloading of music, has been sometimes misunderstood as being a broader exception than it actually is. In 2005, the German entertainment industry blanketed the country with commercials for an information campaign to educate the public regarding the problem of piracy, especially on the Internet. While German federal authorities have been receptive to U.S. IPR concerns, there have been mixed results at the German state-level, which can have broad impact due to Germany's decentralized law enforcement structure. German authorities in several cases have prosecuted pirates who download music and videos from the Internet and then distributed burned CDs or DVDs and arrested four persons in October 2004 who ran a major ring selling pirated videos on the Internet. The German government in July 2003 enacted amendments to the German Copyright Act intended to bring it in line with the EU Copyright/"Information Society" Directive. The Ministry of Justice has introduced additional amendments to the copyright law that are likely to be considered by Parliament in 2006. U.S. publishers have expressed a concern that these amendments might result in insufficient protections for the copyrights of works, particularly in digital format. The United States is watching this issue closely, including by sending an interagency STOP delegation to Berlin in June 2005.

Greece: Although protection of intellectual property rights in Greece is better than it was five years ago, there are troubling signs that violations, particularly in copyrighted audio-visual products and apparel and footwear, are once again on the rise. The United States encourages the Government of Greece to strengthen the enforcement of anti-piracy laws to discourage this trend.

Hungary: On January 1, 2003, Hungary acceded to the European Patent Convention and has amended the Hungarian Patent Act accordingly. Act CII of 2003 modified the Hungarian Copyright Act and the Hungarian Design Act in order to bring them in line with the relevant EU legislation. The Hungarian Patent Office implemented the EU Copyright/"Information Society" Directive. In October 2004, Hungary implemented Council Regulation 1383/2003, concerning customs action against goods suspected of infringing certain intellectual property rights. Further, a government decree established a customs task to accept claims from producers whose trademarks or copyrights were infringed.

Italy: Although Italy has enacted a robust set of anti-piracy laws, the lack of adequate enforcement remains a serious concern. Italy continues to possess one of the highest overall piracy rates in Western Europe. In April 2005, the Italian government created a new "High Commissioner" position with responsibility for coordinating IPR protection. This position was filled in November 2005. Italian authorities have stepped up seizures of counterfeit and pirated goods, though enforcement varies widely from region to region. A new law allows Italian police to impose a fine of up to 10,000 euros for possession of fake goods. This tough measure has served to increase public awareness of IPR crime, but has only been imposed sporadically. Street vendors continue to openly sell pirated and counterfeited goods on Italian street corners. Italy's judiciary rarely hands down meaningful jail sentences for even serious cases of IPR theft.

In 2005, the Italian parliament passed amendments to Italy's Internet piracy and copyright laws that reduce potential jail sentences for illegal Internet file sharing. Under the revisions, Internet piracy conducted for monetary gain remains subject to jail terms. Internet users who swap copyrighted material without a profit motive, however, can now avoid criminal prosecution by paying a fine, in most cases around 1,000 euros. While this represents a de facto roll back of potential penalties for "not-for-profit" Internet piracy, local representatives of the music, film, and business software industries are generally satisfied with the new law.

Lithuania: Piracy of optical media, software, and motion pictures remains a serious problem. The International Intellectual Property Alliance estimates that U.S. businesses lost $27.5 million in 2004 because of copyright piracy in Lithuania. The Lithuanian government is considering draft legislation that would strengthen IPR protection and increase penalties for IPR piracy. In addition to this legislation, however, the Lithuanian government must demonstrate the political will to enforce IPR protection for any effort to reduce piracy to succeed.

Poland: Poland has shown progress on several elements of IP protection. As a result of EU accession, Poland published amendments to its copyright law on April 30, 2004, and the amendments contained several improvements which had been proposed by the copyright-related industries. Poland also published an Optical Disc Decree on June 2, 2004, although concerns over the lack of criminal sanctions remain. The Polish government has increased antipiracy efforts, improving enforcement at the Warsaw Stadium, as well as increased enforcement actions in the border bazaars frequented by German tourists and others. In addition, the Interministerial Antipiracy Group recently published an IPR strategy that emphasizes cooperation with industry. Although Poland has made some progress in strengthening border enforcement in conjunction with rights-holders, problems remain both along the Eastern and Western borders with importation and sale of pirate optical discs.

Spain: Copyright infringement has become an increasing problem in Spain's major urban centers. Street piracy remains a serious issue, although authorities are conducting raids. With respect to copyright, industry representatives stress the importance of Spain passing implementing legislation for the WIPO Internet Treaties and the EU Copyright Directive,

because Internet piracy is becoming an increasingly serious problem. There is also a need to improve the tracking of imports of blank CDs.

On September 28, 2005, the United States and Spain conducted a roundtable that focused on copyright-related IPR concerns. Stakeholders criticized the Spanish government for not implementing an otherwise ambitious government anti-piracy plan. The audio-visual industry also strongly opposes Spain's draft legislation implementing to the EU's copyright directive that would allow three "private copies" of DVDs and CDs.

