EUROPEAN UNION

TRADE SUMMARY

The U.S. goods trade deficit with the European Union (EU) was $107.4 billion in 2007, a decrease of $9.8 billion from the $117.2 billion deficit in 2006. U.S. goods exports in 2007 were $247.3 billion, up 15.1 percent from the previous year. Corresponding U.S. goods imports from the EU were $354.7 billion, up 6.8 percent. EU countries as a group ranked second behind Canada as a U.S. goods export market in 2007.

U.S. exports of private commercial services (*i.e.*, excluding military and government) to the EU (25) were $140.5 billion in 2006 (latest data available), and U.S. imports were $117.3 billion. Sales of services in the EU by majority U.S. owned affiliates were $259.4 billion in 2005 (latest data available), while sales of services in the United States by majority EU owned firms were $225.5 billion.

The stock of U.S. foreign direct investment (FDI) in the EU (27) was $1.1 trillion in 2006 (latest data available), up from $998 billion in 2005. U.S. FDI in the EU is concentrated largely in nonbank holding companies and in the manufacturing and finance sectors.

OVERVIEW

The U.S. economic relationship with the European Union (EU) is the largest and most complex in the world. The generally robust health of this vast transatlantic trade and investment relationship promotes economic prosperity on both sides of the Atlantic. Recognizing the benefits of enhanced transatlantic economic ties, the United States and the EU continue actively to pursue initiatives to create new opportunities for transatlantic economic activity. At the April 2007 United States-EU Summit, leaders launched the Framework for Advancing Transatlantic Economic Integration (Framework), with the goal of fostering cooperation and reducing trade and investment barriers through a multi-year work program in such areas as regulatory cooperation, intellectual property rights, investment, secure trade, financial markets, and innovation. Building upon the 2005 United States-EU Initiative to Enhance Economic Integration and Growth, this new Framework also established the Transatlantic Economic Council (TEC) to oversee the Framework implementation, with input from the Transatlantic Business Dialogue, the Transatlantic Consumers Dialogue, and the Transatlantic Legislators Dialogue.

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.

Barriers to access for key U.S. agricultural exports continue to be a source of particular frustration for the United States. Even where formal EU agricultural tariff barriers may be relatively low, U.S. exports of commodities such as corn, beef, poultry, soybeans, pork, and rice are significantly restricted or excluded altogether due to restrictive EU nontariff barriers or regulatory approaches that often do not reflect science based decision making or a sound assessment of actual risks posed by the goods in question. The United States continues to be concerned about EU and Member State measures that subsidize the development, production, and marketing of large civil aircraft. 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 healthcare 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 new EU chemicals regulation.

IMPORT POLICIES

Customs Administration

Notwithstanding the existence of customs laws that govern all EU Member States, the EU does not administer its laws through a single customs administration. Rather, there is a separate agency responsible for the administration of EU customs law in each of the EU's 27 Member States. No EU institutions or procedures ensure that EU rules on classification, valuation, origin, and customs procedures are applied uniformly throughout the 27 Member States of the EU. 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.

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 (Committee). The Committee is an entity established by the Community Customs Code to assist the European Commission (Commission). The Committee consists of representatives of the Member States and is chaired by a representative of the Commission. While, in theory, the Committee exists to help reconcile differences among Member State practices and thereby help to achieve uniformity of administration, in practice its success in this regard has been limited.

Not only are the Committee and other EU-level institutions ineffective tools for achieving the uniform administration and application 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. Instead, review is provided separately by each Member State's tribunals, and rules regarding these reviews can vary from Member State to Member State. Thus, a trader encountering nonuniform administration of EU customs law in multiple Member States must bring a separate appeal in each Member State whose agency rendered an adverse decision. Moreover, administrative decisions of the Member States have no EU-wide effect, nor are the decisions of one EU Member State's customs authority binding on the customs authorities of the other Member States.

Ultimately, a question of interpretation of EU law may be referred to the Court of Justice of the European Communities (ECJ). The judgments of the ECJ have effect throughout the EU. However, referral of questions to the ECJ generally is discretionary and ECJ proceedings can take years. Thus, obtaining corrections with EU-wide effect for administrative actions relating to customs matters is a cumbersome and frequently time consuming process.

The United States has raised each of the preceding concerns with the EU in various fora, including WTO dispute settlement. The concerns have taken on new prominence in light of the expansion of the EU and the focus of the Doha Development Agenda on trade facilitation. In the trade facilitation negotiations, Members are considering proposals that would clarify the requirement of GATT 1994 Article X that all WTO Members – including WTO Members that are customs unions, such as the EU –uniformly apply and give effect to a Member's customs laws, regulations, procedures, administrative decisions, and rulings. The EU is moving toward formal adoption of the Modernized Community Customs Code (MCCC) in early 2008. EU officials claim the MCCC will streamline customs procedures and that it will apply uniformly throughout the customs territory of the Community. The United States intends to monitor its implementation closely, focusing on its impact on uniform administration of EU customs law.

EU Enlargement

In anticipation of the accession of Romania and Bulgaria to the EU on January 1, 2007, the United States, in December 2006, entered into negotiations with the EU within the framework of GATT provisions relating to the expansion of customs unions. Upon their accessions, Romania and Bulgaria were required to change their tariff schedules to conform to the EU's common external tariff schedule, resulting in increased tariffs on certain products imported into Romania and Bulgaria from third countries. 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 preexisting EU tariff-rate quotas (TRQs) to account for the addition of Romania and Bulgaria to the EU common market is another key element of the negotiations. The United States will seek to conclude in 2008 an appropriate bilateral compensation agreement with the EU and to ensure that its benefits are implemented as soon as possible.

WTO Information Technology Agreement (ITA)

The United States has continued to raise serious concerns both bilaterally with the EU and in the WTO ITA Committee in Geneva about a series of EU measures that have the effect of no longer providing or guaranteeing duty free treatment for certain information technology products, such as set-top boxes with a communication function, liquid crystal display (LCD) computer monitors, and multifunction printers. The EU is applying new duties as high as 14 percent on imports of these products. Despite similar concerns being raised by other ITA members, the EU continued to consider proposals in 2007 that would apply new duties on IT products.

Restrictions Affecting U.S. Wine Exports

On March 10, 2006, the European Union and the United States signed an agreement on certain aspects of wine trade, the planned first part of a broader agreement to remove barriers to bilateral trade in wine. The Agreement, which went into effect upon signature, is intended to eliminate the uncertainties caused by the EU's temporary, piecemeal derogations for current U.S. wine making practices and by restrictions placed on U.S. wine labels, including the use of so-called "traditional terms." Traditional terms for the most part, are terms used with certain other expressions (often geographical indications) to describe a wine (*e.g.*, "ruby" and "tawny"). The Agreement did not provide for the automatic acceptance of new wine making practices, nor did it include a permanent solution for the use of traditional terms, among other issues. It did, however, provide for additional negotiations with a view toward concluding one or more agreements to further facilitate trade in wine. These negotiations began in June 2006, and continued through 2007. Meanwhile, the United States is carefully monitoring compliance with the current agreement.

Bananas

Acting against the backdrop of understandings reached separately with the United States and Ecuador in 2001, setting out the means for reaching a resolution to the long running dispute regarding trade in bananas, the EU instituted a new banana import regime on January 1, 2006. The 2001 understandings required that, by January 1, 2006, the EU put in place a tariff only regime for bananas. The understandings further required the EU to seek waivers of its GATT Article I and XIII obligations in order to continue, temporarily, a modified banana import regime incorporating tariff-rate quotas and import licensing requirements. The Article I waiver, as finally granted by the WTO, required that the future tariff only regime result in at least maintaining total market access for Most Favored Nation (MFN) banana suppliers.

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 (according to the terms of the Article I waiver), which found that both proposals failed to satisfy the EU's obligation at least to maintain total market access for MFN 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 EC's post-January 1, 2006 regime. The regime, as eventually implemented on January 1, 2006, combined a 176 euro/metric ton MFN tariff level with a zero duty tariff-rate quota in amounts up to 775,000 metric tons for bananas originating in Africa, Pacific, and Caribbean (ACP) countries with which the EU maintains a preferential trading relationship. In November 2006, after continued negotiations failed to achieve a satisfactory result, Ecuador filed a request under Article 21.5 of the DSU for consultations with the EU regarding the compliance of this new regime with the EU's obligations under the WTO. A panel was established in March 2007, and issued its confidential final report on December 10, 2007. The public version of the report is expected in early 2008.

In June 2007, the United States filed a request for the establishment of a panel under Article 21.5 of the DSU, challenging the current EC banana regime as being in breach of GATT Articles I and XIII. The final report was issued to the parties on February 29, 2008. The United States' strong interest is 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 nonpreferential 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 the European Union due to the effective price, volume, and access controls placed on medicines by Member State 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 a reimbursement list and the price controls maintained for those products that are on the list generally lack transparency and often adversely affect U.S. exports. The EU also places strict controls on the nature of information that pharmaceutical companies can furnish to patients. The combination of these measures can limit patients' access to innovative products and may diminish investments by U.S. and EU companies in pharmaceuticals research and development.

The EU's single market is intended to allow pharmaceuticals, like other goods, to move freely within the EU, while Member States' controlled prices may vary significantly 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 – a practice known as parallel trade.

Member State Measures

Austria: Austria maintains a complex pharmaceutical reimbursement approval process that affects 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 individually approved by HVB physicians. In 2007, the European Commission filed a suit against Austria for violating the EU's Transparency Directive, challenging the transparency of the approval process, particularly the long delays in securing decisions. Industry estimates that the period between market authorization and actual market access averages nearly 400 days in Austria, the third longest period in the EU.

Belgium: Pharmaceutical companies consider Belgium among the most inhospitable markets in Europe. Taxes and pricing policies discourage investment in research and development. Prices on pharmaceuticals reimbursed through the Belgian healthcare system remain well below European averages, although generic pharmaceutical prices tend to be higher than the European average. In addition to the turnover and profit taxes applied exclusively in this sector, pharmaceutical companies are required to fund fully the first € 100 million of any gap between budgeted and actual government spending on pharmaceuticals. In combination, these tax measures amount to a 10 percent additional levy on the sector's turnover. Patient access to innovative drugs remains, in many cases, slower and more restricted than in other EU countries due to restrictive reimbursement criteria and a slow reimbursement process.

Bulgaria: The Bulgarian government's drug supply mechanism affects the access of U.S. pharmaceutical exports to that market. New drug legislation imposes liability on companies for failures of distributors to meet drug supply obligations (incorrect or late deliveries). Instead of holding distributors accountable for correct distribution, the government holds pharmaceutical manufacturers liable for the distributors' performance over which manufacturers may have no control. The registration processes for pharmaceutical products and for drug pricing and reimbursement, including the process by which the National Health Insurance Fund classifies drugs, are cumbersome and need to be more transparent. Newer drugs are often classified with their older, generic versions for pricing purposes, thereby limiting companies' ability to recover their research and development costs.

Cyprus: Pharmaceutical companies report that the Cypriot pharmaceuticals market suffers from several distortions that have resulted in unnecessary barriers to trade and retail shortages of many pharmaceuticals. For example, of the 3,300 drugs sold in Cyprus prior to May 1, 2004, only around 2,200 were available at the end of 2006. Since acceding to the EU on May 1, 2004, Cyprus has introduced reference prices for certain pharmaceuticals distributed through the private sector, resulting in retail price cuts of around 20 percent, on average. The mechanism used by the government to set pharmaceutical retail prices has proved rather controversial, both in terms of the countries used as pricing benchmarks, and the drugs selected. Local representatives of pharmaceutical companies believe the selected benchmark countries are not representative and that the government has avoided using reference prices for drugs that stood to increase in price. Additionally, the government included inexpensive, over-the-counter drugs in the reference pricing list. Furthermore, the government disfavors new, innovative drugs when procuring pharmaceuticals for the public health sector. Innovative, cutting-edge drugs are generally left off the government's procurement list until competing original drugs or cheaper generic substitutes become available.

Czech Republic: The European Commission won a legal case against the Czech Republic in September 2007 based on a complaint from the International Association of Pharmaceutical Companies (MAFS) over the nontransparent pharmaceutical categorization process that determines which medicines will be covered by public health insurance and the level of reimbursement. Although as a result of this ruling no sanctions are currently being imposed, it requires the Czech legislature to conform national law to European legislation as soon as possible or face monetary sanctions. The bill which accomplishes this has already been drafted and approved by Parliament, but it will not take effect until January 1, 2008. MAFS acknowledges that the new law is an improvement that makes the categorization process more transparent and provides a mechanism for appeal, but association members continue to object to assignment of their products to low value reimbursement groups. The Czech government's use of therapeutic reference pricing, in which a range of patented and nonpatented drugs are grouped together with a single reimbursement amount applied to all products in a therapeutic group, is cited as a particular impediment to the appropriate valuation of innovative medicines.

