

EUROPEAN UNION

TRADE SUMMARY

U.S. goods exports in 2014 were \$276.7 billion, up 5.5 percent from the previous year. European Union countries, together, would rank as the second largest export market for the United States in 2014. Corresponding U.S. imports from European Union were \$417.8 billion, up 7.8 percent. The U.S. goods trade deficit with European Union was \$141.1 billion in 2014, up \$15.7 billion from 2013.

U.S. exports of services to the European Union were \$205.9 billion in 2013 (latest data available), and U.S. imports were \$163.5 billion. Sales of services in European Union by majority U.S.-owned affiliates were \$554.7 billion in 2012 (latest data available), while sales of services in the United States by majority European Union-owned firms were \$426.1 billion.

The stock of U.S. foreign direct investment (FDI) in European Union was \$2.4 trillion in 2013 (latest data available), up from \$2.2 trillion in 2012. U.S. FDI in European Union is primarily concentrated in the nonbank holding companies, finance/insurance, and manufacturing sectors.

OVERVIEW

The United States and the 28 Member States of the EU share the largest and most complex economic relationship in the world. Trade and investment flows between the United States and the EU are a key pillar of prosperity on both sides of the Atlantic.

Transatlantic trade flows (goods and services trade plus earnings and payments on investment) averaged \$4.3 billion each day of 2013. The total stock of transatlantic investment was over \$5.1 trillion in 2013. Countries around the world benefit significantly from the prosperity generated by the transatlantic economy.

U.S. exporters and investors nonetheless face persistent barriers to entering, maintaining, or expanding their presence in certain sectors of the EU market. Some of the most significant barriers, which have endured despite repeated efforts at resolution through bilateral consultations or WTO dispute settlement, have been highlighted in this report for many years. Many are highlighted again in this year's report.

The United States plans to make substantial progress on reducing or eliminating remaining EU barriers to trade and investment by concluding the Transatlantic Trade and Investment Partnership (T-TIP) agreement. U.S.-EU negotiations on this comprehensive trade and investment agreement were launched in July 2013, following an announcement by President Obama and EU leaders. The eighth negotiating round was held in February 2015, and several more negotiating rounds are expected before the end of 2015.

TECHNICAL BARRIERS TO TRADE / SANITARY AND PHYTOSANITARY BARRIERS

Technical Barriers to Trade

Semiconductors and Refrigeration Appliances: Regulation on Fluorinated 67 Greenhouse Gases (F-Gas)

The EU adopted a new regulation phasing-down and phasing-out the use of many high global warming potential (GWP) F-gases on April 14, 2014. The EU had previously notified its intent to change this on February 7, 2013 as G/TBT/N/EU/91. Consistent with President Obama's Climate Action Plan regarding U.S. leadership on global efforts to phase down the consumption and production of climate damaging

HFCs, the United States strongly supports the objectives of the EU's proposed regulation, including its proposed approach that combines both a phase down of hydrofluorocarbons (HFCs) and specific appliance bans. However, a particular ban contained in the proposed measure raised concerns for some U.S. household refrigerator manufacturers. Indeed, several U.S., Korean, and Japanese commenters on the regulation expressed concerns with particular product bans, tight timelines for implementation and the unwillingness of the EU to meet with some impacted industries.

The specific concern among household refrigerator appliance manufacturers is the EU's change to its F-gas regulations to ban the use of HFCs with global warming potential (GWP) of 150 or more in residential refrigerators and freezers, which became effective on January 1, 2015. At least one U.S. based SME indicated that it cannot meet this requirement. The rest of the U.S. appliance industry did not oppose the reduction of HFC use – indeed many companies have already adopted alternative substances. Stakeholders did, however, express concern about particular product specific regulations and the aggressive 2015 timeline for implementation with respect to household refrigerators and freezers. Specifically, the U.S. commenters explained that a few companies, including some U.S. SMEs, that had not yet adopted the alternative substances taken up by others (*e.g.*, more than 50 percent of current new production globally uses hydrocarbons (HC- 600a) instead of HFCs) and cited significant and expensive changes to manufacturing processes that those companies would need to make to produce appliances that use hydrocarbon instead of HFC refrigerants.

The EU's own impact assessment recommended against a ban on HFCs in domestic (residential) refrigeration because of its low effectiveness towards reducing GHG emissions, stating that “a strict regulatory instrument such as a ban would need to be justified with a substantial contribution to the EU's emission reduction targets.” Nevertheless, the EU decided to include this ban. U.S. stakeholders expressed significant concern with the lack of opportunity to participate in the development of this proposal beyond a single public meeting. Stakeholders stated that DG Climate Action rebuffed several of its attempts to discuss the EU's proposal. Further, as noted above, the Commission had already transmitted its proposed regulation to the European Parliament and European Council before notifying WTO Members, and therefore the Commission did not take Members' comments into account by revising its proposed regulation.

Chemicals: Registration, Evaluation, Authorization, and Restriction of Chemicals

The EU regulation for the Registration, Evaluation and Authorization of Chemicals (REACH) began as a Communication from the Commission in 2001, “White Paper on Strategy for a future Chemicals Policy (REACH).” The European Parliament approved REACH and the European Council formally adopted it in December 2006. REACH entered into force on June 1, 2007, and will be fully implemented during 2015. REACH impacts virtually every industrial sector because it regulates chemicals as a substance, in preparations, and in products. It 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 as authorized for specific uses by the European Commission.

Concerns regarding various aspects of REACH have been raised at every WTO TBT Committee meeting since 2003 by the United States and many other WTO Members. WTO Members have indicated the need for greater transparency in the development and implementation of REACH requirements, and frequently cite the need for further information and clarification, as well as problems producers have in understanding and complying with REACH's extensive registration and safety data information requirements. The United States has also raised its concerns regarding REACH directly with the EU and has worked with the European Chemicals Agency (ECHA) on specific technical issues.

Among the substances subject to REACH regulations are nanomaterials, or chemical substances or materials that are manufactured and used at a very small scale (down to 10,000 times smaller than the diameter of a human hair), which are used in products ranging from batteries to antibacterial clothing. The Commission is considering options to adapt the data requirements for nanomaterials in REACH registration dossiers. The European Commission published an impact assessment in March 2014. This legislation will be adopted using the internal committee process that does not require European Parliament or Council action.

Although REACH provides a standardized plan for reporting and registering nanoscale ingredients or products containing nanomaterials, several EU Member states have initiated the development of their own such registries, which often include exemptions for pigments and food additives. The European Commission published its impact assessment on the feasibility of adopting an EU-wide registry of nanomaterials in November 2014. The impact assessment raised significant concerns about the efficacy of establishing such a registry and the Commission has expressed no desire to move forward with this project.

There is also concern over a lack of transparency and science-based analysis associated with the Community Rolling Action Plan (CoRAP). The CoRAP is part of the REACH substance “evaluation” process. Its purpose is to allow EU Member States and ECHA to prioritize substances that are suspected of being hazardous to human health or the environment. Depending on the outcome of the evaluation, a substance evaluated under CoRAP may be considered for classification as a substance of very high concern (SVHC) and become subject to authorization and restriction procedures. It is also possible that after evaluation, a substance will be found to not pose such a risk. ECHA has established criteria for selecting substances for placement on the list. These criteria address concerns about hazard, exposure, and tonnage. Member States are encouraged, but not obliged, to use the ECHA criteria and are empowered to evaluate the 73 substances on the CoRAP list. The most recent CoRAP list was approved by ECHA on March 26, 2014. It is updated every March. The current list contains 120 substances, which will be evaluated during the course of 2015 and 2016. CoRAP preliminary reports should be made available to interested U.S. companies, even if they have not yet registered the particular substance. Currently, the reports are only made available to registrants. More transparency on the part of the EU with respect to U.S. stakeholders impacted by this regulation would help reduce costs and address U.S. stakeholders’ concerns.

The United States has also continued to raise concerns bilaterally with the EU on the lack of public notice and comment associated with the “Risk Management Options” (RMO) analysis phase of the SVHC Roadmap. Under the Commission’s Roadmap for evaluation of individual SVHCs, at the request of the Commission, a Member State Competent Authority or ECHA will conduct an RMO analysis to determine whether regulatory risk management is required for a given substance and to identify the most appropriate regulatory instrument to address a concern. The regulatory decision may be to pursue authorization or restriction, address the concern via other legislation, or take no action. The Commission’s SVHC Roadmap identifies five minimum criteria for the RMO analysis and states that the RMO is not meant to be public. Beyond this, the authority drafting the RMO has discretion with respect to the level of detail provided in its analysis and whether or not consultation of stakeholders is appropriate. ECHA has said that documenting the RMO analysis and sharing it with other EU Member States and the Commission promotes early discussion and should ultimately lead to a common understanding on the regulatory action pursued. The United States supports the EU’s efforts to conduct RMO analysis and believes the RMO analysis should be implemented in a harmonized and consistent manner by Member States. Further, regulatory decisions taken under this process carry the potential to significantly impact trade. To prevent or minimize unnecessary potential adverse effects on trade, the RMO analysis should be subject to public notice and comment, with the views expressed by commenters taken into account by the Member State or ECHA irrespective of the domicile of the commenter.

