2018 National Trade Estimate Report on

FOREIGN TRADE BARRIERS

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EUROPEAN UNION

TRADE SUMMARY

The U.S. goods trade deficit with the European Union (EU) was $151.4 billion in 2017, a 3.2 percent increase ($4.7 billion) over 2016. U.S. goods exports to the EU were $283.5 billion, up 5.2 percent ($13.9 billion) from the previous year. Corresponding U.S. imports from the EU were $434.9 billion, up 4.5 percent.

U.S. exports of services to the EU were an estimated $239.8 billion in 2017 and U.S. imports were $188.5 billion. Sales of services in the EU by majority U.S.-owned affiliates were $651.2 billion in 2015 (latest data available), while sales of services in the United States by majority EU-owned firms were $485.0 billion.

U.S. foreign direct investment (FDI) in the EU (stock) was $2.9 trillion in 2016 (latest data available), a 9.2 percent increase from 2015. U.S. direct investment in the EU is led by nonbank holding companies, finance/insurance, and manufacturing sectors.

OVERVIEW

The United States and the 28 Member States of the EU share the largest 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 $5.2 billion each day of 2017, and the total stock of transatlantic investment was $5.1 trillion in 2016.

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.

TECHNICAL BARRIERS TO TRADE / SANITARY AND PHYTOSANITARY BARRIERS

Technical Barriers to Trade

Transparency and Notification

The United States faces a proliferation of technical barriers to trade in the EU. This is attributable in part to more recent regulatory development processes adopted by the EU, such as for what the EU calls implemented and delegated acts. These processes lack clarity and efficacy with respect to ensuring that technical regulations, guides, or recommendations within the scope of the WTO Agreement on Technical Barriers to Trade (TBT Agreement) are properly notified. The United States regularly raises concerns, both in bilateral engagement and in the context of the WTO Committee on Technical Barriers to Trade, in cases where notification of certain measures that may have a significant effect on trade have not taken place at an appropriate stage, when amendments can still be introduced and comments may be taken substantively into account. In particular, if notification takes place, it often happens at a procedural stage when it is too late to revise the measure to take into account any concerns, including substantive or scientific, raised by other WTO Members.

This has been observed during chemical evaluation under the EU's regulatory processes (Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) and Classification and Labeling (CLP)) where the controls on products are typically notified after scientific review committees have convened, providing affected parties with no reasonable procedural gateway for the input of additional scientific or technical data. In still other cases, measures are simply not notified at all, as is with the case of a series of country of origin labeling (COOL) measures. Improvement and greater consistency in EU notification of measures, particularly implementing and delegated acts that may have a significant effect on trade, could reduce the emergence of technical barriers to trade by ensuring that the EU takes significant concerns into consideration before it finalizes measures.

European Standardization and Conformity Assessment Procedures

The EU's approach to standards-related measures, including its conformity assessment framework, and its efforts to encourage governments around the world to adopt its approach, including European regional standards, creates a challenging environment for U.S. exporters. In particular, the EU's approach impedes market access for products that conform to international standards as opposed to European regional standards (called European harmonized standards or ENs), even though international standards may meet or exceed the EU (or third country) regulatory requirements. U.S. producers and exporters thus face additional burdens in accessing the EU or other markets not faced by EU exporters and producers in accessing the U.S. market.

In 1985, the EU adopted what is known as the "New Approach" to the use of standards for products.[2] The "New Approach" was updated in 2008 and rebranded as the "New Legislative Framework" (NLF). The NLF represents a package of measures meant to clarify EU product marking requirements, establish a common legal framework for industrial products, and improve market surveillance.[3] Product requirements in a variety of sectors (*e.g.*, toys, machinery, medical devices) are regulated through NLF legislation. Under the NLF, EU legislation sets out the "essential requirements" that products must meet in order to be placed in the EU market and benefit from free movement within the EU. Products that conform to ENs under the NLF are presumed to be in conformity with the essential requirements.[4] ENs, however, can only be developed through the European Standards Organizations (ESOs), CEN,[5] CENELEC,[6] and ETSI,[7] as directed by the European Commission through a standardization request. These products can bear what is known as a "CE mark" and can be sold throughout the EU.

While the NLF does not explicitly prohibit other standards from being used to meet the EU's essential requirements, the practical effect of the EU system discourages the use of other standards. Specifically, the costs and uncertainty associated with not using an EN and attempting to demonstrate that use of an alternative standard will fulfill essential requirements is often prohibitive. For example, if a manufacturer chooses not to use an EN, it needs to assemble a technical file through a costly and burdensome process demonstrating how the product meets the essential requirements. Even if a manufacturer assembles such a file, there is no certainty that Member State authorities will treat the product as conforming to the EU's essential requirements. As a result, U.S. producers often feel compelled to use the relevant EN developed by the ESOs for the products they seek to sell on the EU market. This is the case even where U.S. products

[2] Official Journal of the European Communities, C 136, 4.6.1985, p. 1.
[3] Official Journal of the European Union (OJEU), L 218, 13.8.2008, p. 30–47; OJEU, L 218, 13.8.2008, p. 82–128; OJEU, L 218, 13.8.2008, p. 21–29.
[4] Moreover, an EN must be implemented at the national level by an EU Member State, including through the withdrawal of any conflicting national standard.
[5] European Committee for Standardization.
[6] European Committee for Electrotechnical Standardization.
[7] European Telecommunications Standards Institute.

produced according to relevant international standards provide similar or higher levels of safety and performance.

The CEN or CENELEC technical committees that draft the European standards generally exclude non-EU nationals.[8] In the limited instances where non-EU nationals do participate, they are not allowed to vote. Accordingly, when a U.S. producer uses an EN, it is typically using a standard that has been developed through a process in which it had no meaningful direct or representational opportunity to participate or provide technical input. This has a pronounced impact on small and medium sized enterprises and other companies that do not have a European presence. The opportunity for U.S. stakeholders to influence the technical content of EU legislation setting out essential requirements (*i.e.*, technical regulations) is also limited. This is because when the EU notifies proposed legislation containing essential requirements to the WTO, it does not identify the specific CEN or CENELEC standards for which the presumption of compliance will be given. Furthermore, the EU only notifies legislation after the Commission has transmitted it to the Council and Parliament and is no longer in a position to revise the directive in light of comments received. Consequently, U.S. stakeholders often do not have the opportunity to comment on critical technical elements of proposed technical regulations and conformity assessment procedures contained in EU legislation, or on the standards that may be used to fulfill that legislation's essential requirements. In other words, they are precluded from participating in the development of requirements as well as the means by which those requirements will be fulfilled.

Additionally, the United States has serious concerns regarding the EU's conformity assessment framework, as set out in Regulation (EC) No 765/2008 and Decision 768/2008. Regulation 765 requires each Member State to appoint a single national accreditation body and prohibits competition among Member States' national accreditation bodies. Under the EU system, an accreditation certificate from one Member State accreditation body suffices throughout the EU. The regulation further specifies that national accreditation bodies shall operate as public, not-for-profit entities. This regulation effectively bars use of trade-facilitative international accreditation schemes and precludes U.S. accreditation bodies from offering their services in the EU with respect to any mandatory third-party conformity assessment requirements.

Decision 768 sets out reference provisions to be used in EU legislation establishing conformity assessment requirements for products falling within the NLF. Legislation applying Decision 768 requires that any mandatory third-party conformity assessment be performed by a body that has been designated as a "Notified Body" and permits only bodies "established under national law" to become Notified Bodies. In practice, the EU interprets "established under national law" as a requirement that any entity seeking designation as a Notified Body must be established in the EU and, in particular, in the Member State from which it is seeking such designation. This raises serious market access concerns for U.S. producers, whose products may have been tested or certified by conformity assessment bodies located outside the EU, and denies U.S.-domiciled conformity assessment bodies the opportunity to test and certify products for the EU market. This lack of reciprocal treatment of U.S. conformity assessment bodies, in contrast to the U.S. approach to conformity assessment, which provides national treatment to EU bodies, adds increased time to market, increases costs for manufacturers, and requires U.S. testing and certification bodies to establish operations in the EU to remain competitive.

The EU also promotes adoption of ENs in other markets and often requires the withdrawal of non-EU standards as a condition of providing assistance to, or affiliation with, other countries, which can give EU manufacturers commercial advantages in those markets. Where the withdrawn standards are international standards that U.S. producers use, which may be of equal or superior quality to the ENs that replaced them, U.S. producers must choose between the cost of redesigning or reconfiguring their products or exiting the market. Further, EU trade policy seeks to narrow the definition of what is considered an international

[8] For example, CEN/TC 438 is the technical committee for CEN that develops and publishes standards for additive manufacturing.

standard within the meaning of the TBT Agreement. For instance, as part of its free trade agreements, the EU seeks commitments affirming that any standard issued by a subset of specific standards developing organizations, none of which are domiciled in the United States, be considered an international standard.[9] This practice accords preferential treatment to organizations in which the EU tends to carry an outsized influence (*e.g.*, the World Forum for Harmonisation of Vehicle Regulations within the framework of the United Nations Economic Commission for Europe's 1958 Agreement) or with which the ESOs have existing cooperation agreements (*e.g.*, the International Organisation for Standardisation and the International Electrotechnical Commission). Furthermore, this attempt to reinterpret which standards should be deemed international within the meaning of the TBT Agreement is contrary to relevant decisions of TBT Committee, which would recognize that standards developed by organizations domiciled in the United States can be deemed international provided they are developed in accordance with relevant WTO principles.

Civil Nuclear Technologies:

U.S. stakeholders argue that the development of civil nuclear sector technology regulations, standards, or conformity assessment should not require the use of certain EU technologies when U.S. technologies, which meet U.S. civil nuclear safety standards, are equally safe. In the nuclear industry, local standards in the EU may not always conform to international nuclear safety norms, placing U.S. exporters at a disadvantage in markets where they must compete with firms using substandard parts. EU Member States are also under pressure to adopt French civil nuclear regulatory standards, which could potentially create a bias against U.S. firms that adhere to international standards developed by U.S.-domiciled standards developing organizations (*e.g.*, American Society of Mechanical Engineers (ASME)) and want to enter the European market. Furthermore, the EU's approach of explicitly referencing particular standards potentially undermines innovation and eschews more effective means of addressing potential regulatory objectives.

Chemicals: Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH)

The EU regulation concerning the use of chemicals known as REACH entered into force on June 1, 2007. REACH imposes extensive registration, testing, and data requirements on all chemicals manufactured or imported into the EU in quantities greater than one metric ton. It also requires manufacturers or users of certain hazardous chemicals to obtain authorizations for those chemicals. Furthermore, REACH impacts virtually every industrial sector because each entity registering a chemical under the legislation must account for the uses of that chemical in the products it places or intends to place on the EU market.

The United States agrees on the importance of regulating chemicals to ensure public safety. The United States is concerned, however, that REACH appears to impose requirements that are either more onerous for foreign producers than EU producers or simply unnecessary. For example, stakeholders have raised concerns that they must provide data as part of the registration process under REACH that is irrelevant to health and environmental concerns. Additionally, there appears to be inconsistent and insufficiently transparent application of REACH by Member States. The United States and many other WTO Members have raised concerns regarding various aspects of REACH at nearly every WTO TBT Committee meeting for years. WTO Members have emphasized 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.

[9] For example, EU-Japan Economic Partnership Agreement, Article 6.1 (International Standards): http://trade.ec.europa.eu/doclib/docs/2017/december/tradoc_156430.%20TBT%2020170703%20Japan-EU%20EPA%20Chapter_FINAL.pdf.

Community Rolling Action Plan

The United States and stakeholders also have concerns about a lack of transparency associated with the Community Rolling Action Plan (CoRAP). CoRAP is part of the REACH substance evaluation process and is updated every March. Its purpose is to allow Member States and the European Chemicals Authority (ECHA) to prioritize substances they suspect 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 and become subject to authorization and restriction procedures. It is also possible that after evaluation, a substance will be found to pose no such 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. ECHA published the most recent CoRAP list on March 21, 2017. It contains 115 substances, which either have been evaluated or will be evaluated through 2019. CoRAP preliminary reports should be made available to interested U.S. companies, even if they have not yet registered the particular substance, but the reports are currently made available only to registrants. The EU should undertake greater transparency concerning the CoRAP process, including publication of CoRAP preliminary reports, which would both facilitate the EU's objectives and help reduce costs and address U.S. stakeholders' concerns.