Sweden: Sweden is a major contributor to the worldwide problem of Internet piracy. Due to its widely known status as a piracy safe haven, significant Internet source piracy infrastructure and group membership has flourished in Sweden. Sweden is host to: 1) the world's largest Bit Torrent file-sharing tracker, ThePirateBay.org; 2) 52 out of the world's 200 known piracy "top sites"; 3) the largest number of DC++ file-sharing hubs and users; and 4) "Rizon", the most popular Internet relay chat piracy channel.

The legislative and enforcement framework in Sweden is generally effective against conventional hard goods piracy, but actual enforcement with respect to Internet piracy is weak. At least until recently, police and prosecutors have generally failed to act on complaints of Internet piracy made by the Swedish Anti-piracy Bureau (SAB or "APB" in Swedish). A cause for optimism are the two convictions in the fall of 2005, on complaints by the SAB, of two men for the offense of distributing single films using DC++ file-sharing hubs. The defendants were ordered to pay substantial fines and costs. These first convictions suggest that if the authorities give priority to prosecuting Internet piracy cases, the courts may be prepared to apply the law appropriately.

SERVICES BARRIERS

Concerns Related to EU Enlargement

On May 28, 2004, the European Commission notified members of the World Trade Organization of a proposed consolidation of the EU's schedule of specific commitments under the General Agreement on Trade in Services (GATS) pursuant to GATS Article V to reflect both the 1995 accession to the European Union of Austria, Finland, and Sweden, and the 2004 accession of Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic, and Slovenia. As a result of this proposed consolidation, a number of previous GATS commitments by these countries have been modified in a way that may reduce sector-specific or horizontal market access commitments. Although not within the scope of the EU's GATS Article V notification, the EU's consolidation proposal also entails the extension to the new Member States of most-favored nation exemptions reflected in the EU's existing schedule of GATS commitments. As provided for under GATS rules, the United States has engaged in initial consultations with the European Commission to evaluate possible adverse consequences to U.S. services trade of the consolidation and the potential for EU compensation to the United States for such consequences. The two sides plan to consult further on this issue.

Television Broadcast Directive (Television without Frontiers Directive)

The 1989 EU Broadcast Directive (also known as the Television without Frontiers Directive) includes a provision requiring that a majority of television transmission time be reserved for European-origin programs "where practicable and by appropriate means." All EU Member States, including the ten new Member States, have enacted legislation to implement the Broadcast Directive. It remains important to ensure that the flexibility built into the Directive is preserved and that individual broadcasting markets are allowed to develop according to their specific conditions and needs.

The European Commission is currently reviewing the Directive. As a result of consultations held with stakeholders in 2003, the Commission adopted in April 2004, a communication on the future of the European regulatory audiovisual policy, calling for more legal certainty on television advertising and an update on the protection of minors, among other issues. Between September 2004 and February 2005, focus groups on regulation of audiovisual content, advertising, and the right to information discussed several topics. Viviane Reding, Commissioner for Information Society and Media, presented the final results of the focus groups' work in May 2005. This proposal provides a set of current for all audio visual services and modernizes the rules of the current Directive for television services. The European Commission on December 13, 2005, adopted the legislative proposal for revision of the Television Without Frontiers Directive. In line with expert opinion, the Commission adopted an approach based on the introduction of obligations on two levels: a level of fundamental obligations (particularly the protection of minors and human dignity) applicable to all audiovisual services, and a sub-group level of "linear" audiovisual services based on scheduled programs that will be subject to simplified and modified secondary obligations comparable to those in the TVWF Directive.

Several EU Member States have specific legislation that hinders the free flow of some programming. A summary of some of the more salient restrictive national practices follows.

France: France continues to apply its more restrictive version of the EU Broadcast Directive, which was first introduced into French legislation and approved by the European Commission in 1992. In implementing the Directive, France chose to specify a percentage of European programming (60 percent) and French programming (40 percent), which exceeded the requirements of the Broadcast Directive. Moreover, these quotas apply to both the 24-hour day and prime time slots, and the definition of prime time differs from network to network. The prime time rules are a significant barrier to access of U.S. programs to the French market. In addition, the United States continues to be concerned that radio broadcast quotas, which have been in effect since 1996 (40 percent of songs on almost all French private and public radio stations must be Francophone) limit broadcasts of American music.

Italy: Legislation passed in 1998 making Italy's TV broadcast quota stricter than the EU Broadcast Directive remains in effect. The legislation makes 51 percent European content mandatory during prime time, and excludes talk shows from the programming that may be counted toward fulfilling the quota. A 1998 regulation also remains in effect that requires all multiplex movie theaters of more than 1,300 seats to reserve 15-20 percent of their seats, distributed over no fewer than three screens, to showing EU films on a stable basis. In May 2004, Italy enacted controversial media reform through the "Gasparri Law," under which the media/communications market is viewed broadly as one sector. Under this law, no single operator may receive more than 20 percent of overall revenues from the entire sector. In addition, the law provides for the gradual privatization of the state-owned radio and television broadcasting conglomerate, RAI.