Renewable Fuels: Renewable Energy Directive

In April 2009, the EU adopted the Renewable Energy Directive (RED) (2009/28/EC), with the objective of helping lower its greenhouse gas emissions (GHG), reducing its dependence on foreign oil, and increasing rural development. The RED establishes mandatory national targets for the share of energy from renewable sources by 2020. It also establishes a methodology and accounting system by which EU Member states may record and calculate GHG savings as compared to a baseline for fossil fuels. According to the European Commission, this comparison quantifies the total amount of GHG savings in the EU and progress toward the EU's overall goal of a 20 percent reduction in GHG emissions versus 1990 levels by 2020. To count toward Member State specific renewable energy use targets, or benefit from incentives, the RED requires that biofuels and feedstocks for biofuels meet certain sustainability criteria. The RED also sets the reporting and verification requirements for obtaining sustainability certifications.

The United States supports the emissions reduction objectives of the RED, but has expressed concerns both bilaterally and in the WTO that the Directive, and its paperwork and verification requirements, is disrupting trade in U.S. products (specifically soybeans used as biofuel feedstock) in ways that are not necessary for the achievement of its goals. Under Article 18(4) of the RED, which provides for bilateral agreements, the European Commission and the United States jointly established the U.S.-EU Technical Working Group on the RED (TWG), to examine how long-standing U.S. conservation programs address RED sustainability criteria and create the framework for a bilateral agreement to accept U.S. exports of biofuel feedstock as compliant with the sustainability goals of the RED. During the final meetings of the TWG, the Commission stated that U.S. conservation laws and programs must correspond exactly to those outlined in the RED sustainability criteria. At the TWG, the United States noted that requiring identical legislation was not the proper approach as the results of U.S. conservation laws and programs address the RED sustainability criteria and provide verifiable compliance measures for mass balance accounting.

Transport Fuel: Fuel Quality Directive

The EU's revised Fuel Quality Directive (FQD), adopted in 2009 as part of the EU's Climate and Energy package, requires fossil fuel suppliers to reduce the lifecycle greenhouse gas intensity of transport fuel by six percent by 2020. The Directive granted the European Commission the power to develop a methodology for calculating the GHG life-cycle emissions for transport fuels. The United States strongly supports the goal of the FQD of reducing GHG emissions. The United States has, however, raised concerns with the Commission about the lack of transparency and opportunity for public comment in the development of the Commission proposal for the methodology for calculating the GHG life-cycle emissions for transport fuels.

Trucks: Maximum Authorized Dimensions

U.S. stakeholders have long raised concerns that the EU's truck length requirements were too prescriptive and unnecessarily restricted U.S. exports of aerodynamic and fuel efficient trucks to Europe. On April 15, 2013, the EU issued a "Proposal for a Directive of the European Parliament and of the Council amending Directive 96/53/EC laying down for certain road vehicles circulating within the Community the maximum authorized dimensions in national and international traffic and the maximum authorized weights in international traffic." The EU notified the proposal to the WTO on May 24, 2013. The proposal stated that "in light of evolving market and available technologies" it is necessary to amend existing regulations (Directive 96/53/EC) "to improve the aerodynamics of vehicles and their energy efficiency, while continuing to improve road safety."

EU vehicle safety regulations measure truck lengths from the front bumper of the tractor to the rear of the trailer. The regulatory approach taken by the U.S. Department of Transportation is based on the length of the trailer alone. This regulatory divergence has driven the development of two, contrasting schools of

truck design: streamlined aero-nosed products in the United States and shorter, blocky “cabovers” in the EU. In the EU, and among countries that have adopted the EU’s approach, the allowable length of a truck tractor-semitrailer combination is 16.5 meters. Because American aero-nosed truck tractors are approximately 1.5 meters longer than European cabover truck tractors, they must pull shorter semitrailers in order to meet the truck tractor-semitrailer combination limit of 16.5, which diminishes payload capacity. Thus, while the EU approach does not ban American aero-nosed truck tractors, they are economically disadvantaged, because every measured inch/centimeter of the tractor up front means less space for paying cargo. Although aero-nosed trucks are longer, they have many advantages over cabover trucks. The best aero-nosed tractor is over 19 percent more aerodynamic and over nine percent more fuel efficient than the best cabover. As a result, aero-nosed products emit fewer greenhouse gases.

In 2014, the EU revised the proposal to include several elements to promote greater energy efficiency, including revisions that would allow truck tractor-semitrailer combinations to exceed 16.5 meters in length and to add flaps to the rear of the vehicle. The proposal also contained the statement: “The only purpose of these exceedances is to allow the addition to the rear of vehicles or vehicle combinations of devices increasing their aerodynamic characteristics.” It was therefore unclear whether the EU’s proposal would provide an opening to the longer American aero-nosed truck tractors regardless of whether devices were to be added at the rear. The Vice President of the European Commission has stated that the EU’s “intention is precisely to allow the potential use of slightly larger, more aerodynamic tractors - and/or rear devices, at the choice of manufacturers and end-users” and this intention would be captured in the still-to-be-developed technical specifications on aerodynamic designs or rear devices for trucks. The United States raised its concerns regarding the proposed directive in the WTO TBT Committee in 2014 and intends to raise bilaterally and during the Committee discussions in 2015 as well.

Food-Labeling Requirements

EU framework regulation 1169/2011 on the provision of food information to consumers – published in the Official Journal on November 22, 2011 – combines several EU directives and establishes new horizontal food labeling requirements. Most provisions became effective December 13, 2014, with mandatory nutrition labeling effective December 13, 2016. Although regulation 1169/2011 was adopted in December 2011, the EU still needs to propose and adopt a series of additional regulations to implement general provisions of the framework, and if necessary, conduct the corresponding impact assessments that normally accompany such proposals.

The United States has trade concerns regarding how certain elements of regulation 1169/2011 will be implemented, and is monitoring developments closely. The chief concern of U.S. stakeholders is that regulation 1169/2011 appears to provide wide latitude for EU Member States to adopt non-uniform implementing regulations. Specifically, U.S. stakeholders are concerned about the burden of meeting multiple labeling requirements, particularly if those requirements cannot be met through stickering or supplemental labeling. During the consultative process, the United States sought assurances that imported products will be subject to harmonized EU requirements, regardless of port of entry, and that compliance with national schemes (such as the United Kingdom and Ireland’s traffic light requirements) would remain voluntary.

The United States is working bilaterally to better understand the rationale and basis for mandatory labeling requirements that appear more stringent than those found in the Codex General Standard. The United States is also seeking assurances that only harmonized EU requirements will be mandatory and that national labeling requirements remain voluntary.

Agriculture Quality Schemes

Traditionally, EU policies on agricultural quality have been developed on a piecemeal basis. On May 28, 2009, the European Commission published its “Communication on Agricultural Product Quality Policy” aimed at clarifying and simplifying its product quality policies. The Communication addresses EU quality schemes, marketing standards, and other certification and labeling schemes, such as organics and animal welfare. It follows on from a Green Paper published in October 2008 and outlines a policy framework for three complimentary quality schemes: the geographical indication scheme, which consists of Protected Designation of Origin (PDO) and Protected Geographical Indication (PGI); the “Traditional Specialty Guaranteed” (TSG) scheme; and optional quality terms. Optional quality terms are defined as additional information about product qualities such as “first cold-pressed extra virgin olive oil” and “virgin olive oil.” A separate measure addresses the marketing standards for wine and spirits, notified to the WTO on September 11, 2011. The three quality schemes are either certification schemes for which detailed specifications have been laid down and which are checked periodically by a competent body; or labeling schemes which are subject to official controls and communicate the quality of a product to the consumer. Schemes can indicate that a product meets baseline requirements but can also be used to show “value-adding qualities” such as specific product characteristics or farming attributes (e.g. production method, place of farming, mountain product, environmental protection, animal welfare, organoleptic qualities, Fair Trade, etc.). Schemes can be voluntary or mandatory.

The United States submitted comments on the “Proposal for a Regulation of the European Parliament and of the Council on agricultural product quality schemes (COM (2010)733)” to the EU on August 2, 2011, and received a response from the EU in December 2011. The United States asked the EU to clarify the level of specificity required to identify a “place of farming,” as well as the legitimate objective for such a requirement. The U.S. comments also highlighted concerns that the proposal establishes a framework that provides a “legal basis” for expanding place of farming requirements to all processed products from specified commodities. The EU responded that “place of farming” will be applied on a case-by-case basis, following impact assessments, and further noted that the definition of “place of farming” will change from one product to another.

The European Parliament and Council finalized the regulation on quality schemes for agricultural products and foodstuffs (EU 1151/2012) in November 2012. In order to implement its general provisions, EU 1151/2012 gives the European Commission the power to adopt delegated or implementing acts, and the Commission has not yet issued such measures.

The United States remains concerned that “place of farming” requirements are unclear and difficult to comply with, and lack a basis in international standards. Codex, for instance, maintains no recommendation for place of farming designations, and has rejected proposals that would have expanded country of origin designations to foods with multiple ingredients, because such labeling caused consumer confusion.

Further, the United States remains concerned over certain aspects of the TSG requirements, including whether “prior use of a name” includes a trademark or prior geographical indication. The United States is also seeking clarification of the manner of precedence in determining TSG requirements relative to trademarks. Despite assurances from the EU that the provisions of EU 1151/2012 “ensure that a prior trademark is not affected by the registration of a TSG,” it remains unclear whether prior use of a trademark will be grounds for opposing registration of a TSG. Finally, U.S. stakeholders have expressed concern about the EU’s decision to shorten the comment period to oppose a registration from six months to two months.