Denmark: The pharmaceutical industry complains that Danish reimbursement standards lack sufficient transparency and objective criteria. Furthermore, the industry claims that 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 social security system, this has the practical effect of preventing the sale and use of such medicines. The government has maintained pressure to further decrease prices or sales of innovative pharmaceutical products, and in April 1, 2005, a new reimbursement system was introduced. Under these rules, reimbursements are determined on the basis of the lowest priced medicine available in each therapeutic category, meaning that the patients' own contributions increase unless the cheapest product (often generic) is chosen. Reimbursements only apply to medicines purchased in a Danish authorized pharmacy.

Finland: Until 1995, Finland granted only process patents and no product patents for pharmaceuticals. Given the long development period of a product from chemical synthesis to market authorization, few pharmaceuticals developed after 1995 have made it to the market, and therefore all pharmaceuticals are currently protected only by process patents. In addition to this weakened patent protection, the Pharmaceuticals Pricing Board (PPB) – a decision making body controlling both pricing and reimbursement of prescription pharmaceuticals – has the authority to withdraw products from the reimbursement system, which results in further negative consequences for pharmaceutical market access in 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 that limit the price differentials allowed between generic and innovative products. The lengthy process of approving pharmaceutical products for reimbursement under the national insurance scheme (requiring more than 3 years, in some cases) represents a further impediment to access. In 2006, the PPB set a limit for prices of generic products (40 percent lower than the innovative product at the time), and demanded the same price for the innovative product. Innovative pharmaceuticals can be withdrawn from the reimbursement system if they fail to comply with PPB's price reduction decision.

France: The budgetary environment in France remains tight, with hundreds of additional medicines having been dropped from the Reimbursement List in 2006. As a result, the French pharmaceutical market has experienced a significant slowdown since the beginning of 2006, and sales of reimbursable medicines fell in July 2006 for the first time in 10 years. The drug industry association LEEM, which represents French and foreign pharmaceutical companies in France, acknowledges that the French pharmaceutical industry is affected by the cyclical nature of innovation and development associated with new drugs and that a slowdown in such development does not represent a long term decline. LEEM is also pleased regarding an agreement with the French Government's Economic Health Products Committee (CEPS) signed on January 29, 2007, which will speed up market authorization for practically all medicines from the most to the least innovative. At the same time, a recent study shows that the leading drugs affected by the 2006 reimbursement cuts saw double-digit losses to their sales.

Germany: The government 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 substantial share (25 percent) of the German market. U.S. pharmaceutical companies note serious concerns about transparency and fairness in 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." Legislation that went into effect in May 2006 clarified how drugs are declared innovative and provided more transparency in the decision making process, addressing some industry concerns. In April 2007, the German government passed broader healthcare reform legislation designed to introduce more competition in the healthcare market. This legislation did not include further regulations on reference pricing. The new legislation's provisions

directing a greater degree of transparency and the use of international standards by Germany's health technology assessment body are of particular significance, and implementation of these provisions is being closely monitored by the U.S. Government.

Hungary: Hungary's Drug Act – introduced as part of Hungary's broad health care reform package in 2006 to 2007 – has had wide reaching effects for the innovative pharmaceutical industry. Key elements of the reforms include: a 12 percent tax on pharmaceuticals, in addition to standard corporate taxes; a $25,000 registration fee for each sales representative; reductions in the levels of reimbursement; and regulations providing that pharmaceutical companies are responsible for financing gaps in the drug subsidy budget. The transparency of the Hungarian government's drug reimbursement program remains a significant concern.

Italy: U.S. companies have raised concerns about Italian government measures that they believe will have a deleterious impact on their business and could have a negative effect on patient care. Among these are: an across-the-board reduction in reimbursement prices for almost 300 drugs now on the reimbursement list; an increase in the amount that industry must "pay back" to the central government for regions' annualized overspending on pharmaceuticals; and additional discounts on certain classes of drugs that will disproportionately disadvantage U.S. research based companies. In addition, particular concerns have been raised regarding a measure introduced in late 2007 that will limit individual pharmaceutical companies' pricing budgets in 2008 to the level of sales in the previous year, imposing a lack of flexibility to account for the introduction of new products during the course of the coming year. Lack of transparency in Italian procedural measures governing drug pricing and reimbursement has been a longstanding concern of U.S. industry, prompting the filing of a number of complaints to the European Commission under provisions of the EU Transparency Directive.

The Netherlands: The Dutch Ministry of Health views pharmaceuticals as a prime target for savings in its national healthcare budget. Industry has expressed concern that the Ministry does not fully recognize the added value of incremental innovation. Excessive regulation and lack of transparency continue to delay timely introduction of new medicines. Various measures are in force or planned that delay the reimbursement of new compounds. The current multi party Agreement between the Ministry of Health, insurers, pharmacists, and generic manufacturers was extended for another year on September 17, 2007. Nefarma, the association representing the innovative industry, joined the Agreement. Under the current Agreement, Nefarma members will reduce their prices of multi source brands (off-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 are focused on modernizing the current reimbursement system and/or the Pharmaceutical Pricing Act.

Poland: Meaningful access to Poland's pharmaceuticals market often hinges on whether a drug appears on the government's reimbursement list, since doctors most often prescribe drugs from the list, and purchases from the list are subsidized by the Polish National Health Fund, making them more affordable for patients. The government of Poland's general failure to act upon applications to add innovative drugs to the reimbursement list (with some exceptions) has seriously undermined U.S. and international innovative drug producers' market position in favor of the Polish generic industry. In those cases over the last decade where innovative drugs were added to the list, the decision criteria lacked clarity, and the process required greater transparency. Polish legislation that entered into force on September 28, 2007, requires the Ministry of Health to update the drug reimbursement list every quarter and to provide an explanation for negative decisions, which are to be appealable to administrative courts. If implemented effectively, the new legislation will enhance the transparency of the process for adding drugs to the list and may address longstanding concerns regarding the significant backlog in reimbursement approvals.

In July 2006, the Polish government instituted a 13 percent across-the-board price cut on all imported pharmaceutical products. This measure has raised questions of potential discriminatory treatment, in light of the fact that the regulation applies only to imports. In response, the Polish government has stated it plans to cut the prices paid to domestic producers, to reflect a 13 percent reduction in the value of imported inputs. However, the costs of inputs are not the primary determinant of a drug's value. The European Commission is investigating the consistency of the July 2006 price reductions with EU rules.

Slovakia: U.S. and European pharmaceutical companies complain that a Slovakian Ministry of Health Decree (No. 723/2004), which 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 the calculation of the price and the level of reimbursement. However, recent amendment of the Decree cancelled the detailed rules for determining the reimbursement amount and, instead, provided the Ministry of Health, as the deciding authority, with wide discretion to decide on the amount of reimbursement without setting a clear set of guidelines for such decisions. All parameters on the list are reviewable by the Ministry of Health four times a year. Since these decisions fall outside the Slovak Administrative Code, there is no formal process for the decisions to be appealed by the companies. The new regulation has increased the subjectivity of the Board's decision making, thereby minimizing the predictability and transparency of the process.

Slovenia: Innovative U.S. drug manufacturers continue to face pricing related access barriers in Slovenia, with the government setting price limitations based on a "basket" of "European average prices." In January 2007, the government changed its drug pricing from the average price to the lowest price in the "basket," which further inhibits 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. These are the only drugs that are fully reimbursed under the state insurance plan.

United Kingdom (UK): The profits that pharmaceutical companies may earn on sales to the National Health Service (NHS) are limited by a Pharmaceutical Price Regulation Scheme (PPRS). The most recent PPRS, which was agreed to by the pharmaceutical companies in January 2005, required companies that sold more than $2 million worth of branded medicines to the NHS to reduce their average overall prices by 7 percent. The current PPRS is scheduled to remain in place until 2010. Companies that exceed the profit target by more than 40 percent must refund the excess either as a lump sum payment to the Department of Health or as price reductions to the NHS. The Office of Fair Trading (OFT) has recommended replacing the PPRS with a value based pricing system. The OFT recommendations are currently under review by the Department of Health. If the Department of Health accepts the recommendations, the PPRS could be revoked earlier than 2010. U.S. pharmaceutical companies have been notified by the Department of Health of its intention to review the current PPRS arrangements.

Uranium Imports

The United States is concerned that EU policies may unjustifiably 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 justification for the import quotas and the nontransparent

nature of the Corfu Declaration and its application. Further, the United States is closely monitoring whether future EU agreements with Russia under negotiation in the nuclear area will follow WTO rules.

STANDARDS, TESTING, LABELING, AND CERTIFICATION

Overview

As traditional trade barriers such as tariffs decline, U.S. exporters of manufactured and agricultural products increasingly view EU regulatory measures as impediments to market access. U.S. firms frequently cite inadequate transparency in the development and implementation of EU regulations, insufficient economic and scientific analysis to support good regulatory decisions, and a lack of meaningful opportunity for non-EU stakeholders to provide input on draft EU regulations and standards. Further, 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 and product redesign) and increases the time required to bring a product to market. To address these systemic concerns, the United States is working to promote greater U.S.-EU regulatory cooperation and enhanced transparency in the EU regulatory system.

Despite often sharing similar regulatory objectives, the U.S.-EU dialogue frequently is unable to resolve regulation related trade problems promptly. In particular, many U.S. exporters view the EU's growing use of the "precautionary principle" to restrict or prohibit trade in certain products, in the absence of a scientific justification for doing so, as a pretext for market protection. Furthermore, EU regulatory barriers are often compounded by multiple measures affecting particular products. Poultry, agricultural biotechnology products, and chemicals are examples of product areas that face complex and restrictive regulation in the EU marketplace. To illustrate:

- U.S. exports to the EU of poultry washed with anti-microbial treatments (AMT) have been blocked for a decade by cumbersome bureaucratic procedures and unnecessary, redundant health and safety assessments – despite the finding by the EU's European Food Safety Agency that these AMTs are safe.

- U.S. exporters of agricultural biotechnology products have been harmed not only by a *de facto* EU moratorium on approving new products, but also by the existence of certain Member State prohibitions on products already approved by the EU for marketing within the EU. This was the subject of a successful WTO challenge by the United States.

- U.S. producers of chemicals and downstream users of chemicals face the EU's comprehensive new regulatory regime known as Registration, Evaluation, and Authorization of Chemicals (REACH), which adopts a particularly complex and burdensome approach that appears to be neither workable nor cost-effective in its implementation and that could adversely impact innovation and disrupt global trade. This expansive EU regulation affects virtually all industrial sectors, including the majority of U.S. manufactured goods exported to the EU.

Standardization

Given the extensive U.S.-EU economic relationship, EU standards activities are of considerable importance to U.S. exporters. Standards related problems continue to impede U.S. exports, including a general inability to participate in the formation of EU standards and 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 U.S. exporters. In addition, there are concerns

related to the procedures, responsibilities (*e.g.*, accountability and redress), and lack of transparency in the Member States, the European Commission, and the European standards bodies.

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 a European Approval of Materials (EAM). 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 promote cooperation, U.S. and EU officials and stakeholders have initiated a project to eliminate redundant testing requirements for materials.

Ecological-labeling: Ecological-labeling initiatives by the EU and some of its Member States raise concerns that U.S. (and other) exporters may be disadvantaged to the extent that the standards used for labels reflect subjective criteria or are developed without meaningful and thorough consultation with foreign suppliers. One example is the EU Ecological-labeling Regulation for Paper Products. Experience in the ongoing development of an ecological-label for furniture illustrates the need for effective consultations in the development of standards.

Agricultural Biotechnology Products

Since 1998, the European Union's Council of Ministers has not assembled a qualified majority of EU Member States in support of the approval of any agricultural biotechnology products, even though the EU's own scientific authority has offered a positive safety assessment for every product reviewed. In addition, while the European Commission has granted approval for a limited number of biotechnology products under its legislative authority, there have been no approvals of biotechnology products for cultivation within the EU since 1998. The EU continues to lack an approval process that is predictable and that reflects scientific, rather than political, factors.