Spain: Spain**'**s theatrical film system has been modified sufficiently in recent years so that it is no longer a major source of trade friction. Government regulations issued in 1997 require exhibitors to show one day of EU-produced film for every three days of non-EU-produced film. Spanish law requires that the quotas issue be reviewed in 2006.

Postal Services

United States express and package service providers remain concerned that postal monopolies in many EU Member States restrict their market access and create unfair conditions of competition with the incumbents. In October 2001, EU Member States agreed to open additional postal services to competition beginning in 2003, including all outgoing cross-border mail. Depending upon the results of a European Commission study (scheduled to be completed by the end of 2006), full liberalization of the EU postal market could occur by 2009.

Belgium: In October 2005, the Belgian government announced the formation of a strategic partnership between the Belgian Post and two partners: Danish Post and CVC Capitol Partners (a U.K.-based independent buyout group founded in 1981). The move is aimed to modernize and make more competitive the Belgian Post. As of October 2005, the European Commission, in accordance with the EU Council Regulation 139/2004, must still approve this deal.

In October 2005, the Belgian Federal Council of Ministers approved a legislative draft related to the governance of the postal industry. Differing definitions of "universal service" have complicated the debate. Universal service can be understood as the right of customers or consumers to have, in this case, full postal delivery services at a reasonable price, no matter where they live in Belgium. Express delivery companies such as United Parcel Service (UPS) and FedEx contend that their service is "value added" (by providing tracking options, guaranteed delivery, etc). In its present draft form, an explanatory text added to the Royal Decree would exclude value-added services from the universal services definition. If that legislation were approved, express companies would be exempt from the licensing regime as well as the obligation to provide for a compensation fund for universal service. As of October 2005, the legislation must still be forwarded to the Conseil d'Etat for legal review.

Germany: In February 2005, the German Federal Cartel Office took action against Deutsche Post AG (DPAG), in response to complaints from competitors. The ruling forbids DPAG from hindering or discriminating against rival small and medium-sized providers of postal services in their mail preparation services, especially the collection and presorting of letters and the feeding of mail items weighing under 100 grams into DPAG's sorting centers. This ruling follows an October 2004 move by the European Commission to initiate a treaty infringement procedure against Germany for failing to mandate that DPAG offer unbundled access to competitors. Some U.S. companies have indicated they might be interested in providing services such as sorting.

Professional Services

In the area of professional services, there are significant variations among EU Member State requirements for foreign lawyers and accountants intending to practice in the European Union. While many of these are not outright barriers, disparities among Member State requirements can complicate access to the European market for U.S. lawyers and accountants.

Legal Services

Austria: U.S. citizens can only provide legal advice on U.S. law and public international law (excluding EU law) on a temporary basis. Only an Austrian or other EU national can join the Bar Association. U.S. nationals cannot represent clients before Austrian courts and authorities, and cannot establish a commercial presence in Austria. However, informal cooperation with Austrian partners is possible.

Czech Republic: The Czech Republic requires that all attorneys be trained at Czech universities and be members of the Czech bar. U.S. firms are allowed to co-operate with local firms and lend them their name, so firms that operate in the country do so as independent Czech branches. They may have U.S. attorneys that are attached to the staffs as "advisors."

Finland: Foreigners from non-EU countries cannot become members of the Finnish Bar Association and receive the higher law profession title of Asianajaja (Attorney at Law). Persons holding the title of Asianajaja are subject to Asianajaja Law as well as bar regulations. While the title gives added prestige and helps solicit clients, it is not essential to practice domestic or international law or to represent a client in court.

France: Non-EU firms are not permitted to establish branch offices in France under their own names. Also, non-EU lawyers and firms are not permitted to form partnerships with or hire French lawyers.

Germany: U.S. lawyers that have joined the German Bar Association under their home title may practice international law (but not EU law) and the law of their home country. To be admitted to the bar to practice German law, individuals generally have to complete five years of study, then successfully complete the first of two state exams. After

successfully completing the first exam they undertake two years of practical training. Individuals then take the second state exam, and upon passing, are admitted to the bar.

Hungary: Foreign non-EU lawyers may provide legal advice on legislation of their own country and international law. Lawyers registered in the EU may be admitted to the bar. Foreign lawyers from non-EU countries may establish a partnership with a Hungarian legal firm and provide legal services under a "cooperation agreement."

Ireland: In general, lawyers with non-Irish qualifications who wish to practice Irish law and appear before Irish courts must either pass transfer examinations or retrain as lawyers under the direction of the Law Society of Ireland. Only lawyers who have either been admitted to the Bar of England, Wales, or Northern Ireland, practiced as an attorney in New York, California, Pennsylvania (with five years experience required in Pennsylvania), or New Zealand, or have been admitted as lawyers in either an EU or EFTA Member State are entitled to take the transfer examination.