The United States continues to stress to the Commission that common usage names of products should not be absorbed into quality schemes, whether for wine or other products. If a Codex standard exists, or if a

name is used in a tariff schedule or by the World Customs Organization, the United States believes that the name should be excluded from the quality schemes. The United States has further argued that new certification and labeling schemes not be required for market access; however, where the EU implements such schemes, efforts should be made to acknowledge voluntary U.S. industry definitions. Similarly, U.S. processes and procedures should be acceptable for labeling requirements, and system and process comparability with industry definitions should be sought in order to minimize any negative market access impact for U.S. exports.

Wine Traditional Terms

Separate from its policies on agricultural quality schemes, the EU continues aggressively to seek exclusive use for EU producers of “traditional terms,” such as “tawny,” “ruby,” and “chateau,” on wine labels. Such exclusive use of traditional terms impedes U.S. wine exports to the EU, including U.S. wines that include these traditional terms as part of their trademarks. U.S. wines with a trademark granted before 2005 can continue to use the terms as part of their trademarks, but products granted trademarks more recently cannot. In June 2010, the U.S. stakeholders submitted applications to be able to use the terms. In 2012, the EU approved the applications for use of two terms, “cream” and “classic,” but the EU’s delayed application approval process for other terms continues to be a significant concern. The United States has repeatedly raised this issue in the WTO TBT Committee in recent years, and has also pursued bilateral discussions, including through the T-TIP negotiations. Beyond approving the two terms, however, the EU has not taken any visible steps to address U.S. concerns.

During the March 2013 EU-U.S. Wine Bilateral meeting, representatives from the European Commission Directorate for Agriculture and Rural Development (DG AGRI) indicated that the EU would reform the application process. They acknowledged difficulties with the term-by-term approval process and suggested that the European Commission would develop a different approval procedure. The Commission did not provide any timeline for completing the application process reforms.

In 2014, the World Wine Trade Group (WWTG), which includes major wine-producing countries, such as Argentina, Australia, Canada, Chile, Georgia, New Zealand, South Africa, and United States, conveyed to DG AGRI that WWTG countries were frustrated with the EU’s application process and concerned that it may be more trade restrictive than necessary. The European Commission replied in February 2015 that it is discussing with EU Member State governments the conditions under which traditional terms may be used for labelling, but it did not commit to a timeline for resolving the issue.

Distilled Spirits Aging Requirements

The EU requires that for a product to be labeled “whiskey” (or whisky) it must be aged a minimum of three years. It is seen as a quality requirement. 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. In 2014, the United States continued to urge the EU and other trading partners to end whiskey aging requirements which are restricting U.S. exports of whiskey.

Sanitary and Phytosanitary Barriers

The United States is concerned that the EU maintains regulations ostensibly for the purposes of food safety and protecting animal health that may not be based on scientific principles or maintained with sufficient scientific evidence. Moreover, the United States believes there are instances where the EU should recognize

United States food safety measures as equivalent to those maintained by the EU because they achieve the same level of protection. If the EU did so, trade could be facilitated considerably.

Hormones and Beta Agonists

The EU maintains a ban on meat produced using hormones, beta agonists, and other growth promotants, despite scientific evidence indicating that meat produced from animals properly treated with growth hormones and other substances is safe for consumers. U.S. meat bound for the EU must be produced under costly and burdensome programs to verify that hormones, beta agonists, or other growth promotants have not been used. The EU continues to resist the approval or adoption of a maximum residue level (MRL) for the beta agonist ractopamine, which promotes leanness in animals raised for meat. The EU does so even though the Codex Alimentarius Commission (Codex) adopted an MRL for ractopamine following scientific study by the FAO/WHO Expert Committee on Food Additives (JECFA) that found ractopamine at the specified MRL does not have an adverse impact on human health.

In 1998, the United States brought a WTO dispute settlement proceeding against the EU regarding the beef hormone ban. A WTO dispute settlement panel concluded, and a subsequent report of the WTO Appellate Body confirmed, that the EU imposes the ban on hormones in breach of the WTO's SPS Agreement. Following the failure by the EU to implement the recommendations of the WTO Dispute Settlement Body (DSB) resulting from the proceeding, the United States was granted permission by the WTO in 1999 to apply retaliatory tariffs. *Ad valorem* tariffs of 100 percent were levied on imports of EU products. The value of the retaliation, \$116.8 million, represented the damage that the hormone ban caused to U.S. beef sales to the EU.

In 2009, the United States and the European Commission signed a Memorandum of Understanding, which established a new EU duty-free import quota for grain-fed, high quality beef (HQB) as part of a compromise solution to the U.S.-EU hormone beef dispute. Since 2009, Argentina, Australia, Canada, New Zealand, and Uruguay have also become eligible to ship under the HQB quota, and as a result, the market share of U.S. beef in the HQB quota has decreased and currently represents less than 50 percent of the quota.

The United States will continue to engage the EU regarding the unscientific ban on meat and animal products produced using hormones, beta agonists, and other growth promotants.

Agricultural Biotech

The EU's approval process for biotech crops is resulting in a divergence in regulatory outcomes for biotech events approved (and grown) in the United States and those approved in the EU. Moreover, the length of time taken for the EU decisions on new biotech crops appears to be increasing. As of March 11, 2015, 66 biotech applications (for import, renewal, or cultivation approval) remain pending in the EU biotech review system.

The EU approved only five products in 2013 and did not approve any products in 2014, taking an average of 45 months to reach decisions. The delay in EU approvals is a combination of the time it takes for European Food Safety Authority (EFSA) to make its safety determination, and the process for the European Commission to finalize an approval. This gap can take multiple years. Between 1998 and 2003, the EU similarly failed to approve any biotech products for sale in the EU. In 2003, the United States initiated a WTO dispute settlement proceeding against the EU. A WTO dispute settlement panel concluded that the EU applied a general *de facto* moratorium on the approval of biotech products. The WTO panel found this moratorium was inconsistent with the EU's obligations under the SPS Agreement because it led to undue delays in the completion of EU approval procedures.

Currently, exports of U.S. corn have been largely stopped because of concerns that events approved and grown in the United States, but not approved in the EU, will be detected and shipments rejected. U.S. exports of distillers' dried grains and corn gluten feed continue but could be disrupted by the detection of an unapproved event. U.S. rice exports remain well below the levels seen before the discovery of an unapproved event in the U.S. rice crop. Although no agricultural biotech rice varieties are currently grown in the United States, the approval of the single rice event under consideration in the EU could reduce commercial uncertainty associated with concerns about the detection of low-level presence in a shipment.

The United States continues to work with the EU to support continued trade in corn byproducts, but success will depend on the EU addressing the larger issue of delays in the biotech approval process.

Pathogen Reduction Treatments for Poultry

In 1997, the EU began blocking imports of U.S. poultry products that had been processed with pathogen reduction treatments (PRTs), which have been safely used by U.S. poultry producers for decades. In late 2002, the United States asked the EU to approve the use of four PRTs during the processing of poultry intended for the EU market. The PRTs are approved for use in the United States and include chlorine dioxide, acidified sodium chlorite, trisodium phosphate, and peroxyacids. Between 1998 and 2008, various EU agencies issued scientific reports concerning poultry processing and reaffirmed the findings of U.S. food safety authorities that residues of the four 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 during the processing of poultry, but imposed unscientific highly trade restrictive conditions with their use. EU Member States rejected the Commission's proposal in December 2008.

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. In November 2009, the WTO DSB established a panel to address the matter.

In June 2013, USDA submitted a new application to the EU for use of peroxyacetic acid (PAA) as a PRT in poultry. In March 2014, EFSA adopted and published a favorable risk assessment for PAA. The Commission has yet to draft a measure approving the use of PAA on poultry, however, citing the recent transition change of Commissioners. The United States continues to engage the EU regarding the drafting and approval of a draft regulation authorizing the use of PAA as a PRT in poultry.

Export Certification

EU certification requirements are limiting U.S. agricultural exports such as meat, dairy, eggs, composite products, and animal byproducts, adding unnecessary costs to the movement of exports in Europe, irrespective of whether these goods are destined for commercial sale in the EU, transiting through the EU, or intended for cruise ships or U.S. military installations located in the EU. The sanitary and phytosanitary requirements are often inconsistent with international standards or appear to have been implemented without scientific justification. In particular, the certificates are often so rigid that it is nearly impossible to verify the requisite certification requirements even if the product is produced specifically for the EU. The level of detail required on the certificate (the specific attestation language) leads to a multitude of forms being required for each product containing references to multiple levels of EU legislation that in turn cites other legislation. The multitude of certificates/forms also creates enormous confusion for producers, manufacturers and exporters, as well as U.S. regulatory agencies, EU member country authorities, and EU importers. The current legislation related to processed food products containing ingredients of animal and

plant origin (composite products) is also administratively difficult to address in connection with EU border inspections.

Burdensome and confusing export certification requirements amount to a *de facto* ban on exports of certain U.S. agricultural products which otherwise meet EU requirements. The United States continues to engage the EU in various fora to find a resolution to the countless complex issues that are a direct result of the EU's certification requirements.

