Extracts of three 2013 USTR Reports

2013 NATIONAL TRADE ESTIMATE REPORT ON FOREIGN TRADE BARRIERS

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2013 REPORT ON SANITARY AND PHYTOSANITARY MEASURES

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2013 REPORT ON TECHNICAL BARRIERS TO TRADE

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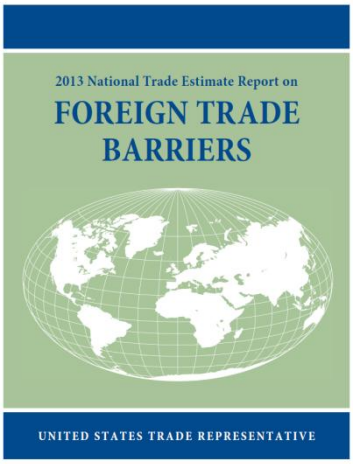


EUROPEAN UNION

TRADE SUMMARY

The U.S. goods trade deficit with the European Union was $115.7 billion in 2012, up $15.8 billion from 2011. U.S. goods exports in 2012 were $265.1 billion, down 1.2 percent from the previous year. Corresponding U.S. imports from the European Union were $380.8 billion, up 3.4 percent. European Union countries, together, would rank as the second largest export market for the United States in 2012.

U.S. exports of private commercial services (*i.e.*, excluding military and government) to the European Union were $188.8 billion in 2011 (latest data available), and U.S. imports were $136.8 billion. Sales of services in the European Union by majority U.S.-owned affiliates were $499.0 billion in 2010 (latest data available), while sales of services in the United States by majority European Union-owned firms were $382.2 billion.

The stock of U.S. foreign direct investment (FDI) in the European Union was $2.1 trillion in 2011 (latest data available), up from $1.9 trillion in 2010. U.S. FDI in the European Union is primarily concentrated in the nonbank holding companies, finance/insurance, and manufacturing sectors.

Overview

The United States and the 27 Member States of the European Union (EU) share the largest economic relationship in the world. The enormous volume of trade and investment is a key pillar of prosperity both in the United States and Europe.

Despite the broadly successful character of the U.S.-EU trade and investment relationship, U.S. exporters and investors face chronic barriers to entering, maintaining, or expanding their presence in certain sectors of the EU market. Some of the most significant barriers, which have persisted despite repeated efforts at resolution through bilateral consultations or WTO dispute settlement procedures, have been highlighted in this report for many years. Many are highlighted again in this year's report.

An important recent development was the announcement by President Obama on February 12, 2013 that the Administration intends to initiate domestic procedures to launch negotiations with the EU on a comprehensive trade and investment agreement. This followed more than a year of work by the U.S.-EU High Level Working Group on Jobs and Growth, headed by U.S. Trade Representative Ron Kirk and EU Commissioner for Trade Karel De Gucht. The Working Group concluded that a comprehensive U.S.-EU agreement that addresses a broad range of bilateral trade and investment issues, including regulatory issues, and contributes to the development of global rules would provide significant mutual benefit to both economies.

MARKET ACCESS FOR NON-AGRICULTURAL PRODUCTS

WTO Information Technology Agreement

In September 2010, the WTO Dispute Settlement Body (DSB) adopted the final report of the panel considering the U.S. claim that the EU violated its tariff commitments under the WTO Information Technology Agreement (ITA) by imposing duties as high as 14 percent on flat panel computer monitors, multifunction printers, and certain cable, satellite, and other set-top boxes. For all three products at issue, the panel concluded that the EU tariffs were inconsistent with its obligations. The United States and the EU agreed to a period of nine months and nine days for the EU to comply with the recommendations and rulings of the DSB, ending on June 30, 2011. While the EU took some steps to bring itself into compliance, the United States remains concerned that, notwithstanding the measures the EU has adopted to date, one or more Member State customs authorities may continue to apply duties to the products at issue. The United States is closely monitoring Member State customs decisions in this regard. With EU compliance, the United States expects that U.S. producers of high technology products will continue to be able to export those products to Europe duty free, as required under the ITA.

Pharmaceutical Products

The U.S. pharmaceutical industry has expressed concerns regarding some EU and Member State policies affecting market access for pharmaceutical products, including nontransparent procedures and a lack of meaningful stakeholder input into policies related to pricing and reimbursement, including therapeutic reference pricing and other price controls. The United States is following with interest EU deliberations on steps to increase the availability of pharmaceutical product information to consumers as a means of promoting consumer awareness and access to medicines, and is also following the current discussions on the review of the EU Transparency Directive. The United States continues to engage with the EU and individual Member States on these matters. In recent years, the U.S. pharmaceutical industry has raised concerns about pharmaceutical market access and government pricing and reimbursement systems in Austria, Belgium, the Czech Republic, Finland, France, Germany, Hungary, Lithuania, the Netherlands, Poland, Portugal, Romania, Spain, and the United Kingdom. Additional detail on some of these countries' measures follows.

Member State Measures:

Austria

In 2011, the government of Austria, public health insurers, and the pharmaceutical industry agreed to a "Frame Contract for Reimbursement of Pharmaceuticals." U.S. companies have voiced concern that, despite the new contract, they are forced to accept significant price reductions to compete with generic pharmaceuticals. In addition, U.S. companies have expressed concern that the

reimbursement structure for biosimilars (biologic pharmaceuticals that are similar, but not equivalent to original biologic pharmaceuticals that received regulatory approval) is too low to allow them to enter or remain in the Austrian market.

Belgium

U.S. pharmaceutical companies have expressed concern about the lack of adequate transparency in the development and implementation of government cost-containment measures in Belgium. The United States has encouraged the government of Belgium to ensure that policies affecting the pharmaceutical industry are developed and implemented in a transparent manner, and that industry has opportunities to engage with the relevant authorities to address their concerns and to ensure the continuing development of their already significant investment in the Belgian market.

In 2012, the government proposed to implement an International Price Referencing System for on-patent medicines. The Ministry of Social Affairs, Public Health and Social Integration modified the proposal, in coordination with the U.S. Government and industry, to ensure that pharmaceutical companies would not be treated differently with respect to budgetary cuts than any other group within the medical sector. The Belgian government agreed not to increase the sales tax on pharmaceuticals and to speed up the approval process for new medicines.

Czech Republic

U.S. pharmaceutical companies previously expressed concern about the Czech Republic's system for determining pricing and reimbursement levels for pharmaceutical products, as well as new legislation that went into effect in December 2011 requiring electronic auctions on pharmaceuticals and medical devices and equipment. The government has not fully implemented this legislation, however, and it is expected that only pharmaceuticals based on a few specified molecules will initially be included, should the auctions be carried out in spring 2013. The United States has encouraged the Czech government to ensure that its current pricing and reimbursement system does not unfairly limit the access of innovative pharmaceutical products to the Czech market.

Finland

U.S. innovative pharmaceutical companies report that the Finnish Pharmaceutical Pricing Board has significantly delayed reimbursement for new drugs by the Finnish national health care system. U.S. pharmaceutical companies have reported that it can take two years to four years for a new drug to become eligible for reimbursement, and only after repeated applications. Such delays have a significant impact on consumer purchasing of new drugs in Finland.

The Finnish Pharmaceutical Pricing Board is also pressuring U.S. pharmaceutical companies to lower the prices of their innovative medicines in line with generic drugs of the same therapeutic class. This is concerning, particularly because a generic drug may treat the same disease or symptoms as the innovative drug in the same therapeutic class, but such drugs may be distinct at the molecular level. The Pricing Board has, at times, threatened to stop reimbursement for innovative drugs if the U.S. companies do not drop their prices.

France

France's "Sunshine Act" reform bill, introduced in December 2011, provides stricter disclosure and drug monitoring rules and also created the National Agency for Health Products Safety. This new regulatory authority can conduct post-authorization studies in cases of reported adverse reactions to a drug. It also reviews all advertising of pharmaceuticals. To prevent conflicts of interest, the law

further requires manufacturers to make agreements with healthcare authorities public. The pharmaceutical industry largely supports the reform, with the exception of two provisions: a new industry tax to finance provision of continuing medical information for doctors and a two-year ban on visits by industry sales representatives to individual doctors.

Hungary

Pharmaceutical manufacturers have expressed concern about Hungary's volume and pricing restrictions, high sector-specific taxes, and delays in reimbursement approvals. The United States has encouraged the Hungarian government to review its pricing and reimbursement system to ensure that affected stakeholders have adequate opportunities to engage with relevant authorities to address their concerns. In August 2012, the government introduced new tax obligations for pharmaceutical companies marketing innovative products, and several pharmaceutical manufacturers raised concerns.

Italy

U.S. innovative companies have expressed concern about Italy's recent cost-containment and other measures that negatively impact the Italian pharmaceutical market. Pharmaceutical companies are required to pay back the Italian government when government spending on pharmaceuticals exceeds the budgeted amount. Furthermore, availability of innovative drugs approved by the European Medicine Agency is significantly delayed by the fragmented healthcare administration system. Concerns also exist regarding the ability of pharmaceutical companies to fully exercise their patent rights for the complete patent term. The United States has encouraged the Italian government to open a dialogue with U.S. industry to address these issues. In October 2012, the Italian government approved a law providing for more expeditious marketing approval for innovative drugs. The new law also states that generic medicines can be included in the approved reimbursable drug list only after the patent expiration of the original innovative medicine. However, concern remains regarding the price reimbursement renegotiation system.

Lithuania

The United States continues to engage with the government of Lithuania regarding pharmaceutical market access issues. The Health Ministry began several reform efforts in 2011, inviting representatives of the pharmaceutical industry to discuss various matters, including the addition of certain drugs to the government's reimbursement list and the procurement of additional innovative drugs. Discussions with pharmaceutical industry representatives are ongoing. *Poland:* U.S. pharmaceutical companies continue to report that there is a lack of adequate transparency and meaningful engagement with industry in the development and implementation of cost-containment measures affecting pharmaceutical reimbursement and pricing policies in Poland. The terms of reimbursement agreements have sometimes been modified unilaterally by the government with little advance warning to companies.

According to U.S. pharmaceutical companies, the new law governing reimbursement by the national health system, which entered into force in January 2012, applies therapeutic reference pricing, a methodology which pools both patented, off-patent pharmaceutical, and generic products into just 300 so-called "limit" groups based on therapeutic categories. By assuming that all products used to treat the same condition are interchangeable, this practice erodes the incentives to invest in the development of innovative medicines and may undermine the availability of such medicines.

Companies also report that they have found it difficult to obtain information from the Ministry of Health or to arrange meetings with its officials. The United States has encouraged the government of Poland to ensure that policies affecting the pharmaceutical industry are developed and implemented in a transparent and consistent manner and that U.S. firms are given opportunities to engage with relevant government ministries on issues of concern.

Portugal

The U.S. pharmaceutical industry reports that there continues to be a lack of transparency in the development and implementation of government cost-containment measures. Portuguese Law No. 52/2011, in effect since January 2012, requires that pharmaceutical patent holders submit cases, including evidence, to arbitration within 30 days of notice of intent by a generic drug manufacturer to distribute the generic product. Industry complains that the new mandatory arbitration process is costly and slow, pointing out that not a single case has been resolved by the body as of October 2012. Moreover, the law does not provide for injunctive relief, instead only requires patent violators to reimburse patent holders for any resulting losses.

Romania

Innovative pharmaceutical products face several significant challenges in Romania due to the government's failure to update the lists of compensated pharmaceuticals that are eligible for reimbursement under the national health system (the reimbursement lists). This severely undermines the ability of U.S. pharmaceutical companies to introduce newer drugs in Romania, because the National Health Insurance House will not reimburse those companies for drugs absent from the reimbursement list. The Ministry of Health has not updated the reimbursement list since 2008. Although 80 drugs based on new molecules have been approved by the Ministry of Health for sale in Romania between 2008 and 2012, the government has not approved their inclusion on the reimbursement list. In contrast, generic drugs have benefited from accelerated, quasi-automatic inclusion on the reimbursement lists. As a result of these practices, research-based pharmaceutical companies are unable to effectively recoup their significant investment in safety and efficacy testing data during the period of that data's protection in Romania. International pharmaceutical companies have repeatedly requested the Romanian government to update the reimbursement lists. The U.S. Embassy in Bucharest has raised the issue several times in the last two years in letters and meetings with government officials. Despite public and private statements to the Embassy and diplomatic community that the government is considering updates to the reimbursement list, there has been little indication to date that a revised list will be issued in the near future. U.S. pharmaceutical company representatives estimate the value of potential increased sales of innovative drugs, through imports or local production, as between $25 million and $100 million.