In May 2003, the United States initiated a WTO dispute settlement process aimed at addressing the EU's *de facto* moratorium on approvals of biotechnology products and the existence of individual Member State marketing prohibitions on biotechnology products that had previously been approved by the EU. The WTO panel issued its final report on September 29, 2006, and the WTO Dispute Settlement Body (DSB) adopted the report on November 21, 2006. The Parties agreed on a 1 year "reasonable period of time" (RPT), expiring on November 21, 2007, for the European Union to come into compliance with the DSB's recommendations and rulings; the deadline was subsequently extended to January 11, 2008. During 2007, the United States and the EU held discussions aimed at resolving the dispute and normalizing U.S.-EU biotechnology trade. When the RPT expired in January 2008, the United States took the first steps toward a resumption of dispute settlement procedures, submitting a request to the WTO for authority to suspend concessions. Under an agreement with the EU, however, proceedings on the U.S. request were suspended to provide the EU an opportunity to demonstrate meaningful progress on the approval of biotechnology products.

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 EU Environment Council rejected, by a qualified majority, eight Commission proposals to lift safeguard measures imposed

by five Member States against biotechnology maize. On September 13, 2007, the European Court of Justice upheld an earlier decision, which Austria had appealed, against Upper Austria's effective ban on growing biotechnology crops, on the grounds that there was no scientific evidence to support the ban. On December 18, 2006, the European Commission presented a proposal to lift import and cultivation bans in Austria, and the Council rejected this measure by qualified majority. On October 30, 2007, the European Commission proposed requiring that Austria lift only its import ban on the biotechnolgy maize product against which the Council did not manage a qualified majority, leaving the Commission an opening to take action. The Commission has, to date, taken no such action against Austria. On April 27, 2007, Germany announced a planned ban on MON810, a biotechnology corn product. The ban was lifted, however, after agreement with the technology provider on post-market monitoring. On February 9, 2008, France imposed a temporary ban on cultivation of MON810, invoking the safeguard clause, and announced that its ban would remain in place contingent on the EU reapproval process that has been ongoing since April 2007.

Delays in the biotechnology product approval process exacerbate the already large asynchronicity of approvals, creating further trade problems. As the U.S. biotechnology firms commercialize new innovative products they may encounter more trade barriers as even minute traces of new products approved in the United States could make them unsellable in the EU.

Rice: In August 2006, USDA announced that a biotechnology rice variety, LL601, had been detected in samples of commercial U.S. long grain rice. LL601 had not been approved for marketing in either the EU or the United States at that time, but it was subsequently approved in the United States. Although EU scientific authorities, like their U.S. counterparts, had concluded that LL601 poses no human health, food safety, or environmental risks, the EU's Directorate for Health and Consumer Protection (DG SANCO) directed Member States to test rice for the presence of LL601 in their markets. Trace elements of LL601 were found both in bulk shipments and in processed food products, prompting the rejection and destruction of shipments. In response, the U.S. Government began intensive talks with EU officials to establish a common protocol for bulk shipments from the United States in an effort to avoid mandatory testing upon arrival in the EU. These talks failed to produce an agreement and the Commission, with Member State support, introduced mandatory testing at destination, effective October 23, 2006.

The zero tolerance policy maintained by the EU for LL601 substantially increased the risk of rejection at EU ports, making it difficult for most U.S. rice exporters and EU buyers to continue normal shipments during the first two-thirds of 2007. The situation for U.S. rice exporters was further complicated in October 2007, when the EU globalized the remaining quantity of the U.S. milled rice tariff quota, allocating approximately 13,000 tons of the quota to non-U.S. suppliers. This occurred just as U.S. suppliers were preparing to resume normal rice exports to the EU from 2007 crop supplies. The United States has requested that the EU restore this quantity of quota to U.S. suppliers. In December 2007, following a review of U.S. industry measures to ensure the exclusion of LL601 from rice shipments, DG SANCO's Standing Committee decided to eliminate the requirement that EU Member States test all U.S. rice shipments for genetically engineered rice upon arrival at EU ports. This decision came into effect in February 2008.

Co-existence: In accordance with the EU 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. France is in the process of developing its co-existence legislation. 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. There is no deadline for Commission action, however.

The Commission and the Austrian EU Presidency co-hosted a conference on coexistence in April 2006. The conference concluded that there was a need for all Member States to define their co-existence policy.

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 operators throughout the supply chain. Operators must also have in place a standardized system to maintain information about biotechnology products and to identify the operator by whom and to whom it was transferred for a period of 5 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 because U.S. food producers have reformulated their products to eliminate the use of biotechnology products. Food producers have expressed concern about needing to find expensive or limited alternatives. The Directives are generally expected to have a negative impact on a wide range of U.S. exports, including processed food exports. A spring 2006 European Commission report on the implementation of the traceability and labeling directive was largely inconclusive, because of the limited number of products containing biotechnology material that have entered the EU market.

Member State Measures

Austria: The Austrian Biotechnology Law allows, in principle, for planting of biotechnology crops, but strict and complicated rules on liability and compensation still represent a *de facto* barrier. All nine Austrian provinces have passed biotechnology bills to protect their organic and small-scale agricultural sectors. Three Austrian ordinances still ban the planting of all EU approved biotechnology crops and a new ordinance bans the marketing of a biotechnology oilseed rape. Under current Austrian rules, unapproved biotechnology events must not be detectable 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 from their shelves, even those labeled according to EC regulations. Austria continues to advocate for a revision of EU decision making for biotechnology approvals, despite the fact that Member States approved the decision making procedures presently in place.

Cyprus: Cyprus has adopted a number of restrictive biotechnology policies. For example, Cyprus has voted consistently against any applications for new bioengineered crops before the EU Standing Committee. On July 12, 2007, the Cypriot House of Representatives passed a law (the first of its kind in the EU) that was controversial and requires local stores to place all bioengineered products (defined as products with a biotechnology content above 0.9 percent) on separate shelves, under a sign clearly declaring them as GMO products. President Papadopoulos has referred this legislation to the Cypriot Supreme Court for a ruling on procedural grounds. Cyprus had failed to give advance notice to the European Commission of its plan to introduce this law, in violation of European Commission Directive on food labeling and advertising 2000/13/EC. The government has declared as "GMO-free" areas under the Natura 2000 project (corresponding to 11.5 percent of the land area of the island). Local environmentalists and others are applying constant pressure on the government of Cyprus to declare the whole of Cyprus as GMO free. Largely as a result of this pressure, the government commissioned, in September 2007, a study aimed at establishing that co-existence between bioengineered and conventional crops is impossible in Cyprus. Meanwhile, government application requirements for new agricultural

biotechnology crops are stricter than in other EU countries. Additionally, permits for such crops must be renewed every 5 years. Biotechnology products already licensed in the EU may circulate in Cyprus freely, but biotechnology organisms must be separately approved in Cyprus, even if they are already licensed in other EU countries.

France: On February 9, the French government published an "arête" in the French Official Journal extending a ban on MON810, and invoking the safeguard clause against MON810 in France, until a reevaluation of the product occurs at the European level. France's decision to invoke the safeguard clause against MON810 has been widely criticized by scientists, French parliamentarians, and French farm organizations as lacking scientific justification.

On February 8, 2008, the French Senate approved a new version of the French biotechnology law, which will be reviewed by the National Assembly in early April 2008. The new bill is intended to meet France's requirement to transpose EU Directive 2001/18 into French law. This was partially accomplished through administrative decrees published in spring 2007, as a result of which France is no longer paying penalties for failing to transpose the Directive correctly.

As a consequence of the ban on MON810, no commercial production of bioengineered corn is expected in 2008. In 2007, 22,000 hectares of bioengineered corn were planted, four times more than in 2006. French corn growers were particularly disappointed by the ban on MON810, as they have become increasingly enthusiastic about the technology in recent years due to encouraging agronomic and economic results; the availability of bioengineered seeds from a larger number of companies; the establishment of effective marketing channels; and the persistent demand from Spain, where virtually the entire harvest was sold.

Bioengineered corn growers and seed companies continued to suffer attacks in 2007 from antibiotechnology activists, who have destroyed commercial fields as well as open field trials. French votes on new bioengineered products in the EU regulatory committee have grown increasingly negative since the Sarkozy Administration took office in May 2007.

Germany: In February 2008, the grand coalition government consisting of the Christian Social Union/Christian Democratic Union and the Social Democratic Party passed an amendment to the biotechnology law of March 2006 that essentially keeps Germany's stringent green biotechnology requirements in place and offers less far-reaching reform than had initially been expected. These requirements include 100 percent accessibility to field registrations; 100 percent farmer liability; plant distance requirements of 150 meters between conventional and bioengineered crops and 300 meters between bioengineered crops and organic fields; and giving German Laender (states) the option of implementing stricter protection measures including distance rules for nature protection purposes. The current biotechnology regulations limit the number of bioengineered plantings. In 2007, only 2,650 hectares of bioengineered corn were grown for commercial purposes in Germany, a relatively small number in comparison with the more than 53,000 hectares planted with bioengineered corn in Spain and the 22,000 hectares planted in France.

In April 2007, the German government issued an order against the technology provider of MON810, requiring it to monitor potential environmental impacts of MON810 corn varieties. In December 2007, the German government declared the monitoring plan provided by the technology provider as sufficient to meet EU requirements and lifted a marketing ban against the product.

Greece: Greece continues to vote against bioengineered varieties that even the European Food Safety Authority (EFSA) has concluded are safe and despite support from a large portion of Greek farmers and Greece's agricultural science community, which favor possible field tests in Greek soil. Greece's

Ministerial Decisions for the 0.5 percent threshold on adventitious presence of transgenic material in corn seed shipments from the United States and "no presence" of such material in cottonseeds for planting have remained in force since 2002.

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. 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, Hungary adopted a moratorium on corn varieties containing MON810. The Hungarian measure bans the production, use, distribution, and import of hybrids derived from MON810 lines. The ban applies to seed producers and distributors as well as farmers.

Italy: In March 2006, the Italian High Court ruled that coexistence legislation enacted by the Italian Parliament was unconstitutional and that Italy's regions are responsible for the development of co-existence legislation. In 2007, several conferences were held to develop national guidelines for use in developing regional coexistence regulations. Although several regions, particularly those representing the major corn growing areas, have worked to draft regulations that will allow the introduction of biotechnology crops, there remains concern that the legislation enacted in many regions will discourage biotechnology crop planting.

In 2007, after years of prohibiting experimental field trials of new genetically modified crops, the Ministry of Agriculture drafted a Ministerial Decree authorizing field trials of nine approved protocols. This Decree was circulated to the Ministry of Environment for its advice, as is required by law. The Minister of Environment (and Green Party founder) rejected the protocols, effectively blocking future action.

Luxembourg: Luxembourg bans the marketing of biotechnology crops in its territory and opposes the approval of new biotechnology products at the EU level. The European Commission has pressed Luxembourg to withdraw its ban. Legislation that would regulate the growing of biotechnology crops in Luxembourg has been stalled in a parliamentary committee for 3 years, and there appears to be little interest in moving it forward during the current legislative session.

Poland: Poland's new government, which was formed in October 2007, has begun to recognize the practical implications of its current antibiotechnology policies. Under the antibiotechnology policy announced at the beginning of 2006, Poland had consistently opposed EU approval of new bioengineered products and had set a goal of becoming a "GMO-free" country. Towards this end, the government banned the sale and registration of bioengineered seeds in mid-2006 and passed legislation that will prohibit import, production, and use of animal feed derived from bioengineered crops by September 2008. This law could cause significant increases in feed prices and limit the protein content of feed, posing a threat to the future viability of commercial animal production in Poland. The European Commission is currently pursuing infringement proceedings against Poland's seed and feed legislation.

The new government has expressed interest in reassessing this legislation. Change is being driven by mounting pressure from the livestock, feed, and seed industries; by demand for biofuel production; and by farmer concerns about the spread of pests such as the corn borer and root worm. Scientists, farm groups, feed processors, and the animal production sector in Poland are growing increasingly vocal in their demand that the feed and cultivation bans be lifted.

Officials recently announced they will appeal an EU ruling against Poland's cultivation ban at the Court of First Instance. Poland voted against approval of new bioengineered corn and potato varieties in October 2007 and against new soybean varieties in February 2008.

Romania: Romania's adoption of EU legislation has resulted in a significant change in the country's biotechnology policy. Before 2006, Romania was the largest planter of biotechnology soybeans in Europe. Despite protests from domestic producers, Romania decided to drastically limit biotechnology soybean cultivation in 2006 and to totally ban it in 2007. Romania has approved one biotechnology corn variety for cultivation in 2007.

Spain: Spain remains the EU member with the largest land area under bioengineered corn cultivation. The current government has tended to take a somewhat restrictive position with respect to biotechnology, however. Spain proposed regulations in 2006 that would impose 220 meter distance requirements between biotechnology crops, on the one hand, and conventional and organic crops, on the other. If these coexistence requirements are approved, biotechnology use is likely to decline in Spain.