Substances of Very High Concern (SVHC) Roadmap

The United States also has 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 Member State authority drafting the RMO has discretion with respect to the level of detail provided in its analysis and whether or not stakeholder consultation is appropriate. ECHA has said that documenting the RMO analysis and sharing it with other 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 analyses and believes the RMO analysis should be implemented in a harmonized and consistent manner by Member States. 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.

Court of Justice of the European Union, Judgment in Case C-106/14

On September 10, 2015, in case C-106/14, the Court of Justice of the European Union (CJEU) released an important ruling on the notification and information duties applicable to the producers and importers of articles under REACH. The CJEU held that the notification and information duties apply to each individual component "article," and not just to the whole assembled or finished "article," for producers and importers that deal with more than one ton per year of any SVHC present in articles over 0.1 percent by weight.

The court's conclusion was contrary to the existing ECHA guidance, which only required notification for SVHCs on the article-level. In June 2017, following a two-step update to the applicable "Guidance on Requirements for Substances in Articles" initiated in 2011, ECHA published new guidance on requirements for substances in articles to assist companies in meeting the requirements of the court ruling. The United States continues to assess the trade impact to manufactured products such as vehicles, information and

communication technology (ICT) equipment, and medical devices, and remains concerned that requiring notification of components rather than the final good will increase burdens on both producers and importers.

Cosmetics: Scientific Committee on Consumer Safety (SCCS) Ingredient Reviews & Amendments to the EU Cosmetics Regulation

Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products (EU Cosmetics Regulation) provides that the SCCS conduct risk assessments for all ingredients approved for use in cosmetics in the EU market. Based on SCCS assessments, the European Commission rules on whether the use of the ingredient should be restricted and, if so, in which Annex within the EU Cosmetics Regulation it should be listed.

The United States and stakeholders have concerns as to the transparency of the process under which the SCCS defines the scope of its risk assessments. While the initial request for stakeholder participation and input into SCCS reviews is public once an assessment starts, changes in scope or the information being considered in the assessment may not be publically notified. According to SCCS Rules of Procedure, the Committee solicits additional information on an invitation-only basis. In practice, this process can prevent non-EU interested parties from providing input and can translate into assessment determinations that are made on the basis of risk assessments that do not fully consider available scientific evidence or relevant uses of a particular cosmetics ingredient. Furthermore, the process of petitioning an opinion from SCCS can often entail significant and unexplained delays, with the overall process often taking two or more years for completion.

Renewable Fuels: Renewable Energy Directive

The EU Renewable Energy Directive (RED) requires that biofuels and biofuel feedstocks obtain a "Proof of Sustainability" (POS) certification to qualify for tax incentives and national use targets. To that end, RED also establishes a methodology and accounting system by which Member States may record and calculate required greenhouse gas emission (GHG) savings as compared to a baseline for fossil fuels. The United States has expressed its concern to the Commission that the RED and its paperwork and verification requirements disrupt trade in U.S. products (specifically soybeans for biofuel and corn ethanol). For instance, one method to meet the sustainability and GHG savings requirements of RED is to certify biofuel production through a voluntary certification system. In April 2015, after having been positively benchmarked against the European Feed Manufacturers' Federation (FEFAC) Soy Sourcing Guidelines through the independent International Trade Center (ITC) customized benchmark, the U.S. Soybean Export Council (USSEC) submitted an application to the Commission to recognize the U.S. Soybean Sustainability Assurance Protocol (SSAP) as a voluntary certification scheme. Although SSAP also has met the Dutch Feed Industry Association's requirements for sustainable feedstuffs, the Commission has indicated it requires additional information and analysis by the U.S. soybean industry before it can determine whether SSAP meets the RED sustainability criteria. As recently as December 2017, the Commission has continued to raise issues with USSEC's voluntary scheme application regarding traceability and GHG calculations.

Under Article 18(4) of RED, the United States requested that the Commission enter into a bilateral agreement to accept U.S. exports of biofuel feedstock as compliant with the sustainability goals of RED. The Commission has responded that U.S. conservation laws and programs must correspond exactly to those outlined in the RED sustainability criteria if the EU is to consider U.S. exports of biofuel feedstock as compliant with RED sustainability criteria.

The Commission presented a new Renewable Energy Directive (RED II) for the period 2020-2030 as part of a comprehensive "Winter Energy Package" of legislative proposals that includes initiatives on bioenergy sustainability (liquid biofuels and biomass). RED II was adopted by the Commission on November 30,

2016, and the Council published its proposal on December 18, 2017. The Parliament then adopted its position on January 17, 2018. It is expected the legislative process will be complete by mid-2018.

Currently, provisions in these drafts introduce onerous and complex sustainability criteria for biomass and could be extremely problematic for U.S. exports of sustainable wood pellets. Although there is uncertainty about the future standards, forest management costs could increase due to increased certification requirements, logger training and monitoring. If the wood cannot be recognized as meeting the sustainable standards for renewable energy, it could lose its competitive advantage to export. The United States exported $655 million of wood pellets to the EU in 2017.

Member State Sustainability Criteria

The Netherlands: In the Netherlands, local organizations and the Dutch government are adopting and implementing standards and standard-related measures that are impeding or threatening to impede U.S. trade. For example, local organizations, such as the Sustainable Trade Initiative (IDH) and the Forest Stewardship Council (FSC) have developed standards for soybeans and wood pellets, respectively, that have been supported by the Dutch government and effectively require U.S. producers to meet onerous certification requirements. After China, the Netherlands is the second largest importer of soybeans and derivatives in the world. In addition, on March 30, 2015, the Dutch government published a notice amending its regulation governing sustainability requirements for solid biomass and implementing onerous sustainability criteria for wood pellets. In particular, the criteria include a requirement for sustainability certification at the forest level, which effectively precludes reliance on the U.S. risk-based approach to sustainable forest management. As a result of the implementation of the criteria, wood pellet exports to the Netherlands have dropped from 7 percent of total U.S. wood pellet exports in 2014 to currently less than 1 percent.

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 6 percent by 2020 and to report on the carbon intensity of these fuels. The directive granted the Commission the power to develop a methodology for calculating GHG life-cycle emissions for transport fuels. The United States has 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 GHG life-cycle emissions for transport fuels.

The FQD also carries implications for U.S. biofuel exports stemming from differing definitions of the term "biodiesel". The practical impact of the diverging definition is a limit or exclusion of the amount of soybean, palm, and sunflower oil feedstocks that can be utilized as a blend with rapeseed oil, diminishing trade opportunities and adding costs to biodiesel exports from the United States to the EU. The EU has not provided a technical justification for this exclusionary definition.

Country of Origin Labeling (COOL)

Eight European Member States – Finland, France, Greece, Italy, Lithuania, Portugal, Romania, and Spain – are in the process of developing and implementing a variety of national COOL schemes that apply to different types of ingredients and finished products, have varying implementation times, and require different wording on labels. The information required on packaging varies according to each individual Member State and can include the country of birth, fattening, and slaughter of animals; country of milking, packaging, or processing for dairy products; and country of cultivation and processing for wheat.

Affected industries have raised concerns that these national COOL requirements could impede market access for imported ingredients. In addition, some of the measures could favor goods produced in certain countries by selectively eliminating the requirements for processed foods produced in EU Member States, Turkey, or EFTA countries that are part of the European Economic Area.

The United States has raised concerns about these measures at the past five TBT Committee meetings. In particular, the United States noted concerns including the treatment of EU versus non-EU origin products, the amount of recordkeeping that may be required to comply with the measures, the apparent favoring of select countries, the impact on U.S. exports, and the failure of the EU or the Member States to notify the measures under the TBT Agreement, solicit and take into account feedback from interested stakeholders, and allow a reasonable interval of time between publication and entry into force of the various measures. On January 4, 2017, the Commission published a draft implementing regulation laying down common rules regarding the indication of the country of origin or place of provenance of primary ingredients. Where appropriate, efforts should be made to harmonize regulations or standards related to prepackaged foods or non-alcoholic beverages.

Member State Measures

Italy: On April 18, 2017, Italy began implementing mandatory labeling requirements for the country of milking, packaging and processing of milk and milk used in dairy products. On May 12, 2017, Italy notified to the European Commission two draft decrees to require COOL for rice and wheat used to make pasta. Under Article 45 of Regulation (EU) No 1169/2011, the notification process requires that there be a three-month waiting period in order for the Commission to consult the Standing Committee on the Food Chain and Animal Health. However, on July 20, 2017, Italy's Ministers for Agriculture and Economic Development signed two inter-ministerial decrees ordering the provisional implementation of the COOL measures, preempting a decision by the European Commission. Both decrees entered into force in February 2018, and will be in effect for two years on a trial basis. Italy's Agriculture Minister has noted publicly that these COOL measures put Italy at the forefront of European countries using labelling as a competitive tool in the agricultural sector. The Economic Development Minister said the measures would support the "Made in Italy" brand and make Italian products more competitive in international markets. On October 21, 2017, Ministers signed a similar decree on tomato products. U.S. wheat exports to Italy totaled approximately $117 million in 2017.

France: In early 2017, after receiving Commission approval, France implemented a COOL scheme for processed food products that contain dairy and meat. The scheme will remain in force until December 31, 2018. For meat ingredients, the relevant measure requires that the label mention the country of the animal's birth, the country of rearing, and the country of slaughter. For dairy ingredients, the label must mention country of milking, processing, and packaging.

Spain: On September 5, 2017, Spain notified to the Commission a Draft Royal Decree on the indication of the origin of milk used as a raw material on the labelling of milk and milk products. This notification followed a February 2017 national public consultation period on the proposed measure. In its consultation, Spain notes that the purpose of such a measure would be to "avoid the loss of competitiveness of milk and milk products produced in Spain that could result from the application of mandatory rules in this area that have already been implemented in other countries in the EU." The consultation document notes further that the measure would be implemented on a two-year trial basis; however, to date, Spain has not moved forward with implementation.

Romania: Effective January 1, 2018, Romania will require dairy processors to specify the country of milking, packaging, and processing for milk and food products containing dairy.

Greece: On October 12, 2017, the Parliament in Greece validated COOL requirements for milk, dairy, and meat products. Law 4492/18-10-2017 mandates that processors specify the country of milking, processing, and packaging for processed food products containing dairy. Traceability is mandatory for all meat products during production and distribution. Greece's milk, dairy, and meat products COOL law will enter into force 180 days from the date of publication in the Gazette (April 16, 2018) and will be in effect for 30 months on a trial basis.

Portugal: On July 27, 2016, Portugal notified to the Commission a draft decree on the mandatory indication of the country of milking and the country of processing for milk or milk used in dairy products. The mandatory measures were approved by the Commission and entered into effect in July 2017 for an initial 18-month period.

Finland: On September 28, 2016, Finland notified to the Commission a draft decree on mandatory origin labelling for milk, milk used as an ingredient in dairy products, and meat used as an ingredient. The measures entered into force on June 1, 2017. The measures apply to pre-packed foodstuffs produced in Finland for a fixed pilot term of two years.

Lithuania: On July 13, 2016, Lithuania notified to the Commission a draft order on mandatory origin labeling for milk and certain dairy products. The measure entered into force on January 1, 2017, and will remain in force on a trial basis until December 31, 2018. At that time, Lithuania is to have provided a report to the European Commission detailing the implementation of the measure.

Nutritional Labeling

EU framework Regulation 1169/2011 on the provision of food information to consumers went into effect on December 13, 2014, except for the provision on mandatory nutrition labeling, which became effective December 13, 2016. The measure regulates the display of product information on product packaging and online stores ostensibly to provide consumers with information related to nutrition, ingredients, and allergens.

The United States has concerns that Regulation 1169/2011 appears to provide wide latitude for Member States to adopt non-uniform and potentially inconsistent implementing regulations. U.S. stakeholders are thus 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 has 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's and Ireland's traffic light nutrition labeling requirements) would remain voluntary. The United States will continue to monitor this issue closely.