Spain

U.S. pharmaceutical companies remain concerned that Spain's pricing and reimbursement system is unpredictable and lacks transparency. U.S. companies reported that Spanish government reforms enacted during 2010, 2011, and 2012 impacted the value of their patents and created a disincentive to innovation and new investment. The reforms, aimed at reducing the national health system budget, require, in general, that the prescription of medicine must be by active ingredient, rather than by brand, and that pharmacies must dispense the lowest cost drugs available. For drugs that lack generic alternatives, the price will be reduced by 15 percent after a period of 10 years on the market. Following discussions facilitated by the U.S. Embassy in Madrid, U.S. companies reached an agreement with the Spanish government in May 2011. In response to those industry concerns, Spain

agreed that the 15 percent price reduction will not apply to products whose patents are in force in all the EU member states.

The Spanish government approved a comprehensive health care reform package on April 20, 2012, which further reduced industry revenues by requiring prescription of generic drugs, even if innovative drugs are the same price, and lowering the reference prices on certain drugs. The reforms also subjected patented drugs with no generic competitors to reference pricing after 10 years of obtaining the first marketing authorization in the EU. The United States worked with the Spanish government refining the scope of the reform package to ensure continued incentives for innovation in Spain.

Uranium

The United States is concerned that nontransparent EU policies may restrict the import into the EU of enriched uranium, the material from which nuclear power reactor fuel is fabricated. Since 1994, the EU has maintained quantitative restrictions on imports of enriched uranium 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 limit the acquisition of non-EU sources of supply of enriched uranium. The United States has raised concerns about the nontransparent nature of the Corfu Declaration and its application.

MARKET ACCESS FOR AGRICULTURAL AND FOOD PRODUCTS

Bananas

In December 2009, the United States and the EU initialed an agreement designed to lead to a settlement of the longstanding dispute over the EU's discriminatory bananas trading regime. In the agreement, the EU agreed not to reintroduce measures that discriminate among foreign bananas distributors and to maintain a nondiscriminatory, tariff-only regime for the importation of bananas. The U.S.-EU agreement complements a parallel agreement, the Geneva Agreement on Trade in Bananas (GATB), between the EU and several Latin American banana-supplying countries, which provides for staged EU tariff cuts to bring the EU into compliance with its WTO obligations. The United States and the Latin American countries signed their respective agreements with the EU in June 2010.

The agreements marked the beginning of a process that, when completed, will culminate with the settling of all of the various banana disputes and claims against the EU in the WTO. The GATB entered into force on May 1, 2012, and certification by the WTO of the EU's new tariffs on bananas was completed on October 27, 2012. On November 8, 2012, the EU and the Latin American signatories to the GATB announced that they had settled their disputes and claims related to bananas. On January 24, 2013, the U.S.-EU bananas agreement entered into force; the final step called for in the U.S.-EU agreement is settlement of the United States' bananas dispute with the EU, provided certain conditions are met.

Husked Rice Agreement

The United States has ongoing concerns regarding the operation of the U.S.-EU husked rice agreement, which has been in effect since 2005. Under the terms of this bilateral agreement, negotiated as a result of the EU's decision to modify the tariff concessions agreed to in the Uruguay Round, the applied tariff for husked rice imports from the United States is determined by the total quantity of husked rice (excluding Basmati) imported by the EU, and is adjusted every six months.

Discussions on this subject with the European Commission (the Commission) have focused on the annual increase in the import reference volume and the longer-term operation of the tariff adjustment mechanism set out in the agreement. The United States has sought a significant increase in the import reference quantity in the husked rice agreement. The longer term U.S. objective is to obtain consistent market access for U.S. brown rice at a tariff well below the WTO-bound tariff of €65 per ton.

Meursing Table Tariff Codes

Many processed food products, such as confectionary products, baked goods, and miscellaneous food preparations, are subject to a special tariff code system in the EU. Under this system, often referred to as the Meursing table, the EU charges a tariff on each imported product based on the product's content of milk protein, milk fat, starch, and sugar. As a result, products that the United States and other countries might consider equivalent for tariff classification purposes sometimes receive different rates of duty in the EU depending on the particular mix of ingredients in each product. The difficulty of calculating Meursing duties imposes an unnecessary administrative burden on, and creates uncertainty for, exporters, especially those seeking to ship new products to the EU.

Subsidies for Fruit

The 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. The CMO makes payments to producer organizations for dozens of products, including peaches, citrus fruits, and olives. In 2013, after the end of a five-year transitional period, EU support for this sector will be fully decoupled from production decisions. However, hidden subsidies remain an ongoing concern for U.S. producers. The decoupled Single Farm Payments are funded by the European Commission and paid to the Member States, channeled through POs. The United States continues to monitor and review EU assistance in this sector, evaluating potential trade-distorting effects.

EU Enlargement

In December 2006, the United States entered into negotiations with the EU, within the framework of the GATT 1994 provisions relating to the expansion of customs unions, regarding compensation for certain tariff increases related to Romania and Bulgaria's EU accession on January 1, 2007. Upon accession to the EU, Romania and Bulgaria were required to change their tariff schedules to conform to the EU's common external tariff schedule, which resulted in increased tariffs on the importation of certain products, mainly agricultural products. Under GATT Articles XXIV:6 and XXVIII, the United States is entitled to compensation from the EU to offset these tariff increases. In late 2011, the United States concluded negotiation of a bilateral compensation agreement with the EU covering several agricultural products, and the two sides signed the agreement in 2012. The agreement establishes or increases EU tariff-rate quotas allocated to the United States for several agricultural products. The United States and the EU will bring the agreement into force in 2013, once final internal approval processes on each side are completed.

INTELLECTUAL PROPERTY RIGHTS PROTECTION

In 2012, the European Commission continued implementation of its 2011 intellectual property rights (IPR) strategy that includes initiatives on enforcement and copyright, as well as a renewed effort to adopt an EU-wide patent regime. Although 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, including the United States. The IPR strategy also included launching a study into extending geographical indication (GI) protection for products other than agricultural products and food stuffs, which are currently eligible for GI protection in the EU.

The United States continues to have serious concerns with the EU's system for the protection of GIs, including with respect to its negative impact on the protection of trademark and market access for U.S. products that use generic names. The EU adopted its current GI regulation for food products, Council Regulation (EC) 510/06, in response to WTO DSB findings in a case brought by the United States (and a related case brought by Australia) that the EU GI system impermissibly discriminated against non-EU products and persons. The DSB also agreed with the United States that the EU could not create broad exceptions to trademark rights guaranteed by the TRIPS Agreement. The United States continues to have some concerns about this regulation, and intends to monitor carefully both its implementation and current initiatives to modify it. These concerns extend equally to Council Regulation (EC) 479/08, which relates to wines, and to Commission Regulation (EC) 607/09, which relates, *inter alia*, to GIs and traditional terms of wine sector products, the implementation of which the United States is also carefully monitoring.

With respect to copyright protection, the European Commission decided in December 2012 to initiate a two-part copyright program. Under the first part of that program, the Commission will launch a stakeholder dialogue to address key copyright issues in the EU. The Commission will take stock of that dialogue in December 2013. The second part of the program will involve completing market studies, impact assessments, and legal drafting work with a view to a decision in 2014 whether to table legislative reform proposals. The United States welcomes the inclusion of U.S. stakeholders in the Commission-led dialogue and urges that any outcomes of this program fully reflect the value of copyright industries to the EU, transatlantic, and global economies and continue to promote strong copyright protection and enforcement internally and internationally.

On enforcement, actions within the EU on the Anti-Counterfeiting Trade Agreement (ACTA) remain a priority concern for the United States, particularly following the European Parliament's vote to reject the Agreement in July 2012, and the Commission's decision in December 2012 to withdraw its request to the European Court of Justice to review the Agreement's consistency with EU law. These actions stand in contrast to the active participation of the Commission and the Member States in the ACTA negotiations, which concluded in November 2010, and which culminated in the EU and 22 of its Member States signing the ACTA on January 26, 2012.

Member State Measures

The United States continues to have concerns about IPR protection and enforcement in several Member States. The United States actively engages with the relevant authorities in these countries and will continue to monitor the adequacy and effectiveness of IPR protection and enforcement, including through the annual Special 301 review process.

Austria

U.S. copyright holders report that while legal protections are strong in principle, procedural roadblocks prevent copyright holders from blocking online access to pirated works and prevent effective prosecution.

Bulgaria

U.S. industry reports continued IPR concerns, particularly with respect to piracy over the Internet, a poor track record on prosecutions, delays and conflicts of interest in enforcing patent protection, and difficulties obtaining information from Internet service providers (ISPs) in Bulgaria to combat piracy over the Internet. Several companies have reported difficulty when seeking recourse for patent and trademark infringement at the Bulgarian Patent Office. Bulgaria has an established process for administrative rulings and appeals in cases of patent and trademark infringement, but the decisions are not well justified and often appear arbitrary.

U.S. exporters of distilled spirits are negatively impacted by trademark violations and limited enforcement against locally-produced counterfeit products.

Regarding the use of legitimate business software, Microsoft concluded a software licensing agreement with the government of Bulgaria and the Bulgarian Armed Forces in 2012.

Czech Republic

The Czech Republic continues to make progress in increasing enforcement in the approximately 50 open air markets that line the Czech Republic's borders with Germany and Austria. Piracy over the Internet, however, has increased in the Czech Republic. Industry is also concerned that the IPR penalties that have been imposed are not sufficient to deter violations.

Finland

Finland was included in the Watch List in the 2012 Special 301 Report. The key concern cited in the report was the lack of product patent protection for certain pharmaceutical products and a regulatory framework that denied adequate protection for some process patents filed before 1995, and those that were pending in 1996. Affected products include many of the top-selling U.S. pharmaceutical products currently on the Finnish market.

Greece

Greece was included on the Watch List in the 2012 Special 301 report. The United States acknowledges some improvements in IPR protection and enforcement in Greece, including actions taken against piracy over the Internet. However, inadequate IPR protection continues to pose barriers to U.S. exports and investment. Key issues cited in the 2012 Special 301 report include widespread copyright piracy and weak and inconsistent IPR enforcement.

Italy

Italy remained on the Watch List in the 2012 Special 301 Report, primarily due to ongoing concerns about piracy over the Internet. USTR conducted an Out-of-Cycle Review (OCR) of Italy that was inconclusive due to lingering concerns about piracy over the Internet and the lack of progress that the Italian Communications Regulatory Authority (AGCOM) had made with respect to the adoption of draft regulations to combat piracy over the Internet. Additional concerns cited in the 2012 report included a Data Protection Agency opinion on the monitoring of peer-to-peer networks, the lack of an expeditious legal mechanism for rights holders to address piracy on the Internet, and a lack of deterrent sentences. In early 2012, AGCOM devoted considerable time and attention to preparing regulations to address online piracy, which included provisions for a notice-and-take-down system. However, the previous commission never finalized the regulations, which were pending in front of a newly appointed board at the time of writing of this report.

Latvia

Recent amendments to Latvia's intellectual property criminal statutes have simplified certain aspects of infringement cases and may result in more successful prosecutions of IPR violations. Police and customs officials continue to gain experience and understanding of intellectual property matters. Police and prosecutors actively pursue IPR cases, but are hampered by a lack of resources and severe backlogs in police forensics labs. The Latvian judicial process still poses significant challenges, including lengthy proceedings, high evidentiary burdens, and a failure to publicize judgments. Latvia hosts a number of file-sharing websites, and software piracy rates remain high.

Malta

Although industry reports that Malta's civil regime regulating copyright is generally adequate, the sufficiency of Malta's criminal law with respect to IPR is mixed. While the relevant provisions of the Maltese Criminal Code are generally satisfactory in the context of trademarks and designs, the Criminal Code provisions governing other IPR have been largely overlooked over the past two decades. For example, the criminal sanctions provisions do not provide adequate deterrence.