Ban on Growth-Promoting Hormones in Meat Production

Since the 1980s, the EU has banned the use of hormonal substances that promote growth in food producing animals. Because the use of growth promoting hormones is approved by the U.S. Food and Drug Administration and is common in U.S. beef cattle production, this ban has effectively prohibited the export to the EU of beef from cattle raised in the United States. The United States launched a formal WTO dispute settlement proceeding in May 1996, challenging the EU ban. In 1999, the WTO ruled that the EU's ban was inconsistent with the SPS Agreement because it was not based on a scientific risk assessment. The WTO authorized the United States to impose sanctions on EU products with an annual trade value of $116.8 million. At present, the United States continues to apply 100 percent duties on imports from the EU valued at $116.8 million.

In September 2003, the EU announced the entry into force of an amendment (EC Directive 2003/74) to its hormone ban that recodified the permanent ban on the use of the hormone estradiol-17β for growth promotion purposes and established provisional bans on the five other growth promoting hormones included in the original EU legislation. The EU argued that the implementation of this new Directive brought it into compliance with the earlier WTO ruling and that U.S. sanctions were no longer justified.

The United States maintains that the revised EU measure cannot be considered compliant with the WTO's recommendations and rulings in the earlier hormones dispute and that U.S. sanctions therefore remain authorized. In November 2004, the EU requested WTO consultations with the United States on this matter. The dispute is currently in the final stages before a WTO panel, which is expected to publish its findings in early 2008.

Animal By-Products Legislation

EC Regulation 1774/2002, which regulates the importation of animal by-products not fit for human consumption, went into force in May 2004. Despite extensive U.S.-EU technical discussions that addressed many problems, an estimated $100 million in U.S. animal by-product exports to the EU remain adversely affected to some degree by Regulation 1774/2002. The U.S. exports most affected by this regulation are dry pet food, tallow, other animal protein products, and some hides and skins. The regulation's effect on products further downstream, such as certain *in vitro* diagnostic products that may use animal by-products, is unclear. In 2007, the European Commission approved several amendments to the regulation, addressing many of the problems it created. The most important amendments for U.S. exporters relate to pet food. The Commission has also indicated that it is drafting changes to the regulation that could help resolve additional issues, including allowing increased market access for tallow, but it has not yet offered details on specific product coverage or timetables. The United States will continue to seek the elimination of remaining impediments to U.S. exports of animal by-products, particularly tallow for industrial use.

Poultry Meat

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 pathogen reducing treatments (PRTs), such as chlorine, to reduce the level of pathogens in poultry meat production, a practice not permitted under the EU sanitary regime. In December 2005, EFSA completed studies of four PRTs and found them to be safe, and in February 2006 the European Commission's Health and Consumer Protection Directorate General circulated the first draft of a proposal to allow PRTs to be used on poultry meat in the EU market. The draft regulation banned the simultaneous use on poultry products of more than one PRT, however, and it required poultry treated with PRTs to be rinsed after treatment. These two requirements are not fully consistent with U.S. production methods and would limit the ability of most U.S. producers to export poultry to the EU. Concerns raised by the Commission's Agriculture and Environment Directorates have kept the draft regulation in inter-services consultation for more than 18 months. The concerns of the Agriculture Directorate on marketing standards for PRT-treated poultry appear to have been resolved. Late in 2007, however, Directorate General Environment ordered new studies, due to be completed in the Spring of 2008, of the potential impact of PRTs on water pollution and antimicrobial resistance, issues that the United States contends are not relevant to the safety of poultry that is treated with PRTs in the United States and then exported to the EU.

During the November 2007 meeting of the Transatlantic Economic Council, the EU committed "to act definitively to resolve the long-standing issue regarding the importation into the EU of U.S. poultry treated with pathogen reduction treatments… [b]efore the next U.S.-EU Summit."

Member State Measures

Finland and Sweden: In their EU accession agreements in 1995, Sweden and Finland received derogations allowing them to enforce for an indefinite period stricter salmonella controls for food products and stricter border controls for live animals (quarantine) than those maintained by other EU Member States. Imports of fresh or frozen beef, pork, poultry, and eggs from other EU countries and third countries must be certified to be free from salmonella in accordance with Commission Regulation (EC) No. 1688/2005. These special certification requirements are burdensome to U.S. exporters.

Romania and Bulgaria: The EU has granted Romanian and Bulgarian domestic meat-processing facilities a transition period, ending in 2009, for the adoption of certain EU poultry and pork meat requirements. Imports from non-EU sources, such as the United States, however, must immediately comply with the EU

requirements, creating a national treatment issue. This change has nearly halted trade in what was previously the top U.S. agricultural export to Romania, frozen broiler chickens.

Mycotoxins

The EU regulations set maximum limits on mycotoxins for a variety of foodstuffs, including cereals, fruit and nuts. In many cases, including for almonds, peanuts and wheat, the EU limits are lower than maximums set by the U.S. Food and Drug Administration. The United States will work with U.S. industry to gain EU acceptance of U.S. origin testing and certification for mycotoxins for U.S. almond and wheat shipments. The United States will continue to seek the development of international standards for mycotoxins within CODEX. In recent years, there have been an increased number of U.S. almond shipments rejected at EU ports because import controls have found excessive levels of aflatoxin. A voluntary aflatoxin sampling plan has been implemented by the U.S. almond industry in coordination with the EU and the U.S. Department of Agriculture to address this problem. The U.S. wheat industry is concerned that EU testing for vomitoxin and ochratoxin in imported wheat shipments will be disruptive for trade.

Barriers Affecting Vitamins and Health Food Products

France: France transposed the EU's food supplement directives 2002/46/EC and 2006/37/EC by government decree on March 20, 2006. The scope of the government decree is broader than the directives, however, as it included plants and plant based substances in addition to food supplements. The list of 147 plants and plant based substances was issued separately.

Greece: In implementing the 2002 Food Supplement Directive (2002/46/EC), 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.

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 EU with respect to the issues outlined below.

Chemicals and Downstream Products

The EU's new chemicals management regulation, REACH, entered into force on June 1, 2007. REACH requires all chemicals produced or imported into the EU in volumes above one ton per year (affecting approximately 30,000 chemicals) to be registered in a central database, and imposes new testing and marketing requirements. Chemicals of very high concern will require an authorization for specific uses in the EU when determined necessary by the new European Chemicals Agency (ECHA). This legislation will impact virtually every industrial sector, from automobiles to textiles because it regulates substances on their own, in preparations, and in products.

The European Commission is presently working on implementation guidance. The United States and other EU trading partners have been stressing since July 2006 that the EU's interpretation and implementation of REACH will determine its environmental and public health benefits as well as the economic and trade costs. We have urged the European Commission to seek input from all stakeholders regarding the REACH Implementation Projects and the resulting guidance before ECHA adopts these guidelines. In addition, the United States has urged the European Commission to provide guidance on its

"candidate list" of substances of very high concern to ensure that downstream users do not use this as a "black list," and to ensure that specific uses of substances and viable alternatives have had the benefit of a risk assessment. Guidance should clarify that without going through this step, premature substitution could have negative environmental or public health effects while greatly increasing costs.

One particular concern is the treatment of monomers. Although polymers (mostly plastics) are exempted from REACH registration, monomers used in the EU to make polymers must be registered due to potential exposure during polymer manufacture. But REACH also requires registration of monomers used abroad to create imported polymers, despite the fact that the monomers no longer exist in the imported product and even though the polymers themselves are exempt from registration. Besides the unnecessary costs of collecting information on substances that do not create any risk of exposure in the EU, industry is concerns that the provision may also force these polymer importers to disclose confidential business information.

Another issue of concern relates to the treatment of imported cosmetics. REACH does not appear to provide producers of cosmetics imported into the EU the benefit of any transition period to register inputs, whereas comparable domestic products may benefit from a 3 year to 11 year transition period.

Cosmetics

The EU's cosmetics 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. This 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 EU has approved an alternative testing method. The bans will go into effect in 2009 and 2013 whether or not there are validated nonanimal tests by these dates.

To minimize possible trade disruption, the United States and the European Commission have embarked on a joint project to develop harmonized, alternative, nonanimal 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 an average of 7 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 related to the growing volume of waste electrical and electronic equipment. The Waste Electrical and Electronic Equipment (WEEE) Directive focuses on the collection and recycling of electrical and electronic equipment waste. The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (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, as of August 2005, producers are held individually responsible for financing the collection, treatment, and recycling of the waste arising from their new products. 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. The WEEE Directive required that by December 31, 2006, 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 (PBB), and polybrominated diphenyl ethers (PDBE) has been prohibited, with some limited exemptions. A European 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, PBB, and 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 EU on product scope and, in cases where technically viable alternatives do not exist, businesses face a lengthy, uncertain, and nontransparent exemption process. The European Commission will consider RoHS exemption requests on an ongoing basis, and will be regularly reviewing the need for existing exemptions. 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.

Increasing the uncertainty for U.S. manufacturers is the fact that enforcement of RoHS will be managed at the Member State level. In the absence of a common approach to approval and established EU-wide standards and test methods, a product may be deemed compliant in one country and noncompliant in another.

Given the substantial impacts of RoHS substance bans on international trade, the United States has urged the European Commission to ensure that sufficiently detailed guidance is provided in order to give companies seeking to comply with RoHS commercial certainty. The United States has also urged the European 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 and to move towards greater harmonization of approaches in the implementation and enforcement of both Directives.

Energy Using Products Directive

The EU framework directive promoting ecological design for energy using products (EuP) entered into force on August 11, 2005, and EU Member States had until August 11, 2007 to transpose it into national law. As of September 2007, only Austria, Belgium, Ireland, UK, Slovakia, and Sweden have reported full or partial transposition of the law to the European Commission. Through this directive, the EU means to regulate the integration of energy efficiency and other environmental considerations at the design phase of a product. Once in place, design requirements will become legally binding for all products sold in the EU. The legislation commits the European Commission to adopt "implementing measures," which will be developed after completion of a series of technical studies covering various products, including lighting, office equipment, heating equipment, domestic appliances, air conditioning, consumer electronics, and energy losses from standby modes. The directive sets out CE marking requirements for the items covered by implementing measures. 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

Metric-Only Directive

As of January 1, 2010, the EU Council Directive 80/181/EEC (Metric Directive) requires the use of metric-only measurement units for most products sold in the EU. Going well beyond labeling, the Metric

Directive would make the use of metric-only units obligatory in all aspects of life in the European Union, including on labels, packaging, advertising, catalogs, technical manuals, and user instructions. This prohibition would end a longstanding practice in the European trade community of allowing manufacturers flexibility in labeling products in metric and standard units. When implemented, the Directive would also create an inconsistency with U.S. law.

In response to strong concerns conveyed by the United States and transatlantic stakeholders about needless additional costs and trade disruption stemming from this directive, the European Commission in September 2007 proposed to amend the EU Metric Directive to permit an indefinite extension in the use of supplementary units (metric and standard units). The Commission proposal is now before the European Parliament and the Council for adoption in 2008.

EU Directive on Wood Packaging Material (WPM)

The EU's Directive on wood packaging material (WPM) would impose a debarking requirement, in addition to heat treatment fumigation, on WPM from the United States and other countries. This directive could impact tens of billions of dollars of U.S. agricultural and commercial exports to the EU that are shipped on wooden pallets or in wood packaging materials. In response to extensive foreign concern, the EU suspended implementation of this directive in February 2005 and postponed the bark-free requirement until January 1, 2009.

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.

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 EU adopted legislation in May 2006 to regulate the emission of fluorinated gases (f-gases). Two pieces of legislation were adopted – a regulation on f-gases used in stationary applications and the other, a Directive regulating hydrofluorocarbons (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 in them. The second will affect U.S. car and parts manufacturers by phasing-out HFC134a in vehicle air conditioning beginning in 2011 with a complete ban by 2017. The Regulation allows Member States to maintain or introduce stricter protective measures in order to reach Kyoto targets by December 21, 2012. The United States will continue to closely monitor Member States' implementation.

Member State Measures

Austria: Austria became the second EU Member State 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 in 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. A 2007 amendment exempted "mobile applications" (*e.g.*, vehicle air conditioning) from the bans. The ban appears to exempt production of HFCs in Austria for the export market. Even under

the new EU regulation that focuses on containment instead of bans, the Austrian government has indicated it will try to retain its own national HFC bans.