Italy: In 2001, Italy passed a law implementing EU Directive 98/5 on EU lawyers' freedom to establish themselves EU-wide and enabling Italian lawyers to practice jointly, including with EU lawyers, through a limited liability partnership or through the Italian branch of a partnership formed in another EU Member State, as long as the limited liability partnership is composed exclusively of Italian and EU lawyers. The status of non-EU lawyers is not explicitly addressed by the law. This omission leaves the status of international law firms with offices in Italy uncertain, insofar as they have Italian and non-EU lawyers as partners.

Lithuania: Only EU citizens may join the Lithuanian bar and establish law firms that provide the full range of legal services. Lithuanian law permits U.S. attorneys to establish law offices that provide paralegal services. These firms differ from traditional law firms, however, in that they cannot compel Lithuanian institutions to provide information, nor can they protect legally the lawyer-client privilege. U.S. firms can, however, easily partner with a local law firm to provide a full range of legal services.

Slovakia: Effective January 1, 2004, Act No. 586/2003 (the Advocacy Act) forces non-EU-based law firms to change their legal status from a branch partnership to a limited liability company (LLC). An LLC must be owned by an EU advocate registered in Slovakia or a Slovak national. As a result, non-EU law firms cannot market themselves under their internationally recognized corporate identities and incur extra costs to comply with the special rules.

The law also requires non-EU-based lawyers and law firms to register with the Slovak Bar Association to practice law in Slovakia. In 2005, no U.S. attorneys have been able to register. The United States is concerned that the Slovak Bar consistently has tried to limit foreign lawyers' ability to practice law in Slovakia; the Advocacy Act appears to facilitate the Slovak Bar's ability to deny foreign lawyers registration.

In addition, the Slovak Bar approved internal rules (which are binding for all Bar members) in 2004 that restrict a firm's name to that of living partners. U.S. companies consider this a discriminatory measure as most of them bear names of their partners and/or founders who died long ago, but they want to keep the business name as it represents their brand and reputation.

Accounting and Auditing Services

France: There is a nationality requirement for the establishment of a practice, which can be waived at the discretion of the French authorities. An applicant for such a permit, however, must have lived in France for at least five years.

Greece: U.S. access to the Greek accounting market remains limited. A 1997 Presidential decree established a method for fixing minimum fees for audits and established restrictions on the use of different types of personnel in audits. It also prohibited auditing firms from doing multiple tasks for a client, thus raising the cost of audit work. The Greek government has defended these regulations as necessary to ensure the quality and objectivity of audits.

Hungary: Only Hungarian-certified accountants may conduct audits, but this individual may work for a foreign-owned firm.

Architectural Services

The U.S. National Council for Architectural Registration Boards and the E.U. Architect's Council of Europe are currently working to develop an agreement on mutual recognition of professional qualifications that would be valid for all 25 EU Member States.

Austria: Only citizens from EU and EEA Member States are eligible to obtain a license to provide independent architectural services in Austria. This restriction does not appear to be reflected in the European Communities' Schedule of Specific Commitments under the GATS.

Financial Services

Poland: Citibank and other service providers have requested that the Polish government treat independent legal persons as a single taxable person as allowed by the EU VAT Directive. VAT grouping is already employed by the U.K., the Netherlands, Ireland, Germany, Austria, Denmark, Finland, and Sweden. VAT grouping would allow financial service providers to recover VAT charges they incur upon making intra-company payments for supplies, including labor costs.

Telecommunications Market Access

Both the WTO commitments covering telecommunications services and the EU's Common Regulatory Framework for Electronic Communications Networks and Services (Framework Directive) have encouraged liberalization and competition in the European telecommunications sector. As part of the WTO Agreement, for example, all EU Member States made commitments to provide market access and national treatment for voice telephony and data services. The Framework Directive imposes additional liberalization and harmonization requirements, and the Commission has taken action against Member States that have not implemented the Framework Directive. However, implementation of these requirements has been uneven across Member States, and in many markets significant problems remain, including with the provisioning and pricing of unbundled local loops, line sharing, co-location, and the provisioning of leased lines. Partial government ownership of some Member States' incumbent telecommunications operators also has the potential to raise problems for new entrants.

In 2002, the EU issued a new regulatory framework for electronic communications that includes the EU Framework Directive and four specific Directives on: 1) licensing; 2) access and interconnection; 3) universal service and user rights; and 4) data protection.

This new regulatory framework requires Member States to update and adapt legislation to account for converging technologies and for future technological and market developments. It applies to all forms of electronic communications networks and associated services, not just traditional fixed telephony networks. The long-term goal is to phase out sector-specific, ex-ante regulation (for all but public interest reasons) in favor of reliance on general competition rules.

Beginning in December 2005, the European Commission began a process of reviewing the directives under the regulatory framework for electronic communications. This process will proceed throughout 2006 to analyze whether the framework needs to be updated further still in order to respond to the changing needs of the telecommunications sector based upon evolving communications technology.