Poland

Thanks to Poland's more stringent IPR enforcement, physical piracy (*e.g.*, optical discs) is no longer the problem it once was. Online piracy of movies, music, and software, however, continues to be widespread, despite progress in enforcement. Rights holders continue to express concern that penalties for digital IPR infringement are not at levels sufficient to deter violations. In an effort to address these concerns, the government has put in place a national IPR strategy, entitled "Program for the Protection of Copyright and Related Rights 2011-2013," which aims to adopt EU IPR protection strategies.

In January 2012, the Polish government organized a series of stakeholder workshops on copyright law and related issues. The government is now in the process of updating legislation on the delivery of services by electronic means, and is also reviewing the possibility of updating Poland's 1994 copyright law. The government meets with rights holder groups and ISPs to increase cooperation in combating Internet piracy, and the government's interagency IPR working group met in January 2013.

Portugal

Portugal regularly conducts inspections for illegal goods at street fairs, markets, and festivals. However, it does not have adequate mechanisms to deter piracy over the Internet. Court cases involving IPR often take years to resolve, and rarely result in convictions. Furthermore, courts rarely order an injunction against the activity in question while a case is pending.

Romania

Romania remained on the Watch List in the 2012 Special 301 Report. Concern about counterfeit physical goods, infringing optical discs, and street piracy continued to decline, while increasing levels of piracy over the Internet, especially peer-to-peer downloading, remain a top concern. However, enforcement efforts have not adequately addressed the Internet piracy problem. The United States is concerned by an apparent decrease in the overall commitment to IPR enforcement in Romania, reflected in reduced cooperation among enforcement authorities, decreased cooperation of police and prosecutors with rights holders, and a decline in the number of enforcement actions. In 2010, changes to the Penal Code provided for IPR cases to be adjudicated in lower-level courts, whose

judges and prosecutors have substantially less IPR expertise. Deficiencies in IPR protection and enforcement, including overall judicial inefficiency and a failure to impose deterrent sentences, have posed barriers to U.S. exports and investment.

Spain

Spain was removed from the Watch List in the 2012 Special 301 Report in recognition of efforts with respect to IPR protection and enforcement, including the December 2011 adoption of regulations implementing provisions of the Sustainable Economy Law (commonly known as the "*Ley Sinde*"), a law to combat copyright piracy over the Internet. However, the copyright industry continues to be disappointed by the Spanish government's pace of implementation of the *Ley Sinde* and to be concerned with the 2006 Prosecutor General's Circular that appears to decriminalize illegal peer-to-peer file sharing of infringing materials, further perpetuating the ongoing perception by the public and judges that unauthorized Internet downloads are not an illicit activity.

The Ministry of Culture's 2012-2015 Strategic Plan sets objectives and strategies to guide Spain's cultural policy over the next four years including strengthening the legal framework for the protection of rights derived from intellectual property. In 2013, the United States will continue to carefully monitor the implementation of the *Ley Sinde* provisions, as well as the reform of Spain's IP, criminal, and civil procedure laws. Despite enforcement efforts, piracy remains a significant problem.

Sweden

Sweden continues to grapple with widespread piracy on the Internet, but government enforcement efforts have begun to show positive results. Following the entry into force in April 2009 of legislation implementing the EU Enforcement Directive, several major pirate websites left Sweden. Nonetheless, Sweden still hosts some large on-line pirate sites -- several of which are listed in USTR's Notorious Piracy Markets report. Legal sales over the Internet have increased in recent years, in part because of better legal alternatives and Swedish enforcement efforts.

SERVICES BARRIERS

Telecommunications

EU Member States' WTO commitments covering telecommunications services and EU legislation has encouraged liberalization and competition in the telecommunications sectors in EU Member States since the late 1990s. All EU Member States made WTO commitments to provide market access and national treatment for voice telephony and data services. The EU's 2002 Common Regulatory Framework for Electronic Communications Networks and Services (Framework Directive) imposed additional liberalization and harmonization requirements on Member States. 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.

In 2009, the Commission amended EU telecommunications legislation, including the Framework Directive, with a third telecoms package with the aim of harmonizing Europe's telecommunications markets. Perhaps the most significant change was the creation of the Body of European Regulators for Electronic Communications (BEREC). Increased Member State coordination, a larger role for the Commission, and the creation of BEREC were intended to help ensure fair competition and more consistency in the regulation of telecommunications markets within the EU. The Member States were supposed to transpose the new rules into the national laws by May 2011, but most have

moved forward with much delay and with various discrepancies in interpretation. The Commission has begun infringement procedures against delinquent Member States.

The Digital Agenda Commissioner has announced that she will present new rules on net neutrality and network investments in early 2013. The new rules on network investment will seek to create a consistent, investment-friendly application of nondiscrimination and price control remedies to broadband networks in all Member States.

EU institutions are also discussing proposals on data protection, which could restrict international data flows, and are reviewing the Data Retention Directive. In addition, the Commission has launched a European Radio Spectrum Policy Program to improve radio spectrum management in Europe.

Member State Measures:

Austria

Austria has implemented all relevant EU directives. Legal reforms effective as of October 2010 anchored the independence of Austria's telecommunications regulators. The incumbent telecommunications provider, Telekom Austria, offers fixed-line networks, mobile telephony, and Internet access, including broadband, and is the market leader in all of these areas. The Austrian mobile market is highly competitive, in contrast to the more concentrated fixed-line market, and continues to expand, and retail rates for mobile communications continue to decline. If EU competition regulators approve a planned merger, the number of wireless operators in Austria will decrease to three. The broadband Internet market (fixed and mobile) is highly dynamic and growing, and while the incumbent's market share is still around 50 percent, currently 35 providers offer retail services.

France

In 2012, France finished enacting the provisions of the 2009 EU Telecommunications Directives. Free Mobile, the country's fourth mobile operator, entered the market in January 2012, forcing prices down. Competition for the fixed market remains strong. France Telecom continues to dominate the sector, notwithstanding its various efforts to partner with other operators to avoid duplication in fiber optic installation. *Germany:* Despite increased competition in some sectors of Germany's telecommunications market, Deutsche Telekom (DT) retains a dominant position in a number of key market segments, including local loop and broadband connections. DT's competitors continue to call for more effective regulation of the competitive environment. Nonetheless, since the passage of the Telecommunications Act in 2003, DT's share has decreased to below 60 percent in the fixed-line market and to below 45 percent in the broadband market.

Greece

Greece has incorporated the 2009 EU telecommunications package into national legislation. The 2009 EU telecommunications package includes European Directives 2009/136/EC and 2009/140/EC. Both Directives are included in Law 4070 that was passed on October 4, 2012.

Italy

Telecom Italia (TI), the former state-owned monopoly operator, is the largest telecommunications provider in Italy. Domestic political pressure has prevented foreign operators (*e.g.*, AT&T in 2007) from gaining a controlling interest in TI. However, as of November 2012, Telecom Italia is considering

a proposed significant investment by an Egyptian. TI owns most of Italy's fixed-line telecommunications infrastructure, and competitors have complained about high access costs and allegedly unfair practices aimed at retaining TI customers. TI's market share, however, is decreasing, with its share of the fixed-line market declining to approximately 66 percent in the second quarter of 2012 (down from 67.3 percent in the second quarter of 2011). Similarly, TI's share of the Italian retail broadband market was 52.4 percent in the second quarter of 2012 (compared to almost 54 percent in the second quarter of 2011). TI's market share for mobile subscribers was 34.9 percent in the second quarter of 2012 (an increase of 0.6 percent over the second quarter of 2011). Although TI has expressed interest in upgrading its broadband infrastructure, it has also voiced concern that the main beneficiaries of TI broadband investment would be businesses selling goods and services online, in particular, large U.S. companies. At the end of November 2012, Telecom Italia was also considering whether to separate its fixed-line assets into a new company and sell a stake to the state-owned agency *Cassa Depositi e Prestiti* (CDP) in order to free economic resources and to speed up the rollout of a national broadband network.

Television Broadcasting and Audiovisual Services

The 2007 EU Directive on Audiovisual Media Services (AVMS) amended and extended the scope of the Television without Frontiers Directive (which already covered traditional broadcasting, whether delivered by terrestrial, cable, or satellite means) to also cover audiovisual media services provided on-demand, including via the Internet. EU Member State content quotas for broadcasting remain in place. On-demand services are subject to somewhat less restrictive provisions than traditional broadcasting under the AVMS Directive, which does not set any strict content quota, but still requires Member States to ensure that on-demand services encourage production of, and access to, EU works. This could be interpreted to refer to the financial contribution made by such services to the production and rights acquisition of EU works or to the prominence of EU works in the catalogues of video on-demand services. EU Member States had to implement the AVMS Directive into their national law by December 19, 2009. In its first report on the application of the Directive from May 2012, the Commission announced that 25 Member States have notified complete implementation into their national legislation. Poland and Belgium, however, still need to adapt their legislation, and the former is currently subject to an infringement procedure for failing to fully implement the Directive.

Member State Measures

Several EU Member States maintain measures that hinder 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 in a restrictive manner. France's implementing legislation, which was approved by the European Commission in 1992, requires that 60 percent of programming be EU and 40 percent French language. These requirements exceed those of the Broadcast Directive. Moreover, these quotas apply to both the regular and prime time programming 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. Internet, cable, and satellite networks are permitted to broadcast as little as 50 percent EU content (the AVMS Directive minimum) and 30 percent to 35 percent French-language product, but, in exchange, channels and services are required to increase their investment in the production of French-language product. In addition, radio broadcast quotas that have been in effect since 1996 specify that 40 percent of songs on almost all French private and public radio stations must be in French.

Beyond broadcasting quotas, cinemas must reserve five weeks per quarter for the exhibition of French feature films. This requirement is reduced to four weeks per quarter for theaters that include a French short subject film during six weeks of the preceding quarter. Operators of multiplexes may not screen any one film with more than two prints, or through staggered and interlocking projection techniques, 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 be advertised on television.

Italy

Broadcasting Law DL 44, which implements EU regulations, reserves 50 percent of the programming time (excluding sports, news, game shows, and advertisements) for EU works. Ten percent of transmissions (and 20 percent for state broadcaster RAI) must be reserved for EU works produced during the preceding five years. Within this quota, an undefined percentage of time must be reserved for Italian movies.

Poland

Broadcasters in Poland must devote at least 33 percent of their broadcasting time each quarter to programming that was originally produced in the Polish language.

Spain

For every three 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 four to one if the cinema screens a film in an official language of Spain and keeps showing the film in that language throughout the day. In addition, broadcasters and providers of other audiovisual media services must annually invest 5 percent of their revenues in the production of EU and Spanish films and audiovisual programs. In 2010, the government revised the audiovisual law and imposed restrictions on non-EU ownership (limited to no more than 25 percent share) and leasing of AV licenses, which have negatively impacted U.S. investors.

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.

Member State Measures

Belgium

U.S. nationals may practice foreign law in Belgium only if they are associated with qualified members of the Belgian bar. The Belgian Judicial Code provides that only Belgian or EU lawyers can be fully admitted to the bar. An exception exists for foreign non-EU lawyers who meet certain requirements.

Bulgaria

The July 2010 amendments to the Bulgarian Bar Act allow law firms registered in the EU to practice in Bulgaria under their original name after they register with the local bar association. Foreign lawyers registered in another EU Member State are also allowed to practice law or register a local office in partnership with other foreign or local lawyers. However, at least one of the partners has to be registered both in Bulgaria and in another EU Member State if the local partnership is to use an internationally recognized name.

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. In contrast to EU-based law firms, U.S. law firms cannot establish Czech branches to practice law (*i.e.*, operate directly through their home legal entities). Attorneys from U.S. law firms admitted as foreign lawyers, together with Czech lawyers, may establish local partnerships.

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.

Hungary

U.S. lawyers may provide legal services only under a "cooperation agreement" in partnership with a Hungarian legal firm and can only provide information to their clients on U.S. law or on international law.

Portugal

Portuguese law requires that practicing lawyers be members of the Portuguese Bar Association. The Portuguese Bar Association requires that members graduate from a Portuguese or Brazilian law school and that foreign lawyers be citizens of the EU or a country with a reciprocal agreement permitting foreign lawyers to be bar-certified. U.S. citizens with a law degree may apply as legal trainees if the law degree is recognized by a Portuguese law school and if the U.S. citizen has a valid Portuguese residence authorization. The successful completion of legal internship and the mandatory Bar Association exams enable the U.S. citizen to practice law in Portugal.