Denmark: Denmark has introduced a general ban, effective January 1, 2006, to January 1, 2011, on the sale, use and import of the fluorinated gases, HFCs, perflourocarbons (PFCs), and sulphur hexafluorides (SF6). These f-gases were already being gradually phased out as of September 2002. As of January 1, 2007, new systems containing more than 10 kilos of f-gases (most air conditioning systems, industrial installations, and cooling systems in supermarkets) were included in the ban. New systems containing less than 150 grams of f-gases (most refrigerators in private households) were already included in the ban, while products for the export market generally are exempt. The European Commission has allowed Denmark to retain its ban on f-gases. The exemption applies until the Kyoto Protocol's first commitment period expires in 2012. In the meantime, a decision will be made in 2009 about a possible revision of EU rules. The Danish government has announced that it will continue its efforts to make the EU introduce rules similar to those that apply in Denmark.

In 2004 Denmark implemented a maximum two percent trans fat acid limit for the total fat content in foods, far below the EU limit. The European Commission decided in March 2007 not to file a case against Denmark, thus accepting the claim that use of trans fat acids entails health risks as a valid legal argument for the tougher Danish requirements.

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 refrigeration 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.

Sweden: On November 23, 2005, Sweden notified the WTO of its intention to ban Deca-BDE effective on January 1, 2007. Under the ban, Deca-BDE may not be placed on the Swedish market or used as a substance or an ingredient in a substance or preparation in concentrations exceeding 0.1 percent by weight. Articles, or flame-protected components thereof, containing Deca-BDE in concentrations exceeding this weight requirement may not be placed on the Swedish market. This prohibition does not apply to motor vehicles or to electrical and electronic equipment. The Swedish Chemicals Inspectorate (Inspectorate) may issue regulations on exceptions to the ban. The Inspectorate may also, until December 31, 2009, grant exceptions to the ban on a case-by-case basis.

The United States and other WTO Members have raised concerns with Sweden. As a result, Sweden agreed to review the ban and consider a complete withdrawal. In March 2007, the European Commission formally adopted an infringement letter against Sweden's partial ban.

GOVERNMENT PROCUREMENT

Since the EU is signatory to the GPA, all of the Member States are also subject to the GPA. This includes Romania and Bulgaria, which became subject to the GPA upon their accession to the EU in January 2007.

In 2004, the EU 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, but some EU Member States still have not implemented it. This Directive requires open, objective bidding procedures, but 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.

While U.S. suppliers participate in EU government procurement, the lack of availability of statistics on public procurements conducted in EU Member States makes it difficult to accurately assess the level of participation.

Member State Measures

Member States have their own national practices regarding government procurement. Some Member States require offsets in defense procurement, defined as a contract condition or undertaking that encourages local development or improves a party's balance of payments accounts, such as the use of domestic content, the licensing of technology, investment, counter-trade, and similar actions or requirements. Not all defense procurement is covered by the GPA. A brief discussion of several 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. In major defense purchases related to national security, most government procurement regulations do not apply, and offset requirements can reach up to 200 percent of the value of the contract. Defense offsets in Austria are linked to political considerations and transparency remains limited.

Czech Republic: U.S. and other foreign companies express great concern about the lack of transparency in the public procurement process. A 2006 law on government procurement that was intended to bring the Czech Republic in line with EU legislation did little to improve procurement transparency. Over 50 percent of all public contracts awarded in 2006 fell under the 6 million Czech koruna threshold and thus were not subject to the transparency requirements of the new law. Of those remaining, the government only offered a third of the contracts to open and competitive tenders. Transparency International Czech Republic notes that while EU membership appears to have had a positive effect on new Member States, the Czech Republic remains near the bottom, 23rd of the 28 EU and Western European countries surveyed in its Corruption Perceptions index.

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 difficult for non-European firms to participate in. Even in the case of competition among European suppliers, French companies are often selected as prime contractors. Nevertheless, U.S. firms have been successful as component and systems suppliers in instances where U.S. products provide capabilities required for interoperability or where the cost of internal development is prohibitive.

Greece: Greece imposes onerous qualification requirements on companies seeking to bid on public procurement tenders. Companies must submit documentation from competent authorities indicating that they have paid taxes, are not in or have not been in bankruptcy, and have paid in full their social security obligations for their employees. All board members and the managing director must submit certifications from competent authorities that they have not engaged in fraud, money laundering, criminal activity, or similar activities. These requirements are especially difficult for U.S. firms because there are no competent authorities that issue these types of certifications in the United States. While companies submitting bids are allowed to submit sworn, notarized, and translated statements from corporate officers, there is considerable confusion among Greek authorities as to how U.S. firms may comply with these requirements. Greece continues to require offsets as a condition for the awarding of defense contracts.

Ireland: Government procurement in Ireland is generally 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 projects. U.S. firms complain that lengthy budgetary decisions delay procurements and that unsuccessful bidders often have difficulty obtaining information regarding the basis of a tender award. Once awarded a contract, companies can experience significant delays in finalizing contracts and commencing work. Successful bidders have also found that tender documentation may not have accurately described the conditions under which the contract is to be performed.

Italy: Procurement authority is widely dispersed with over 22,000 contracting agencies at the national, regional, and local levels (including municipalities, hospitals, and universities). Italy's public procurement sector is noted for its lack of transparency and its corruption, which have created obstacles for some U.S. firms. Laws implemented in the mid-1990s have reduced corruption, but it still exists, especially at the local level.

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 so that only one company can provide the good or service. Since 2003, the Lithuanian government has required offset agreements as a condition for the award of contracts for procurement of military equipment exceeding LTL 5 million (about $1.8 million). While the Lithuanian government purchases most U.S. military equipment using U.S. Government grant money, which precludes offsets, the Lithuanian government has requested offsets for defense purchases that use its own funds. This offset requirement adds an unnecessary level of complexity to exporting military equipment to Lithuania.

Portugal: U.S. firms continue to face stiff competition when bidding against EU firms on public procurements in Portugal. The Portuguese government tends to favor EU firms, even when bids from U.S. firms appear technically superior or lower in price. There is a general lack of transparency in procurement procedures. U.S. firms appear to be more successful when bidding as part of a consortium or via a joint venture entity with Portuguese or other EU firms. Although this trend has held for the past several years, there was a recent success in the defense technology sector, with a U.S. firm securing a contract to provide avionics services to the Ministry of Defense.

Romania: Romania requires offsets as a condition for awarding of defense contracts.

Slovenia: The Slovenian government has indicated that it intends to improve the transparency of its public procurement process. While the Ministry for Public Administration stated that it plans to create an electronic procurement system, its efforts in this area have stalled. U.S. firms continue to express concerns that the public procurement process in Slovenia is nontransparent. Many U.S. bidders report that European firms are favored and usually win contracts in spite of more costly tenders and questionable ability to deliver and service their products. This is a problem across the entire range of public procurement, but it seems most prevalent in telecommunications, medical equipment, and defense procurement.

Spain: U.S. construction companies view Spanish public sector infrastructure projects as effectively closed to them. During the past 10 years, at least two major U.S. construction firms closed their Spanish offices due to insufficient business. This period coincided with strong growth in the Spanish construction sector. Two U.S. construction and engineering firms were interested in the Spanish government's major program to build large desalinization plants. However, after reviewing prospects, the U.S. firms concluded that outside bidders would not be seriously considered and given high bidding costs, they did not compete. Of 10 desalinization plant contracts that have been awarded, all but one was awarded to Spanish firms. Spain's exclusionary procurement policies contrast with those of the United States, where

Spanish companies in several sectors, including construction, have won sizeable contracts at the state and local levels.

United Kingdom (UK): The UK defense market is to an increasing extent defined by the terms of the December 2005 Defence Industrial Strategy (DIS). The document highlights specific sectors and capabilities that the government believes are necessary to retain in the UK; in these areas, procurement will generally be based on partnerships between the Ministry of Defence (MoD) and selected companies. DIS does not preclude partnerships with non-UK companies and U.S. companies with UK operations may be invited by MoD to form partnerships in key programs in the future. Outside of those areas of partnership highlighted in the DIS, defense procurement is to a large extent an open and competitive process. There have been examples of noncompetitive procurements in recent years, however, as well as instances where a U.S. supplier was initially selected, but the decision was subsequently overturned and the contract awarded 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 have 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 for Airbus programs, including 751 million euros spent by the City of Hamburg to create land that Airbus is using for assembly of the A380 "superjumbo" aircraft and 182 million euros spent by French authorities to create the AeroConstellation site, which also contains facilities for the A380. The beneficiary of more than $6 billion in subsidies, the Airbus A380 is the most heavily subsidized aircraft in history. Some 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.

Airbus SAS, the successor to the original Airbus consortium that is owned by the European Aeronautic, Defense, and Space Company (EADS), is now the second largest aerospace company in the world. Accounting for more than half of worldwide deliveries of new large civil aircraft 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 United States-EU agreement that would end subsidies for the development and production of large civil aircraft, the United States submitted a WTO consultation request with respect to the launch aid and other 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 United States-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.

On May 31, 2005, the United States submitted a WTO panel request. The WTO established the panel on July 20, 2005, and panel proceedings are currently ongoing. The United States has consistently noted its willingness to negotiate a new bilateral agreement on large civil aircraft, even while the WTO litigation proceeds, but it has 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 Belgium's three regional governments, subsidizes Belgian manufacturers that supply parts to Airbus. In the fall of 2006, the EU Commissioner for Competition concluded that Belgium's 195 million euro support program exceeded the allowable level of support under EU regulations. The Belgian federal government in June 2007 subsequently reduced its support fund to 150 million euros (of which 40 million euros have not been disbursed to date), but simultaneously, the Flemish Regional government set up a 50 million euro start-up fund for the aviation sector in Flanders. It thus remains unclear how much assistance already paid to the companies for the A350 program, if any, has been reimbursed. The Belgian commitment to the A380 superjumbo was 195 million euros, not all of which was disbursed. Airbus A380 related research and development started in 2001, and costs covered to date have netted orders worth 1.3 billion euros for the A380. Belgium claims that its A380 support was structured in accordance with the 1992 bilateral agreement and covers nonrecurring costs.

France: In addition to the launch aid that the French government provided for the development of the Airbus A380 super jumbo aircraft, France provides aid in the form of reimbursable advances to assist the development by French manufacturers of products such as planes, aircraft engines, helicopters, and on-board equipment by French manufacturers. French appropriations supporting new programs in these areas in 2007 totaled 209.8 million euros, of which 150.5 million euros were committed to the A380. Overall 2007 appropriations, including 44.7 million euros in support of research and development in the aeronautical sector, amount to 258.4 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 an agreement to provide 376 million euros in direct assistance through 2013.

The regional government of Andalucia has channeled an additional 13 million euros in State General Administration regional incentive funds and 17.5 million euros of its own funds into A380 project subsidies. Spain has provided numerous additional grants to Airbus' parent company, EADS.

United Kingdom (UK): UK government support for Airbus has most recently included investment in the Integrated Wing Program, announced in December 2006. The Department for Business, Enterprise, and Regulatory Reform (DBERR) and selected regional development agencies will provide half of the funding for the $68 million program, with the remainder drawn from Airbus and participating suppliers. The Integrated Wing Program is one of twelve key technologies identified in the National Aerospace Technology Strategy (NATS), which largely directs UK government investment in strategic aerospace capabilities.

Government Support for Aircraft Engines

United Kingdom: In February 2001, the UK 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 UK 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 pound "reimbursable advance" without opening a formal investigation into whether the advance constituted illegal state aid (under EU law). According to a European Commission statement, the "advance will be reimbursed by Rolls-Royce

to the UK 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.

Propulsion is another area considered important to the future of the UK aerospace industry, and DBERR has extended support to Rolls-Royce for the development of environmentally friendly engine technologies. This funding is directed through established research funding channels, though the government has provided occasional direct support to Rolls-Royce over the past 5 years.

France: In 2005, the French government owned engine manufacturer, Snecma SA, merged with technology and communications firm Sagem to form the SAFRAN Group. The government supports the SAFRAN SaM146 propulsive engine program with a reimbursable advance of 140 million euros.

Canned Fruit Subsidies

The new EU Common Market Organization (CMO) for fruit and vegetables came into effect on January 1, 2008. Implementing rules, covering fresh and processed products, are designed to encourage the development of Producer Organizations (POs) as the main vehicle for crisis management and market promotion. Although export subsidies have been eliminated, processing aid subsidies are only gradually being phased out in favor of decoupled Single Farm Payments, limited by national envelopes. At the end of a 5 year transitional period, the EU expects to "fully decouple" its support for the sector. Hidden subsidies remain an ongoing concern for the United States. The 1985 U.S.-EU Canned Fruit Agreement attempted to impose some discipline on EU fruit processing subsidies. Despite this agreement, EU growers and producers, particularly in the peach industry, continued to receive a range of assistance payments, including producer aid, market withdrawal subsidies, sugar export rebates, producer organization aid, and regional development assistance. The United States continues to monitor and review EU assistance in this sector, evaluating potential trade distorting effects.