Member State Health Labeling

Ireland: On June 9, 2016, Ireland notified its proposed Public Health (Alcohol) Bill 2015 to the WTO's TBT Committee. The proposal contains a range of provisions, including minimum unit pricing of alcohol products; health labelling of alcohol products; regulation of advertising and sponsorship; structural separation of alcohol products in mixed trading outlets; and the regulation of the sale and supply of alcohol in certain circumstances. These proposed measures, which diverge from EU-wide requirements, have the potential to generate additional administrative costs and detrimentally impact the ability of U.S. exporters to reallocate product in the European market. Further, in late 2017 a number of amendments were made to the bill, including with respect to health labelling. The United States has asked Ireland to notify those amendments to the WTO in accordance with the transparency provisions of the WTO TBT Agreement.

Agriculture Quality Schemes

In 2012, the EU adopted Regulation 1151/2012 "on quality schemes for agricultural products and foodstuffs." Regulation 1151/2012 combines into one regulation rules for two different EU schemes and adds new rules on optional terms. The regulation applies to a range of agricultural products, covering: Protected Designations of Origin (PDO) and Protected Geographical Indications (PGI); "Traditional Specialties Guaranteed" (TSG); and optional quality terms. Optional quality terms are intended to provide additional information about product characteristics such as "first cold-pressed extra virgin olive oil" and "virgin olive oil." A separate measure addressing the marketing standards for wine and spirits was notified to the WTO on September 11, 2011.

The schemes covered by the regulation are: (1) certification schemes for which detailed specifications have been laid down and are checked periodically by a competent body; and (2) labeling schemes, which are subject to official controls and communicate the characteristics 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.).

The United States remains concerned that "place of farming" requirements are unclear, difficult to comply with, and lack a basis in international standards. International standards promulgated by the Codex Alimentarius Commission (Codex), for instance, maintain 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 (GIs). The United States also is seeking clarification of the manner of precedence used 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 names of products should not be absorbed into quality schemes, whether for wine or other products. For instance, 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 takes issue with the Commission's allowing two PGI applications for "danbo" and "havarti" to proceed, despite the existence of Codex standards and objects to the 2017 registration of danbo as a PGI. The United States has further argued that new certification and labeling quality 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 regulation on agricultural quality schemes, the EU continues to aggressively 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 within their trademarks. U.S. wines sold under a trademark that includes

one of the traditional terms can only be marketed in the EU if the trademark was registered before May 2002. In June 2010, U.S. stakeholders submitted applications to be able to use the terms in connection with products sold within the EU. 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 also has pursued bilateral discussions. Beyond approving the two terms, the EU has not taken any visible steps to address U.S. concerns.

In 2013, the Commission started discussions with the Member States on a possible simplification of wine labeling set out in Regulation 607/2009, but appears to be facing resistance to any changes that would lessen the protection of traditional terms.

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. The EU considers this 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 that adopt EU standards, such as Israel and Russia. The United States has a long history of quality whiskey production, particularly by micro-distillers, which has not entailed minimum aging requirements, and views a mandatory three-year aging requirement for whiskey as unwarranted. Recent advances in barrel technology enable U.S. micro-distillers to reduce the aging time for whiskey while producing a product commensurate in quality. In 2017, the United States continued to urge the EU and other trading partners to end whiskey aging requirements that are restricting U.S. exports of whiskey from being labeled as such.

Certification of Animal Welfare

The EU requires animal welfare statements on official sanitary certificates. The EU's certification requirements do not appear to advance any food safety or animal health objectives and thus do not belong on sanitary certificates. The U.S. 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 Codex, World Animal Health Organization (OIE), and the International Plant Protection Convention, or have scientific justification.

Sanitary and Phytosanitary Barriers

The United States remains concerned about a number of measures the EU maintains ostensibly for the purposes of food safety and protecting human, animal, or plant life or health. Specifically, the United States is concerned that these measures unnecessarily restrict trade without furthering their safety objectives because they are not based on scientific principles, maintained with sufficient scientific evidence, or applied only to the extent necessary. Moreover, the United States believes there are instances where the EU should recognize current U.S. food safety measures as equivalent to those maintained by the EU because they achieve the same level of protection. If the EU recognized the equivalence of U.S. measures, trade could be facilitated considerably.

Hormones and Beta Agonists

The EU maintains various measures that impose bans and restrictions on meat produced using hormones, beta agonists, and other growth promotants, despite scientific evidence demonstrating that such meat is safe for consumers. U.S. producers cannot export meat or meat products to the EU unless they participate in a

costly and burdensome process verification program to ensure that hormones, beta agonists, or other growth promotants have not been used in their production.

For example, the EU continues to ban the use of the beta agonist ractopamine, which promotes leanness in animals raised for meat. The EU maintains this ban even though international standards promulgated by the Codex have established a maximum residue level (MRL) for the safe trade in products produced with ractopamine. The Codex MRL was established following scientific study by the Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Joint Expert Committee on Food Additives (JECFA) that found ractopamine at the specified MRL does not have an adverse impact on human health.

The EU's ban on growth promotant hormones in beef is inconsistent with its WTO obligations. Specifically, in 1996, the United States brought a WTO dispute settlement proceeding against the European Communities (the EU predecessor entity) over its ban on beef treated with any of six growth promotant hormones. A WTO dispute settlement panel concluded – and a subsequent report of the WTO Appellate Body affirmed – that the ban was maintained in breach of the EU's obligations under the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). Following the failure by the EU to implement the recommendations of the WTO Dispute Settlement Body (DSB) to bring itself into compliance with its WTO obligations, the United States was granted authorization by the WTO in 1999 to suspend concessions. Accordingly, the United States levied *ad valorem* tariffs of 100 percent on imports of certain EU products. The value of the suspended concessions, $116.8 million, reflected the damage that the hormone ban caused to U.S. beef sales to the EU.

In September 2009, the United States and the Commission signed a Memorandum of Understanding (MOU), 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 begun to ship under the HQB quota. As a result, the market share of U.S. beef in the HQB quota has decreased and accounted for only 35 percent of the quota in the 2016-2017 quota year. Since 2014, the United States has engaged in discussions with the EU on the future operation of the MOU to ensure that U.S. producers are compensated through increased export benefits in the EU market in exchange for the continued suspension of WTO-sanctioned trade action. In December 2016, the United States sought public comments related to a request from the U.S. beef industry to reinstate trade action against the EU. The United States also held a public hearing in connection with this request on February 15 to 16, 2017. The United States considered the various views and points in the public comment submissions and testimony at the public hearing. The United States continues to engage the EU regarding the unscientific ban on meat and animal products produced using hormones, beta agonists, and other growth promotants.

Animal Cloning

Currently, the EU Novel Foods and Novel Food Ingredients Regulation (Novel Foods Regulation) issued in 1997 is the only EU measure that potentially addresses the use of animal cloning for food production.[10] The Novel Foods Regulation would appear to encompass food products derived directly from cloned animals.[11] Food products subject to the Novel Foods Regulation require a pre-market authorization by the EU Member State decision and potentially the Commission in order to be imported or sold in the EU.

[10] Regulation (EC) No 258/97.

[11] The Novel Foods Regulation covers certain types of "foods and food ingredients which have not hitherto been used for human consumption to a significant degree within the Community..." *Id.*

In January 2008, the Commission proposed a revision of the Novel Foods Regulation to simplify the authorization procedure for placing new food products on the market. The proposed revision failed in significant part due to a disagreement among the Commission, the Parliament, and the Council regarding the need for specific rules on food from cloned animals.

In December 2013, the Commission published two new proposals on animal cloning, in conjunction with a new proposal for a novel foods regulation. One of the proposed directives (the Cloning Technique Proposal) would ban animal cloning for food purposes in the EU and the import of cloned animals or embryos, while the other (the Cloning Food Proposal) would ban the marketing of food, both meat and dairy, from cloned animals, but not from their offspring. However, both of these proposals appear to be inconsistent with risk assessments done by competent authorities in the EU and other countries that show no differences in terms of food safety between food products produced from cloned animals or their offspring and those produced from conventionally-bred animals.

In June 2015, the European Parliament's Agriculture and Rural Development (AGRI) Committee and Environment, Public Health and Food Safety (ENVI) Committee, adopted a joint report proposing amendments to the Commission's aforementioned proposals that would vastly extend their scope and impact and change the measure from a directive into a regulation. The substance of these proposed amendments included permanent bans on clones and their offspring for all farmed animals, including fish and poultry, as well as bans on all agricultural products derived from them, including food, semen, and embryos. The proposed amendments also included a ban on cloning of animals for sports. In September 2015, the full Parliament, or Plenary, approved the AGRI/ENVI report and amendments. A new EU framework regulation 2015/2283 on Novel Foods was adopted in November 2015 and published in Official Journal L 327 on December 11, 2015. Most provisions of the new Novel Foods Regulation became applicable on January 1, 2018. Food from clones but not offspring will continue to fall within the scope of the Novel Foods Regulation until separate legislation on cloning is adopted. Although the EU proposal on animal cloning was approved by the EU Parliament in September 2015, the file is still at the technical level in the Council and has reportedly seen no progress. The United States believes the use of cloning technologies are beneficial for herd improvement and that no differences have been demonstrated in terms of food safety between food products produced from cloned animals or their offspring and those produced from conventionally-bred animals.

Agricultural Biotechnology

Delays in the EU's approval process for genetically engineered (GE) crops have prevented GE crops from being placed on the EU market even though the GE events have been approved (and grown) in the United States. Moreover, the length of time taken for EU approvals of new GE crops appears to be increasing.

As of January 2017, the United States is tracking 25 agricultural biotechnology product applications of corn, soybean, canola, and cotton submitted to the European Food Safety Authority (EFSA) for a scientific review, and eight such product applications waiting approval action by the EU Commission. Additionally, in the last year, EFSA has issued five inconclusive opinions, keeping these events out of risk analysis procedure until the applicant responds to new questions from EFSA.

In 2017, the EU Commission authorized 11 GE products for food or feed import use: four soybean, four corn (two were an authorization renewal), two cotton, and one rapeseed. While these new authorizations and renewals are welcome, these approvals took an average of over seven years to complete from the time the applications were submitted. The EU's own legally prescribed approval time for biotechnology imports is 12 months (six months for the review with the EFSA and six months for the political committee process (comitology)).

Exports of U.S. corn and rice to the EU continue to be adversely impacted. Due to extensive EU approval delays of GE corn products, industry continues to express concerns that exports containing a low-level presence (LLP) of unapproved GE crops (LLP is the result of asynchronous approvals, where the GE product is approved and cultivated in the country of export, yet not approved for use in the country of import) are at risk. For instance, the United States continues to export distillers' dried grains and corn gluten feed (corn byproducts), yet such shipments could be disrupted at any moment by an LLP incident. Although three GE rice events (LL601, LL62, and LL06) are approved for cultivation in the United States, no GE rice varieties are grown for commercialization. In 2006, due to an exposure of LL601 to commercial channels before it was approved for use by U.S. producers, the EU suspended progress on the approval of LL62. Since that time, rice exports to the EU from the United States remain well below former levels and commercial uncertainty continues with LLP concerns. The application for rice event LL62, which was originally requested in the EU in 2004, has been pending with the European Commission since 2007.

The United States continues to work with the EU to support trade in corn byproducts and rice, but success will depend on the EU addressing the larger issue of delays in the biotechnology approval process. The United States continues to urge the EU to participate in discussions of a practical approach to LLP under the auspices of the Global Low-Level Presence Initiative.

Pathogen Reduction Treatments

The EU maintains measures that prohibit the use of any substance other than water to remove contamination from animal products unless the substance has been approved by the Commission. U.S. exports of beef, pork, and poultry to the EU have been significantly hurt, because the Commission has failed to approve several pathogen reduction treatments (PRTs) that have been approved for use in the United States. PRTs are antimicrobial rinses used to kill pathogens that commonly exist on meat after slaughter. The PRTs at issue have been approved by the U.S. Department of Agriculture (USDA), after establishing their safety on the basis of scientific evidence.

In 1997, the EU began blocking imports of U.S. products that had been processed with PRTs, which have been safely used by U.S. meat producers for decades. After many years of consideration and delay, in May 2008 the Commission prepared a proposal to authorize the use of the four PRTs during the processing of poultry, but imposed unscientific highly trade restrictive conditions with respect to their use. Member States rejected the Commission's proposal in December 2008.