Accounting and Auditing Services

Member State Measures

Portugal

Portuguese law requires that practicing accountants and auditors be accredited by one of two Portuguese accounting associations, which require legal residency. Portuguese language ability and citizenship of a country with a reciprocal agreement or EU citizenship are prerequisites for membership.

Energy Services

Member State Measures

Ireland

Industry reports that bureaucratic delays and other obstacles that benefit vested local interests and state-owned enterprises have impeded new entrants in the energy sector, consequently raising the costs of doing business in Ireland. Significant U.S. investments in a waste-to-energy project and a liquefied natural gas terminal proposal stand to be cancelled as a result of such delays.

EU Enlargement

Upon each of the three most recent rounds of EU enlargement, the EU has submitted notifications to WTO Members concerning the modification of existing commitments under the GATS by the newly acceded members of the EU. In accordance with GATS Article XXI, the EU was required to enter into negotiations with any other WTO member that indicated that it was affected by the modification of existing commitments. In connection with the largest of these rounds of enlargement, the expansion to 25 members in 2004, the United States and EU successfully negotiated a compensation package, which was agreed on August 7, 2006. To date, however, the European Commission has failed to secure the approval of all EU Member States, which is necessary to implement the agreement. USTR will continue to monitor this process to ensure the agreement is implemented as soon as possible.

INVESTMENT BARRIERS

The EU accords national treatment to foreign investors in most sectors and, with few exceptions, EU law requires that any company established under the laws of one Member State must receive national treatment in all other Member States, regardless of the company's ultimate ownership. As discussed below, however, EU law does impose some restrictions on U.S. and other foreign investments and, in many instances, individual Member State policies and practices have had a more significant impact on U.S. investment than EU-level policies.

Prior to the adoption of the Lisbon Treaty in December 2009, the European Commission shared competence with Member States on investment issues. Member States negotiated their own bilateral investment treaties (BITs) and generally retained responsibility for their investment regimes, while the EU negotiated investment-related market access provisions in EU economic agreements. Article 207 of the Lisbon Treaty brings foreign direct investment (FDI) under the umbrella of Europe's common commercial policy, making it the exclusive competence of the EU. FDI is not defined in the Treaty, however, leaving many practical implications of the Treaty for EU external investment policy unclear.

In July 2010, the Commission issued two communications aimed at defining a comprehensive EU international investment policy and establishing transitional arrangements for investment agreements between Member States and third countries. Under these communications, which were presented to the European Parliament and EU Member State governments for endorsement under the co-decision process, the Commission will "authorize" the more than 1,200 BITs concluded by Member States, including some with the United States, to remain in force (though the Commission will evaluate their content to assess their conformity with EU law and the EU's common commercial policy). A regulation establishing transitional arrangements for existing BITs between Member States and third countries, based on the Commission's July 2010 communications, was agreed between the Council and the Parliament in July 2012, and went into effect in January 2013.

Member State Measures

Bulgaria

Weak corporate governance remains a problem in Bulgaria. Although legislative protection for minority shareholders has been improved through insolvency rules in Bulgaria's Commercial Code and 2007 changes to its Law on Public Offering of Securities, enforcement of these statutory provisions is inadequate.

Cyprus

Cypriot law imposes significant restrictions on the foreign ownership of real property. Non-EU residents may only purchase a single piece of real estate (not to exceed three *donums*, or roughly one acre) for private use (*e.g.,* a holiday home). Exceptions can be made for projects requiring larger plots of land, but are rarely granted. Under the Registration and Control of Contractors Laws of 2001 and 2004, only citizens of EU Member States have the right to register as construction contractors in Cyprus, and 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 Cypriot Council of Ministers. *France:* Pursuant to a November 2004 law that streamlined the French Monetary and Financial Code, the State Council defined a number of sensitive sectors in which prior approval would be required before foreign acquisition of a controlling equity stake is permitted. A December 2005 government decree (Decree 2005-1739) lists the 11 business sectors in which the French government will monitor, and can potentially restrict, foreign ownership through a system of "prior authorization."

The government of France has expressed concern over the acquisition of "strategic" companies, whose stock prices fell steeply in the wake of the financial crisis. Near the end of 2008, then-President Sarkozy announced the establishment of a "strategic investment fund," to assume stakes in companies with "key technologies." The fund would be run as a "strategic priority" by the *Caisse des Depots et Consignations*, a state-sponsored financial institution and France's largest institutional investor, under parliamentary supervision. The government has also asked the *Caisse des Depots et Consignations* to work as a domestic buffer against foreign takeovers by increasing its stake in French companies. The government may also become directly involved in mergers and acquisitions, using its "golden share" in state-owned firms to protect perceived national interests.

Greece

All purchases of land in border areas and on certain islands require approval from the Ministry of Defense. The definition of "border area" is broader for non-EU purchasers of land, and obtaining approval for purchase is more burdensome. Greek authorities consider local content and export performance criteria when evaluating applications for tax and investment incentives, although such criteria are not prerequisites for approving investments.

Italy

In July 2012, the government announced a new incentive scheme for photovoltaic solar energy production that provides advantages for plants built with EU-made components. All made-in-the-EU photovoltaic (PV) plants smaller than 12kW are automatically eligible for a premium over the normal incentivized feed-in-tariff (FiT). PV plants that do not meet the requirements for direct access to the FiT must enroll in a special register, and their ability to obtain the FiT is based on a ranking, the criteria for which includes whether they use components produced in the EU. In the case of PV plants larger than 12kW, those built with made-in-EU components qualify for a higher ranking position and therefore have a better opportunity of getting both the incentivized tariff and the premium mentioned above.

Lithuania

U.S. citizens and foreign investors report difficulties in obtaining and renewing residency permits. In principle, Lithuanian embassies abroad are able to initiate the application process for residency permits, but in practice, U.S. citizens only are able to begin the residency permit process upon arrival

in Lithuania. Decisions by the Migration Office regarding the issuance of residency permits can take up to six months. Non-Lithuanians are generally not able to buy agricultural or forestry land. As part of its EU accession agreement, the Lithuanian government was required to eliminate this restriction by 2011. However, that year the government successfully negotiated with the EU to postpone the removal of the restriction until 2014.

Romania

Uncertainty and a lack of predictability in legal and regulatory systems pose a continuing impediment to foreign investment in Romania. Tax laws change frequently and many companies experience long delays in receiving VAT refunds to which they are legally entitled. Deadlines stipulated by law for the processing and payment of refunds are often not respected. Companies have reported frequent instances in which the government has issued legal decrees or regulations affecting the business climate without following required transparency and public consultation procedures. Tort cases often require lengthy, expensive procedures and judicial rulings are reportedly often inconsistent.

GOVERNMENT PROCUREMENT

The EU is a signatory to the WTO Agreement on Government Procurement (GPA). U.S. suppliers participate in EU government procurement, but the lack of EU statistics makes it difficult to assess the level of U.S. and non-EU participation.

In 2004, the EU adopted a revised Utilities Directive (2004/17), covering purchases in the water, transportation, energy, and postal services sectors. This directive requires open, competitive 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 foreign 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.

In 2011 and 2012, the European Commission published four legislative proposals in the area of public procurement. One of these proposals, to regulate access of third-country goods and services to the EU's internal market in public procurement (relative to the access provided to EU goods and services in third-country public procurement markets), is being debated in the European Parliament and in the EU Member States as of the time of drafting of this report. In addition, if this proposal is approved, the above-mentioned provisions in the Utilities Directive would be dealt with under the Regulation on Foreign Access to the EU public procurement market, and become subject to proposed negotiations on reciprocal access. U.S. access to the EU's non-GPA covered procurement would also be dealt with under this new Regulation.

Member State Measures

Austria

U.S. firms continue to report a strong EU bias in government contract awards. U.S. industry asserts that invitations for bids for the Austrian government's vehicle fleet are tailored for German competitors. Additionally, offset requirements can reach up to 200 percent of the value of the contract for major defense purchases. The ceiling for contracts to be awarded without public tenders is set relatively high at €100,000 ($130,000). Although Austria's power utilities are majority

government-owned, under a European Commission ruling (2008/585/EC), they are exempted from having to issue public tenders for power generation projects.

Bulgaria

The public procurement process in Bulgaria is not always transparent. There are persistent complaints that some tenders are so narrowly defined that they appear tailored to a specific company. U.S. companies also complain that they face difficulties having their certification documents accepted to qualify as bidders on public procurement projects.

Czech Republic

In 2012, the Czech government adopted a major public procurement reform bill which addresses some transparency and corruption concerns. The legislation, which came into effect in April 2012, lowers the threshold for the application of procurement rules to one million CZK ($55,000). It also requires more than one bidder for all procurements and publication of tender specifications. The law also requires bidders to disclose more of their ownership structure in the bidding process. However, it maintains loopholes that could permit bidders to subcontract to anonymously-held companies. The Ministry of Justice and the Ministry of Finance are now working on related legislation requiring full identification of ownership for all recipients of public tenders. The Ministry of Regional Development is developing guidelines to make the process clearer for bidders and for state institutions that issue tenders.

France

The French government continues to maintain shares in several major defense contractors (EADS 0.06 percent, Safran 30.20 percent, and Thalès 27.00 percent as of November 2012). It is generally difficult for non-EU firms to participate in French defense procurement and, even when the competition is among EU suppliers, French companies are often selected as prime contractors.

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, have not been in bankruptcy, and have paid in full their social security obligations for their employees. All managing directors and board members of companies that want to participate in procurements must submit certifications from competent authorities that they have not engaged in fraud, money laundering, criminal activity, or similar activities. It is difficult for U.S. firms to comply with these requirements, because there are no competent authorities in the United States that issue these types of certifications.

The U.S. Embassy in Athens and the Greek Ministry of Development reached an agreement in late 2008 that would allow U.S. companies to submit sworn, notarized, and translated statements from corporate officers, along with an official statement from the U.S. Embassy in Athens stating that no U.S. federal authority issues the documents otherwise required under Greek procurement law. Despite this agreement, there remains considerable confusion among Greek authorities as to how U.S. firms may comply with these requirements.

Additionally, U.S. industry has complained that procurements in Greece are not always transparent and that some tenders, such as for medical equipment to be installed in hospitals, contain technical specifications that favor specific Greek suppliers. The U.S. Government is continuing to engage with

the Greek government on this issue. Greece also continues to require offsets as a condition for the awarding of defense contracts.

The Ministry of Development announced a new electronic procurement platform for public sector tenders in February 2013. The National System of Electronic Public Contracts (ESIDIS) began operating a pilot program (www.eprocurement.gov.gr) on February 4 that will become available to all public sector agencies by April and to all local government authorities by May. According to the Greek government, the system, once fully operational, is intended to improve transparency by allowing citizens and suppliers to check on tenders.

Hungary

Inadequate transparency in public procurement continues to be a significant problem in Hungary. Citing governing parties' disinterest, Hungarian non-governmental organizations have abandoned efforts to reach an agreement on the reform of campaign finance laws, which could have helped to reduce politically motivated procurement decisions and make public procurement more transparent and competitive. In January 2012, a new, shorter, and more flexible Public Procurement Act came into force, although some experts consider the new law too vague, and as a result, ineffective. State-owned companies or those close to the government still appear to have an advantage over private players in public tenders.

Italy

Italy's public procurement practice is often criticized for a lack of transparency, which has created obstacles for some U.S. firms bidding on public procurement. Laws implemented in the mid-1990s reduced corruption, but industry asserts that it still exists, especially at the local level. Italian press has reported on alleged corruption involving the abuse of emergency procurement laws. In 2012, the Italian parliament approved an anticorruption bill which, among other things, introduces greater transparency and more stringent procedures in the public procurement process. To increase transparency, the Italian government has also started publishing online information regarding the use of public funds including data on procurement.

Lithuania

The public procurement process in Lithuania is not always transparent. There are persistent complaints that some tenders are so narrowly defined that they appear tailored to a specific company. The government has made procurement reform a top priority and is starting to improve transparency by implementing online public procurement of its central purchasing body, the central project management agency. Now, over 70 percent of public procurement occurs online. Since 2003, the Lithuanian government has often required offset agreements as a condition for the award of contracts for procurement of military equipment.

Portugal

U.S. firms report that the Portuguese government tends to favor EU firms, even when bids from U.S. firms are technically superior or lower in price. U.S. firms also report that they are more successful when bidding as part of consortia or as part of joint ventures with Portuguese or other EU firms. U.S. based firms may bid on public tenders covered by the GPA, while EU subsidiaries of U.S. firms may bid on all public procurement contracts covered by EU directives.