INTELLECTUAL PROPERTY RIGHTS (IPR) PROTECTION

Overview

The EU and its Member States support strong protection for IPR. In the EU-U.S. Action Strategy endorsed at the June 2006 U.S.-EU Summit, the United States and the EU have committed to enforcing IPR in third countries, with each further committing to enforce IPR at its respective border. In addition, the United States and the EU are working together to advance negotiations for an Anticounterfeiting Trade Agreement (ACTA), intended to set leadership standards for enforcement and international cooperation in the fight against IPR counterfeiting and piracy.

In 2006, the European Commission issued communications on strengthening the criminal law framework to combat IP infringement, and a renewed effort to introduce a community patent. Efforts to create a community patent appear to be stalled for the moment.

The United States has raised certain concerns regarding the IPR practices of the EU and its Member States, both through the U.S. Special 301 process and through WTO dispute settlement procedures. The United States continues to be engaged with the EU and individual Member States on these matters. Examples of concerns with respect to EU Member States are described below, and notably include the problem of pirated merchandise being shipped to and sold in Czech border markets.

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 to serve as 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 rights holders to defend their IPR. Member States were supposed to have implemented the Directive by April 2006.

Patents

Despite the fact that patent filing costs have decreased in the EU, patent filing and maintenance fees in the EU and its Member States remain significantly higher than in other countries. Fees associated with the filing, issuance, and maintenance of a patent over its life far exceed those in the United States.

In some countries, such as Portugal and Hungary, generic copies of medicines that are still under patent are allowed on the market by the Ministries of Health.

Data Exclusivity

In some of the new Member States in particular, there is a need to improve protection for undisclosed data submitted to obtain marketing approval for pharmaceutical and agricultural chemical products. Article 39.3 of the 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. However, Hungary has not yet implemented in full the EU regime for data protection.

Poland: Concerns remain over delays in full implementation of the EU data protection regime. In addition, no concrete actions have been taken to ensure against the market approval of drugs that may infringe valid patents.

Patenting of Biotechnological Inventions

A 1998 EU Directive (98/44) on the legal protection of biotechnological inventions harmonizes EU Member State rules on patent protection for biotechnological 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.

Geographical Indications (GIs)

The United States has long had concerns about the EU's system for the protection of GIs, reflected in Community Regulation 1493/99 for wines and spirits and in Regulation 2081/92 for certain other agricultural products and foodstuffs, which raise questions with respect to what is required under the TRIPS Agreement.

In a WTO dispute launched by the United States, a WTO Panel found that the EU regulation on food-related GIs was inconsistent with EU obligations under the TRIPS Agreement and the General Agreement on Tariffs and Trade (GATT) of 1994. In its report, the Panel determined that the EU regulation impermissibly discriminated against non-EU products and persons, and agreed with the United States that the EU could not create broad exceptions to trademark rights guaranteed by the TRIPS Agreement. The Panel's report was adopted by the WTO Dispute Settlement Body (DSB) on April 20, 2005. In response to the DSB's recommendations and rulings, the EC published an amended GI regulation in April 2006.

The United States continues to have some concerns about this amended regulation and is carefully monitoring its application. In addition, as it appears that the amended regulation is serving as a model for GI regulations for wines and spirits, which have not yet been amended to incorporate national treatment obligations, the United States will be carefully monitoring developments in this respect as well.

Member State Measures

Belgium: While Belgium transposed the EU Copyright Directive into national law in May 2005, it failed to meet the April 2006 deadline to implement the EU Enforcement Directive. Belgium finally implemented EU Regulation 1383/2003 concerning customs actions against goods suspected of infringing certain IPRs on October 1, 2007. Digital video discs (DVDs) that are pirated in Belgium and imports of DVDs intended for sale in other EU Member States are a growing problem in Belgium. In addition, according to the Belgian Antipiracy Foundation (BAF) some 250,000 illegal downloads of DVDs occur daily in Belgium. Illegal copies on video home system (VHS), compact disc recordable (CD-R), and digital video disc recordable (DVD-R) media are distributed by specialty stores (10 percent), retail outlets (10 percent), and local and international Internet sites (80 percent). The recording industry estimates that 85 percent of blank compact discs (CDs) and other digital media storage devices 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. Belgium's 1994 Copyright Law provides deterrent penalties for piracy, but legal procedures are cumbersome and the court system is overburdened. Obtaining a judicial restraining order against Internet piracy, for example, takes 2 to 3 months, and judges demand proof of damages to assign more than token fines. However, the country's first-ever prison sentence for copyright piracy was imposed in April 2006, and Belgium was the first of the EU-15 to ratify the WIPO Copyright Treaty and the WIPO Performance and Phonograms Treaty (referred to jointly as the WIPO Internet Treaties) in May 2006.

Bulgaria: Despite the improved coordination by a strong interagency IPR council, enforcement remains a concern. Optical disc (OD) piracy rates have flattened, while Internet piracy is on the rise, with the piracy rate of copyrighted material on the web at over 90 percent. On a positive note, the business software industry for the first time in the last 4 years reported a 2 percent drop in piracy rates down to 69 percent, which nevertheless remains among the highest in the EU. End-user software piracy, especially among small and medium sized businesses, remains an obstacle to the software industry.

Cyprus: According to industry sources, the level of DVD and CD piracy in Cyprus continues at roughly 50 percent. Software piracy, largely fueled by small personal computer assembly and sale operations, has declined to 53 percent but is still significantly above the European average. Internet piracy is a growing concern.

Czech Republic: The Czech Republic is the source of significant and ongoing problems with piracy and counterfeiting in open-air markets along the Czech border. Although the Czech Parliament added new amendments to the Copyright Law and the Law on Consumer Protection in 2006 granting the Customs Office greater authority to seize pirated and counterfeit products, this has had little effect on copyright and trademark infringement at the border markets. The level of piracy and counterfeiting is rising, according to IPR watchdog groups, especially those from the recording and manufacturing industries. Problems in court proceedings persist. Court cases, including IPR related cases, can often stretch to 5 years on average, and even then the current system for the calculation and collection of damages favor defendants, according to legal experts who work in the field.

France: In order to strengthen French policy on illegal downloading of music and movies, President Sarkozy appointed a committee composed of entertainment producers, copyright holders, and Internet access providers to present a series of proposals to prevent piracy and to stimulate the growth of a legal

digital music and movie market. On October 16, 2007, the French Parliament approved a bill on counterfeiting, which transposes into French law the April 29, 2004, EU Directive on the enforcement of IPR. Also during 2007, the government issued an implementing decree regarding the interoperability articles of the French Digital Copyright Law of August 2006. The decree established a Technical Measures Regulation Authority (TMRA), which will decide on issues of interoperability of digital rights management (DRM) systems, as well as rights to copy original works for private use. The United States believes that the law and decree create an uncertain environment for proprietary DRM systems in France and set a troubling precedent for government-mandated interoperability. The United States also remains concerned about a second pending decree implementing Article 15 of the Digital Copyright Law. The decree could impose source code disclosure obligations on technical protection measures and security software providers who make their products available in France. The United States continues to engage France on this issue.

Germany: Non-retail outlets (Internet, print media, mail order, and open-air markets) are the primary distribution channels for pirated goods in Germany. Pirated videos, video compact discs (VCDs), and DVDs are sold primarily by residential mail-order dealers who offer the products via the Internet or through newspaper advertisements, or directly sell them in open-air 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 broad exception. 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 downloaded music and videos from the Internet and then distributed burned CDs or DVDs. The government in July 2003 enacted amendments to the German Copyright Act intended to bring it in line with the EU Copyright/"Information Society" Directive. Additional amendments to the copyright law were passed by Parliament in 2007. U.S. publishers have expressed a concern that these amendments may result in insufficient protections for copyrighted works, particularly those in digital format. The United States continues to engage the German government on the issue.

Greece: Although protection of IPR in Greece is better than it was during the last decade, violations, particularly in copyrighted audio-visual products, software and apparel, and footwear continue to raise concerns. Despite the existence of adequate IPR legislation, a lack of emphasis on training with respect to IPR issues has led to widespread tolerance of piracy, including in the judiciary. This tolerance has meant that enforcement is not as aggressive as it might be, and penalties for violators are usually not enforced at deterrent levels. The United States has encouraged Greece to raise enforcement levels and educate the judiciary on IPR matters to discourage this trend.

Italy: Italy's antipiracy laws, which also address Internet piracy, are among the toughest in Europe. However, Italy possesses one of the highest overall piracy rates in Western Europe due to a lack of adequate enforcement efforts. Street vendors continue to openly sell pirated and counterfeited goods. Italian judges rarely hand down meaningful jail sentences for cases of IPR infringement, which gravely diminishes Italy's efforts to combat piracy effectively. Leaders in industry, government, and academia agree that a change in public perception of the seriousness of IPR crimes is a prerequisite for improved IPR protection in Italy.

Lithuania: Estimates of piracy levels of optical media, software, and motion pictures in Lithuania vary. The situation appears to be improving, however. Lithuania adopted legislation in 2006 that harmonizes Lithuania's laws with EU regulations, which strengthened IPR protection by increasing penalties and making it easier for prosecutors to present necessary evidence. The government has demonstrated the political will to enforce IPR protections in specific cases and continues to seize pirated goods when identified at the border or in the territory of Lithuania. The government made progress in early 2007 by

closing down a number of Internet pirate websites. In September 2007, the government of Lithuania instituted a resolution guided by Directive 2000/31/EC that regulates the procedures for eliminating the possibility of access to unlawfully obtained, created, amended, or utilized information and establishes criteria for when the service provider shall be deemed to be aware of unlawful activity on the part of a service recipient or of the fact that information provided by a service recipient has been unlawfully obtained, created, amended, or utilized.

Poland: As border enforcement continues to strengthen, Internet piracy of movies and music is becoming a more serious problem. According to an antipiracy group, the Polish court system remains overburdened, with nearly 5,000 pending IPR protection cases. Cases in large cities may not be prosecuted for several years.

Romania: Although authorities have made gradual improvements, the rates of copyright piracy remained high in Romania in 2007: 70 percent in business software, 89 percent in entertainment software, and 65 percent in records and music. However, levels of DVD and videocassette piracy are falling and most of the blatant retail piracy has been eliminated. Romania has established a dedicated IPR prosecutor in the General Prosecutor's Office (GPO). However, few IPR cases are prosecuted.

Spain: Copyright infringement remains a serious problem, with illegal Internet downloads growing rapidly in scale. Content provider companies say that Internet service providers (ISPs) resist their requests to deny access to their networks to websites illegally trafficking in copyrighted material and to shut down service to persons uploading or downloading large quantities of copyright protected material. The United States pursued an intensified dialogue with Spain on these matters in 2007, with a particular focus on Internet piracy. The status of pharmaceutical patent protection is weaker in Spain than in many other places in Europe, by virtue of the fact that, under the terms of Spain's accession to the EU, Spain was not required to recognize pharmaceutical product claims that had been made in European patent applications prior to October 7, 1992. Consequently, a number of pharmaceutical products whose patents predate 1992 are subject only to relatively weaker process patent protection.

Sweden: Internet piracy is a significant problem in Sweden, and the government's enforcement efforts have not been effective. During 2007, the government took several potentially helpful steps to address the problem, but the incidence of piracy had not declined as of early 2008.

A May 2006 police raid of Pirate Bay, the world's largest Bit Torrent tracker and a major worldwide facilitator of illegal Internet trade in copyright-protected digital content, sent shockwaves through the international file-sharing community, but Pirate Bay was back in operation within a few days. Even though the Pirate Bay tracker site is no longer located in Sweden, other parts of Pirate Bay's operations appear to be running on servers in Sweden. Sweden also remains host to a large number of the world's piracy "top sites" and possibly to the largest number of DC++ file-sharing hubs and users. An estimated one million Swedes, out of a total population of 9 million, are said to have engaged in illegal file sharing.

Sweden's government has repeatedly signaled to police and prosecutors over the past year that it wants them to step up antipiracy efforts. Following an 18 month investigation, the government initiated the prosecution of four key Pirate Bay figures in January 2008. The trial is expected to begin before the summer. To discourage illegal file sharing, the government has also urged content providers to provide legal alternatives for the delivery of content over the Internet. This recommendation was embraced in 2007 by the high profile Renfors Commission. The Renfors Commission also notably recommended that ISPs be given the right and the obligation to cancel service to users who have repeatedly conducted copyright infringing activities over a network. The rights holder community praised the Renfors report, which was circulated for public comment near the end of 2007.