Dairy Products

Effective April 1, 2012, all shipments of dairy products requiring EU health certificates must comply with new certification requirements regarding EU somatic cell count (SCC) and standard plate count requirements that reflect farm level sampling and must be accompanied by an updated Certificate of Conformance. The EU requires attestation and certification to SCC requirements not to exceed 400,000 cells/ml. The EU SCC requirement is not a public health issue but a quality issue. The EU maintains that the SCC requirements are an animal health/welfare indicator, but has also surmised during the T-TIP negotiations that SCC is a quality parameter. The U.S. maximum SCC for Grade 'A' milk is 750,000 cells/ml and is included in the model Pasteurized Milk Ordinance. The United States continues to engage the EU regarding their SCC requirement and has stressed the fact that the requirement is not a public health concern.

DPA Apples

In 2009, the EU removed Diphenylamine (DPA) as a plant protection product authorized for use within the EU. Subsequently, the EU established a maximum residue limit (MRL) of 0.1 parts per million (ppm) for DPA on apples and pears. This MRL was implemented on March 2, 2014, and affects both domestic and imported product. The MRL will be reviewed two years following the implementation date. However, the MRL of 0.1 ppm greatly limits the use of DPA on U.S. products destined for the EU. Such a low MRL could also result in rejection of untreated fruit due to inadvertent cross-contamination during handling and storage.

Without the use of DPA or a workable MRL that accounts for cross contamination, the European market is significantly limited for U.S. apple exports. The United States and Codex have a harmonized standard of 10 ppm for apples and 5 ppm for pear. EU residue testing for DPA on apples falls under the coordinated multiannual control program of the Union to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin within the EU. The United States will continue to engage the EU regarding this issue.

Animal Byproducts

The EU considers all animal byproducts sourced from animals raised under conditions not essentially identical to those in place in the EU to be hazardous materials (category 1 and 2 materials). Between 2002 and the present, the EU has made modifications to their regulations and implementation practices governing animal byproducts that have resulted in the treatment of U.S. products as hazardous. The current EU interpretation of the animal byproducts regulations could prevent most exports of U.S. animal byproducts. Several Member States border inspection posts have already begun to block consignments of various technical blood products.

The EU imposes requirements on U.S. tallow exports for non-food uses to meet criteria that appear to be maintained without sufficient scientific evidence and exceed OIE requirements. The United States and EU are engaging to seek a resolution on this longstanding barrier to trade in animal by-products.

EU Flavorings

There are five substances (1-methylnaphthalene, furfuryl methyl ether, difurfuryl sulphide, difurfuryl ether, and ethyl furfuryl ether) proposed for deletion from the EU Regulation 1334/2008 flavoring list. Restricting the use of these substances within the EU will limit the ability of the U.S. food and flavor sector to continue to use the substances in the global food chain, despite the fact that these proposed deletions are based on purely procedural grounds. The substances are proposed for deletion based on the fact that stakeholders were unable to provide the requested scientific data for additional evaluation by the EFSA within the legal deadline for submission of December 31, 2013.

These five substances have already been evaluated or are under consideration by other safety assessment bodies such as the UN FAO/WHO Joint Expert Committee on Food Additives JECFA, and are considered generally recognized as safe (GRAS) by the Flavor and Extract Manufacturers Association (FEMA) for their intended use as flavoring substances in the United States. The U.S. industry reports these substances are used in Europe as well as in other countries globally such as China, Japan, Latin America, Brazil, Mexico, and other countries that have adopted FEMA GRAS substances by reference.

Proposal for Categorization of Compounds as Endocrine Disruptors

Endocrine disruptors are naturally occurring compounds or man-made substances that may mimic or interfere with the function of hormones in the body. While the United States shares public health concerns with respect to endocrine disruptors, the United States is concerned that the EU appears to be contemplating approaches to regulating these compounds that are not based on scientific principles and evidence and thus would restrict trade without improving public health. Specifically, under the proposed approaches, the EU could ban a substance without considering exposure and evaluating the weight of evidence to determine whether there are any actual adverse effects to human and animal health. Active substances that are considered to have endocrine disrupting properties could potentially be banned and be required to be either withdrawn entirely or limited to permissible levels in food set at a default residue level of 0.01 ppm.

In 2013 and 2014, the United States raised this issue in WTO SPS Committee meetings and asked the EU to keep WTO Members informed of next steps. The EU officially notified a public consultation process to the WTO/SPS Committee on October 8, 2014, inviting all stakeholders to submit comments by January 16, 2015 as part of a “Public Consultation on Defining Criteria for Identifying Endocrine Disruptors.” The United States submitted official comments on the roadmap to the EU. The U.S. submission expressed concern that the options in the EU’s Roadmap omitted a risk-based scientific approach to regulating chemicals, which is likely to have severe implications both for EU growers and for third-country suppliers. The United States also suggested that a more extensive and developed public consultation process could result in measures that meet the objective of protecting human, animal, or plant life or health, while not unnecessarily restricting trade.

MARKET ACCESS

Non-Agriculture

Pharmaceutical Products

U.S. pharmaceutical stakeholders have expressed concerns regarding several EU 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. Such policies reportedly create uncertainty and unpredictability regarding investment in these markets and can undermine incentives to market and innovate further. These policies have been identified in several Member States, including: Austria, Belgium, the Czech Republic, Finland, France, Hungary, Lithuania, the Netherlands, Poland, Portugal, Romania, Spain, and the United Kingdom. Additional detail on some of these Member State policies follows. Pharmaceutical firms have also expressed concern regarding recent changes to European Medicines Agency (EMA) policy regarding disclosures of clinical trial data, including potential disclosure of confidential commercial information submitted to EMA by pharmaceutical firms seeking marketing authorization. The United States continues to engage with the EU and individual Member States on these matters.

Austria: U.S. companies have expressed concern regarding the transparency of, and opportunity for meaningful stakeholder input in, reimbursement rules and determinations for biosimilar pharmaceutical products.

Belgium: Over the past 15 years, U.S. pharmaceutical companies have repeatedly expressed concern about the Belgian government's lack of adequate transparency in the decision-making process related to cost-containment measures in the pharmaceutical sector. These companies have identified several tax-related measures, such as a 6.73 percent turnover tax, the 1 percent crisis tax, the 0.13 percent marketing tax, and the claw back tax, as exemplifying such concerns. The United States continues to highlight the need for closer dialogue with the government and meaningful opportunities for stakeholder input into budget and pricing decisions.

Czech Republic: While pharmaceutical approvals in the Czech Republic often exceed the EU timetables, U.S. stakeholders report that the duration for such approvals has decreased incrementally in recent years. Regarding the Czech Republic's system for determining pricing and reimbursement levels for pharmaceutical products, U.S. stakeholders continue to express concerns, including with respect to the transparency of, and opportunity for meaningful stakeholder engagement in, such determinations. For example, questions persist regarding how the Czech government's practice of setting maximum medicine prices based on the average of the three lowest prices in a basket of countries (currently a group of 18 EU Member States) reflects the Czech market and adequately incentivizes innovation in research and development of pharmaceutical products in its market.

Finland: U.S. innovative pharmaceutical companies continue to raise concerns regarding Finnish Pharmaceutical Pricing Board determinations with respect to the transparency and opportunity for meaningful stakeholder engagement in the pricing and reimbursement of pharmaceutical products as well as delays in reimbursement determinations by the Finnish national healthcare system. Such delays can in turn delay market entry for products with marketing authorization and create uncertainty and unpredictability regarding future market access.

Hungary: Pharmaceutical manufacturers have expressed several concerns about Hungary's pharmaceutical policies, including: the transparency of, and opportunities for meaningful stakeholder engagement in, volume and pricing determinations; high sector-specific taxes; and delays in reimbursement approvals.

U.S. stakeholders have also identified negative impacts of Hungary's "blind-bidding" system, which provides for reference pricing and de-listing of pharmaceuticals from reimbursement respect to therapeutic reference categories every six months. There are concerns with respect to the lack of transparency regarding the creation of such reference groups and that this system does not adequately incentivize innovation in research and development of pharmaceutical products.

Hungary has taken some positive steps to address the concerns of pharmaceutical manufacturers, including adoption of amendments to the Hungarian Act 95 of 2005 Medical Products for Human Use (also known as the Medicines Act) in June 2013, which empowers the National Institute of Pharmacy with investigative tools and powers to impose fines, conduct dawn raids, and conduct searches of premises and seize goods.

Italy: U.S. innovative companies have expressed concern about Italy's pharmaceutical policies, including with respect to transparency and opportunities for meaningful stakeholder input. Pharmaceutical companies report that, as in some other EU Member States, those companies are required to pay money back to the Italian government when government spending on pharmaceuticals exceeds the budgeted amount. According to industry reports, market entry for innovative drugs approved by the EMA has also been significantly delayed in Italy. Concerns also exist regarding the ability of pharmaceutical companies to fully exercise their patent rights for the complete patent term given the lack of an effective mechanism for the early resolution of patent disputes in the context of marketing authorization. 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.

Lithuania: The United States continues to engage with the government of Lithuania regarding pharmaceutical market access issues. Discussions between the Health Ministry and U.S. stakeholders have made little progress to add innovative drugs to the government's reimbursement list. Stakeholders remain concerned about the lack of transparency in the pricing and reimbursement process for innovative drugs.