Romania

Romania requires offsets as a condition for the awarding of defense contracts. Romania revised its public procurement law in 2010, particularly with regard to procedures for handling challenges to contract awards. While an award must still be temporarily suspended if a losing bidder challenges it, the revised law allows procuring entities to conclude the contract within 11 days after a decision by the National Complaint Council or a court upholding the initial award, even if the challenger chooses to appeal that decision. Should the Complaint Council find the challenge ungrounded, the procuring entity can withhold a percentage of the plaintiff's bid participation fee as a penalty.

Slovenia

U.S. firms continue to express concern that the public procurement process in Slovenia is non-transparent. Other complaints include short time frames for bid preparation, lack of clarity in tendering documentation, and opacity in the bid evaluation process. One specific complaint involves the quasi-judicial National Revision Commission (NRC), which reviews all disputed public procurement cases. The NRC has extraordinary powers to review, amend, and cancel tenders, and its decisions are not subject to judicial appeal. There also are concerns that the NRC favors EU, and especially Slovenian, firms under its ambiguous "national interest" standard, regardless of cost or doubts about a firm's ability to deliver and service its products.

United Kingdom

The United Kingdom (UK) requires offsets in its defense procurement, but has no set percentage for them. Bidders are free to determine their own level of "industrial participation," as well as with whom to do business. The UK defense market is, to an increasing extent, defined by the terms of the 2005 Defense Industrial Strategy (DIS), which 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 Defense and selected companies. The DIS does not preclude partnerships with non-UK companies, and U.S. companies with UK operations may be invited by the Ministry of Defense to form partnerships in key programs. Outside of those areas of partnership highlighted in the DIS, defense procurement is to a large extent an open and competitive process.

The UK has implemented the EU Defence and Security Procurement Directive through the Defence and Security Public Contracts Regulations 2011. One key provision of the Regulations is a prohibition of industrial participation or offsets. Although the UK's source selection process appears open and competitive, there appears to be a perception among U.S. defense industries that the UK Ministry of Defence prefers national and EU equipment solutions over superior U.S. offerings.

The U.S.-UK Defense Trade and Cooperation Treaty took effect in April 2012 and is designed to ease the burdens associated with obtaining permission to export military technologies between the U.S. and UK. A key aspect of the treaty is to create an approved community of known and trusted corporate entities that have a streamlined export license approval process. Since implementation, the list of these vendors has grown substantially and this is seen as a significant reduction of trade barriers between the United States and the UK.

SUBSIDIES

Government Support for Airbus

Over many years, the governments of France, Germany, Spain, and the United Kingdom have provided subsidies to their Airbus-affiliated companies to aid in the development, production, and marketing of Airbus's large civil aircraft. These governments have financed between 33 percent and 100 percent of the development costs of all Airbus aircraft models (launch aid) and have provided other forms of support, including equity infusions, debt forgiveness, debt rollovers, and marketing assistance, in addition to 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 EU civil aeronautics industry. EU governments have spent hundreds of millions of euros to create infrastructure for Airbus programs, including €751 million spent by the City of Hamburg to drain the wetlands that Airbus is currently using as an assembly site for the A380 "superjumbo" aircraft. French authorities also spent €182 million to create the AeroConstellation site, which contains additional facilities for the A380. The Airbus A380, the beneficiary of more than $5 billion in subsidies, 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 barely begun to repay the financing it has received for the A380.

Airbus SAS, the successor to the original Airbus consortium, is owned by the European Aeronautic, Defense, and Space Company (EADS), which 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 U.S.-EU agreement that would end subsidies for the development and production of large civil aircraft, the United States exercised its right to terminate the 1992 U.S.-EU Bilateral Agreement on Large Civil Aircraft. The United States also commenced WTO consultations, which failed to resolve the U.S. concerns. A renewed effort to negotiate a solution ended without success in April 2005.

On May 31, 2005, the United States requested establishment of a WTO panel to address its concern that EU subsidies were inconsistent with the WTO *Agreement on Subsidies and Countervailing Measures*. The WTO established the panel on July 20, 2005. In 2010, the dispute settlement panel found in favor of the United States on the central claims, and the Appellate Body upheld the finding of WTO inconsistency in 2011. On December 1, 2011, the EU submitted a notification to the WTO asserting that it had taken appropriate steps to bring its measures into conformity with its WTO obligations. On December 9, 2011, the United States requested consultations with the EU to address its concern that the EU had failed to bring its Airbus subsidies into conformity with WTO rules.

During this period, the ongoing WTO dispute did not cut the flow of money to Airbus. In 2009, EADS's total European government (UK, France, Germany, Spain) refundable advances outstanding amounted to €5.3 billion, of which €3.6 billion was for the A380, €1.2 billion for long-range wide body aircraft, and €0.2 billion for Eurocopter.

In September 2009, the UK government announced it would lend plane maker Airbus £340 million ($540 million) in launch aid to develop its new wide-body aircraft, the A350XWB. The loan for the A350 XWB model comes partly from the UK government's £750 million ($1.2 billion) Strategic Investment Fund. The launch aid is intended to safeguard 1,200 jobs at Airbus's plants in Filton, near Bristol, and Broughton in north Wales. It also secures Britain's share of the work on the Airbus aircraft and a further 5,000 jobs at Airbus suppliers. Airbus's sites in the UK specialize in wing manufacturing, but also make landing gear and fuel integration systems.

Government Support for Airbus Suppliers

Member State Measures

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 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, but simultaneously, the Flemish Regional government set up a €50 million start-up fund for the aviation sector in Flanders. It is 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, not all of which was disbursed. Belgium claims that its A380 support was structured in accordance with the 1992 bilateral agreement and covers nonrecurring costs.

In the spring of 2009, the Commission once again notified the Belgian government that its 2008-2013 program of federal aid to the aeronautical sector was illegal. However, in May 2010, after being provided with supplemental information from the government, the Commission ruled that the program, for €178 million, was compatible with article 87(3)c of the EC Treaty. Industrial research or experimental development projects linked to the A350 and A380 were cited as examples of projects that could benefit from the program.

France

In addition to the launch aid that the French government provided for the development of the A380 and A350 aircraft, France provides assistance in the form of reimbursable advances for the development by French manufacturers of products such as planes, aircraft engines, helicopters, and onboard equipment. French appropriations for new programs included €148 million in support of research and development in 2011. In 2012, such support decreased to €120 million. The 2011 government budget included €230 million in reimbursable advances for the civil aviation. In 2011, the government financed the military airplane A400 with redeemable advances. To have sufficient redeemable advances available for the A400 the government financed the A350 with €450 million from a government fund "Grand Emprunt" now called "Investment for the future." The government's 2012 budget included €148 million in reimbursable advances, and €143 million was in the budget for 2013.

In July 2008, Airbus, the parastatal *Caisse des Dépôts et Consignations*, and the Safran Group announced the launch of the AEROFUND II equity fund, capitalized with €75 million destined for the French aeronautical sector. The equity fund's objective is to support the development of the small- and medium-sized subcontractors that supply the aeronautical sector. In March 2009, the state's

Strategic Investment Fund (FSI) and AEROFUNDs I and II purchased a nearly 20 percent stake in Daher, a French company, for €80 million, to help that private aerospace group accelerate its development and seize strategic opportunities. Since its creation in 2008, AEROFUND II has made investments in about ten companies, including helping to finance Mecachrome's purchase of Mecahers, and Prosnic's acquisition of Industron. The Fund also helped finance the sale of Esterel Technologies to the U.S. group Ansys in 2012. In 2013, its unit ACE Management will work on the creation of a third AEROFUND. On April 14, 2010, the European Commission authorized France to grant reimbursable advances totaling €35.14 million to Daher-Socata and Sogerma for two research and development projects for the future Airbus A350XWB. In addition, the FSI allocated €1.5 billion for the development of environmentally safe planes and €500 million for aerospace, through a combination of development support, reimbursable advances, and direct equity investments. In 2007, OSEO (the state-backed company that provides financial support to innovative small and medium sized enterprises) signed a contract with the French Civil Aviation Authority for European aerospace project development to finance up to 40 percent of spending. In 2010, OSEO announced €80 million in reimbursable advances over two years for French small- and medium-sized enterprise sub-contractors and suppliers of large aerospace firms. Zodiac Aerospace received €230 million in reimbursable advances during the August 2008 to August 2009 period. In 2009, Latécoère received €50.4 million in reimbursable advances. In 2011, Figeac Aero received €10 million and Slicom received €1 million. The government pledged €60 million in aid in 2012 to assist the company Sky Aircraft to continue development of a light passenger aircraft.

Government Support for Aircraft Engines

Member State Measures

United Kingdom

In February 2001, the UK government announced its intention to provide up to £250 million to Rolls-Royce to support development of the Trent 600 and 900, two additional engine models for large civil aircraft. 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 "reimbursable advance" without opening a formal investigation into whether the advance constituted illegal state aid under EU law. According to a 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 models has been repaid.

Propulsion is another area considered important to the future of the UK aerospace industry, and the Department for Business, Innovation, and Skills (BIS) 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 five years.

France

In 2005, the French government-owned engine manufacturer, Snecma SA, merged with Sagem, a technology and communications firm, to form the Safran Group. The government supported the Safran SaM146 propulsive engine program, a turbofan engine produced by the PowerJet joint

venture between Snecma of France and NPO Saturn of Russia, with a reimbursable advance of €140 million. In 2009, Safran received new reimbursable advances of €69 million.

Other Civil Aircraft

In July 2008, Bombardier Aerospace announced an investment of £519.4 million in Northern Ireland to support the design and manufacture of the wings for its 110 to 130 seat CSeries family of aircraft. In an agreement with BIS, the Northern Ireland Executive has offered assistance to the investment of £155 million. This includes a maximum of £130 million (Northern Ireland's contribution of £78 million of repayable Launch Investment assistance for the CSeries and up to £25 million Selective Financial Assistance).

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. 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, 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 non-uniform administration of EU customs law in multiple Member States must bring a separate appeal in each Member State whose agency rendered an adverse decision.

Ultimately, a question of interpretation of EU law may be referred to the European Court of Justice (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 the WTO Dispute Settlement Body. The concerns have taken on new prominence in light of the expansion of the EU and the focus of the WTO on trade facilitation. In the WTO trade facilitation negotiations, WTO 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, uniformly

apply and give effect to a Member's customs laws, regulations, judicial decisions, and administrative rulings. EU officials claim that the Modernized Community Customs Code (MCCC), which formally entered into force in 2008, will streamline customs procedures and will apply uniformly throughout the customs territory of the EU. Implementation of the MCCC is expected to be completed by 2013. The United States will monitor its implementation closely, focusing on its impact on uniform administration of EU customs law.

ELECTRONIC COMMERCE

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

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 (Commission) to provide an adequate level of protection by reason of their domestic law or their international commitments (Article 25(6)). The Commission has thus far recognized Switzerland, Canada, Argentina, Guernsey, the Isle of Man, Jersey, the Faroe Islands, Andorra, New Zealand, Uruguay and Israel as providing an adequate level of protection. The United States does not yet benefit from a blanket adequacy finding, but the Commission has recognized a series of specific and limited programs and agreements as providing adequacy. The most all-encompassing of these is the U.S.-EU Safe Harbor Framework, but others include the U.S.-EU Agreement on the Transfer of Air Passenger Name Records to the U.S. Bureau of Customs and Border Protection.

The Safe Harbor Framework provides U.S. companies with a simple, streamlined means of complying with the EU rules. It is the result of an agreement that allows U.S. companies that commit to a series of data protection principles (based on the EU Data Protection Directive) and that publicly state their commitment by "self-certifying" on a dedicated website (http://www.export.gov/safeharbor) to continue to receive personal data from the EU. Signing up to the Safe Harbor Framework is voluntary, but the rules are binding on signatories. A failure to fulfill commitments under the Safe Harbor Framework is punishable either as an unfair or deceptive practice under Section Five of the U.S. Federal Trade Commission Act or, for air carriers and ticket agents, under a concurrent U.S. Department of Transportation statute.