In July 2007, the government of Sweden presented a proposal for the implementation of the EU Enforcement Directive. The government proposal includes a provision that would give courts the authority to order ISPs to give rights holders pursuing civil claims information about the identity of persons that commit copyright infringement on the Internet. The enforcement legislation was still under government review in early 2008. The government has stated that it intends to send a bill to parliament before the summer.

SERVICES BARRIERS

Concerns Related to EU Enlargement

On May 28, 2004, the European Commission notified Members of the WTO 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 EU of Austria, Finland, and Sweden, and the 2004 accession of Cyprus, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia. As a result of this proposed consolidation, a number of 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.

Following GATS rules, which allow a Member to reduce or withdraw commitments provided that they negotiate offsetting compensation to maintain the overall level of market access, the United States worked closely with Brazil, Hong Kong, Japan, Canada, and 12 other WTO Members to negotiate a compensation package with the European Union. Negotiations were successfully completed on September 25, 2006. The agreed compensation package contains new and enhanced commitments in several other services sectors, including public utilities, engineering, computer, advertising, and financial services. The European Commission appears to be having difficulty gaining the approval of Member States for these commitments, however.

Television Broadcasting and Audiovisual Services

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 Member States that acceded to the EU in May 2004 and January 2007, have enacted legislation to implement the Broadcast Directive. The United States has sought 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.

Member State Measures

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

France: France continues to apply the EU Broadcast Directive restrictively. France's implementing legislation, which was approved by the European Commission in 1992, specifies percentages of European programming (60 percent) and of French programming (40 percent) that exceed 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 restrictions pose a significant barrier to U.S. programs in the French market. In addition, the United States continues to be concerned

that radio broadcast quotas that have been in effect since 1996 (specifying that 40 percent of songs on almost all French private and public radio stations must be Francophone) limit broadcasts of American music.

In addition to the broadcasting quotas, cinemas must reserve 5 weeks per quarter for the exhibition of French feature films, or 4 weeks per quarter for theaters that include a French short-subject film during 6 weeks of the preceding quarter. Operators of multiplexes may not screen any one film with more than two prints, or through interlocking, in such a way as to account for more than 30 percent of the multiplex's weekly shows. Theatrically released feature films are not allowed to advertise on television.

Italy: Legislation approved in 1998 that made 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 requires all multiplex movie theaters of more than 1,300 seats to reserve 15 percent to 20 percent of their seats, distributed over no fewer than three screens, for the showing of EU films. In May 2004, Italy enacted controversial media reform through the "Gasparri Law," under which the media/communications market is considered one sector. Under this law, no single operator may receive more than 20 percent of the sector's total revenues. In addition, the law provides for the gradual privatization of RAI, the state-owned radio and television broadcasting conglomerate.

Spain: For every 3 days that a film from a non-EU country is screened – in its original language or dubbed into one of Spain's languages – one EU film must be shown. This ratio is reduced to 4 to 1 if the cinema screens a film in an official language of Spain and keeps showing the film during all sessions of the day in that language.

Postal and other Delivery Services

U.S. express delivery service suppliers have in the past expressed concern that postal monopolies in many EU Member States restrict their market access and create unfair conditions of competition. On October 1, 2007, EU Transport Ministers approved a plan to liberalize postal services by 2011. Eleven Member States (Cyprus, Czech Republic, Greece, Hungary, Latvia, Lithuania, Luxembourg, Malta, Poland, Romania, and Slovakia) were permitted to delay opening of their postal markets until 2013, however. Member States opening their postal markets on time can delay market access by entities from late Member States until 2013.

Member State Measures

Belgium: While the Belgian Post has taken some modest steps in recent years to liberalize, industry competitors continue to express concerns about market access. The Belgian postal regulator, BIPT, appears to lack a mandate to ensure competition and to prevent abuse of the dominant position of the historic postal operator, and it continues to define postal services more broadly than does current EU legislation. A January 2006 law introduced a new licensing regime as well as a compensation fund for universal service. The licensing regime would provide revenue to the Belgian Post if liberalization proved unprofitable due to its universal service obligation. Under the current legal framework, private express delivery operators appear to be covered by the licensing regime as well as by the obligation to contribute to a compensation fund for universal postal service. Belgian and foreign express delivery operators continue to argue that they should be excluded from the scope of the universal service obligation because their services are clearly distinct from conventional postal services by virtue of their value added characteristics.

Germany: In February 2005, the Federal Regulatory Agency (Bundesnetzagentur) took action against Deutsche Post AG (DPAG) in response to complaints from competitors. The regulator's ruling forbids DPAG from hindering or discriminating against rival small- and medium-sized providers of mail preparation services, especially those collecting and presorting letters and feeding mail items weighing less than 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. In September 2007, the European Commission opened a formal investigation against Germany to assess whether DPAG was overcompensated for carrying out its universal service obligation, in addition to the aid already found to be incompatible in a previous Commission decision.

Professional Services

Professions are licensed at the Member State level. Member states maintain nationality and other country level requirements that impede professional mobility or market access by foreign service providers.

Legal Services:

Austria, Cyprus, Greece, Hungary, Lithuania, Malta, and Slovakia require EU nationality for full admission to the bar, which is necessary for the practice of EU and Member State law. Belgium and Finland require EU nationality for legal representation services.

Austria: U.S. nationals cannot represent clients before Austrian courts and authorities, and cannot establish a commercial presence in Austria. Informal cooperation with Austrian partners is possible, however.

Czech Republic: U.S.-educated lawyers may register with the Czech Bar and take an equivalency exam, but they are limited to practicing home country (U.S.) law and international law. To represent clients in Czech courts, U.S. lawyers must first undergo a 3 year legal traineeship and pass the Czech bar exam. U.S. firms are allowed to cooperate with local firms and lend them their name; as a result, firms that operate in the country do so as independent Czech branches. These firms may employ U.S. attorneys that are attached to the staffs as "advisors."

Finland: Citizens of countries outside the European Economic Area (EEA) can practice domestic and international law and represent clients in court, but they are not entitled to the title of Asianajaja (Attorney at Law). Only a Finn or an EEA citizen who meets certain requirements may be accepted as an Asianajaja. In addition to conferring prestige, the Asianajaja designation helps in the solicitation of clients, because Asianajaja may be held accountable for their actions by the Board of the Bar Association and by the Chancellor of Justice, while other lawyers and legal advisers are not subject to such oversight.

France: New law firms entering the French legal services market must apply for a license from the French Bar. In practice, many U.S. firms register with the French authorities as a branch of an existing EU-registered partnership.

Hungary: U.S. lawyers may provide legal services only under a "cooperation agreement" in partnership with a Hungarian legal firm.

Ireland: In general, lawyers holding degrees from non-Irish law schools 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 5 years experience required in Pennsylvania), or New Zealand; or 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. The law enabled 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 was composed exclusively of Italian and EU lawyers. U.S. lawyers working in Italy are usually members of international partnerships, related to their parent companies (U.S. law firms), and are not licensed to practice Italian law.

Slovakia: Slovak law requires lawyers holding credentials from, and law firms registered in, non-EU countries to register with the Slovak Bar Association to practice home country and international law in Slovakia. In the past several years, however, no U.S. attorneys have been able to register. The United States is concerned that the Slovak Bar has consistently tried to limit foreign lawyers' ability to practice law in Slovakia based on their interpretation of the Slovak Advocacy Act.

Accounting and Auditing Services:

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. The Decree also prohibited auditing firms from doing multiple tasks for a client, thus raising the cost of audit work. While the restrictions in the 1997 Decree apply equally to Greek and foreign accountants, the restrictions are especially burdensome to U.S. and other foreign accounting firms because they make it difficult for those firms to take full advantage of the capabilities of their staffs and the diversity of their practice areas.

Architectural Services:

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: Foreign service providers have requested that Poland treat independent legal persons as a single taxable person (*i.e.*, VAT grouping) as allowed by the EU VAT Directive. VAT grouping is already employed by the United Kingdom, the Netherlands, Ireland, Germany, Austria, Denmark, Finland, Sweden, Romania, Belgium, and Hungary. Spain and the Czech Republic also will be introducing VAT grouping soon. VAT grouping would allow financial service providers to recover VAT charges they incur when making intracompany 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. All EU Member States made commitments in the WTO 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. Implementation of these requirements has been uneven across

Member States, however, and significant problems remain in many markets, 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 cause difficulties for new entrants.

In November 2007, the European Commission issued a major package of proposed revisions to the existing regulatory framework for electronic communications, following a review which began in December 2005. Key proposals included the creation of an EU-wide regulatory authority, explicit affirmation of functional separation of provider networks and services divisions as a National Regulatory Authority (NRA) remedy, a reduction in the number of markets subject to *ex-ante* regulation, reform of spectrum management, strengthening of consumer rights and data protection, and the extension of Commission veto powers over NRA remedies. The proposals generated immediate controversy, however, with a number of Member States and members of Parliament opposed to the creation of an EU-wide authority and to the functional separation plans. The proposals are under discussion in the Parliament and in the Council. While all parties seek to conclude action on the proposals by early 2009, their contentious nature may produce significant modifications before final adoption at the EU level. The Commission hopes for Member State transposition into national legislation during 2010.

Member State Measures

Enforcement of existing legislation by 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 EU directives. Implementation of the new regulatory framework is also well advanced. The incumbent, Telekom Austria, offers fixed line networks, mobile telephony, and Internet access, including broadband. It is the market leader in all of these areas, although its share of the national telephony market has dropped to about 60 percent in recent years, as new entrants have entered the market. Per capita mobile phone penetration has reached more than 110 percent, since some individuals have more than one mobile phone. Recent takeovers have led to increased concentration in the mobile phone sector, however, the number of mobile providers dropped from six in early 2006 to four operators in 2007. Consumer prices for fixed line voice telephony, mobile communication, and broadband have declined, but pricing is nontransparent. The two biggest operators account for more than 70 percent of the market.

Finland: Finland has one of the most mature mobile markets in Europe, with the overall penetration rate at 107.6 in 2006. Fierce competition and a tough regulatory environment have created a difficult market for mobile operators. Mobile call charges in Finland continue to be the cheapest in Western Europe (the 15 EU Member States, Iceland, Norway, and Switzerland), although rates in Finland rose by 12 percent between March 2006 and March 2007. The merger of Telia and Sonera in 2002 reduced the number of competitors, since Telia in consequence relinquished its Finnish mobile business, and Tele2 also withdrew in late 2005.

Finnish mobile phone operators have systematically been appealing the significant market power decisions of the Finnish NRA. Several recent cases (*e.g.*, Elisa and Sonera), appeals for which have taken as long as three to 5 years, underscore the high degree of regulatory uncertainty that operators currently face.

France: New entrants into the French telecommunications market face stiff competition and negotiating access can be problematic. A French court of appeals fined France Telecom 80 million euros in July 2006 after finding that the company had abused its position as France's dominant telecommunications operator by blocking access for rival asymmetric digital subscriber line Internet operators to its network between 1999 and 2002. The French Conseil de la Concurrence (Competition Council) had previously fined Orange, SFR, and Bouygues Telecom a total of $640 million – the largest fine ever levied in France – for having exchanged information between 1997 and 2003 designed to deter competition.

Germany: Germany has made slow progress in introducing competition to some sectors of its telecommunications market. New entrants report they 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, the passage of the Telecommunications Act in 2003 and subsequent amendments have led to an increase in competition in the German market, enabling competitors to gain more than 20 percent of the local calling market.

In 2006, the German government amended the Telecommunications Act to boost customer protection rules, including more transparent pricing and billing, and to introduce liability limitations for service providers. Section 9a of the amended Telecommunications Act, which took effect in February 2007, authorizes the granting of "regulatory holidays" for services in new markets. DT lobbied hard for such an exemption. Competitors complain that the exemption will shield DT from regulation as it installs a lucrative fiber optic network in order to provide triple play services (digital telephone, television, and Internet services). Since DT lacks a significant competitor capable of making a similar offering, this provision risks creating a *de facto* monopoly for services that do not meet the criteria of a "new market." The United States has raised concerns on this issue with the German government. In addition, the European Commission initiated infringement proceedings immediately after Section 9a entered into force.

One U.S. trade association representing competitive telecommunications carriers has complained that there have been long delays in obtaining access to and use of unbundled DT network elements, such as IP and ATM bitstream access. This association also reports that DT has not yet begun to deliver high capacity trunk lines and lower capacity end user links, despite a mandate from Germany's national regulatory agency to do so.