Poland: U.S. stakeholders report improved transparency and engagement with the Ministry of Health regarding the development and implementation of cost-containment measures affecting pharmaceutical reimbursement and pricing policies. The Ministry consults with stakeholders on a monthly basis about proposed legislative changes and policy changes. The Ministry publishes every two months lists of pharmaceuticals that the national health system will reimburse. However, U.S. stakeholders continue to identify concerns in Poland, including with respect to its therapeutic reference pricing system for reimbursements, which provides no opportunity for differentiation of innovative products, thereby removing a key incentive for innovation in research and development of pharmaceutical products in its market. In addition, U.S. companies have expressed concern regarding the transparency of, and opportunity for meaningful stakeholder input in, reimbursement rules and determinations for biosimilar pharmaceutical products. Some pharmaceutical manufacturers have also expressed concerns regarding the length of time it takes the Ministry to add a new drug to the official reimbursement list.

Portugal: U.S. stakeholders report that there continues to be a lack of transparency in the development and implementation of government cost-containment measures. In addition, pharmaceutical companies continue to raise concerns regarding the patent dispute resolution mechanism established under Portuguese Law No. 52/2011, which has been in effect since January 2012. The law does not provide for injunctive relief with respect to the marketing of pharmaceutical products that infringe patents covering pharmaceuticals already authorized to be on the market. Instead, the law provides only for damages for patent infringement. While the arbitration system has proven to be faster than the Portuguese court system, stakeholders report that this mechanism is costly, lacks injunctive relief and has resulted in questionable rulings.

Romania: Innovative pharmaceutical producers have identified several significant challenges in Romania due to the fact that the government has not updated the lists of innovative pharmaceuticals that are eligible for reimbursement under the national health system, despite repeated requests. According to industry reports, Romania has yet to add 130 innovative drugs to the list that have been approved for marketing. This severely undermines the ability of U.S. pharmaceutical companies to introduce newer drugs in Romania because the National Health Insurance House will not pay reimbursement for drugs that are not included on the reimbursement list. The claw back tax is another major challenge for U.S. stakeholders, equivalent to roughly 20 percent of total gross sales. This tax rate is determined on the basis of the difference between the state's budget for reimbursable drugs and the amount consumers actually spend on the drugs.

Spain: U.S. stakeholders remain concerned that Spain's pricing and reimbursement system is unpredictable and lacks transparency. Stakeholders reported concerns regarding several pricing and reimbursement measures in Spain, including certain reference pricing requirements (e.g., reference groups containing both on-patent and non-innovative products), significant reimbursement rate reductions (between 30 and 50 percent in certain instances) as well as mandatory rebates on non-reimbursed medicines and medical devices. The industry is concerned that these measures do not adequately incentivize innovation in research and development of pharmaceutical products. The United States is working with the Spanish government on these issues.

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. The EU maintains quantitative restrictions on imports of enriched uranium in accordance with the terms of the Corfu Declaration, a joint 1994 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 reportedly by reserving 80 percent of the EU enriched uranium market for European suppliers. Such restrictions on imports of enriched uranium may raise concerns under the EU's obligations under the WTO. The United States has conveyed to the European Commission its concerns about the non-transparent nature of the Corfu Declaration and its application.

Agriculture

Bananas

In June 2010, the United States and the EU signed 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 banana 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 (also signed in June 2010), which provides for staged EU tariff cuts to bring the EU into compliance with its WTO obligations.

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 U.S. bananas dispute with the EU, provided certain conditions are met.

Concerns have been expressed by U.S. stakeholders about actions taken by Italian customs authorities, and related decisions taken by Italian courts, challenging the use of certain EU banana import licenses under pre-2006 EU regulations. The U.S. Government is pressing the European Commission to clarify its position on this matter.

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, adjusted every six months. Discussions on this subject with the European 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 the elimination of EU tariffs on brown rice and other U.S. agricultural products in the T-TIP negotiations.

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 POs 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 was fully decoupled from production decisions. However, potential hidden subsidies remain an ongoing concern for U.S. producers. In their view, the decoupled Single Farm Payments are funded by the European Commission and paid to the Member States, then channeled through POs to producers. 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 GATT 1994 rules, regarding compensation for certain tariff increases related to Romania's and Bulgaria's EU accession on January 1, 2007. In late 2011, the United States concluded negotiation of a bilateral compensation agreement with the EU covering several agricultural products. The two sides signed the agreement in December 2012 and it entered into force on July 1, 2013. The agreement establishes or

increases EU tariff-rate quotas allocated to the United States for several agricultural products; however, an EU requirement that U.S. exports be accompanied by a certificate of origin issued by U.S. federal authorities has prevented U.S. firms from taking advantage to date of the new country-specific TRQ for food preparations.

Certification

In an attempt to “level the playing field,” the EU is requiring animal welfare statements on official sanitary certificates. Although the United States supports efforts to promote animal welfare, the EU’s certification requirements do not appear to advance any food safety or animal health objectives. The United States position is that official sanitary and phytosanitary certificates – the purpose of which is broadly limited to prevent harm to animal, plant, or human health and life from diseases, pests, or contaminants – should only include statements related to animal, plant, or human health, such as those recommended by the Codex, the World Animal Health Organization (OIE), and the International Plant Protection Convention.

INTELLECTUAL PROPERTY RIGHTS PROTECTION

In 2014, 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, as well as the United States. The IPR strategy also included launching a green paper consultation 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 that provides over-broad 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 findings by the WTO DSB 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 concerns about this regulation and intends to monitor carefully both its implementation and current initiatives to modify it. These concerns also extend 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 United States is carefully monitoring the implementation of each of these regulations.

Furthermore, some EU Member States that are party to the Lisbon Agreement are leading an initiative to hold a closed diplomatic conference of the World Intellectual Property Organization (WIPO) in May 2015 to expand the current Agreement’s subject matter to include GIs. These negotiations raise serious trade and procedural concerns, including with respect to market access for U.S. producers, including with respect to protection for U.S. trademark holders and market access for U.S. exporters that use generic terms. During the October 2014 preparatory committee meeting for the Lisbon diplomatic conference, Lisbon Agreement members rejected the request from the United States and 14 other WIPO members that the draft rules of procedure be changed to allow full participation by all WIPO members. This refusal to allow all WIPO members to participate deviates from WIPO practice for the last 25 years.

With respect to copyright protection, the European Commission decided in December 2012 to initiate a two-part copyright program, set out in the Commission Communication entitled “Content in the Digital Single Market.” Under the first part of that program, the Commission launched a stakeholder dialogue,

known as “Licenses for Europe,” to address key copyright issues in the EU. The stakeholder dialogue was divided into four working groups: cross-border access and portability of services, user generated content and micro-licensing, audiovisual heritage, and text and data mining. In November 2013, stakeholders agreed to a series of pledges, contained in “Ten Pledges to Bring More Content Online.” The second part of the program involves completing the Commission’s review of the EU copyright legislation framework with a view to reaching a decision on whether to table legislative reform proposals. As part of this review, the Commission launched a public consultation to gather input from all stakeholders on the review of the EU copyright rules between December 5, 2013 and February 5, 2014 and was set to release a White Paper in summer of 2014. However, the paper has been delayed as a result of the transition to the new European Commission. The United States encourages the Commission to provide meaningful opportunities for U.S. stakeholder engagement in these Commission-led processes 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.

Member State Measures

While there have been improvements in some Member States, 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: Austria was not listed in the 2014 Special 301 Report. U.S. film and music copyright holders report, however, that while legal protections are strong in principle, procedural obstacles continue to limit efforts to effectively combat online piracy. In a positive development, the Vienna Trade Court ordered Austria’s major cable and internet provider UPC (subsidiary of Liberty Global) and four other Internet service provider (ISPs) in October 2014 to block access to popular illegal video streaming sites. This follows an Austrian High Court ruling from June 2014 that web blocking of Internet content is legal when the content is not in conformity with national or EU laws.

Bulgaria: Bulgaria continues to be listed on the Watch List after it was added in the 2013 Special 301 Report. U.S. stakeholders report continued concerns about IPR enforcement, including with respect to piracy over the Internet. Stakeholders have also highlighted the need for Bulgaria to enhance the effectiveness of its patent and trademark enforcement system, including with respect to prosecutions and to address bad-faith trademark registration at the Bulgarian Patent Office. Bulgaria has an established process for administrative rulings and appeals in cases of patent and trademark infringement, although significant concerns remain regarding the decisions issued in those adjudicatory proceedings.

Czech Republic: The Czech Republic was not listed in the 2014 Special 301 Report. While sale of copyright-infringing media in physical form continues at a modest level in outdoor markets, rights-holding organizations did not identify any problematic physical markets during the 2015 Special 301 mid-cycle Notorious Markets review. Due to the advance of technology, digital piracy in the Czech Republic, as elsewhere, has migrated primarily to the online realm, where rights-holders have identified several “cyberlockers” that feature pirated material for download and streaming. Rights-holders have experienced positive results in a number of instances when they have gone to court - though websites often reappear under a new name.

Estonia: Estonia was not listed in the 2014 Special 301 Report. While the new draft IPR legislation is not in force yet, the U.S. software and entertainment industries have raised concerns that the draft law is too consumer-oriented and will not adequately protect IP. Also, according to industry reports, a lack of adequate resources continues to limit efforts by law enforcement agencies to effectively combat online piracy.