In June 2013, USDA submitted an application dossier for the approval of peroxyacetic acid (PAA) as a PRT for poultry. In March 2014, EFSA published a favorable Scientific Opinion on the safety and efficacy of PAA solutions for reduction of pathogens on poultry carcasses and meat. After a long period of inaction, the Commission eventually put forward the authorization of PAA as one part of a three-pronged strategy to mitigate campylobacter in poultry. It later withdrew the proposal from the Standing Committee agenda in December 2015, citing lack of evidence of PAA's efficacy against campylobacter. The Commission has no plans to put forward the proposal for approval at the Standing Committee at this time.

The United States believes the use of PRTs is a critical tool during meat processing that helps further the safety of products being placed on the market. The United States has engaged the EU to share scientific data regarding the safe use of PRTs, and the United States will continue to engage the EU regarding the approval of PRTs for beef, pork, and poultry.

In March 2017, the National Pork Producers Council submitted an application for the approval of two organic acids, lactic and acetic, for use on pork. The application was submitted to EFSA by the Commission in September and the dossier is currently under review.

Export Certification

EU certification requirements are limiting U.S. agricultural exports such as fish, meat, dairy, eggs, processed 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 even intended for cruise ships or U.S. military installations located in the EU. These requirements often appear inconsistent with international standards and to have been implemented without scientific evidence or a risk assessment. Moreover, the certificates are often very complex and burdensome to the point that it is very difficult to verify the applicable certification requirements. For example, the level of detail required on the certificate (*e.g.*, the specific attestation language) necessitates a multitude of forms for each product containing references to multiple levels of EU legislation that in turn cites other legislation. This creates enormous confusion and burden for manufacturers and exporters, as well as U.S. regulatory agencies, EU Member State authorities, and EU importers. Codex guidance and ongoing work in the Asia Pacific Economic Cooperation (APEC) forum seek to limit certification to the minimum amount of information necessary to ensure the safety of the product being traded. The United States continues to engage the EU in various international fora and bilaterally to find a resolution of these concerns regarding the EU's certification requirements.

Somatic Cell Count

Somatic cell count (SCC) refers to the number of white blood cells in milk. The count is used as a measure of milk quality and an indicator of overall udder health; however, it does not have any bearing on the safety of the milk itself. Since April 1, 2012, the EU has required imports of dairy products that require EU health certificates to also comply with EU SCC requirements. Specifically, the EU requires certification to establish that the SCC does not exceed 400,000 cells per milliliter, a threshold that is significantly lower than the U.S. requirement for Grade A milk of 750,000 cells per milliliter. The certification necessary to meet the EU requirement is burdensome, requiring farm level sampling and a Certificate of Conformance. Accordingly, while U.S. dairy products can continue to be shipped to the EU, the EU's SCC requirements hinder trade by adding unnecessary costs. The United States continues to engage the EU regarding their SCC requirement in the appropriate technical working groups.

EU Flavorings

In the EU, the food industry can only use flavoring substances that are on the EU flavoring list.[12] On July 29, 2015, five substances (1-methylnaphthalene, furfuryl methyl ether, difurfuryl sulphide, difurfuryl ether, and ethyl furfuryl ether) were deleted from the list. These five substances are generally recognized as safe (GRAS) by the Flavor and Extract Manufacturers Association (FEMA) for their intended use as flavoring substances. FEMA makes a GRAS determination following an expert panel's evaluation of the substance. The expert panel includes experts in toxicology, organic chemistry, biochemistry, metabolism, and pathology. Accordingly, the United States and other countries, including China, Japan, Brazil, and Mexico, accept the use of flavorings deemed by FEMA to be GRAS. In addition, these five substances have already been evaluated, or are under consideration by, other safety assessment bodies such as JECFA. The United States will continue to raise this issue with the EU.

Animal Byproducts, Including Tallow

The EU considers all animal byproducts sourced from animals raised under conditions not essentially identical to those in the EU to be hazardous materials (category 1 and 2 materials). Between 2002 and the present, the EU has made modifications to its regulations and implementation practices governing animal

[12] See Annex I of Regulation 1334/2008) & Regulation 872/2012.

byproducts that have resulted in the treatment of U.S. products as being considered hazardous. The current EU interpretation of the animal byproducts regulations could potentially prevent most exports of U.S. animal byproducts. Several Member State border inspection posts have already begun to block consignments of various technical blood products.

Tallow exported to the EU must meet criteria that are not scientifically justified and significantly exceed the recommendations of the OIE. The United States has requested that tallow be allowed entry into the EU for any purpose without verification other than that the tallow and derivatives made from this tallow contain no more than a maximum level of insoluble impurities consistent with international recommendations. Specifically, tallow with less than 0.15 percent insoluble impurities does not pose any risk of bovine spongiform encephalopathy (BSE). Tallow under these specifications should be allowed for import without any animal health-related requirements according to the OIE's international – and scientifically based – recommendation.

Used cooking oil (UCO) is used for the production of biodiesel. Currently, individual Member States implement national measures for the importation of UCO. However, in 2016 the EU circulated a draft regulation to harmonize requirements EU-wide. The draft requirements follow the EU's non-science based approach regarding importation of tallow and would curtail U.S. exports of UCO to the EU. The United States provided feedback in writing to the EU on their proposed measure and is working with the EU to resolve these concerns.

Live Cattle

Live cattle from the United States are not authorized to be exported to the EU, or transited through the EU on route to third countries, due to EU certification requirements for several bovine diseases. Although the U.S. Animal and Plant Health Inspection Service (APHIS) successfully resolved issues related to bovine leucosis and bluetongue in 2003, the EU subsequently established certification requirements for BSE that precluded U.S. exports. Since then, the EU model certificate has been amended to align the BSE requirements with the OIE Code. Although the United States can now meet the BSE certification requirements, U.S. exporters remain blocked because the United States and EU have not agreed on the conditions and format for the export certificate. APHIS continues to work with the EU to resolve the remaining import health conditions and agree on a mutually acceptable certificate through the U.S.-EU Animal Health Technical Working Group.

Certification Requirements for Marinated Pork

The EU meat preparations certificate for marinated pork includes the condition that the product must be frozen. The United States is concerned that this condition has resulted in a *de facto* ban on shipments of chilled marinated pork, which by definition is not frozen. The United States will continue to engage with the EU on this issue.

Specified Risk Materials Certification Requirement

The EU has a different definition of specified risk materials (SRM) than the United States for the animal tissues most at risk of harboring the transmissible spongiform encephalopathies. The EU requires that materials exported to the EU meet the EU's SRM definition and be derived from carcasses of animals that can be confirmed as never having been outside of regions that the EU considers to be of negligible risk for BSE. Although the United States has been recognized by OIE as having negligible risk, the source cattle for U.S. ruminant origin animal byproduct exports may not necessarily come from negligible risk countries. The SRM requirement thus unnecessarily impedes U.S. exports of ruminant origin animal byproducts and would potentially limit the market for ovine/caprine meat were other market impediments removed.

This requirement otherwise has not been an issue for bovine meat for human consumption, because the special EU required production controls in the non-hormone treated cattle (NHTC) program already provides the necessary verifications regarding the history of the animal. The United States has requested the removal of the EU's "born and raised" requirement for all U.S. commodities. Consistent with the recommendations of OIE, it is the BSE status of the country of export that should determine whether SRMs have to be removed. The United States continues to raise this issue in the appropriate bilateral technical working groups and the WTO SPS Committee.

Agricultural Chemicals

Hazard-based Cutoff Criteria - Categorization of Compounds as Endocrine Disruptors

Regulation (EC) No. 1107/2009, which governs the registration of crop protection products, establishes several hazard-based "cut-off" criteria that exclude certain categories of products from consideration for normal authorization for use in the EU. For such products, the EU will not perform a risk assessment. Rather, it will discontinue EU authorization for a particular product at the time of re-approval, as has already happened for some substances, or, in the case of new products, declare them to be ineligible for authorization, based solely on their intrinsic properties, without taking into account important risk factors such as level of exposure or dosage. The United States is concerned that increasing numbers of safe and widely-used substances will not be reapproved or not have reasonable import tolerances set for their use due to these arbitrary cut-off criteria when current registrations expire.

One category of crop protection products subject to this hazard-based approach includes substances classified as endocrine disruptors (EDs). EDs are naturally occurring or man-made substances that may mimic or interfere with hormone functions. While the United States has programs to evaluate possible endocrine effects associated with the use of certain chemicals to ensure protection of public health and the environment, 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, thereby restricting trade without improving public health.

On June 15, 2016, the European Commission presented two draft legal acts outlining scientific criteria to identify EDs in agricultural products, one falling under the Biocidal Products legislation and the second under the Plant Protection Products legislation. In the draft legal acts, the Commission proposes to use the WHO definition of endocrine disruptors and include examination of all available information in order to base decisions on weight of evidence. However, the proposal does not specifically state that it will include consideration of other hazard characterizations such as potency, severity, and reversibility in these examinations. Without such considerations, the EU may potentially block substances regardless of the actual level of risk to human health.

In December 2016, the Commission produced a revised proposal that split the issue into two components: establishing criteria to classify a substance as an endocrine disruptor; and a proposal to amend the derogation to allow for substances classified as endocrine disruptors to be used under limited circumstances. There was no consensus among Member States at the December 2016 meeting on the EC proposal. For the February 2017 Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) meeting, the Commission chose to put only the proposal for the criteria up for discussion. However, the Committee again failed to reach a qualified majority on the criteria proposal. Many of the Member States asked for the re-introduction of the derogation that would allow for maximum residue levels and import tolerances to be set if a critical plant protection product is banned under the criteria. In July 2017, the SCoPAFF voted to approve the proposed criteria. Many countries supported the approval because the Commission committed to discussing the question of the derogation once the criteria were adopted. However, as the criteria went through the regulatory process with scrutiny, the Parliament in October 2017 rejected the

criteria on legal grounds, sending the draft back to the Commission for further revision. On December 14, 2017, Member States voted to adopt the newly revised criteria. The plant protection products criteria have been under scrutiny by the European Parliament and Council since that time, which have until April 2018 to raise any objections prior to final adoption. The biocidal products criteria have been published and will apply from June 7, 2018. and the plant protection products criteria have been under scrutiny by the European Parliament and Council. The United States continues to monitor this issue and raise concerns in international and bilateral fora.

Pesticide Maximum Residue Limits

Maximum Residue Limits (MRLs) and import tolerances are established under separate legislation, Regulation (EC) No. 396/2005, which is risk-based rather than hazard-based. The United States is concerned that for substances not approved under Regulation 1107/2009 due to the cut-off criteria, the EU has the authority and mandate to ignore the risk assessment process established under Regulation 396/2005 and automatically reset MRLs and import tolerances to the default level of 0.01 mg/kg, which is not commercially viable. The EU is currently conducting an evaluation of existing legislation on plant protection products and pesticide residues, through a Regulatory Fitness and Performance (REFIT) process. Through this process it is unclear whether the EU may choose to adjust Regulation 396/2005 to bring it in line with the hazard based principles of Regulation 1107/2009. As the number of substances ineligible for reauthorization by the EU increases, and as the EU resets the corresponding MRLs and import tolerances to the default level, the significant negative effect on agricultural production and trade is likely to increase. U.S. exports valued at over $5 billion and global trade amounting to $75 billion are at risk of significant damage. Discontinuing the use of critical substances without a proper science-based risk assessment to provide justification would have serious adverse effects on agricultural productivity and global markets.

Fosetyl-aluminum (Fosetyl-al)

Fosetyl-al is a fungicide that is not authorized to be used on nut trees in the United States. The United States does allow the use of phosphonate fertilizers on nut trees, however, because such fertilizers have low toxicity. Residues of phosphonic acid on crops such as tree nuts could result from the use of fungicides or fertilizers containing phosphonic acid. In late 2013, the Commission changed the designation of phosphonates as both a fertilizer and pesticide to only a pesticide. In doing so, residue levels detected on crops resulting from either pesticide or fertilizer use would be covered under the same MRL. However, after changing the designation, the Commission did not extend the number of crops covered by the MRL to include those crops that might be grown with phosphonate fertilizers. The application of the existing fosetyl-al MRL without extending the crops covered by the MRL could result in several U.S. nuts and fruits exceeding the MRL and thus being prohibited from the EU market.