Outside of the programs and agreements that explicitly enjoy an adequacy finding, U.S. companies can receive or transfer employee and customer information from the EU only under one of the exceptions to the EU Data Protection Directive's adequacy requirements, if they develop binding corporate rules to allow global intra-company transfers and gain EU data protection authorities' approval of them, which fewer than 50 companies have done at this time. These requirements can be burdensome for many U.S. industries that rely on data exchange between the United States and the EU.

In recent years, a number of U.S. companies have faced obstacles to winning contracts with EU governments and private sector customers because of public fears in the EU that any personal data held by these companies may be collected by U.S. law enforcement agencies. Since mid-2011, EU media reports have suggested that U.S. laws, such as the Patriot Act, offer the U.S. Government *carte blanche* to obtain private data of EU citizens when stored by U.S. cloud computing service providers. The United States is seeking to correct misconceptions about U.S. law and practice and to engage with EU stakeholders on how personal data is protected in the United States.

The United States actively supports the Safe Harbor Framework and encourages EU institutions and Member States to continue to use the flexibility offered by the EU 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.

The European Commission is currently reviewing the EU Data Protection Directive as part of a broader review of the EU legislative framework for data protection, encompassing both commercial and judicial/law enforcement uses of data. In January 2012, the Commission issued its legislative proposals, initiating a potentially lengthy process of consultation and negotiation with EU Member States and the European Parliament. Given the importance of this issue to the business models of many U.S. companies, the United States is closely monitoring the development of this revised framework legislation to ensure that it does not adversely impact transatlantic trade and investment.

Member State Measures

France

Since 2011, sales of electronic books (e-books) by foreign merchants fall under a French law that sets a fixed price that French retailers may charge on a particular hard copy book. Since taking office in May 2012, the Hollande administration has undertaken a review of digital economic policy that may result in moves to levy additional taxes on certain online companies. The government, which has the backing of a consortium of domestic media and telecommunications companies in this effort, is seeking new funding for France's IT infrastructure and cultural industries. In early 2013, the French government is expected to unveil a comprehensive digital economy strategy – known as the Lescure Report -- that will include recommendations in this area, as well as proposals that would update regulations on copyright protection and data privacy.

2013 REPORT ON TECHINCAL BARRIERS TO TRADE

EUROPEAN UNION

Regulatory Cooperation Fora

European Union

The EU's approach to standards-related measures (as described in the 2012 TBT Report), and its efforts to encourage governments around the world to adopt its approach, presents a strategic challenge for the United States in the area of standards-related measures. In 2013, U.S. officials will continue to encourage systemic changes in the EU approach in existing bilateral fora, such as the Transatlantic Economic Council (TEC) and the United States – European Union High- Level Regulatory Cooperation Forum (HLRCF). The TEC is designed to give high-level political direction to bilateral initiatives aimed at promoting increased bilateral trade, job creation, and economic growth through deeper transatlantic economic integration. The HLRCF, comprising U.S. and EU regulatory and policy officials and oversees a program of bilateral cooperation on regulatory issues. The group has convened in advance of each of the previous four TEC meetings to identify projects for the TEC to consider.

In November 2011, the Leaders of the United States and the EU launched the U.S.-EU High

Level Working Group on Jobs and Growth (HLWG) with the objective of identifying new ways to increase transatlantic trade and investment in support of job creation, economic growth, and international competitiveness. Leaders directed the HLWG to examine options in specific areas (including possible trade agreements) *inter alia* to reduce and prevent non-tariff barriers.

On February 13, 2013, President Obama and EU leaders announced that they would initiate the internal procedures necessary to launch negotiations on a Transatlantic Trade and Investment Partnership (TTIP). President Obama and EU leaders' announcement followed issuance of the HLWG's final report to leaders (http://www.ustr.gov/about-us/press-office/reports-andpublications/2013/final-report-us-eu-hlwg) in which it recommended that the United States and the EU pursue a comprehensive agreement that would include ambitious, reciprocal market opening in goods, services and investment, make substantial progress on reducing non-tariff barriers, and address global trade issues of common concern. The report's specific recommendations for

negotiations on "regulatory issues and non-tariff barriers" include that a comprehensive agreement pursue: SPS and TBT issues; regulatory coherence and transparency; sector-specific outcomes and regulatory cooperation; and the development of a framework for future U.S.-EU progress on the regulatory issues.

(...)

Background on Specific Trade Concerns Contained in the Country Reports

Bilateral Engagement

The United States has actively engaged the EU on TBT-related matters in the TBT Committee, the WTO Trade Policy Review of the EU, and in bilateral meetings. The United States also raises concerns and encourages reform in EU approaches to key TBT issues in the Transatlantic Economic Council (TEC) and the United States – European Union High-Level Regulatory Cooperation Forum (HLRCF).

In addition, the United States and the EU work together to promote the importance of maintaining open and transparent regulatory and standards development processes in emerging markets, as well as jointly advocating on specific market access issues on behalf of US and EU exporters.

The announcement by President Obama and EU leaders that the United States and the EU intend to pursue a comprehensive trade and investment agreement will provide new opportunities to address TBT-related issues with the EU.

Honey – Biotechnology Labeling

EC Regulation No. 1829/2003 addresses GE crops for food use and for animal feed. The United States, along with other WTO Members, has expressed concerns in TBT Committee meetings, most recently in March 2013, regarding the requirement in Regulation No. 1829/2003 that honey containing pollen derived from GE plants must be labeled as such in accordance to EU regulations. This requirement was the result of the ECJ 2011 decision in Case C-442/09 that interpreted EC Regulation No. 1829/2003. The United States will continue to monitor this issue in 2013. In September 2012, the EU Commission proposed an amendment to Directive 2001/100/EC to clarify that pollen is not an ingredient of honey, but it has not been finalized. In addition, the European Food Safety Authority issued an opinion that pollen from the genetically engineered corn approved for cultivation in the EU was equivalent to pollen from conventionally bred varieties of corn. The United States raised this issue during the March 2013 TBT Committee meeting.

In addition, industry has raised concerns on several occasions about the impact the EU's restrictive stance on biotechnology has had on U.S. exports of soy, grains, corn, and other crops.

The United States have repeatedly raised concerns and objections with the EU regarding the EU's biotechnology regulations and legislation and their detrimental effect on U.S. exports.

With respect to SPS issues arising from the EU's policy regarding food and agricultural products derived from modern biotechnology, please refer to the SPS Report.

Accreditation Rules

As noted in previous *TBT Reports*, the United States has serious concerns regarding the EU's accreditation framework set out in EC Regulation No. 765/2008. The regulation, which became effective in January 2010, requires each Member State to appoint a single national accreditation

body and prohibits competition among Member States' national accreditation bodies. The regulation further specifies that national accreditation bodies shall operate as public, not-forprofit entities.

Under the regulation, Member States can recognize non-European accreditation bodies at their discretion. Member States may refuse to recognize non-European accreditation bodies and refuse to accept conformity assessments issued by these bodies. The regulation raises market access concerns for U.S. producers, whose products may have been tested or certified by conformity assessment bodies accredited by non-European accreditation bodies.

The United States will continue to press the EU on these issues in 2013.

Foods - Quality Schemes

New framework legislation for quality schemes in agriculture, EU No. 1151/2012, became effective in January 2013. The quality schemes provide for (1) "certification" procedures, in which detailed specifications are checked periodically by a competent body and (2) "labeling" systems to communicate information regarding product quality to the consumer, and which are subject to official controls. The United States is concerned with an element of the legislation that establishes a new framework for the development and protection of optional "quality terms." For example, it creates and protects the term "mountain product."

In particular, the United States is concerned that the legislation incorporates commonly used terms into the EU's quality schemes and subjects them to registration requirements. The United States is concerned that, as result, the legislation will negatively impact U.S. producers' ability to export and market their products in the EU. The United States will seek to work with the EU to address these concerns in 2013.

Chemicals – REACH Regulation

The EU's REACH regulation imposes extensive registration, testing, and data requirements on tens of thousands of chemicals. REACH also subjects certain chemicals to an authorization process that would prohibit them from being placed on the EU market except for specific uses.

U.S. industry is concerned that REACH requires polymer manufacturers and importers to register reacted monomers in many circumstances. This is problematic because reacted monomers no longer exist as individual substances in polymers and would not create exposure concerns in the EU. In addition, EU polymer manufacturers generally can rely on the registrations of their monomer suppliers and do not need to be individually registered. Since U.S. monomer suppliers are generally not located in the EU, U.S. polymer producers cannot likewise rely on registrations of their monomer suppliers. As a result, the reacted monomer registration requirement provides an incentive for distributors to stop importing polymers and switch to EU polymer suppliers. The United States has pressed the EU to eliminate the registration requirement.

Moreover, REACH contains notification and communication obligations with respect to substances on the Candidate List, a list of substances that may become subject to authorization procedures. Differing interpretations between the Commission and several Member States regarding when these obligations apply has created uncertainty among industry over how to comply. The Commission has indicated that notification and communication obligations apply if a substance on the Candidate List is present in an article in concentrations above 0.1 percent of the article's entire weight. However, Member States have stated that these obligations should apply when a substance

on the Candidate List is present in concentrations above 0.1 percent of the weight of the article's components or homogenous parts. In 2010, these Member States pushed the Commission to reverse its position as part of what may have been an effort to seek to protect the EU market from imports. Departure from the Commission's interpretation would present a much more difficult compliance problem for U.S. industry since it would require companies to perform an analysis of individual component concentration levels in their products, which would be extremely time-consuming and burdensome. Given that an alteration of the EU's approach could substantially disrupt U.S. exports, the United States has asked the EU to ensure that all Member States follow the Commission's current interpretation.

Other problematic issues with the EU's REACH regime include inadequate transparency and differing registration requirements for EU and non-EU entities. In general, the European Commission regularly publishes notices of draft EU measures in the Official Journal of the European Union and sends notifications to the WTO Secretariat. However, U.S. and other non- EU interested persons allege such notifications occur far too late in the process for them to familiarize themselves with the new requirements and submit timely comments. In advance of these notifications, European Commission trade and regulatory officials consult primarily with EU stakeholders.

The United States has raised concerns regarding REACH at nearly every TBT Committee meeting since 2003, and has been joined by many other WTO Members, including Argentina, Australia, Brazil, Canada, Chile, China, Colombia, Cuba, the Dominican Republic, Ecuador, Egypt, El Salvador, India, Israel, Japan, Korea, Malaysia, Mexico, Qatar, Russia, Singapore, Switzerland, Taiwan, and Thailand. The United States also has raised its concerns regarding REACH directly with the EU and has worked with the European Chemicals Agency on specific technical issues.

In addition, the United States registered concerns with the EU during the November 2011 TBT Committee meeting regarding a costly REACH requirement, applied only to manufacturers outside the EU, to appoint "Only Representatives" (ORs). An OR is a natural or legal person established in the EU authorized to carry out the obligations that REACH imposes on importers.

REACH bars U.S. producers from registering substances for use in the EU and thus they must engage an OR for this purpose.

The United States also encouraged the EU to address in its 2012 REACH review data compensation issues in connection with the operation of Substance Information Exchange Forums (SIEFs). Specifically, U.S. industry has raised concerns that the "lead registrant" for each SIEF may take commercial advantage of its position in dealing with other SIEF members, particularly SMEs. Because other SIEF members must negotiate with the lead registrant to register their chemicals, a lead registrant could unfairly charge members registration fees at a level that would reduce competition in the EU market. The United States urged the EU to consider issuing guidance for cost-sharing that would place limits on what lead registrants can charge other SIEF members, thus preventing undue financial burdens on those members, especially SMEs.

The United States will continue to monitor closely REACH implementation in 2013, and will raise trade concerns, as appropriate, in the TBT Committee and other pertinent fora.

Wine – Traditional Terms

The EU continues to seek exclusive use of so-called "traditional terms" such as tawny, ruby, reserve, classic, and chateau on wine labels, but may allow third-country producers to use such terms if their governments enter into an agreement with the EU regulating use of the terms in their markets. Regulation EC No 607/2009 implements EU protections on designations of origin and geographical indication, traditional terms, labeling, and presentation of certain wine products.

The EU's regulation of traditional terms severely restricts the ability of non-EU wine producers to use common or descriptive and commercially valuable terms to describe their products sold in the EU. While no shipments have been blocked, U.S. industry reports that the regulation has deterred exporters from seeking to enter the EU market. The EU's efforts to expand the list of so-called "traditional terms" to include additional commercially valuable terms are also problematic because some of these terms do not have a common definition across all EU Member States. Additionally, the United States remains concerned about the EU's decision to withdraw permission to use certain "traditional terms" under the United States – EU agreement on trade in wine, as well as the EU's limitation on the use of traditional expressions in trademarks.