Finland: Finland remained on the Watch List in the 2014 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.

Greece: Greece remained on the Watch List in the 2014 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 2014 Special 301 Report include widespread copyright piracy and weak and inconsistent IPR enforcement.

Hungary: Hungary was not listed in the 2014 Special 301 Report. Hungary and the United States have had an established bilateral Intellectual Property Agreement for over a decade. In 2012, Hungary joined the Patent Prosecution Highway (PPH) program, signing a Memorandum of Understanding with the United States. The PPH program is a process that allows a patent ruling in one country to begin a fast track process in another country for the same patent.

Italy: In 2014, Italy was removed from the Special 301 Watch List consequent to the Italian Communications Authority (AGCOM) having implemented Internet piracy regulations (a notice and take-down system) aimed at streamlining efforts to combat online piracy. The regulations took effect March 31, 2014. According to sources, the mechanism, while new and improvable, is working well and already bearing positive fruit in reducing online piracy in Italy.

Latvia: Latvia was not listed in the 2014 Special 301 Report. In recent years, Latvia has continued with its efforts to improve IPR protection and enforcement in its market, including amendments to its intellectual property criminal statutes that have simplified aspects of infringement cases and may result in more successful prosecutions of IPR violations. Concerns remain with respect to Latvian law, however, including regarding the ability to secure deterrent penalties under the Copyright Law, and the lack of provisions in the Public Procurement Law requiring use by government authorities of legitimate software. On enforcement, Latvia's police and prosecutors actively pursue IPR cases, but a lack of resources and severe backlogs in police forensics labs hamper their efforts.

Malta: Malta was not listed in the 2014 Special 301 Report. Although stakeholders report indicate that Malta's civil regime for copyright is generally adequate, they also report that Malta's criminal law is insufficient, including with respect to inadequate deterrence of IPR infringement. While the relevant provisions of the Maltese Criminal Code are generally viewed as satisfactory in the context of trademarks and designs, the Criminal Code provisions governing other intellectual property rights remain largely unenforced and should be updated to reflect technological advances.

Portugal: Portugal was not listed in the 2014 Special 301 Report. Portugal regularly conducts inspections for illegal goods at street fairs, markets, and festivals. However, it does not have adequate mechanisms to effectively deter piracy over the Internet. In 2012, Portugal established an Intellectual Property Court with two dedicated judges, which by last year reduced the average decision time to 119 days. However, stakeholders have complained about the unavailability of injunctive relief while a case is pending, as well as the need to recover monetary damages through separate civil actions.

Romania: Romania remained on the Watch List in the 2014 Special 301 Report. While counterfeit physical goods, infringing optical discs, and street piracy continued to decline in 2013 and 2014, piracy over the Internet, especially peer-to-peer downloading, remains a serious concern. IPR enforcement also remains inadequate, with serious questions arising regarding Romania's commitments to such enforcement,

reflected in reduced cooperation among enforcement authorities, a decline in the number of enforcement actions and a lack of meaningful sanctions. Other enforcement concerns include the 2010 changes to the Penal Code, which provide for trial court adjudication of IPR cases, where the judges and prosecutors have substantially less IPR expertise, higher rates of turnover, judicial inefficiency, and only limited use of deterrent sentences.

Spain: Spain has been part of a Special 301 Out-of-Cycle Review in 2013 and 2014, after Spain was removed from the Watch List in the 2012 Special 301 Report. Spain was removed from the Watch List in recognition of efforts with respect to IPR protection and enforcement, including the December 2011 adoption of the Copyright Act, a law to combat copyright piracy over the Internet. In October 2014, Spain approved amendments to its Copyright Act in several areas, including with respect to the authority of the IP Commission, linking sites, and damages for infringement. Spain has also enhanced its enforcement against copyright infringement over the Internet. U.S. stakeholders, however, continue to seek greater efficiency and efficacy from the Spanish government in this regard. In addition, Spain is undertaking amendments to its Penal Code, including with respect to IPR provisions. The United States will continue to carefully monitor the Spanish government's enforcement of IP protections as piracy remains a significant problem.

Sweden: Sweden was not listed in the 2014 Special 301 Report. Sweden continues to grapple with widespread piracy on the Internet. While several major piracy websites left Sweden following the entry into force of the April 2009 law implementing the EU Enforcement Directive, some large piracy websites continue to reside in Sweden. In response, government enforcement efforts have shown positive results, and police and prosecutors are now working more efficiently to investigate and move cases to prosecution. Legal sales over the Internet have increased in recent years, in part because of these enforcement efforts. In November, rights-holders brought a case to Swedish courts requesting that Bredbandsbolaget (one of the major ISPs in the country) block customers' access to the Pirate Bay. This is the first major case in Sweden of this type, and rights-holders are generally optimistic about the direction of enforcement efforts.

SERVICES BARRIERS

Telecommunications

In September 2013, the European Commission presented its draft for a regulation “[l]aying down measures to complete the European single market for electronic communications and to achieve a Connected Continent.” The proposal, often referred to as the Telecoms Single Market Regulation, includes new rules on net neutrality, network investments, spectrum management, and roaming, and would update the Common Regulatory Framework for Electronic Communications Networks and Services, last updated in 2009. The European Council agreed on a negotiating mandate on March 4, 2015, and so-called “trialogue” discussions between the European Parliament, Council, and Commission were scheduled to begin later that month.

Member State Measures

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. At the end of 2013, Germany's Monopolies Commission published a report recommending that the government sell its direct and indirect stake in Deutsche Telekom. Since then, the German government has sold a minimal share and, as of September 2014, still held a 31.7 percent stake, with 14.3 percent in direct shares and 17.4 percent through the state-owned KfW-Bank.

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 covered traditional broadcasting, whether delivered by terrestrial, cable, or satellite means) to also cover audiovisual media services provided on-demand, including via the Internet. The AVMS established minimum content quotas for broadcasting that must be enforced by all EU Member States. EU Member State requirements are permitted to exceed this minimum quota for EU content, and several have done so, as discussed below. The AVMS does not set any strict content quotas for on-demand services, but it 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.

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 AVMS 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 be French language. These requirements exceed those of the AVMS. 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 content, but 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 TV. France also maintains a four-month waiting period between the date a movie exits the cinema and the date when it can be shown on video-on-demand.

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 content. Ten percent of transmissions (and 20 percent for state broadcaster RAI) must be reserved for EU content produced during the preceding five years. Within this quota, an undefined percentage of time must be reserved for Italian movies.

Poland: TV and radio broadcasters must adhere to content quotas in Poland. TV broadcasters must devote at least 33 percent of their broadcasting time each quarter for programming originally produced in the Polish language, except information services, advertisements, telesales, sports broadcasts, and TV quiz shows. Radio broadcasters are obliged to dedicate 33 percent of their broadcasting time each month, and 60 percent of broadcasting time between 5:00 a.m. and midnight, to Polish language programming. TV broadcasters must dedicate more than 50 percent of their broadcasting time quarterly to programs of EU origin, except information services, advertisements, telesales, sports broadcasts, and TV quiz shows. On-demand

audiovisual media services providers also must promote content of EU origin, especially content originally produced in Polish, and dedicate at least 20 percent of their catalog to EU content.

Spain: For every three days that a film from a non-EU country is screened, one EU film must be shown. This ratio is reduced to four days 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 annually must invest five 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, and U.S. investors report that they have been negatively impacted. Following the 2010 amendment, several U.S. investors signed agreements with Spanish AV license holders to provide content for free-to-air TV channels. These investments were disrupted by a November 2012 Spanish Supreme Court decision, however, which annulled the DTT broadcasting licenses of these Spanish firms on the basis that the government had not followed the proper public tender process in allocating the licenses in 2010. As of May 2014, all of the annulled DTT channels have ceased broadcasting, and the Spanish government will hold a tender process in summer 2015 to reallocate the channels. U.S. investors will not be able to participate directly in this tender process due to restrictions on foreign ownership. The United States continues to engage on these issues with the Spanish government.

Legal Services

Austria, Belgium, Bulgaria, 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. In many cases, non-EU lawyers holding authorization to practice law in one Member State face more burdensome procedures to obtain authorization in another Member State than would a similarly situated lawyer holding EU citizenship.

Member State Measures

Bulgaria: The Bulgarian Bar Act allows law firms registered in the EU to practice in Bulgaria under their original name after they register with the local bar association. 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: 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). However, attorneys from U.S. law firms admitted as foreign lawyers may establish a business entity to engage in the practice of law under the U.S. company name.

Hungary: U.S. lawyers may provide legal services only under a “cooperation agreement” in partnership with a Hungarian law firm and can only provide information to their clients on U.S. or 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. 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 are required for a U.S. citizen to practice law in Portugal.

Accounting and Auditing Services

Member State Measures

Austria: Tax advisors must hold Austrian or EU nationality to represent clients before tax authorities. Foreign tax advisors may not hold more than 25 percent of the equity of Austrian entities.

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 in the associations.

Czech Republic and Slovakia: the Czech Republic and Slovakia both maintain an equity cap requiring that 60 percent of the voting rights of companies providing auditing services be held by EU nationals.

Retailing

Member State Measures

EU nationality is required for operation of a pharmacy in Austria, France, Germany, Greece, and Hungary.

EU Enlargement

After 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 EU Members. 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 to 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. The United States will continue to monitor this process to ensure the agreement is implemented as soon as possible.