On November 9, 2015, the PAFF approved the draft Commission Regulation to extend the temporary MRL of 75 mg/kg for almonds, cashew nuts, hazelnuts, macadamia, pistachios, and walnuts – but not pecans – until March 1, 2019. Under the higher MRL, U.S. trade is able to continue. The draft act was formally adopted by the Commission on January 25, 2016, but made retroactive to January 1, 2016, to minimize trade disruptions. The Commission instructed Member States to follow this guidance for import checks and sampling. An import tolerance application to replace the temporary MRL for tree nuts is under currently under review in the EU.

The United States was pleased by the extension of the temporary MRL for certain tree nuts. However, a number of other U.S. producers were affected as a result of the temporary fosetyl-al MRL reverting to the default level of 2 mg/kg. For example, exports of fresh and processed commodities such as stone fruits (apricots, cherries, peaches, and plums), blueberries, figs, and papayas became subject to the default MRL as of January 1, 2016. The berry industry is gathering residue monitoring data and preparing a dossier to

submit to the Commission in support of a higher MRL in early 2018, but in the meantime, more than $100 million of fresh and dried fruit and berry exports (including $68 million of dried plums alone) may no longer be able to enter the EU.

Diphenylamine

In 2009, the EU removed Diphenylamine as a plant protection product authorized for use within the EU. Subsequently, the EU established a temporary MRL of 0.1 parts per million (ppm) for Diphenylamine on apples and pears. The United States and Codex have a harmonized standard of 10 ppm for apples and 5 ppm for pear. The EU MRL was implemented on March 2, 2014, and affects both domestic and imported products. In January 2016, the MRL was extended for two additional years and will be reviewed in accordance with monitoring data available by January 22, 2018, after which time the EU may set an even lower MRL. The MRL of 0.1 ppm already greatly limits the use of Diphenylamine on U.S. products destined for the EU. Further reducing the MRL below 0.1 ppm has no basis in public health protection, given that the United States and Codex have found residue levels ten times higher than the current EU MRL for apples to be safe for consumers. 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 Diphenylamine or a workable MRL that accounts for cross contamination, the European market is significantly limited for U.S. apple and pear exports. The United States will continue to engage the EU regarding this issue.

Agriculture Biotechnology Cultivation Opt-Out

In March 2015, the EU adopted a directive that allows Member States to ban the cultivation of GE plants in their respective territories for non-scientific reasons. Under the transitional measures, the Member States had until October 3, 2015, to request to be excluded from the geographical scope of the authorizations already granted or in the pipeline. Nineteen Member States "opted-out" of GE crop cultivation for all or part of their territories. These decisions have not led to a change in the field, since none of the five Member States (Spain, Portugal, the Czech Republic, Slovakia, and Romania) that grew GE corn opted out.[13] As of 2017, only Spain and Portugal cultivate GE corn.

Seventeen Member States and four regions in two countries have opted-out of cultivation using biotechnology seeds. The 17 Member States that requested their entire territory to be excluded from the geographical scope of biotechnology applications are Austria, Bulgaria, Croatia, Cyprus, Denmark, France, Germany, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Slovenia, and Poland. The four regions are Wallonia in Belgium and Northern Ireland, Scotland, and Wales in the United Kingdom. All of these Member States and regions have decided to ban the cultivation of Monsanto 810 corn (MON810) and the seven varieties of corn that were in the pipeline in 2015, apart from Denmark and Luxembourg that have only banned MON810 and three of the seven varieties of corn in the pipeline.

Member State SPS Measures:

Austria: The Austrian government implemented its right to opt-out of GE cultivation through the Biotechnology Cultivation Framework Law, promulgated in August 2015. Austria also maintains earlier cultivation bans (most importantly, Monsanto's MON810 corn) although such bans have been rendered obsolete by the opt-out clause and the 2015 legislation. In addition, Austria's import and processing bans for Monsanto GT73 rapeseed and Monsanto 863 corn are still in force.

Bulgaria: In 2015, Bulgaria decided to ban entirely the cultivation of MON810, seven varieties of corn, soybeans 40-3-2, and carnation Moonshadow 1. The ban also extended to field research.

[13] Source: USDA FAS, GAIN Report: EU28: 19 European Countries Restrict the Cultivation of GE Crops.

France – Ban on Food Packaging Containing Bisphenol A: The production or import of food containers containing Bisphenol A (BPA) has been banned in France since January 1, 2015. The law applies to all products manufactured using BPA, where BPA is "intentionally" used to manufacture part or all of the final product, or where the BPA comes from an environmental or adventitious source. The French law contradicts a January 21, 2015, EFSA opinion, which stated that BPA does not present any risk to consumers. Noting differences in interpretation concerning the methodological limitations of toxicity studies on BPA, the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) recommended on October 12, 2017, that specific objective criteria be defined and harmonized between EFSA and national health agencies, taking into account the new EFSA assessment launched in 2017 on risks associated with BPA.

France – Ban on Cherries from Countries that Authorize Dimethoate: On April 27, 2017, France reinstated an April 22-December 31, 2016, ban on the import and sales of cherries from countries where dimethoate – a pesticide and acaricide (kills mites and ticks) – can be used on cherries and cherry trees. France's decision followed a ban on domestic production of this chemical compound, which France claims is harmful to human health. France imports roughly one-fifth of its cherry consumption, the bulk coming from EU countries including some (such as Spain and Germany) that have already banned dimethoate. Under the ban, the United States is not allowed to export cherries to France, even if the producer has never applied dimethoate. This ban ignores information provided by the United States documenting that dimethoate is not used in certain cherry producing states, or that it is used post harvest when there is no possibility for residues, and thus no risk to consumers. The dimethoate ban potentially sets a precedent for France to unilaterally ban products from countries using compounds approved for use in the EU but banned only in France under safeguard measures intended for short-term emergency cases. For example, France in late 2017 announced its intention to ban glyshosate in three years, despite the fact that the EU reauthorized the chemical's use for five years.

Greece: Greece has banned cultivation under various procedures and has opted out of GE corn cultivation under EU Directive 2015/412. Greece does not have a coexistence policy and maintains a *de facto* ban on both the cultivation and importation of GE products and has yet to adopt national legislation to officially implement the cultivation "opt out" provision.

Poland: The Feed Act of 22 July 2006 (OJ 2006 No. 144, item 1045) includes a prohibition on the manufacture, marketing, and use of GE feed and GE crops intended for feed use. The Polish parliament voted to prolong this suspension until January 1, 2019.

MARKET ACCESS

Tariffs

The EU's average applied MFN tariff rate is 4.8 percent. The average agricultural tariff rate is 10.9 percent, and the average non-agricultural rate is 3.9 percent. All of the EU's tariffs are bound at the WTO.

Although the EU's tariffs are generally low for non-agricultural goods, there are some high tariffs that affect U.S. exports, such as rates up to 26 percent for fish and seafood, 22 percent for trucks, 14 percent for audio-visual equipment, 14 percent for bicycles, 10 percent for passenger vehicles, 10 percent for processed wood products, and 6.5 percent for fertilizers and plastics.

Non-Agriculture

Member State Measures: Pharmaceutical Products

U.S. pharmaceutical stakeholders have expressed concerns regarding several Member State policies affecting market access for pharmaceutical products, including non-transparent procedures and a lack of meaningful stakeholder input into policies related to pricing and reimbursement, such as therapeutic reference pricing and other price controls. Such policies reportedly create uncertainty and unpredictability for 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, Cyprus, the Czech Republic, France, Hungary, Italy, Lithuania, Poland, Portugal, Romania, and Slovakia. Additional detail on some of these Member State policies is set out below. Pharmaceutical firms also have 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. pharmaceutical companies have expressed concern regarding non-transparent decisions by the Austrian Social Insurance Carriers Association (HVB). In a system approved in 2016, the EU average price was set as a ceiling for price negotiations, essentially ensuring a below-average price outcome for pharmaceutical products. The HVB also agreed to a rebate agreement with producers of branded medicine (not demanded of generic drug producers), which requires a so-called "solidarity contribution" for the sector ($148 million in 2016, and even up to $190 million subject to a growth-related calculation method in 2017 and again in 2018). This "contribution" is a *de facto* prerequisite to receiving reimbursement for prescribed drugs.

Belgium: Over the past 15 years, U.S. pharmaceutical companies have repeatedly expressed concerns about the Belgian government's lack of adequate transparency in the decision-making process related to cost-containment measures in the pharmaceutical sector. The Pact for the Future, signed between the federal government and the pharmaceutical industry in July 2015, addressed some of these concerns. Still, the budget measures of the Pact are very strict, while the initiatives that purported to lead to faster access of new innovative drugs are being implemented at a much slower pace. The 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, an orphan drug tax, and the claw back tax (an additional 3.29 percent of turnover as initially defined in 2017), as exemplifying such concerns. The claw back tax system was changed in 2017, and since is defined as 2.5 percent of the total reimbursable drug budget, instead of a fixed cap of €100 million ($112.4 million). This has led to a small increase of the claw back tax to €101.4 million ($113.9 million). In 2017, these taxes amounted to €370 million ($415.7 million). The Belgian government revoked a plan to abolish a 1 percent crisis tax during the 2017 budget discussions and imposed an additional €187 million ($210.1 million) savings in order to respect the budgetary trajectory set in the Pact for the Future. Overall, pharmaceutical companies contributed about 80 percent of the budget cuts in the Belgian healthcare system in 2017. The United States continues to highlight the need for a continued dialogue with the government and meaningful opportunities for stakeholder input into budget and pricing decisions.

Bulgaria: U.S. pharmaceutical companies also expressed concerns about the government's one-year moratorium on payments for newly-patented and innovative treatments, which the government introduced for 2018 in an effort to contain healthcare costs. The first Bulgarian government e-health tender was fast-tracked in 2017 for hospital purchase of cancer pharmaceuticals worth $518 million, but it is currently on hold pending litigation. U.S. companies have reported that the tender specifics were narrowly written to exclude some branded biotech medicine and included strict sanctions for products with shorter shelf life.

Czech Republic: While pharmaceutical approvals in the Czech Republic often exceed the EU timetables, U.S. stakeholders report that the time required 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 about such determinations. For example, U.S. stakeholders continue to raise questions regarding the Czech government's practice of setting maximum medicine prices based on the average of the three lowest prices in a basket of countries (a group of 17 Member States as of January 1, 2018). Such determinations should be made transparently and with meaningful opportunities for stakeholder input, as well as engagement by Czech authorities with stakeholders regarding concerns about whether such determinations reflect market circumstances in the Czech Republic or adequately incentivize innovation in research and development of pharmaceutical products. Additionally, the United States urges the Czech Republic to engage meaningfully with stakeholders regarding their concerns that such policies incentivize third parties to re-export pharmaceuticals to third-country markets, where they are sold at a profit.

In early 2017, Czech insurance companies, including the largest provider, VZP, started to use "internal guidelines" to put budget limits on drug payments. This new requirement, over and above the EU law, complicates the reimbursement process by essentially requiring a company to obtain an agreed budget for the drug from VZP before the State Institute for Drug Control (SUKL) can determine the reimbursement price. Czech medical societies and patient groups publically oppose these limits as they believe they limit access to new, innovative medicines. The U.S. Government continues to engage with insurance companies and the Czech government on this issue.

France: Pharmaceutical industry stakeholders continue to raise concerns about the French pharmaceutical market, including with respect to the significant tax burden on the industry and the constraints facing the sales of reimbursable medicines, sales of which dropped by 1.5 percent from 2015 to 2016 and by 2 percent per year over the previous four years. As an example of such constraints, U.S. stakeholders have expressed concern that market access for drugs in France is slower than elsewhere in Europe, resulting from delays in reimbursement approvals of as much as 405 days after marketing authorization, compared to the 180 days required by EU law.