Member State Practices

Enforcement of existing legislation by the National Regulating Authorities (NRAs) has been hampered by unnecessarily lengthy and cumbersome procedures in France, Italy, Austria, and Portugal, among others. The European Commission has also found that incumbents in Germany, Greece, Spain, Italy, Ireland, Austria, Finland, and Sweden have slowed the arrival of competition by systematically appealing their national regulators' decisions.

Austria: In general, Austria has moved toward a more open and competitive telecommunications market and has implemented the relevant directives. There are several outstanding concerns related to: 1) the market for public telecommunications transit services; 2) interconnection fees; 3) deficient procedures for the wholesale

broadband access market (including bitstream access); 4) problems with the wholesale line rental; and 5) the unbundling of the "last mile." Generally, Austria's NRA – the TKC – provides timely initial decisions, but follow-up on those decisions, including the appeals process for such decisions, remains uncertain and slow.

Belgium: Belgium has implemented the EU Framework Directive governing electronic communications, and it went into effect July 1, 2005. Businesses continue to complain of excessively high mobile termination rates. Under a new Regulatory Framework agreement, BIPT (the Belgian NRA for telecommunications and postal services) has the authority to regulate mobile termination rates for all three mobile providers in Belgium – Proximus, Mobistar, and Base. Of the three, Base's rates are generally the highest and, at certain times of the day, can be as much as 50 percent above those of its two competitors. On February 24, 2006, BIPT issued a draft decision proposing to remedy excess rates charged by the three main mobile operators for terminating calls on mobile networks. BIPT recommended that these operators reduce their mobile termination rates by 10.7 percent to 12.9 percent every six months until 2008.

Finland: The Finnish government implemented a comprehensive reform effort in July 2003 – the Communications Act -- that aimed to improve the legislative environment for competition and the development of communications technology and innovations. The Act implemented four new Directives on electronic communications. Internet service providers are also included in the scope of the Act. The Act also applies specific requirements to telecommunications operators with significant market power. Regulation of smaller operators is less stringent. The Finnish NRA – Finnish Communications Regulatory Authority or FICORA – is in the process of conducting market analyses to determine whether there is sufficient competition within a particular market, and if so, what remedial requirements may be appropriate.

France: France implemented the EU Framework Directive in 2004, and the NRA – ARCEP – has made some progress in subsequently conducting the required market analyses of telecommunications sectors.

In the mobile termination market, the ARCEP designated both Orange (France Telecom) and SFR (Cegetel) as having significant market power and ordered them to reduce their rates by a total of 36 percent by the beginning of 2006. In addition, ARCEP remains concerned about France Telecom's predatory pricing of broadband connections at the retail level and overpricing at the wholesale level, as high rates have made it difficult for new players to compete.

The French government continued to further privatize France Telecom in 2005, reducing state ownership of the company to 33.1 percent, which still gives the government a blocking minority share. The company continues to dominate the fixed line market and is a major player in mobile and Internet services through its subsidiaries Orange and Wanadoo.

Germany: Germany has made slow progress in introducing competition to some sectors of its telecommunications market. However, new entrants continue to face difficulties competing with the partially state-owned incumbent Deutsche Telekom AG (DT), which retains a near-monopoly in a number of key services, including local loop and broadband connections. On the positive side, implementation of carrier selection and pre-selection for local calling has helped competitors gain close to 20 percent of the local calling market since 2003. The revised Telecommunications Act entered into force in June 2004 and most competitors to DT believe that it creates a structure that should facilitate enhanced competition. Currently, Germany's NRA – Bundesnetzagentur (BNetzA) of the Federal Network Agency (FNA) – is studying how it should regulate 18 individual market segments, as required by the Framework Directive. After more than a year, the BNetzA has completed twelve market studies.

Companies have complained that DT and other mobile providers charge excessive termination rates when fixed-line users call mobile phones. In June 2004, DT and other mobile producers agreed on a voluntary reduction of these fixed-to-mobile termination rates over 2004 and 2005. While other providers welcomed this as a step in the right direction, some questioned if the reductions go far enough. In October 2005, in response to complaints by competitors, Germany's Federal Networks Agency launched a probe into whether Deutsche Telekom is violating its dominant market position with the offer of a new low-cost ISDN Internet connection subscription fee.

Hungary: The Hungarian telecommunications market is almost fully liberalized. However, legal obstacles, as well as a lack of investors, have hindered competition. In May 2005, following the general policy of majority owner Deutsche Telekom (DT), the Hungarian "T-Brands" (Axelero, the Internet service provider; the business solutions branch; and the cable provider branch) merged with Matáv, the former monopolist and today's market leading telephony provider, under the name of Magyar Telekom Rt. In October, Magyar Telekom Rt. merged with T-Mobile Hungary, the leading mobile phone operator, which is also partially owned by DT. This involved changes in management and strengthened Magyar Telekom's leading position on the voice and communications market. UPC and TELE2, as new-fixed line providers, launched their services offering lower tariffs than Matav.