INVESTMENT BARRIERS

Foreign investors in the EU are accorded national treatment 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.

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 changes to its Law on Public Offering of Securities, enforcement of these statutory provisions remains inadequate. A history of non-payment of contractual obligations, particularly in the energy sector, is a significant deterrent to investment. Foreign and local businesses have also identified corruption as a major obstacle to business and a deterrent to foreign investment in Bulgaria. Oligarchs exert influence over significant aspects of the economy and the political system. Politicians themselves often have substantial private business interests that are not publicly disclosed.

Cyprus: Cypriot law imposes significant restrictions on the foreign ownership of real property. Non-EU residents may purchase no more than two independent housing units (apartments or houses), or one housing unit and a small shop or office. Exceptions can be made for projects requiring larger plots of land, but are difficult to obtain and rarely granted. Only EU citizens have the right to register as construction contractors in Cyprus, and non-EU investors 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 has defined a number of “sensitive” sectors in which prior approval is 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.” On May 14, 2014, the government issued decree 2014-479, expanding the list of strategic sectors to include energy, water, health, transportation, and telecommunications, as well as any installation, facility or structure “vital” within the meaning of the Defense Code. The decree affects both EU and non-EU foreign investors.

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. In late 2008, France established a strategic investment fund (Fonds Stratégique d’Investissement – FSI) to assume a stake in companies with “key technologies.” The fund is majority-owned and run as a “strategic priority” by the Caisse des Dépôts et Consignations (CDC), a state-sponsored financial institution and France’s largest institutional investor. The government has also asked the CDC to work as a domestic buffer against foreign takeovers by increasing its stake in French companies. The government is also able to become directly involved in mergers and acquisitions by 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.

Hungary: Since 2010, the Fidesz government has used its two-thirds majority in parliament to replace the constitution and pass several hundred laws – including many “cardinal” laws that require a two-thirds majority to repeal. U.S. investors have expressed concern about the impact of the volume and pace of these legislative changes on the predictability of Hungary’s investment climate, as well as concern that future governments may be unable to change laws that require a two-thirds majority to repeal or amend. U.S. embassy officials have repeatedly raised concerns that these laws are frequently enacted with little time for debate and no consultation with affected businesses and stakeholders.

Some companies claim that recent “crisis taxes” target foreign-owned firms in a disparate way – either by hitting sectors dominated by foreign-owned firms, or by taxing larger foreign-owned firms at a far higher rate than smaller Hungarian firms –and there is uncertainty about which sectors could be targeted next, which undermines the business environment. Recent examples of these “crisis taxes” have been implemented retroactively, which has created an even greater sense of uncertainty within the business community.

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 and expensive procedures, and judicial rulings are reportedly often inconsistent.

Slovenia: Weak corporate governance and a lack of transparency, particularly in the case of state-owned enterprises, continue to be a significant challenge in Slovenia. Potential U.S. investors have reported that opaque decision-making processes in the government's privatization program have discouraged investment.

GOVERNMENT PROCUREMENT

The EU is a signatory to the WTO Government Procurement Agreement (GPA). U.S. suppliers participate in EU Member States' government procurement tenders, but the lack of quality EU statistics that take into account the country of origin of winning bids makes it difficult to assess the level of U.S. and non-EU participation.

The EU Utilities Directive covers 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 for tenders 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 2014, the European Parliament approved three legislative proposals on public procurement including: (1) a revised Public Procurement Directive for general sectors; (2) a revised Public Procurement Directive for the utilities sectors; and (3) a new EU Public Procurement Directive on concessions contracts. A fourth proposal, aimed at regulating access of third-country goods and services to the EU public procurement market (relative to the access provided to EU goods and services in third-country public procurement markets), is still being debated in the European Parliament and in the Council. The Italian Presidency had hoped to move the file forward but failed because Member States could not find a common position. U.S. access to the EU's non-GPA covered procurement could be affected under this new regulation.

Member State Measures

Bulgaria: The public procurement process in Bulgaria is not always transparent, and stakeholders report that it is frequently discriminatory and unfair. There are persistent complaints that tenders are narrowly defined and that they appear tailored to a specific company. In certain cases the Bulgarian government has included mandatory specifications, which in practice could be met by only one of the bidders thus putting others at a disadvantage in winning the tender. In other cases companies are asked to provide superfluous certification documents in order to qualify as bidders on public procurement projects, and are asked to do so on unreasonably tight deadlines

Czech Republic: In 2012, the Czech government adopted a major public procurement reform bill which addressed some transparency and corruption concerns. The legislation also lowered the threshold for the application of procurement rules to CZK 1 million (\$50,000). But in 2013, the Senate voted in an extraordinary session to restore the original, CZK 6 million (\$300,000) threshold for construction contracts and CZK 2 million (\$100,000) for other services. The law continues to require 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. In October 2014, an analysis of financing of all

political parties represented in the Chamber of Deputies between 2006 and 2013 (published by NGO Index) showed that sponsors of political parties received public contracts for 390 billion CZK (\$20 billion). According to the study, some donor companies that received public contracts were registered overseas, did not declare ownership or had no employees. The Ministry of Regional Development is currently working on the new amendment to reflect/transpose requirements of EU Procurement Directive into the Czech legislation.

France: The February 2014 EU anti-corruption report emphasized France should root out corruption of public procurement contracts at the local level, calling on it to take action “to identify risks at local levels” and also “to set priorities for anti-corruption measures.” France has taken some anti-corruption steps such as requiring electronic bid applications for any calls for tender over €90,000 to lower corruption risks and allows for improved quality control. However, French laws that make it a crime to breach public procurement rules rarely result in criminal charges and when they do, the punishment is not severe.

The French government continues to maintain ownership shares in several major defense contractors (EADS, now Airbus – 10.97 percent of shares; Safran – 22.4 percent of shares and 25.7 percent of voting rights; and Thalès – 36.65 percent of indirect share ownership). 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.

Additionally, U.S. stakeholders have 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 often requires suppliers to source services and production locally or partner with Greek manufacturers as a condition for the awarding of some defense contracts.

Hungary: Inadequate transparency in public procurement continues to be a significant problem in Hungary. In January 2012 a new Public Procurement Act came into force with the government claiming that it would speed procurement and improve transparency. The new procurement law has been criticized by transparency watchdogs because state enterprises and ministries can conduct procurement without a public announcement for the purchase of goods or services up to HUF 25 million (\$112,000) or for construction valued at less than HUF 150 million (\$675,000). Analysts have also noted that larger contracts that would have required a public bid are now broken up into smaller contracts that fall under the thresholds. Hungarian companies, state-owned enterprises, or companies close to the government still appear to have an advantage over other players in public tenders.

Italy: Italy’s public procurement practice often lacks transparency; this has created obstacles for some U.S. bidders. Laws implemented following a major 1992 corruption scandal somewhat reduced corruption, but stakeholders assert that it is still widespread, especially at the local level. In 2012, the Italian parliament approved an anticorruption bill that introduced greater transparency and more stringent procedures to the public procurement process. In 2013, additional implementing regulations were introduced to increase transparency, including measures regulating the conduct of civil servants. To increase transparency, the

Italian government has also started publishing information online about the use of public funds, including data on procurement. However, in 2014, a series of large corruption scandals have come to light leading to the arrests or investigations of hundreds of people mainly in Milan, Umbria and most recently in Rome. These recent corruption scandals show how deeply rooted corruption still is in public procurement. The GOI has now appointed a national anti-corruption commissioner and introduced draft legislation near the end of 2014 that would further increase penalties for corruption. The proposal will still need to be reviewed by parliament.

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. In 2013, the government adopted legislation requiring all public procurement to occur through a centralized online portal by 2014 and all contracts to be published by 2015. In general, procurement documents are only available in Lithuanian.

Poland: U.S. firms report disappointment with the speed of changes in public procurement regulations in Poland. Company representatives note “lowest cost” is the main criterion Polish officials use to award contracts, often overlooking other important factors, like quality, company reputation, and prior experience in product and service delivery, in bid evaluation. U.S. firms also state the high cost of tender document preparation discourages participation in public tenders. Polish officials plan to comply with EU public procurement directives during 2015.

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.

Romania: Romania revised its public procurement law in 2013, exempting certain state owned enterprises from the public procurement law and allowing them to use nontransparent procedures for their procurements. In an effort to enhance absorption of EU funds, the government has simplified the procurement procedures for private sector beneficiaries. Romania, like all EU Member States, must transpose the new Procurement Directives into national legislation and to move away from the current practice of using the lowest price as the sole selection criterion, but it is delaying consultations with stakeholders. Romania requires offsets as a condition for the awarding of defense contracts.

Slovakia: U.S. stakeholders cite corruption, inefficient government bureaucracy, inadequate transparency, unfair competition, and poor law enforcement as barriers to public procurement opportunities in Slovakia. Poor transport infrastructure is also often mentioned as an important technical barrier by potential foreign investors. The public procurement legislative framework lacks stability, with some 25 amendments in the past 7 years, and another amendment is currently being drafted.