Hungary: Pharmaceutical industry stakeholders express concern that the Hungarian government's pricing and reimbursement policies, which include extended delays in decision-making and reimbursement, and frequent changes to the list of drugs approved for reimbursement, cause considerable unpredictability in the Hungarian market. U.S. stakeholders also raise concern with high sector-specific taxes, including a $35,000 per year tax levied on each sales representative employed by pharmaceutical companies and a claw back tax that requires firms to pay for any government spending on drugs that exceeds the pharmaceutical budget. Finally, industry experts note that a government procurement process for eight oncological therapies is based on cost, rather than medical benefit, and fails to adequately consult with physicians and patient groups or with industry.

Italy: U.S. healthcare companies face an unpredictable business environment in Italy, which includes highly variable implementation of complex budget policies. One such policy is the "payback system" for hospital pharmaceutical purchases, which was first applied in 2013. It requires that pharmaceutical companies pay back 50 percent of the amount spent over budgetary limits for pharmaceutical spending. The pharmaceutical companies pay back the overspending to the national government through the Italian Drug Agency (AIFA), which is the organization in charge of calculating the overspending and collecting return payments. The Italian central government determines the overall annual budget for pharmaceutical products, which is then transferred to each region responsible for managing the healthcare system locally. Industry estimates that the Italian government has asked for roughly $1.48 billion from pharmaceutical companies between 2013 and 2015 as part of this policy. U.S. pharmaceutical firms account for 30 percent of the market but are asked to contribute 50 percent of the payback amount. Several U.S. and European

companies have prevailed on appeal to the Regional Administrative Court when challenging the 2013, 2014, and 2015 payback calculations. The 2018 budget law requires companies to refund the overrun on 2016 pharmaceutical expenditures and to conclude the settlement agreements defined with the AIFA for the payback amounts for 2013, 2014 and 2015.

In August 2015, the Italian government published a law (D.L. 78/2015) applying the payback system to hospital purchases of medical equipment. That same law authorized hospitals to renegotiate signed agreements with medical device suppliers in order to reduce the unit price or purchase volume as previously defined in the contract. Since this law was introduced, the government has not provided further guidance or legislation on its implementation, creating significant uncertainty among U.S. medical device companies operating in Italy, forcing them to hold excessive amounts of capital in reserve.

Stakeholders also have raised concerns regarding delays in market approval for pharmaceutical products and payments for medical devices. For example, it can take more than two years for new pharmaceutical products to reach the Italian market. The average payment time from public hospitals to medical devices suppliers in Italy continues to exceed the EU average as well as the maximum period permitted by EU law.

Lithuania: The United States continues to engage with the Lithuania government 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 have expressed concern regarding the tendering processes and the transparency of, and opportunity for meaningful stakeholder input in, reimbursement rules and determinations for biosimilar pharmaceutical products. Private hospital owners complain that a new hospital network law enacted on October 1, 2017 makes it difficult to get reimbursed by the national health fund for lifesaving procedures, forcing the closure of some private hospitals, particularly in cardiology. Poland is in the process of drafting a new reimbursement law that would move from a cost recovery pricing model to a price justification pricing model for so-called "orphan drugs." The United States urges Poland to engage meaningfully with stakeholders regarding their concerns that the new law could potentially put confidential commercial information at risk of disclosure.

Romania: Innovative pharmaceutical producers have identified several significant challenges in Romania resulting from the Romanian government's failure to update, despite repeated requests, the lists of innovative pharmaceuticals that are eligible for reimbursement under the national health system. According to U.S. stakeholders, Romania added several new innovative drugs to the reimbursement list in 2017 and concluded the process of developing treatment protocols to make 19 new drugs available to patients. Numerous applications remain pending with no progress. 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. Both innovative and generic pharmaceutical companies also have started to withdraw drugs from the Romanian market, as the low official prices set in Romania can fall below production costs and create parallel trade problems. The claw back tax, equivalent to 19.42 percent of total gross sales for the third quarter of 2017, is another major challenge for U.S. stakeholders. This tax rate is determined on the basis of the difference between the state's budget for reimbursable drugs and the amount actually spent on the drugs. U.S. stakeholders continue to raise concerns regarding a lack of transparency, particularly in pricing and computation of the claw back tax.

Slovakia: The process for marketing approval of new pharmaceutical products in Slovakia reportedly lacks transparency and deadlines are reportedly missed with some frequency. Medicine prices in Slovakia are capped based on the average of the three lowest prices within the EU. U.S. stakeholders report that this

methodology incentivizes third parties to re-export pharmaceuticals to third-country markets, where they are sold at a profit. Until 2016, the Slovak State Institute for Drug Control had the right to monitor and ban the export of certain pharmaceutical products. As a result of legal proceedings launched by the Commission against Slovakia, this law was amended in January 2017, scrapping the option to ban export of pharmaceuticals and instead banning distribution companies from exporting pharmaceutical products unless they have approval of the producer or the license holder.

Uranium

The United States is concerned that non-transparent EU policies may restrict the import into the EU of enriched uranium, the material from which nuclear power reactor fuel is fabricated. The EU appears to limit 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 civilian enriched uranium market for European suppliers. The United States has conveyed to the 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 resolution 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.

U.S. stakeholders have expressed concerns about actions taken by Italian customs authorities since 2013, and related decisions taken by Italian courts, challenging the use of certain EU banana import licenses under pre-2006 EU regulations. The United States has pressed the Commission to clarify its position on this matter.

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 and Vegetables

The EU Common Market Organization (CMO) provides a framework for market measures under the EU's Common Agricultural Policy (CAP), including for measures related to the promotion of fruit and vegetables. 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 2015 a new basic payment scheme and greening payments were introduced, replacing the single payment scheme. Direct payments also are paid to support certain processing sectors, including, for example, peaches for juicing in Greece. The general lack of transparency around the distribution of EU subsidies at the Member State level in the fruit and vegetable industry raises questions about whether the payments are decoupled from production, and U.S. producers remain concerned about potential hidden subsidies. The United States continues to monitor and review EU assistance in this sector, evaluating potential trade-distorting effects.

INTELLECTUAL PROPERTY RIGHTS PROTECTION

As part of its Digital Single Market (DSM) Strategy, on September 14, 2016, the European Community issued a package of proposals aimed at updating and reforming EU rules related to copyright with the stated goal of addressing legal uncertainty for both rights holders and users with regard to certain uses of copyright-protected works in the digital environment. Discussions on proposals in the package continue, including a proposed directive on Copyright in the DSM (COM(2016) 593 final) and a draft regulation laying down rules applicable to certain online transmissions of broadcasting organizations and retransmissions of television and radio programs (COM(2016) 594 final). In addition, the Commission published a communication on promoting a fair, efficient, and competitive European copyright-based economy in the DSM (COM(2016) 592 final).

The United States continues to work with the EU and its Member States on copyright issues, which may raise concerns from a trade perspective, and is following implementation of the copyright package closely including the following provisions:

- A new right for press publishers: According to the Commission, the contribution of publishers in producing press publications needs to be recognized and further encouraged to ensure the sustainability of the publishing industry. The Commission proposed the introduction of harmonized rights and remuneration for publishers related to copyright for the reproduction and making available to the public of press publications in the online environment.

- "Value gap" provision: Online service providers that store and provide access to the public to copyright-protected works uploaded by their users would be obligated to deploy means to automatically detect songs or audiovisual works that rights holders have identified and agreed with the platforms either to authorize or remove.

- Mandatory exceptions in the field of research and education: The proposal includes an exception for public interest research institutes regarding the use of text and data mining technologies for the purposes of scientific research, as well as exceptions for illustrations used for teaching in the online environment and for digitization of works by cultural heritage institutions.
- Rules regarding online broadcasting: Aimed at removing perceived obstacles to the creation of a

DSM, this proposal has two main provisions, which would: (1) apply a "country of origin" principle to online services related to an initial broadcast; and (2) require rights holders to license certain retransmission rights through collective rights management societies.

As these proposals continue through the decision-making process in the Parliament and Council, the United States will continue to follow developments and engage with various EU entities to ensure that the equities of U.S. stakeholders are protected.

Additionally, two DSM regulations may negatively affect territorial licensing, including the proposed "Regulation laying down rules on the exercise of copyright and related rights to online transmissions of broadcasting organizations and retransmissions of television and radio programs." Contractual freedom to license on a territorial basis and respect for international copyright norms are of paramount importance to the audiovisual sector, where the exclusive rights to authorize or prohibit the distribution of creative works through licensing is the basis for recouping substantial upstream production costs, often through pre-sales of exploitation rights. The Portability Regulation (EU) 2017/1128 was formally adopted on June 14, 2017, and will become applicable in all Member States as of April 1, 2018. This legislation seeks to give EU subscribers to online content services the ability to access this content when temporarily present in another Member State.

In January 2016, a new trademark directive (2015/2436) entered into force. Member States were given three years to transpose the directive into their national laws. A trademark regulation (2015/2424) also entered into force in early 2016. The United States continues to work with the EU and its Member States on trademark issues and is following implementation of the trademark package closely.

Regarding trade secrets, a "Directive on the Protection of Undisclosed Know-How and Business Information (Trade Secrets) Against Their Unlawful Acquisition, Use and Disclosure" (2016/943) was adopted by the Parliament and Council on June 8, 2016. The aim of the directive is to standardize the national laws of Member States against the unlawful acquisition, disclosure, and use of trade secrets. The directive also harmonizes the definition of trade secrets. Member States must bring the laws and administrative provisions necessary to comply with the directive into force by June 2018. The United States is monitoring the implementation of the directive closely.

With respect to Geographical Indications (GIs), the United States remains troubled with the EU system that provides overbroad protection of GIs, adversely impacting the protection of U.S. trademarks and market access for U.S. products that use generic names in the EU and third country markets. Regulation 1151/2012, for example, contains numerous problematic provisions with respect to the protection and enforcement of protected designations of origin (PDOs) and protected geographical indications (PGIs). Troubling provisions include those governing the scope of protection of PDOs and PGIs, including expansive rules addressing evocation, extension, co-existence, and translation, among others, which not only adversely affect trademark rights and the ability to use generic names, but also undermine access to the EU market for U.S. rights holders and producers.

As confirmed in the recital to Regulation 1151/2012, this measure also serves as the basis for the EU's international GI agenda, which includes requiring EU trading partners to protect and enforce in their markets lists of specific EU GIs, according to EU rules, with often only limited due process requirements to safeguard existing producers, rights holders, consumers, importers, and other interested parties.
Regulation 1151/2012 replaced the former GI regulation for food products, Council Regulation (EC) 510/06, which was adopted in response to WTO DSB findings in a successful challenge brought by the United States (and a related case brought by Australia) that asserted 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. Regulation 1151/2012 sped up the registration procedure for registering GIs, reduced the opposition period from six to three months, and expanded the types of products capable of being registered as a GI.

The United States continues to have concerns about the EU's GI regulations and monitors carefully its implementation and effects on bilateral trade. These concerns also extend to the EU's attempts to restrict common terms for wine in third country markets; 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.

The EU also continues to consider expanding the scope of GI protection in the EU territory to include non-agricultural products. At present, EU law only harmonizes the protection of GIs in the EU for wines, spirits, foodstuffs, and agricultural products. On July 15, 2014, the Commission issued a green paper entitled "Making the most out of Europe's traditional know-how: a possible extension of geographical indication protection of the European Union to non-agricultural products" (COM(2014) 469 final). This was followed by the Parliament's adoption of a resolution inviting the Commission to propose legislation providing for such extension. The United States is closely monitoring EU proposals and developments relating to the possible extension of GI protection beyond existing product categories.

Finally, the United States remains extremely concerned by the conduct and outcome of the 2015 World Intellectual Property Organization (WIPO) negotiations to expand the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration to include GIs. Of particular concern to the United States was the manner of engagement in these negotiations by the European Commission and by several EU Member States, including the Czech Republic, France, Greece, Italy, and Portugal, which took precedent-setting steps to deny the United States and the vast majority of WIPO countries full negotiating rights, and to depart from longstanding WIPO practice regarding consensus-based decision-making in this international organization. Likewise, the resulting text – the Geneva Act of the Lisbon Agreement – raises numerous and serious legal and commercial concerns, including with respect to the degree of inconsistency with the trademark systems of many WIPO countries, and could have significant negative commercial consequences for trademark holders and U.S. exporters that use generic terms.