The number of fixed line subscriptions is constantly decreasing, at a rate of 50,000 per month. Mobile phone penetration reached 90 percent with three providers on the market (T-Mobile, Pannon GSM, and Vodafone).

Ireland: The government privatized the state monopoly, Telecom Eireann, in 1999. The new company, Eircom, retains an 80 percent share of the fixed lines in Ireland and dominates leased line services and national interconnection. Thus, while there are currently 69 operators authorized to provide publicly available telephone services/public voice telephony in the Irish market, these new entrants only account for a total of 20 percent of the fixed line market. While competition has significantly reduced prices for international business and residential calls, the price for local service remains high, discouraging both broadband development and Internet use. As of October 2005, only five percent of the population has broadband. Ireland has adopted EU local loop unbundling (LLU) legislation, and the government has initiated legal action to compel Eircom to complete LLU in order to promote competition and innovation in the DSL market.

Significant competition is now emerging in the mobile phone market, with four licensed and active operators. The mobile penetration rate in Ireland in 2005 was 94 percent, with 3.9 million mobile subscribers.

Italy: Italy is widely viewed as having a sophisticated and liberalized telecommunications market. The Government of Italy has divested its shares of Telecom Italia, maintaining only an indirect, residual interest in WIND, Italy's second largest telecommunications company. Despite this development, the Ministry of Communications continues to overshadow Italy's NRA – the Italian Communications Authority – calling into question its independence.

Lithuania: The Lithuanian government still has not issued a tender for the two-way radio system referenced in the 2005 NTE. The government has not yet published specifications for the tender.

Luxembourg: In 2005, Luxembourg began undertaking revised administrative procedures to implement the EU Framework Directive to liberalize Member States' telecommunications markets and allow for more fair competition. Despite these efforts, state-owned P&T continues to dominate the nation's telecommunications market. In addition, despite a 1998 court ruling opening Luxembourg's small mobile phone market to competition, the wireless communications market remains dominated by only two companies, one of which is half-owned by the state company.

Poland: Over the past year, there has been a surge of activity related to both telecommunications and Internet investment in Poland. New competitors (Netia) have entered the cellular market, and well-known Internet presences, such as Google, are locating brick and mortar investments in Warsaw. Still, the ability of new entrants to compete may have been hindered by the failure of Poland's NRA – URTiP – to implement the EU Framework Directive in a timely manner.

Slovenia: Slovenia has harmonized its telecommunications legislation with EU's acqui communitaire, but it has failed to adopt many by-laws. In October 2005, the European Commission opened infringement proceedings against Slovenia to determine whether Slovenia's NRA – the Telecommunications, Broadcasting and Post Agency – is sufficiently independent from the industry players which it regulates.

U.S.-owned wireless operator Vega continues to face problems in the Slovenia and alleges that its small market share is driven by the unfair pricing practices of Mobitel (the wireless subsidiary of state-owned, fixed line provider Telekom Slovenije). In May 2005, Vega filed a lawsuit against Mobitel and the Government of Slovenia seeking in excess of Euro 200 million in damages.

Spain: Access to leased lines in Spain remains problematic because rates are not based on actual cost. Despite actions by CMT, Spain's NRA, wholesale prices are still above the European average and approximately 100 percent above U.S. prices. This has allowed the incumbent operator Telefónica to offer services to customers at substantially lower rates than competitive carriers.

U.S. companies have complained that Spanish mobile operators are charging excessively high mobile termination rates and that they are squeezed out of the fixed-to-mobile communications market, because mobile operators offer their subscribers mobile-to-mobile and fixed-to-mobile calls at below wholesale rates. Spanish anti-trust authorities are considering penalizing these providers.

Evolution of the broadband market has been slow and problematic, and many operators have ceased offering these services. Telefónica's market share is being challenged though by two operators: Ya.com and Wanadoo. Both of these companies have established partnerships with Spanish fixed and mobile line carriers.

United Kingdom: There is limited competition in advanced data services over fixed-line incumbent British Telecom's (BT) infrastructure. The U.K.'s new NRA, Ofcom, was launched in late 2003. Ofcom recently concluded its Strategic Review of the U.K. telecommunications sector. One outcome is that Ofcom has required BT to undergo an internal reorganization to separate its retail and wholesale arms. The mandatory reorganization is aimed at increasing BT's competitors' access to BT's wholesale products. These structural changes are still being implemented.

INVESTMENT BARRIERS

Overview

The European Commission's mandate on investment issues is evolving. EU Member States negotiate their own bilateral investment protection and taxation treaties and generally retain responsibility for their investment regimes. In many areas, individual Member State policies and practices have a more significant impact on U.S. firms than do EU-level policies and practices.
Under the 1993 Maastricht Treaty, free movement of capital became an EU responsibility, and capital controls both among EU Member States and between EU members and third countries were lifted. A few Member States' barriers remain in effect, although in particular cases EU law may supercede these. Right of establishment issues, particularly regarding third countries, are a shared competence between the EU and the Member States. The division of this shared competence varies from sector to sector, based on whether the EU has issued regulations in that sector. Direct branches of non-EU financial service institutions remain subject to individual Member State authorization and regulation.