Slovenia: As in previous years, U.S. firms continue to express concerns that the public procurement process is nontransparent. They also alleged short timeframes for bid preparation, tendering documentation that was difficult to understand, and opacity in the bid evaluation process. Slovenia’s quasi-judicial National Revision Commission (NRC), which reviews all disputed public procurement cases, received multiple complaints. The NRC has the authority to review, amend, and cancel tenders, and its decisions are not subject to judicial appeal. In the instances where U.S. companies alleged improprieties in the procurement process, Slovenian authorities pointed them to the NRC, which has relied on an ambiguous “national interest” standard to steer tenders toward Slovenian firms, regardless of cost or doubts about the firms’ ability to deliver and service their products.

SUBSIDIES

Government Support for Airbus

Over many years, the governments of Belgium, 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, research and development funding, 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 Member State 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 Member State 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 Airbus Group, which is now the second largest aerospace company in the world. This entity was previously known as the European Aeronautic, Defense, and Space Company (EADS). The name change accompanies a reorganization of the company's ownership structure, resulting in the governments of Germany and France each owning up to 11 percent of the shares, Spain approximately 4 percent, and the remaining approximately 72 percent of shares trading on open markets. The reorganization also ended these governments' rights to veto strategic decisions and to appoint directors to the Airbus board. Instead, the governments only have the right to veto board members appointed by the company. The Airbus Group accounted for more than half of worldwide deliveries of new large civil aircraft over the last few years, and is a mature company that should face the same commercial risks as its global competitors.

On May 31, 2005, the United States requested establishment of a WTO panel to address its concern that EU Member State 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. That dispute is currently before a WTO panel, which has indicated that it expects to complete its work by the end of 2014.

Government Support for Airbus Suppliers

Member State Measures

Belgium: The Belgian federal government coordinates with Belgium's three regional governments on the subsidies for Belgian manufacturers that supply parts to Airbus. Recently, Belgium had a €195 million support program for the A380 superjumbo, and a €175 million support program for the A350. Belgium has always claimed that these were refundable advances, structured in accordance with the 1992 bilateral agreement, and that they covered nonrecurring costs. Both in 2006 and in 2009, the EU Commission initially disputed that view, but later acquiesced. Industrial research or experimental development projects

linked to the A350 and A380 were cited as examples of projects that could benefit from the program. However, Eurostat, the EU Commission's statistical unit, notified the Belgian government in 2014 that these amounts should not be considered advances but subsidies, because they were never reimbursed. Beginning in 2015, Belgian federal and regional governments will have to include the Airbus subsidies as such in their budgets, something which they have never done before. For the A350 and A380 programs, the price distortion coming from Belgian subcontractors is estimated to be a minimum of €370 million.

France: In addition to the seed investment 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. In February 2013, the government confirmed €1.4 billion in reimbursable advances for the A350 over the 2009-2017 time period and a similar scheme for the helicopter X6 to be built by Eurocopter. At the same time, the government announced the implementation of tax and financial assistance for airline companies to restore their competitiveness. The government's 2014 budget included €136 million in reimbursable advances, and the same amount is expected in the 2015 budget. French appropriations for new programs included €87 million in support of research and development in the civil aviation sector in 2014. In 2015, such support is expected to decrease by 4.9 percent to €83 million.

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 Industro. The Fund also helped finance the sale of Esterel Technologies to the U.S. group Ansys in 2012. In 2013, Airbus, the Caisse des Dépôts et Consignations Entreprises, Safran group, and Eurocopter set up Aerofund III, an investment fund designed to raise €150 million for the French aeronautical sector. The goal of the investment fund, run by ACE Management, is to prolong Aerofund II with a target of raising a total of €300 million. In 2014, Aerofund III acquired stakes in AEDS, a firm producing joints and wire pullings; in Test & Services, a firm specializing in the development, production and maintenance of test equipment; and in Finaero, a company in the finishing of planes and helicopters.

Germany: In 2013, the German Ministry of Economic Affairs and Energy suspended the payment of the second tranche of a loan package to Airbus for the development of its latest wide-bodied A350 jetliner. Press reports indicate that the total A350 loan package is €1.1 billion and the outstanding amount equals €600 million. A Ministry spokesperson said that disbursement of the outstanding loan amount will only be possible with concrete commitments by Airbus to Germany on locations and jobs. These commitments have not been agreed upon by Airbus executives, according to recent press reports. In addition to the A350 loan package, Airbus continues to receive funds from the 2012–2015 aeronautics research program for a number of projects. In their 2013 coalition agreement, the German government pledged further support for the aeronautics program.

Spain: In July 2014, the European Commission authorized the Spanish state-owned industrial holding company Sociedad Estatal de Participaciones Industriales' (SEPI) and AIRBUS' rescue plan for ALESTIS Aerospace, a first level provider for Airbus, which supplies airframes for both commercial and military production. The Commission's decision about the validity of the agreements makes possible the future feasibility of ALESTIS. According to SEPI and Airbus, in order to develop the agreement, Spain's Ministry of Finance and Public Administrations authorized a settlement submitted by ALESTIS which includes a 7-

year, interest-free extension of the payment of ALESTIS' €176 million debt, both in its capacity as a common creditor and in regard to its patent terms. Additionally, the Spanish Ministry of Industry, Energy, and Tourism will disburse around €19 million as part of a collaboration agreement it has with ALESTIS for the development of the Airbus A350 XWB aircraft. After a shareholder restructuring, SEPI will subscribe and disburse a capital increase through a cash contribution amounting to €13.5 million, in exchange for receiving 24.3 percent of ALESTIS's capital. The final shareholder structure will be as follows: Airbus (62 percent), SEPI (24 percent), and Unicaja (14 percent). In the case of Airbus-Commercial, ALESTIS supplies parts and components for the A380, A330, A320, and A350 aircrafts, among others. Regarding Airbus Military programs, ALESTIS supplies parts and components for the CN235/C295 and A400M. It is also a supplier for Embraer and Boeing. Headquartered in Seville, ALESTIS has seven production facilities, six in Spain and one in Brazil, and employees approximately 1,600 people.

Government Support for Aircraft Engines

United Kingdom: Propulsion is an area considered important to the future of the United Kingdom 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. The United Kingdom also provides repayable funds, known as Repayable Launch Investment (RLI), towards the design and development of civil aerospace projects in the United Kingdom. In 2011-2012 the United Kingdom RLI expenditure totaled £75 million (\$120 million). BIS forecasts current commitments from 2012–2013 to 2014–2015 to be £160 million (\$256 million) with a further £200 million (\$320 million) forecasted beyond this period. Since 1997, the United Kingdom has invested nearly £1 billion (\$1.6 billion) in RLI projects.

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 28 Member States. No EU institutions or procedures successfully ensure that EU rules on classification, valuation, origin, and customs procedures are applied uniformly throughout the 28 Member States of the EU, other than the Binding Tariff Information program offered at the EU level that provides advance rulings on tariff classification and country of origin. 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 (CCC). The CCC is an entity established by the Community Customs Code to assist the European Commission. The CCC consists of representatives of the Member States and is chaired by a representative of the Commission. While a stated goal for the CCC is 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 CCC and other EU-level institutions ineffective tools for achieving the uniform administration and application of EU customs law, but the EU also lacks tribunals or procedures for the prompt review and EU-wide correction of administrative actions relating to customs matters. Instead, review is provided separately by each Member State's tribunals, and rules regarding these reviews vary from Member State to Member State. Thus, a trader encountering differing treatment 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 T-TIP negotiations.

The European Commission has expressed its intent to modernize and simplify customs rules and processes. The Commission issued the Union Modernized Community Customs Code (UMCC) in November 2013, and sent it to the European Council and the European Parliament for co-decision under the ordinary legislative procedure. The UMCC is expected to enter into effect in 2016, once the UMCC-related Commission acts (delegated and implementing acts) are adopted and in force. The United States will monitor its implementation closely, focusing on its impact on lack of consistent treatment under EU customs law.

ELECTRONIC COMMERCE

The European Commission announced in 2014 that it would present a legislative proposal for the creation of a Digital Single Market, intended to eliminate internal market barriers within the EU's digital services economy.

Safe Harbor

The U.S.-EU Safe Harbor Framework, or "Safe Harbor," was negotiated between the Department of Commerce (DOC) and the European Commission in 2000 to enable U.S.-based companies in all sectors of the economy to receive personal data of EU citizens in compliance with the EU's 1995 Data Protection Directive (1995/46). DOC administers the Framework and enforcement is handled by the Federal Trade Commission. Today, more than 3,900 U.S.-based companies from all sectors are self-certified to the program, including major EU companies with subsidiaries in the United States. Companies that annually self-certify on a dedicated website (<http://www.export.gov/safeharbor>) may continue to receive personal data from the EU.

U.S. companies may also receive or transfer employee and customer information from the EU if they obtain approval from EU data protection authorities for binding corporate rules that allow global intra-company transfers. These requirements can be burdensome for many U.S. industries that rely on data exchange between the United States and the EU.

On November 27, 2013, following press disclosures on U.S. intelligence activities, the Commission issued a Communication on the Safe Harbor Framework, which made 13 recommendations for improvement, eleven of which are commercially focused and two of which relate to national security. DOC is discussing with EU counterparts and stakeholders potential ways to address the EU recommendations. The United States actively supports Safe Harbor and will work to ensure that it remains available to support transatlantic data flows, which are vital to both the U.S. and EU economies and continues to serve all stakeholders well.

Following the 2013 intelligence disclosures, U.S. companies have reported having greater difficulty winning contracts due to concerns over U.S. Government access to the data they hold. 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.