Member State Measures

Generally, Member States maintain high levels of intellectual property rights (IPR) protection and enforcement. While some Member States made improvements in 2017, the United States continues to have concerns with respect to the IPR practices of several countries. 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: With regard to trade secrets, U.S. companies report gaps in criminal liability, insufficient specialization of judges, low criminal penalties, and procedural obstacles, which limit efforts to effectively combat trade secret theft and misappropriation. As Austria drafts legislation to implement the EU trade secrets directive, the United States will monitor developments closely and urge Austria to adopt model EU language on trade secrets.

Bulgaria: Bulgaria continues to be listed on the Special 301 Watch List in 2017. U.S. stakeholders report continued concerns about IPR enforcement, including with respect to online and cable television piracy, despite alternative paid options for both music and films. Rights holders and police try to restrict unauthorized releases of new films and music online, but IP enforcement is not a priority and administrative capacity remains low. The Special 301 Report also notes a need for legal reform to address gaps in

Bulgaria's law with respect to the exclusive rights granted to right holders, a specialized IP prosecutorial unit, and improvements to the efficiency of the judicial system in dealing with IP cases.

Czech Republic: While sale of copyright-infringing media in physical form continues at a modest level in outdoor markets, the Czech Republic has not been included on a Special 301 Watch List since 2009. Digital piracy in the Czech Republic, as elsewhere, has migrated primarily online, where right holders have identified several online sites, including "cyberlockers" that feature pirated material for download and streaming. Rights holders have had positive outcomes in a number of instances when they have gone to court, although websites often reappear under a new name. Also commendable is the Czech government interagency IPR task force, led by the Ministry of Industry and Trade, which coordinates policy and oversees implementation of laws involving IPR.

France: Online piracy continues to be a concern; however, the French government's efforts to reduce online piracy have yielded some successes. While civil proceedings in French courts continue to provide the most effective channel for enforcement against piracy, non-deterrent sentencing in criminal proceedings remains a problem.

Greece: Greece remained on the Watch List in the 2017 Special 301 Report. The United States acknowledges some improvements in IPR protection and enforcement in Greece, including actions taken to address online piracy. However, inadequate IPR enforcement continues to pose barriers to U.S. exports and investment. Key issues cited in the 2017 Special 301 Report include widespread copyright piracy and limited and inconsistent IPR enforcement. Greece has introduced draft legislation to address online piracy but the Greek parliament has yet to pass the legislation. The Greek public sector, including the Ministry of Defense, continues to be a significant consumer of pirated U.S. software.

Italy: Italy passed robust regulations to combat online piracy violations in 2014. These regulations established a "notice and takedown" system managed by Italy's communications regulator. This framework has been widely praised by stakeholders. While copyright protection is improving, industry stakeholders report social attitudes towards online piracy remain a challenge. Additionally, the Mercato dei Venerdi in Ventimiglia was added to the 2017 Notorious Markets List as an example of a market where counterfeit and pirated goods are widespread and enforcement has been ineffective.

Poland: Stakeholders continue to identify copyright piracy online and counterfeit seeds as a significant concerns in Poland.

Romania: Romania remained on the Watch List in the 2017 Special 301 Report. While some categories of infringement, such as street sales of counterfeit goods and piracy of optical discs, have continued to decline in past years, online piracy remains a serious concern. Some notorious pirate sites have connections to Romania. Criminal IPR enforcement remains generally inadequate, with questions arising regarding Romania's commitment to resolute enforcement, reflected in reduced cooperation among enforcement authorities and a lack of meaningful sanctions. Additional resources are also needed to achieve effective enforcement in Romania, such as increased training of law enforcement and prosecutors.

Spain: Spain was the subject of a Special 301 Out-of-Cycle Review from 2013 to 2017, after Spain was removed from the Watch List in the 2012 Special 301 Report. In 2015, Spain took several positive legislative steps, including amending its civil and criminal copyright laws. In December 2015, Spain's Prosecutor General also issued a new circular with respect to copyright piracy over the Internet. Spain took additional steps in 2017 to implement these amendments and increase staff and resources of "Section 3" of the Intellectual Property Commission. However, Els Limits de La Jonquera in Girona was added to the Notorious Markets List in 2017 for widespread sales of counterfeits and ineffective enforcement. The

United States will continue to carefully monitor developments and work closely with Spain to address these issues.

Sweden: Sweden continues to grapple with widespread online piracy. Government enforcement efforts have shown positive results, and right holders report that court cases to enforce their rights are successful in the vast majority of cases. Meanwhile, levels of illegal streaming remain high. As a result, the movie, television, and live sports telecast industries continue to lose revenue. However, legal sales of music and film have increased dramatically in recent years, in part because of Swedish enforcement efforts and increased political awareness of the importance of IPR to Sweden.

SERVICES BARRIERS

Telecommunications

Electronic Communications Code

Telecommunications in the EU are currently regulated through five directives and one regulation: the Framework Directive; the Access Directive; the Authorization Directive; the Universal Service Directive; the Directive on Privacy and Electronic Communications; and the Regulation on Roaming. Each Member State has its own independent national regulatory authority (NRA) for the telecommunications sector. The Body of European Regulators for Electronic Communications (BEREC) consists of the heads of these independent regulators and provides advice to the Commission regarding measures affecting telecommunications.

As part of the EU's DSM strategy, in September 2016, the Commission released a proposal for a common "European Electronic Communications Code" (Code) that would update and merge four existing telecommunications directives (Framework, Authorization, Access, and Universal Service) into a single measure that would include rules on network access, spectrum management, communication services, universal service, and institutional governance. The Commission asserts that the proposed Code will promote infrastructure competition, greater investment in high-speed broadband networks, and greater harmonization of spectrum management across the EU. U.S. suppliers welcomed the Commission's attempt to reduce market fragmentation, promote the development and introduction of innovative services, and harmonize spectrum management. Negotiation on the Code in the so-called "trilogue" mechanism (discussions involving the EU Commission, Council, and Parliament) is currently ongoing.

The proposed Code would extend European telecommunications regulations to "over the top" (OTT) Internet services, such as voice, messaging, and other communications applications. Most of the obligations in the Code would apply to "number-based" Internet services that enable communications with mobiles and landlines. These obligations would address requirements relating to access to emergency services, duration of contracts, quality of service, number portability, and switching rules for service bundles. All covered Internet services, including those that do not use public numbering, would be bound by rules on security and integrity of services that govern their risk management strategies and their reporting of security incidents to competent authorities. U.S. suppliers have expressed significant concerns with the proposed expanded scope of EU telecommunications law and have highlighted that Internet services face low barriers to entry by new competitors, while traditional telecommunications services providers enjoy high barriers to new entry and little direct competition, thus justifying asymmetrical regulation. In addition, this extension of NRA authority to Internet services raises concerns given that most traditional telecommunications services suppliers historically serve one or a limited number of Member State markets, whereas most Internet "interpersonal communications services" are available in every Member State, thereby potentially subjecting them to conflicting NRA jurisdiction.

Regulation on Privacy and Electronic Communications

In January 2017, the Commission proposed a new Regulation on Privacy and Electronic Communications, which would replace the e-Privacy Directive of 2002. The Commission has stated that the proposed Regulation will align rules for telecommunications services in the EU with the General Data Privacy Regulation (GDPR) and cover confidentiality of business-to-business communication and communication between individuals. The proposal gives Member State Data Privacy Authorities (DPAs) the authority to enforce its requirements. While it would remove existing inconsistencies between Member State rules, it would also expand regulatory coverage intended for traditional telecommunications services providers to Internet-enabled communication and messaging services (*i.e.*, OTT services), thereby imposing additional costs on those suppliers.

The Commission originally aspired to have a new regulation in place by May 2018, when the GDPR is scheduled to take effect. While the Parliament adopted its final amendments and voted on a mandate for the trilogue on October 26, 2017, the Council is continuing technical discussions as many Member States have not yet formed their final position on the Commission's proposal. Consequently, it is unlikely that the Commission's self-imposed May 2018 deadline for replacing the 2002 e-Privacy Directive will be met.

International Termination Rates

One of the main cost components of an international telephone call from the United States to an EU country is the rate a foreign telecommunications operator charges a U.S. operator to terminate the call on the foreign operator's network and deliver the call to a local consumer. The GATS Telecommunications Services Reference Paper includes disciplines designed to ensure that the charge for terminating a call on a network of a major supplier (which in most countries is the largest or only fixed-line telecommunications supplier) is cost-oriented. This ensures that a major supplier is not able to gain an unfair competitive advantage from terminating foreign or competitive carriers' calls, and also helps to ensure that U.S. carriers can offer reasonable and competitive international rates to consumers located in the United States. Termination rates for both fixed and wireless traffic should be set in relationship to the costs of providing termination, as would be reflected in a competitive market. Where competition does not discipline the costs of termination services, governments should ensure that the termination rates charged by its operators are not unreasonably higher than cost.

Most of the EU Member State NRAs permit major suppliers to charge different rates for the termination of international traffic originating outside of the EU, or in some cases outside the European Economic Area (EEA, which is comprised of the EU plus Iceland, Liechtenstein, and Norway), than for international traffic between sovereign states within the EU or EEA. Only a few Member States prohibit such differentiation (Denmark, Ireland, and Sweden), and two Member State NRAs are considering adopting such a prohibition (Romania and the United Kingdom). Several other Member States allow for different rates based on reciprocating rates in the other country (Austria, France, Luxemburg, the Netherlands), and one Member State NRA is considering such an approach (Spain). A number of suppliers in the remaining Member States, however, are currently charging U.S. suppliers differentiated rates that are higher than the rates charged for terminating traffic originating in one of the other Member States. These Member States include: Croatia, Cyprus, the Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Poland, Portugal, and Slovenia. Neither the Commission nor BEREC have made efforts to resolve this issue.

These discrepancies in termination rates do not appear to reflect incremental costs for termination of such traffic. Termination rate increases also disadvantage enterprises in those foreign markets for which foreign communications is a key part of business (*e.g.*, traders, hotels). The United States remains concerned that the Commission and Member States appear to endorse, explicitly or implicitly, a two-tier approach to the termination of international traffic. These actions adversely affect the ability of U.S. telecommunications

operators to provide affordable, quality services to U.S. consumers calling Europe and may raise questions regarding the treatment of U.S. suppliers by certain Member States.

United Kingdom: In 2017, the Office of Communications (Ofcom) published two consultations for comment: the Narrowband Market Review and the Mobile Call Termination Review. In both consultations, Ofcom proposes not to allow UK operators to apply differential termination charges for calls originating outside the EU/EEA, but instead to require them to apply the same termination rate to all calls regardless of the country of origin. The United States encourages the United Kingdom to adopt these proposals.

Roaming

Germany: In November 2017, the German government imposed a regulation requiring that any devices that will be permanently located in Germany and that use a foreign telephone country code be registered with the telecommunications regulator (BNetzA). This regulation raises concerns for U.S. companies providing global machine to machine (M2M) and Internet-of-Things (IoT) services because it appears to impose additional requirements that will not apply to domestic providers of such services. The United States will monitor the implementation of this new regulation.

Television Broadcasting and Audiovisual Services

Audiovisual Media Services Directive

A legislative proposal amending the 2007 Audiovisual Media Services Directive (AVMSD) (COM/2016/0287 final) was issued by the Commission on May 25, 2016. This proposal aims to update the 2007 Directive to reflect developments in the audiovisual and video on-demand markets. The 2007 directive established minimum content quotas for broadcasting that must be enforced by all Member States. Member State requirements are permitted to exceed this minimum quota for EU content, and several have done so, as discussed below. The AVMSD did not set any strict content quotas for on-demand services, but it still required 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.

The proposed updated AVMSD includes provisions that would impose on Internet-based video-on-demand providers, which already must promote European works under current rules, a minimum 20 percent threshold for European content in their catalogs and require that they give prominence to European content in their offerings. The proposal also provides Member States the option of requiring on-demand service providers not based in their territory, but whose targeted audience is in their territory, to contribute financially to European works, based on revenues generated in that Member State. On May 18, 2017, the Parliament's Culture Committee, which took the lead on the proposal, voted to increase the quota of European content to 30 percent. Member States could also choose to go higher. In addition, the Parliament voted to extend the scope of the directive to video-sharing platforms that tag and organize content, which raised concerns among social media platforms. Trilogue discussions among the Commission, Parliament, and Council were still under way in early 2018, but the three institutions had not yet reached agreement on a number of important issues, such as financial requirements to promote EU works and potential measures applied to video-sharing platforms.