The EU requires national treatment for foreign investors in most sectors. EU law, with a few exceptions, requires that any company established under the laws of one Member State must, as a Community undertaking, receive national treatment in all Member States, regardless of its ultimate ownership. However, some restrictions on U.S. investment do exist under EU law and others have been proposed (see below).

Ownership Restrictions and Reciprocity Provisions

EU Treaty Articles 43 (establishment) and 56/57 (capital movements) have helped the EU to achieve one of the most hospitable climates for U.S. investment in the world, but some restrictions on foreign direct investment remain in place. 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. EU banking, insurance, and investment services directives currently include "reciprocal" national treatment clauses, under which a financial services firm 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. The right of U.S. firms to national treatment in this area was reinforced by the EU's GATS commitments, however.

After years of discussion, the Council of Ministers finally agreed in March 2004 on a directive on takeover bids, which is scheduled to enter into force on May 20, 2006. The original proposal would have banned any national legislation allowing companies to prevent hostile takeovers through the use of defensive measures (i.e., "poison pills" or multiple voting rights). The final directive makes it optional for Member States and companies to apply a regime that rules out these defensive measures or to opt out of such rules. The European Parliament debated whether to limit the benefits of the new directive to companies that apply the same provisions, (e.g., limiting the right of a board to take defensive measures or to mitigate the role of restrictions on share transfers or voting in a takeover bid). Article 12.3 of the final text is ambiguous as to whether the limitation would apply to non-EU firms, although the preamble of the legislation states that the application of the optional measures is without prejudice to international agreements to which the EC is a party.

Under the 1994 hydrocarbons directive (Directive 94/22/EC), the notion of reciprocity may have been taken further to require "mirror-image" reciprocal treatment, under which an investor may be denied a license to explore for and exploit hydrocarbon resources if its home country does not permit EU investors to engage in activities under circumstances "comparable" to those in the EU. These reciprocity provisions thus far have not affected any U.S.-owned firms.

Member State Practices

Austria: While European Economic Area (EEA) Member States' banks may operate branches on the basis of their home country licenses, banks from outside the EEA must obtain Austrian licenses to operate in Austria. However, if such a non-EEA bank has already obtained a license in another EEA country for the operation of a subsidiary, it does not need a license to establish branch offices in Austria.

Cyprus: Tertiary education investment restrictions: Cypriot legislation for foreign investment in tertiary education distinguishes between colleges and universities. Investment in universities, defined as institutions with no fewer than 1,000 students enrolled in a sufficiently diverse range of classes and curricula, is encouraged. Foreign (including non-EU) investors can set up or acquire a university in Cyprus by simply registering a company on the island and following a set

of non-discriminatory criteria. By contrast, non-EU investment in colleges is discouraged. Non-EU investors can set up or acquire a local college by registering a company in Cyprus or elsewhere in the EU provided that the company has EU-origin shareholders and directors. As a consequence, non-EU investors are not allowed to have any participation, whether as directors or shareholders, in the administration of local colleges.

Investment Restriction in Media Companies: Cyprus also restricts non-EU ownership of local mass media companies to 5 percent or less for individual investors, and 25 percent or less for all foreign investors in each individual media company.

Property Acquisition: Cypriot law imposes significant restrictions on the foreign ownership of real property. Persons not ordinarily resident in Cyprus (whether of EU or non-EU origin) may purchase only a single piece of real estate for private use (normally a holiday home). Exceptions can be made for projects requiring larger plots of land (i.e., beyond that necessary for a private residence) but are difficult to obtain and are rarely granted. The restriction on property acquisition for non-Cypriot EU residents will expire in May 2009. (Cyprus received a temporary derogation from the EU *acquis communautaire* on this issue, lasting for five years after accession.) The restrictions will continue to apply, however, to non-EU residents, including U.S. nationals.

France: There are generally no screening or prior approval requirements for non-EU foreign investment in France. As part of a November 2004 law that streamlined the French Monetary and Financial Code, however, the State Council was directed to define a number of sensitive sectors that would require prior approval for acquisition of a stake.

These areas have yet to be defined, but are expected to include national defense, public safety, nuclear energy, cryptology, and nanotechnologies. France continues to apply reciprocity requirements to non-EU investments in a number of sectors. For the purpose of applying these requirements, the French government generally determines a firm's residency based on the residency of its ultimate owners rather than on the firm's place of business or incorporation.

Germany: Germany's takeover law, which came into effect in 2002, has reintroduced measures that allow firms to ward off hostile takeover bids: first, at the stockholder level, where management may be given authority at the annual shareholders' meeting to take measures deemed necessary to guard against unwanted interest; and, second, at the management level, where the managing board can take protective measures, upon approval by the supervisory board, bypassing the need for stockholder approval altogether. These provisions may have negative consequences for outside investors and stockholders.