The EU justifies these above-mentioned efforts to limit use of traditional terms on the ground that misuse of the terms may confuse consumers. However, these terms have been used without incident on U.S. wines in the EU market for many years. Moreover, the EU has allowed the use of the terms by other countries, including Chile, South Africa, Canada, and Australia. Although the EU recently approved the use by U.S. industry of the terms "cream" and "classic" it has not issued a decision with respect to use on U.S. products of the terms "chateau," "clos," "ruby," and "tawny." During 2013, the United States will continue to coordinate with U.S. wine exporters on how best to address and resolve concerns regarding the EU's wine policy, and will engage with EU officials at the TBT Committee and in bilateral meetings.

Distilled Spirits – Aging Requirements

The EU requires that for a product to be labeled "whiskey" it must be aged a minimum of three years. U.S. whiskey products that are aged for a shorter period cannot be marketed as "whiskey" in the EU market or other markets such as Israel and Russia that adopt EU standards. The United States views a mandatory three-year aging requirement for whiskey as unwarranted. In fact, recent advances in barrel technology enable U.S. micro-distillers to reduce the aging time for whiskey. Variations in climate can also shorten aging time. In 2013, the U.S. will continue to urge the EU and other trading partners to end whiskey aging requirements that serve as barriers to U.S. exports.

Biofuels – Renewable Energy Directive

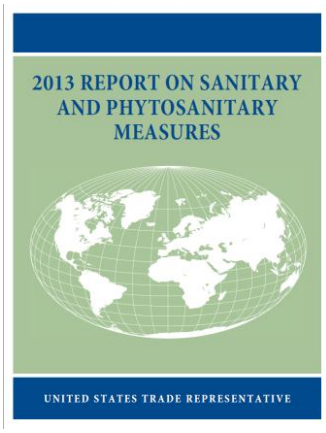
The EU's renewable energy directive (RED) provides for biofuels (such as biodiesel and ethanol) and biofuel feedstocks (such those derived from soybeans or canola) to be counted toward fulfilling Member State biofuel use mandates. It also provides for biofuels and biofuels feedstocks to benefit from RED tax incentives but only if they qualify for a sustainability certificate. However, to qualify for a sustainability certificate biofuel or biofuel feedstock must meet a patchwork of standards or be subject to a bilateral agreement with the EU. The use of varying approaches and sustainability standards has disrupted U.S. trade in soybeans.

To find alternative approaches to address U.S. concerns with the EU's certification scheme, the United States and the EU began discussions to explore a possible bilateral agreement that would

recognize that longstanding U.S. conservation programs correspond to RED sustainability criteria. In July 2011, a high-level delegation from the U.S. Government met with officials from the EC Directorate-Generals for Trade and Energy to address U.S. concerns. Additional discussions were held in September, November, and December 2011, leading to the creation of a working group to explore the possibility of a bilateral agreement as provided for under the RED.

The working group met in February, April and June 2012, but did not reach agreement on the basis for a bilateral agreement. In the November 2012 TBT Committee meeting, the United States continued to urge the EU to show flexibility and openness in recognizing different approaches that could provide equivalent outcomes when it comes to sustainable energy feedstocks. In 2013, the United States will continue to work with the EU and push for resolution of U.S. concerns.

2013 REPORT ON SANITARY AND PHYTOSANITARY MEASURES



EUROPEAN UNION

Agricultural Biotechnology

European Union (EU) measures governing the importation and use of GE products have resulted in substantial barriers to trade. Restrictions on GE products can result in import prohibitions on U.S.-produced commodities and foods, as well as prohibitions on the cultivation of GE seeds.

EU policies restrict the importation and use of U.S. agricultural commodities derived from agricultural biotechnology. These restrictions include but are not limited to:

- Delays in approvals of new GE traits despite positive assessments by the European Food Safety Authority (EFSA);
- Imposing commercially infeasible requirements on GE content in food products under EU Traceability and Labeling (T&L) regulations;
- Prohibitions on importation of GE commodities by certain EU Member States;
- Difficulties in applying for registration of GE commodities in the National Seed Catalog; and
- Application of unnecessary and burdensome coexistence requirements to planting of GE crops alongside non-GE crops by certain EU Member States.

Under EU law, each GE trait, as well as each combination of traits, must be approved for a specific use before an agricultural product containing or produced from that trait or traits is allowed to be imported or used in the EU. The EU approval system has two basic steps: an initial scientific assessment, followed by a "comitology" process, which involves interactions between the European Commission and the EU Member States. Even when the EU approves a particular GE product, EU biotechnology legislation provides that individual Member States may invoke their own bans under a so-called "safeguard clause."

EFSA undertakes the scientific assessment. EFSA assessments of GE products generally take longer than comparable scientific assessments in the United States and other countries. However, EFSA generally reaches the same scientific conclusion for a specific GE product as scientific authorities in the United States and other countries. EFSA has never concluded that a GE variety in U.S.

commercial production is unsafe. If EFSA concludes that the GE product is as safe as its conventional counterpart, the application proceeds to the comitology process. In 2012, the European Commission proposed to change its regulations governing the EFSA evaluation to specify the data and testing necessary for all applications. The Commission finalized this proposal in February 2013 despite U.S. government comments questioning the scientific basis for the regulation. The regulation requires certain tests, including feeding studies, irrespective of whether they are scientifically necessary and appropriate to the application and go beyond or conflict with the approach to safety assessment as outlined in the Codex plant guideline. The new regulation risks further increasing the length of time EFSA needs to evaluate applications.

Under the comitology process, the European Commission first prepares an approval measure based on the scientific assessment. The Commission then submits the measure to a regulatory committee comprised of representatives from each of the 27 EU Member States. Not once in over 12 years has an EU regulatory committee accepted a proposed measure to approve a new GE product. Instead, EU regulatory committees have always issued a "no-decision." This non-result leads to further, time-consuming procedures in the comitology process. The failure of EU regulatory committees to make decisions in accordance with the EU's own scientific opinions has resulted in substantial delays in the approval of GE products.

In response to these types of problems, in May 2003, the United States – joined by Canada and Argentina – initiated a WTO challenge to the EU's operation of its biotech approval system. In September 2006, a WTO dispute settlement panel upheld the U.S. claims. The panel found: (1) that the EU had adopted a *de facto*, across-the-board moratorium on the final approval of GE products and that the moratorium resulted in undue delays in violation of the EU's obligations under the SPS Agreement; (2) that the EU had violated its SPS obligations to consider biotech applications without undue delay with respect to 24 specific GE product applications; and (3) that EU Member State bans on products approved in the EU prior to the moratorium were not supported by scientific evidence and were thus inconsistent with the EU's SPS obligations.

The WTO Dispute Settlement Body adopted the report in November 2006, and the EU's "reasonable period of time" for compliance expired in January 2008. At that time, the United States submitted a request to the WTO for authority to suspend trade 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 GE products. The United States continues to engage the European Commission in an effort to normalize trade in GE products.

At the end of 2012, 72 GE product applications (for import, renewal, and cultivation) were pending approval in the EU system. The EU approved only six GE products in 2012 (5 new products and one renewal of a previously approved product), with an average processing time of 40 months. In addition, the EU has not approved for cultivation a single GE product of commercial significance to the United States in over 12 years.

EU delays in GE product approvals can block trade not only for the products subject to the delays, but also for approved varieties. Under the EU's implementation of its biotechnology legislation, the presence in U.S. grain or oilseed shipments of trace amounts of GE crops that are legally grown in the United States, but not yet approved in the EU, can make U.S. crops unmarketable in the EU. In July 2011, the EU implemented a "technical solution" to address the presence of trace amounts of

EU-unapproved GE products in import shipments. The new rules only cover shipments of imported animal feed (thus excluding food for human consumption) and provide an impractically low threshold level. The Commission has announced that it will assess the need to include food within the scope of the rules, but has yet to issue any proposals. The EU has taken steps to address some but not all of the Member State bans that the WTO panel found to be inconsistent with the EU's WTO obligations. Member States have continued to adopt new bans on products approved at the EU-level, however. In most cases, the Commission asks EFSA to issue an opinion on whether the Member State ban can be justified on a scientific basis. EFSA consistently has determined that the Member State bans lack a scientific justification. In several instances, the Commission has proceeded to draft a measure, in accordance with the EFSA scientific opinion, that would require a Member State to lift an unjustified ban. However, the EU regulatory committees have blocked each such measure, just as the regulatory committees have failed to approve new GE varieties.

In July 2010, the Commission presented a package of proposals that would expand the reasons that a Member State could use to justify bans on cultivating GE crops in its territory. The package includes a new recommendation on the co-existence of GE crops with conventional and organic crops and a proposal amending the governing legislation. The recommendation on co-existence took immediate effect. It provides Member States greater flexibility when developing national co-existence measures and allows them to define GE-crop-free areas. The legislative proposal, which is still under consideration and is subject to "co-decision" by the Member States and the European Parliament, would allow Member States to restrict or prohibit the cultivation of GE crops in all or part of their territory. The proposal does not require Member States to base any such restrictions on safety concerns, but allows them to take into account other societal concerns.

The EU continues to restrict imports of U.S. long grain rice following the discovery in a 2006 shipment of the genetically engineered Liberty Link 601 (LL601) trait. Since 2006, the U.S. rice industry has effectively removed the trait through rigorous seed testing under an industry-wide protocol (called "the Seed Plan"), but European rice importers and retailers have largely refused to purchase U.S. rice out of fear of the legal and commercial consequences should a detection of the LL601 trait occur again.

See section also section "Country Specific Issues".

Food Safety

Beef and Beef Products – Hormones

In May 2009, the United States signed a memorandum of understanding (MOU) with the EU to resolve on a provisional basis their WTO dispute over U.S. beef raised with growth-promoting hormones. The MOU, which took effect in August 2009, provides additional duty-free access to the EU market for high-quality beef produced from cattle that have not been raised with growth-promoting hormones – 20,000 metric tons (MT) in each of the first three years, increasing to 45,000 MT beginning in the fourth year. The EU increased the quota to 48, 200 MT beginning in August 2012.

The United States will continue to monitor EU implementation of the MOU, as well as other developments affecting access to the EU market for U.S. beef products. *Beef – Pathogen Reduction Treatments*

The EU's failure to approve pathogen reduction treatments (PRTs) that are used in the United States is still an issue. In December 2010, USDA requested the Commission to approve the use of lactic acid as a pathogen reduction treatment (PRT) in processing of beef carcasses and meat. The European Commission subsequently requested EFSA do a risk assessment on the use of lactic acid as a beef PRT. In July 2011, EFSA issued its risk assessment, which concluded that beef treated with lactic acid as a PRT is safe for human consumption. After considerable delay, the European Commission published a final regulation allowing the use of lactic acid, which entered into effect on February 25, 2013.

Cherries

The EU requires cherries to be free of *Monilinia fructicola* (brown rot) and requires written proof that controls have been applied in the field. This requirement limits the supply of U.S. cherries that would otherwise qualify for export to the EU. While brown rot is known also to exist in some EU Member States, the EU does not require the same field trials for EU Member States where brown rot is found. The United States is currently engaged with EFSA to find a resolution to this issue.

Poultry – Pathogen Reduction Treatments

In 1997, the EU began blocking imports of U.S. poultry products that had been processed with PRTs. The EU has further prohibited the marketing of poultry as "poultry meat" if it has been processed with PRTs. In late 2002, the United States requested the EU to approve the use in the processing of poultry intended for the EU market of four PRTs that are approved for use in the United States: chlorine dioxide, acidified sodium chlorite, trisodium phosphate, and peroxyacids.

Between 1998 and 2008, various EU agencies issued scientific reports concerning poultry processed with these PRTs. Taken together, the reports conclude that residues of these PRTs do not pose a health risk to consumers.

In May 2008, the European Commission, after years of delay, prepared a proposal that approved the use of the four PRTs for processing of poultry, but imposed highly trade restrictive conditions that did not appear to be based on science. EU Member States rejected the Commission's flawed proposal, first at the regulatory committee level and then, in December 2008, at the ministerial level.