Luxembourg: In 2005, Luxembourg began revising administrative procedures to implement the EU Framework Directive to liberalize Member States' telecommunications markets and allow for fairer competition. Despite these efforts, the state owned Post and Telecommunication Company (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 three companies, one of which, market leading LUXGSM, is 85 percent owned by the P&T.

Poland: Poland's telecommunications market has continued to liberalize. In February 2007, Poland's Electronic Communications Office (UKE) fined Telekomunicja Polska (TPSA), the former state operator and currently Poland's largest telecommunications group, a record 339 million zloty ($136 million) for hindering competition. TPSA, which is now owned 47.5 percent by France Telecom, has appealed the fine and pressed UKE to allow higher prices for landline subscriptions. While UKE has generally been successful in increasing competition and lowering prices, the costs of long-distance and international calls in Poland are still among the highest in the EU. Overall, Poland's telecommunications market has showed signs of maturation, including higher market penetration (approximately 120 percent for cell phones), industry consolidation, slower growth, and less room for new competitors. In provincial towns and villages, one of the few remaining unsaturated telecommunications markets in Poland, some U.S.

companies have complained that requirements on general tenders are prewritten in favor of TPSA, and they are unable to compete.

Energy Market Access

Cyprus: The government of Cyprus expects the European Commission to soon conclude that Cyprus qualifies under Articles 22 and 28 of EU Directive 2003/55/EC as a developing and protected market for natural gas. This designation will likely reinforce the dominant position of the Electricity Authority of Cyprus (EAC), a semi-governmental power supplier that in many respects remains a monopoly. In collaboration with the EAC, the government has established a new Public Company for Natural Gas (PCNG), giving it a monopoly on the importation of natural gas for the 10 year to 12 year period permitted under the EU Directive. The government of Cyprus will own 51 percent of the PCNG, the EAC 39 percent, and private parties only 10 percent. The EAC earlier decided to participate in the PCNG and in the construction and operation of a land-based liquid natural gas unit (an immediate and urgent need for the Cyprus energy market) based on the presumption that the country's natural gas market would be declared an emerging one and that the PCNG would be given authority to set gas prices. The EAC's influence, through the PCNG, over natural gas prices and power distribution could adversely affect foreign power suppliers.

INVESTMENT BARRIERS

Overview

The European Commission shares competence on investment issues with Member States. 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 State barriers remain in place, in some cases in apparent contravention of EU law. 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 a particular 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 the company's ultimate ownership. As discussed below, however, EU law imposes some restrictions on U.S. and other foreign investments, and other restrictions have been proposed.

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. The right to provide maritime transport services within certain EU Member States is currently 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.

After years of discussion, the Council of Ministers finally agreed in March 2004 on a directive on takeover bids (Takeover Directive). The original proposal would have banned any national legislation allowing companies to prevent hostile takeovers through the use of defensive measures (*e.g.*, "poison pills" or multiple voting rights). The final directive makes it optional for Member States and companies to maintain a regime that rules out these defensive measures. 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 EU is a party.

The Takeover Directive was due to be implemented by Member States by May 20, 2006. Implementation has been delayed, however. By February 2007, 17 Member States had transposed the Directive or adopted necessary framework rules. Belgium implemented the directive in April 2007, while Cyprus, the Czech Republic, Estonia, Italy, Poland, and Spain had not yet fully aligned their legislation with the Directive. The Netherlands adopted its implementing law in October 2007. Other Member states have tabled draft legislation.

Under the 1994 hydrocarbons directive (Directive 94/22/EC), an investor may be denied a license to explore for and exploit hydrocarbon resources, if the investor's home country does not permit EU investors to engage in those activities under circumstances "comparable" to those in the EU. These reciprocity provisions thus far have not affected any U.S. owned firms.

On September 19, 2007, the European Commission released two draft directives and three draft regulations designed to promote internal energy market integration and enhance EU energy security. Specifically, the proposals would separate energy production and supply from transmission through the forced unbundling of major EU energy firms; require that energy companies from third countries seeking a significant interest in EU energy networks comply with the same requirements (*e.g.*, vertically integrated firms will not be allowed to invest in EU grids); and prevent third country firms from majority ownership or control of transmission lines for gas and electricity networks within the EU. If this package were to be adopted in the form in which it was proposed, it would be the first time that EU-wide restrictions had been imposed upon inward investment by companies from non-EU countries. A proposed savings clause would allow countries with preexisting international agreements with the EU (*e.g.*, WTO or partnership and cooperation agreements) to maintain existing investments in the EU. The draft proposals have proved controversial, and the unbundling clauses have generated opposition from key Member States, including France and Germany. The European Parliament and Council are considering the proposals and may act on them during 2008.

EU institutions and individual Member States separately are reviewing growing investments by sovereign wealth funds (SWFs) and other assets owned or controlled by governments. The Commission has begun considering the establishment of an investment review process that would focus on specific, "strategic" sectors, such as energy, but no formal proposals have yet been made. As of early 2008, the Commission had not yet determined whether EU-level action with respect to SWFs was either necessary or appropriate.

The United States and EU formally established a bilateral Investment Dialogue in November 2007. The dialogue will initially focus on three areas of work: cooperation on promoting open investment climates; discussion of laws, policies, and practices that could adversely impact investment flows in the EU and the

United States; and reviewing recent trends in global investment flows and exploring joint effort to reduce global investment barriers.

Member State Measures

Austria: While 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 a non-EEA bank has already obtained a license for the operation of a subsidiary in another EEA country, it does not need a license to establish branch offices in Austria.

Bulgaria: Local companies in which foreign partners have controlling interests must obtain licenses to engage in certain activities, including production and export of arms/ammunition; banking and insurance; exploration, development, and exploitation of natural resources; and acquisition of property in certain geographic areas. On February 23, 2007, the United States and Bulgaria signed the Treaty on Avoidance of Double Taxation, but a protocol to the agreement must be negotiated before the package can be submitted to the U.S. Senate for advice and consent and ratified by the Bulgarian Parliament.

Cyprus: 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 (not to exceed three donum, or roughly one acre) 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 they are difficult to obtain and are rarely granted. Upon its accession to the EU, Cyprus received a 5 year derogation from the EU *acquis communautaire* on this issue, and the restriction on property acquisition for EU citizens not normally resident in Cyprus will expire in May 2009. The restrictions will continue to apply, however, to non-EU residents, including U.S. nationals.

Tertiary education investment restrictions: Cypriot legislation on 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 nondiscriminatory 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 participate in the administration of local colleges, whether as directors or shareholders.

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.

Construction: Under the Registration and Control of Contractors Laws of 2001 and 2004, the right to register as a construction contractor in Cyprus is reserved for citizens of EU Member States. Non-EU entities are not allowed to own a majority stake in a local construction company. Non-EU natural persons or legal entities may bid on specific construction projects, but only after obtaining a special license from the Council of Ministers.

Professional recognition of real estate agents: The current law licensing real estate agents to practice in Cyprus, last amended in 2007, creates significant barriers to entry into the profession. The law recognizes only licensed individuals (not companies) to act as authorized real estate entities and licenses are only granted to individuals who have served as apprentices to licensed individuals for up to 5 years (recently amended from 8 years). The amended law also fails to address the operation of franchises. Existing real

estate agents are trying to use the law to restrict new entrants in the local real estate market. To obtain a license to practice real estate in Cyprus, an individual must seek approval from the Licensing Board, which is made up of seven members, four of whom are real estate agents.

Professional recognition of medical doctors: As of October 2007, Cyprus complies fully with EU Directive 2005/36, allowing doctors who are either EU citizens or spouses of EU citizens to register to practice medicine in Cyprus. Doctors from non-EU countries can register only in "extreme cases," however.

France: There are generally few screening or prior approval requirements for non-EU foreign investments 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 in which prior approval would be required before acquisition of a controlling equity stake. A December 2005 government Decree (Decree 2005-1739 of 30 December 2005) lists 11 business sectors in which the French Ministry of Economy, Finance, and Industry has the right to monitor and restrict foreign ownership through a system of "prior authorization." In addition, the government implemented the EU Takeover Directive with a March 31, 2006 bill ("*loi du 31 mars 2006 relative aux offres publiques d'acquisition*") that also includes specific measures related to hostile takeovers. Implementing legislation allows companies to resort to a U.S.-style "poison pill" takeover defense, including granting existing shareholders and employees the right to increase their leverage by buying more shares through stock purchase warrants at a discount in case of an unwanted takeover. The government has also asked the state-owned financial institution, *Caisse de Depots et Consignations*, France's largest institutional investor, to work as a domestic buffer against foreign takeovers by increasing its stake in French companies. The French government has thus demonstrated an inclination in certain sectors to intervene in potential transnational mergers and to otherwise signal an interest in defending French private "champions" from foreign takeover attempts. The Finance Ministry becomes involved in mergers and acquisitions when the government uses its "golden share" in state owned firms to protect national interests.

Germany: Germany's 2002 takeover law was marginally changed by the implementation of the EU Takeover Directive. Germany made use of its "opt-out" right and retained measures that allow firms to ward off hostile takeover bids, first at the shareholder level, where management may be given authority at annual shareholder meetings to take necessary measures to guard against unwanted takeover interest; and, second, at the management level, where the managing board may take protective measures upon approval by the supervisory board, bypassing the need for shareholder approval altogether. The EU directive offers companies the choice either to abide by the German law or to "opt-in" to the EU regulation. Companies using the "opt-in" may limit their waiver of Germany's protective measures to companies that also have no measures in place to fend off hostile takeover bids.

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 1 month of receipt of a notification. The German government expanded the scope of the law in 2005 to include tank and tracked vehicle engines.

The Ministry of Economics is drafting a legislative proposal for a national security based review mechanism for foreign investments. Parliament may consider legislation enacting the proposal in early 2008.

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.

Prospective non-EU investors in Greece's mining, maritime, air transport, broadcast, and banking sectors are required to obtain licenses and other approvals that are not required of Greek or EU investors. In the mining industry, for example, non-EU investors need special approval from the Greek cabinet for the use and exploitation of mines. An additional approval from the Ministry of Defense is required for purchases by foreign investors of land in border areas and on certain islands. In the banking sector, non-EU banks are subject to a special minimum capital requirement. EU banks established in other EU countries (or a U.S. bank with a subsidiary in the EU) are not subject to this requirement.

Italy: On September 13, 2007, the government of Italy approved a legislative decree incorporating the EU Takeover Directive into Italian law. The decree was passed by parliament in November and went into force in December. The new regulation will require the target of a hostile takeover or merger bid to obtain authorization from shareholders before undertaking defensive measures. It also includes a "break-through rule" on the most common pre-bid defensive tactics (*i.e.*, shareholder voting agreements). The new regulation is aimed at protecting minority stockholders and permitting Italian companies to defend themselves from takeover attempts by companies from countries whose merger and acquisitions laws do not provide similar protection for shareholders.

Lithuania: Some foreign investors, including U.S. citizens, report difficulties in obtaining and renewing residency permits. U.S. citizens can stay in Lithuania no more than 90 days without a visa (and no more than 180 days total per calendar year). Those who stay longer face fines and deportation. The current residency permit process is not user-friendly. In principle, Lithuanian embassies abroad are able to initiate the application process for residency permits. In practice, U.S. citizens are only able to begin the residency permit process upon arrival in Lithuania. Decisions by the Migration Office regarding the issuance of residency permits may take up to 6 months.

Non-Lithuanians are generally not able to buy agricultural or forestry land. As part of its EU accession agreement, however, the Lithuanian Government must eliminate this restriction by 2011.

Romania: Uncertainty and lack of predictability in Romania's legal and regulatory system pose a continuing impediment to foreign investors. Tax laws change frequently. Tort cases often require lengthy, expensive procedures, and judges' rulings often do not follow precedent.

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 their domestic law or of the international commitments they have 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 (http://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 or deceptive practice under Section V of the FTC Act or, for air carriers and ticket agents, under a concurrent Department of Transportation statute.

The United States actively supports the Safe Harbor framework and encourages the EU 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, the United States expects the EU and Member States to fulfill their commitment to inform the United States 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

Healthcare

Ireland: U.S. healthcare firms have faced difficulties entering Ireland's hybrid public-private health system. To generate sufficient revenues to justify investments in Irish hospitals and equipment, U.S. firms usually seek to treat both private and public patients. The treatment of public patients, however, requires a Service Level Agreement from the Health Service Executive (HSE), the administrative agency that oversees Ireland's hospital system. U.S. firms report difficulties in securing such an agreement from the HSE.

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 quasigovernmental 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.