Germany passed legislation in July 2004, requiring notification by foreign entities of investments expected to exceed 25 percent of the equity of German firms engaged in the production of armaments and cryptology technology used for classified government communications. Following an inter-ministerial review, the government may veto such sales within one month of receipt of a notification. Chancellor Schroeder's cabinet expanded the scope of the law in 2005 to include tank and tracked vehicle engines to block a U.S. financial investor from buying a tank engine manufacturer.

Greece: Greek authorities consider local content and export performance when evaluating applications for tax and investment incentives. Such criteria are not prerequisites for approving investments, however.

Greece has opened its telecommunications market and is in the process of gradually liberalizing its energy sector. At present, however, Greece's inhospitable regulatory framework has hampered efforts by U.S. firms to develop energy production facilities. U.S. and other non-EU investors receive less advantageous treatment in Greece than domestic or other EU competitors in the banking, mining, maritime, air transport and broadcast industries (which were opened to EU citizens due to EU single market rules). For reasons of national security, non-EU investors are restricted in their ability to purchase land in border regions and on certain islands.

Italy: With few exceptions, Italy provides national treatment to foreign investors established in Italy or in another EU member state, as required by Article 43 of the EU Treaty. The exceptions include limits on access to government subsidies for the film industry and additional capital requirements for banks from non-EU countries. U.S. and other firms from non-EU countries may operate with authorization from Italy's securities market regulator, CONSOB.

CONSOB may deny authorization to firms from countries that discriminate against Italian firms. Finally, foreign insurance firms must prove that they have been providing life and property insurance for more than ten years and must appoint a general agent domiciled in Italy.

Malta: Maltese law requires that anyone buying residential or commercial real estate must obtain a permit from the Minister of Finance. EU citizens and returning Maltese migrants who have lived in Malta for more than five years receive a waiver from these permits. Non-EU citizens are not entitled to this waiver. Despite the restriction, permission to purchase land for commercial or residential purposes is normally granted. No U.S. businesses appear to have been discouraged from investing in Malta because of these restrictions. The restrictions have, however, delayed certain business investment projects involving American businesses.

Electronic Commerce

U.S. businesses and the U.S. government continue to monitor potential problems related to data privacy regulation and legal liabilities for companies doing business over the Internet in the EU.

Data Privacy:

The EU Data Protection Directive (1995/46) allows the transmission of EU data to third countries only if those countries are deemed by the European Commission to provide an adequate level of protection by reason of its domestic law or of the international commitments it has entered into (Article 25(6)). U.S. companies can only receive or transfer employee and customer information from the EU by using one of the exceptions to the Directive's adequacy requirements or by demonstrating they can provide adequate protection for the transferred data. These requirements can be burdensome for many U.S. industries that rely on data exchange across the Atlantic.

Currently, the Commission has recognized Switzerland, Canada, Argentina, Guernsey, Isle of Man, the U.S. Department of Commerce's Safe Harbor Privacy Principles, and the transfer of Air Passenger Name Record to the U.S. Bureau of Customs and Border Protection as providing adequate protection. The U.S. Safe Harbor framework provides U.S. companies with a simple, streamlined means of complying with the adequacy requirement. The agreement allows U.S. companies that commit to a series of data protection principles (based on the Directive), and that publicly state their commitment by "self-certifying" on a dedicated website (www.export.gov/safeharbor), to continue to receive and transfer personal data from the EU. Signing up to the Safe Harbor is voluntary, but the rules are binding on signatories. A failure to fulfill the commitments of the Safe Harbor framework is actionable either as an unfair and deceptive practice under Section 5 of the FTC Act or, for air carriers and ticket agents, under a concurrent Department of Transportation statute.

The U.S. Government actively supports the Safe Harbor framework and encourages the European Commission and Member States to continue to use the flexibility offered by the Data Protection Directive to avoid unnecessary interruptions in data flows to the United States. Furthermore, we expect the European Commission and EU Member States to fulfill their commitment to inform us if they become aware of any actions that may interrupt data flows to the United States.

Brussels Regulation:

On December 22, 2000, the EU adopted the so-called Brussels Regulation which allows consumers to sue companies in the court of their country of residence, "when the website is directed to [his/her] Member State or to several countries, including that Member State." Industry has complained that the practical effect of this regulation is that companies doing business on the Internet in the EU risk being sued in every EU Member State, as opposed to being subject to the jurisprudence of their country of origin.

OTHER BARRIERS

Health Insurance

Ireland: In the health insurance market, Ireland has espoused "risk equalization," whereby private insurers are required by law to compensate the Voluntary Health Insurance (VHI) Board, a quasi-governmental body, for the additional risk that it accepts in offering community (or equal) rating for policy-holders of different ages and medical profiles. Compensation is to be paid once a certain threshold based on the number of insured is reached, but the Irish government has not clarified the formula for determining the threshold. This ambiguity has been a factor in discouraging U.S. insurance firms from entering the Irish market.