In January 2009, the United States requested consultations with the EU on whether the EU's failure to approve the four PRTs was consistent with the EU's commitments under various WTO agreements, including the SPS Agreement. The United States and the EU held those consultations in February 2009 but failed to resolve the matter. In November 2009, the WTO Dispute Settlement Body established a panel to address the matter. That litigation is pending.

Ractopamine

The EU currently maintains a ban on pork produced with ractopamine, a feed additive that promotes feed efficiency in pigs and certain other livestock, despite U.S. government approval, establishment of a Codex standard, and scientific evidence indicating that ractopamine can be used safely. As a consequence of this ban, U.S. pork exporters must participate in the burdensome *Pork for the EU Program* to verify that the pork has not been produced using ractopamine. In addition, U.S. pork shipments to the EU must undergo expensive laboratory testing to verify the absence of ractopamine residue. These requirements, which appear to lack scientific justification, pose a major impediment to U.S. pork exports to the EU, confining U.S. exports to a small group of U.S. suppliers.

On July 5, 2012, Codex adopted standards for the maximum residue levels for ractopamine. The United States will continue to encourage the EU to implement the international standards or provide sufficient scientific evidence to support its unwarranted SPS trade barriers.

Seafood

Prior to 2008, the EU authorized imports of U.S.-origin molluscan shellfish under the terms of the United States-European Community Veterinary Equivalence Agreement. In 2008, the Commission's Directorate General for Health and Consumers notified FDA that the import approval for U.S.-origin molluscan shellfish would expire at the end of 2009. Despite high-level U.S. Government engagement on the issue, the EU began barring imports of all U.S.-origin molluscan shellfish other than scallops in July 2010.

Since that time, the U.S. Government has actively engaged with the European Commission on this issue and has provided the EU sufficient evidence that U.S. molluscan shellfish are safe to consume. The United States considers that it has provided the EU the information it needs in order to reach an equivalence determination and allow imports of U.S. molluscan shellfish to resume.

Animal Health

Animal By-Products

Tallow

In 2002, the EU published Regulation (EC) 1774/2002, which established problematic new requirements related to BSE for marketing animal by-products that are not intended for human consumption, including by-products used in materials intended for animal consumption. The regulation effectively prohibited the import of U.S. tallow that is not intended for human consumption. Between 2002 and 2007 the United States and the EU engaged in discussions resulting in an agreement with the EU to amend its regulation to allow tallow for some technical purposes. In the years 2007-2009 the EU stated that they had to wait until they had replaced Regulation (EC) 1774/2002 to make those changes. In 2009, the EU published Regulation (EC) 1069/2009, which began the process of replacing Regulation (EC) 1774/2002. Upon publication of Regulation (EC) 1069/2009, the EU stated that the changes related to tallow would not come until new implementing regulations for Regulation (EC) 1069/2009 were implemented. In 2011, the EU published Regulation (EU) 142/2011, which took effect in March 2011 and did revise the requirements for importing tallow. While this regulation contained requirements for tallow intended for technical purposes that exceeded the recommendations of the OIE, the EU assured the United States that the EU would not apply the regulation in such a manner to block the import of U.S. tallow intended for certain technical purposes. U.S. industry began preparing to meet these new requirements. However, in 2012, the EU began applying the regulation in such a manner to effectively prohibit the import of U.S. tallow. Later in 2012, the United States began high level discussions with the EU to try to re-open the market. As a first step, the EU is preparing a draft amendment that could remove the effective prohibition on tallow intended for the manufacture of biodiesel, while retaining some costly requirements for U.S. producers. The United States continues to press the EU to remove those unwarranted requirements and allow more market access for U.S. tallow.

Milk

Under requirements for dairy product imports, the EU limits the number of somatic cells in raw milk, as measured by the somatic cell count (SCC). This requirement is burdensome for U.S. exporters, as the FDA allows raw milk to be sold in the United States with higher SCC levels than the EU does. Moreover, the FDA considers the SCC level to be a quality rather than food safety criterion and, as such, SCC should not be required for public health purposes. The United States will continue to work with EU authorities to resolve these issues.

EU Country Specific Issues

Austria

Agricultural Biotechnology

Since 1997, Austria has maintained a series of cultivation and import bans on agricultural products derived from GE. The United States challenged several of these bans at the WTO, which found them inconsistent with Austrian and EU obligations under the SPS Agreement. In May 2008, Austria lifted its import bans on the MON 810 corn (a pest-resistant corn variety) and T25 GE corn varieties, but left in place its cultivation ban on these varieties. Moreover, in July 2008, Austria issued new import bans on MON 863 corn as well as on three rapeseed (canola) lines.

Bulgaria

Agricultural Biotechnology

In March 2010, Bulgaria issued a new biotechnology law, which prohibits the cultivation of GE crops in all protected regions, as well as surrounding areas. The combined restrictions cover the entire country and, in effect, ban all biotech field trials and production. In addition, the law requires the Minister of Agriculture to invoke a "safeguard clause" for a particular GE crop in Bulgaria whenever another Member State applies a safeguard clause for that same crop in its own territory. Separately, in July 2010, Bulgaria enacted a prohibition on the use of GE products and ingredients in the production of foods for children and in baby food. The new regulation also banned distribution and sale of GE foods and food products in nurseries, kindergartens, and schools, as well as in retail outlets and within 100 meters of such establishments. The United

States has raised concerns with these measures with the government of Bulgaria and has asked Bulgaria to provide justifications for them.

France

Agricultural Biotechnology

Cultivation in France of MON 810 corn grew from 500 hectares in 2005 to 22,000 hectares in 2007. However, in January 2008, following a review by a new "interim" biotechnology authority, France banned the cultivation of MON 810 and invoked the "safeguard" clause under EU regulations. In October 2008, EFSA found that France had presented no scientific basis to justify the safeguard measure. Nonetheless, France has left in place its ban on the cultivation of MON 810. While the French State Council lifted the ban November 2011, pursuant to the conclusions of the European Court of Justice, France re-initiated its national ban on the cultivation of MON 810 on March 18, 2012. The press revealed that the Government of France reinitiated the ban without the advice of the High Council on Biotechnology.

BPA Ban

In late 2012, France adopted legislation that bans the use of materials produced using bisphenol A (BPA) in food contact surfaces for food products designed for infants or pregnant and lactating women, effective in January 2013, and for all foods beginning in 2015. In addition, the law requires the development of warning labels to be placed on all foods. If fully implemented, this measure is expected to severely limit U.S. exports of canned and many packaged foods, which can use packaging containing BPA. Currently, the U.S. Government is engaging with other stakeholders while considering options. The U.S. Government has expressed its concerns via a demarche to the French Prime Minister and French officials at the Ministries of Health, Agriculture, Trade and Finance, and has discussed the issue with the European Commission.

Germany

Agricultural Biotechnology

In 2009, Germany banned the cultivation of MON 810 corn and invoked the "safeguard" clause under EU regulations. EFSA determined that Germany had not presented any scientific evidence to justify the new ban. Despite the EFSA evaluation, the German Agricultural Ministry has maintained the MON 810 ban.

Greece

Agricultural Biotechnology

Greece maintains a ban on all biotech cultivation as well as the importation of several GE products. Since April 2005, Greece has implemented and extended bans on MON 810. In July 2008, EFSA determined that Greece's ban lacked a scientific basis. Nevertheless, in August 2009, Greece extended the ban for another two years and expanded the measure to include cultivation. Greece now maintains its bans on MON 810 by invoking the "safeguard clause" under the EU regulations.

Hungary

Agricultural Biotechnology

In 2011, Hungary implemented new rules relating to GE seed testing. The testing policy does not address any identifiable environmental or health risks, the testing methodologies are not transparent, and test results may not be challenged on technical grounds. In senior level meetings, USDA registered concern with how Hungary is handling the issue of seed testing and advocated the importance of science-based, transparent regulations to agricultural investment.

Hungary maintains three differing testing policies based on the origin of the seed. Seed produced in Hungary is subject to random testing for the presence of GE products, but no comprehensive testing and certification is required. Seed imported from another EU Member State is required to have a testing certificate from an accredited EU laboratory. Seed imported from a third country requires testing by a Hungarian government laboratory. As the Hungarian laboratories do not follow transparent processes, do not use standard methodologies, and do not allow test results to be challenged, non-EU seed producers appear to be at a disadvantage to EU seed producers.

In 2012, Hungary adopted an amendment to its 1998 Act on Biotechnology. The amendment refines the rules that apply to non-commercial release of GE varieties for research purposes, expands the regulatory powers of the relevant Hungarian authorities, and mandates that administrative procedures for imports of GE food and feed align with EU rules.

Italy

Agricultural Biotechnology

Numerous actions attest to the fact that Italy is pursuing a GE-free strategy. Italy has one of the most anti-GE voting records in the EU and has failed to authorize biotech field trials despite EU ministerial approval. For the past decade, Italy has maintained a *de facto* ban on the cultivation of EU-approved GE crops by creating fragmented national and regional biotech authorities in addition to the EU authority. Moreover, Italy has not established a national legal framework for the cultivation of GE products. Seed importers report that they are subject to criminal penalties for the adventitious (i.e., accidental or unintended) presence of GE seeds in commercial shipments of non-GE seeds.

In September 2012, the European Court of Justice (ECJ) issued a decision that Italy's additional national authorization procedures for GE crops are unlawful, concluding that the cultivation of such varieties cannot be made subject to a national authorization when their use has been authorized at the EU level. The ECJ was ruling on a case brought against the Italian Ministry of Agriculture, which had denied authorization to plant a GE corn variety pending the adoption of a national coexistence measures.

Latvia

Agricultural Biotechnology

On June 18, 2009, Latvia modified its Law on Circulation of Genetically Modified Organisms to grant decision-making authority on biotech cultivation to local municipalities. Since passage of the law, 95 percent of the 109 municipalities in Latvia have banned the cultivation of GE crops in response to strong consumer activism and tacit support of the Ministry of Environment. According to Latvia's Ministry of Environment, the basis for the current regulation is the "EU Environment Ministers agreement - Council Conclusions," which notes that GE-free zones can be created on the basis of voluntary agreements among the "economic operators" in an area.

Prior to June 18, 2009, Latvian law provided that only the Cabinet of Ministers could prohibit biotech plantings and such a decision had to be based on scientific evidence that a specific GE crop posed safety concerns for the environment, health, or economy. The United States has engaged the government of Latvia regarding this shift in policy and has requested further information about the basis for the current biotech cultivation bans.

Luxembourg

Agricultural Biotechnology

In March 2009, Luxembourg banned the cultivation of MON 810. EFSA found that Luxembourg's ban lacked a scientific basis, yet the ban remains in place.

Poland

Agricultural Biotechnology

Since 2006, Poland has not only opposed the approval of GE crops at the EU level, but has taken official steps to become "GE-free." In 2006, Poland passed legislation that banned the sale and registration of GE seeds, restricted Polish representatives to the European Parliament from supporting pro-biotechnology legislative proposals, and prohibited the importation, production, and use of animal feed derived from GE crops beginning in August 2008. On August 28, 2012 the Polish

President Komorowski signed an amendment to the Feed Act pushing back the implementation of a ban on entry, prohibition of manufacturing, marketing, and use of animal feeding containing GE components till January 1, 2017. Current legislation envisaged that the ban was to be implemented on January 1, 2013. The signed amendment ensures access for imported feed with GE component to Poland until at least the end of 2016.

On December 21, 2012, President Komorowski signed into law amendments to the Law of the Seed that should bring Poland into compliance with EU legislation. On January 2, 2013, the Polish Council of Ministers, at the request of the Minister of Agriculture, re-authorized its 2008 framework position on agricultural biotechnology and permitted the Ministry to ban cultivation of GE crops by applying the EU safeguard clause. On January 28, 2013, the ban on GE crop cultivation entered into force along with the amended Law of the Seed.

Portugal

Agricultural Biotechnology

In May 2010, the Autonomous Region of Madeira (a Portuguese archipelago) became the first region of the EU to declare itself free of biotech cultivation after the European Commission failed to oppose Madeira's request by the legislated deadline. Madeira's authority for the ban was further codified when, in July 2010, the Commission announced new "co-existence" measures that authorize Member States to allow, restrict, or ban the cultivation of GE crops in part or all of their territory. The net effect of the Madeira GE-free declaration is that no GE crops can be grown in Madeira. The United States has raised this issue in bilateral meetings with Portugal.