Satellite and Cable Directive

The 1993 Satellite and Cable Directive (SatCab) governs satellite broadcasting and cable retransmission. It was enacted to promote cross-border satellite broadcasting of programs and their cable retransmission from other Member States and to remove obstacles arising from disparities between national copyright provisions. Under SatCab's country-of-origin principle, the satellite broadcasting of copyrighted works requires the authorization of the rights holder, and such rights may only be acquired by agreement.

In 2016, the Commission carried out a review (REFIT) of the 1993 directive, with the aim of enhancing cross border access to broadcasting and related online services across the EU. This review was followed by a Commission proposal for a "Regulation laying down rules on the exercise of copyright and related rights applicable to certain online transmissions of broadcasting organizations and retransmissions of television and radio programmes" (Broadcasting Regulation), which as of March 2018 was still going through the decision-making process in the European Parliament and Council. The proposed Broadcasting Regulation seeks to extend the country-of-origin principle to online programming, a development strongly opposed by the U.S. film and commercial television sectors. U.S. studios are particularly concerned that the proposed regulation would interfere with the ability of rights holders to continue licensing on a country-by-country basis and tailor audiovisual content for specific cultural audiences at different price points. There is also increasing concern about the proposed expansion of mandatory collective rights management in relation to re-transmission, which is viewed by commercial producers as another encroachment on freedom to contract.

Member State Measures

Several 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 AVMSD in a restrictive manner. France's implementing legislation, approved by the Commission in 1992, requires that 60 percent of programming be of EU origin and 40 percent include French-language content. These requirements exceed AVMSD thresholds. 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 content. In addition, radio broadcast quotas require that 35 percent of songs on almost all French private and public radio stations be in French. The quota for radio stations specializing in cultural or language-based programing is 15 percent. A July 2016 regulation specifies that only if the top ten most played French songs on a station account for less than 50 percent of the songs played are they counted towards the quota. France's Broadcasting Authority, Conseil supérieur de l'audiovisuel, oversees implementation of the quotas.

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 in such a way as to account for more than 30 percent of the multiplex's weekly shows. While they are in theatrical release, feature films may not be shown or advertised on television. 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: The Italian Broadcasting Law, which implements EU regulations, provides that the majority of television programming time (excluding sports, news, game shows, and advertisements) be EU-origin content. Ten percent of transmissions (and 20 percent for state broadcaster RAI) must be reserved for EU works produced within the past five years.

Poland: Television broadcasters must devote at least 33 percent of their broadcasting time each quarter for programming originally produced in the Polish language, except for information services, advertisements, telesales, sports broadcasts, and television 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. Television broadcasters must dedicate at least 50 percent of their broadcasting time quarterly to programs of EU origin, except for information services, advertisements, telesales, sports broadcasts, and television quiz shows. Television broadcasters must devote at least 10 percent of their broadcasting time to programs by EU independent producers, and compliance is reviewed every three months. As of July 5, 2017, Poland implemented an EU directive that allows concession-holders to apply for an exception allowing for 25 percent Polish and 40 percent EU content in some specific cases. 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.

Portugal: Television broadcasters must dedicate at least 50 percent of air time to programming originally produced in the Portuguese language, with at least half of this produced in Portugal. Music radio broadcasters must dedicate between 25 percent to 40 percent of programming time to music produced in the Portuguese language or in traditional Portuguese genres, with at least 60 percent of this produced by citizens of the EU.

Slovakia: Since January 2017, private radio stations have been required to allocate at least 25 percent of airtime to Slovak music, and state-run radio at least 35 percent. In addition, at least one-fifth of the Slovak songs must have been recorded in the past five years.

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 other than Spanish and keeps showing the film in that language throughout the day. In addition, broadcasters and providers of other audiovisual media services annually must invest 5 percent of their revenues in the production of EU and Spanish films and audiovisual programs.

In 2010, the Autonomous Community of Catalonia passed the Catalan Cinema Law, legislation that requires distributors to include the regional Catalan language in any print of any movie released in Catalonia that had been dubbed or subtitled in Spanish, but not any film in Spanish. The law also requires exhibitors to exhibit such movies dubbed in Catalan on 50 percent of the screens on which they are showing. In 2012, the European Commission ruled that the law discriminated against European films and must be amended. Additionally, the Spanish constitutional court ruled in July 2017 that the law was disproportionate, and reduced the requirements of movies to be dubbed in Catalan to 25 percent. To date, the law has not been amended, nor has the issue been brought before the CJEU. Although the Catalan Cinema Law technically came into force in January 2011, the Catalan regional government has not yet approved its implementation, giving the law no effect. In the absence of the regulation, in 2012 the regional government and major movie studios agreed to dub 20 films in Catalan annually, in addition to 20 independent films, with dubbing financed by the regional government.

In 2010, the Spanish government revised its audiovisual law and imposed restrictions on non-EU ownership (limited to no more than 25 percent share) and leasing of audiovisual licenses, and U.S. investors report that they have been negatively impacted. Following the 2010 amendment, several U.S. investors signed agreements with Spanish audiovisual license holders to provide content for free-to-air television channels.

These investments were disrupted by a 2012 decision by the Spanish Supreme Court, which annulled the nine digital terrestrial television (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. In 2014, all of the annulled DTT channels ceased broadcasting, and in 2015 the Spanish government awarded six new licenses through a public tender process. U.S. investors were unable 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.

Video-on-demand services in Spain must reserve 30 percent of their catalogs for European works (half of these in an official language of Spain) and contribute 5 percent of their turnover to the funding of audiovisual content.

Legal Services

Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Greece, Hungary, Latvia, Lithuania, Malta, and Slovakia require EU or EEA nationality or citizenship 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 Member State if the local partnership is to use an internationally recognized name.

Czech Republic: Unlike 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" with a Hungarian law firm, and may only provide information to their clients on U.S. or international law.

Accounting and Auditing Services

The European Commission has taken the position that its directive on statutory auditing prohibits Member States from considering professional experience of foreign auditors acquired outside of the EU when considering whether to grant statutory auditing rights. This interpretation has hampered movement of experienced professionals and inhibited Member States from participating in the growing movement towards mutual recognition in this field. The United States will continue to advocate for Member States to take into account experience of U.S. CPAs acquired in the United States.

Member State Measures

Czech Republic: The Czech Republic requires that at least a majority of the voting rights in an audit firm must be held by auditors licensed in the EU or by a firm licensed to perform statutory audits in a Member State.

Hungary: Foreign investors must have a Hungarian partner in order to establish accounting companies.

Slovakia: Slovakia requires that companies providing auditing services be registered in a Member State, and requires that at least a majority of the voting rights in an audit firm be held by auditors licensed in the EU or by a firm licensed to perform statutory audits in a Member State.

Retailing

Member State Measures

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

Hungary: A 2015 law requires that food retail chains with annual revenue of $55 million or greater shut down if they incur losses for two consecutive years. In 2016, the European Commission started infringement proceedings against Hungary, seeking the repeal of the law. While the EU forced Hungary to repeal a sanitation tax levied only on large, multinational supermarkets, Hungarian government officials have stated they will find new ways to make foreign retailers pay more tax.

Romania: In July 2016, Romania passed a law requiring large supermarkets to source from the local supply chain at least 51 percent of the total volume of their merchandise in meat, eggs, fruits, vegetables, honey, dairy products, and baked goods. The law vaguely defined the local supply chain and is intended to favor Romanian products. This law applies to high-volume supermarkets with more than €2 million ($2.2 million) in annual sales, affecting all major chains. The law also bans food retailers from charging suppliers for any services, including on-site marketing services, thereby preventing producers from influencing how stores market or display their products and injecting greater unpredictability into the business environment. The government has not yet implemented the 51 percent provision by passing the required secondary legislation, although it announced its intention to do so even after the European Commission notified Romania of possible infringement proceedings on February 15, 2017. The parliament has yet to finalize the implementing legislation.

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 Member States. 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 the EU agreed to a compensation package on August 7, 2006. To date, however, the Commission has failed to secure the approval of all Member States, which is necessary to implement the agreement. The United States will continue to monitor this process to ensure the agreement is implemented before the EU's modifications enter into effect.

INVESTMENT BARRIERS

With few exceptions, EU law generally requires that any company established under the law of one Member State must receive national treatment in all other Member States, regardless of the company's ultimate ownership. Laws and regulations pertaining to the initial entry of foreign investors, however, are largely still the purview of individual Member States. As discussed below, the policies and practices of the EU and its Member States can have a significant impact on U.S. investment.

Member State Measures

Bulgaria: Weak corporate governance remains a problem in Bulgaria. While legislative protection for minority shareholders has 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. Inadequate judicial mechanisms for resolution of commercial disputes and a perception that foreign investors are unlikely to receive impartial treatment in Bulgaria's judicial system create further barriers to investment.

The natural gas market in Bulgaria remains largely closed to competition, with gas supplied almost entirely by Russia's Gazprom under a long-term contract and domestic distribution dominated by Bulgaria's state-owned company, Bulgargaz. These conditions have led to antitrust actions by the European Commission against both Gazprom and Bulgargaz's parent company, Bulgaria Energy Holding, which the Commission alleges is conspiring to restrict would-be competitors from accessing key gas infrastructure in Bulgaria. With respect to the supply of gas into Bulgaria from foreign markets, a sharp increase of entry-exit tariffs by the Bulgarian energy regulator beginning on October 1, 2017, has made commercial gas trade unviable, including for U.S.-sourced liquefied natural gas. The higher tariff does not apply to Russia's Gazprom, raising concerns about discrimination.

Croatia: U.S. companies doing business in Croatia complain that their operations are negatively affected by frequent, unexpected legislative changes. Investors reportedly find it difficult to make sound, long-term business plans due to the unpredictable legislative environment.

Although Croatian law calls for mandatory regulatory impact assessments of proposed legislation, that requirement is not strictly observed. In 2014, for example, less than 10 percent of the laws enacted were subject to proper regulatory impact assessments. The Croatian government has presented no clear commitment or timeline to increase meaningfully its conduct of such impact assessments.

Cyprus: Cypriot law imposes restrictions on the foreign ownership of real property and construction-related businesses. 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 are available for projects requiring larger plots of land, but are difficult to obtain and rarely granted. Separately, 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 residents 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 December 2004 law that streamlined the French Monetary and Financial Code, the State Council designated a number of "sensitive" sectors in which prior approval is required before foreign acquisition of a controlling equity stake is permitted. In a December 2005 decree, the French government identified 11 business areas in which such approval would be required, and in which the Ministry of Economy and Finance must authorize in advance investment activity related to foreign ownership. In May 2014, the government expanded these areas to include energy, water, health, transportation, and telecommunications, as well as any installation, facility, or structure deemed to be "vital" under the Defense

Code. In addition to being able to restrict foreign ownership through the prior approval process, France also takes ownership stakes in companies in strategic sectors, which serves as a buffer against foreign takeovers.

Greece: All purchases of land in border areas and on certain islands require approval from the Ministry of Defense. The definition of "border areas" is broader for non-EU purchasers of land than for purchasers from within the EU, and obtaining approval for such purchases 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: Investors have expressed concern that Hungary passes tax laws and regulations that disproportionately impact foreign-owned firms, often with limited consultation with affected businesses and stakeholders, and that tax larger (primarily foreign-owned) firms at a far higher rate. In 2016, the Commission determined that Hungary's advertising and tobacco taxes, as well as supermarket inspection fees, unfairly discriminate against large companies. While Hungary suspended the tobacco tax and food inspection fee, it maintains the advertising tax.

Transparency experts have expressed concern that confidential "strategic agreements" that the Hungarian government has signed with over 70 major companies are a hidden forum for lobbying and preferential treatment.

Italy: Some U.S. companies claim to have been targeted adversely by the Italian Revenue Authority by virtue of the fact that they engage in international operations. Tax rules in Italy change frequently and are interpreted inconsistently. U.S. companies report long delays in receiving VAT refunds to which they are legally entitled. Tax disputes are resolved slowly, and initial findings are frequently reversed, which reduces certainty and increases compliance costs. U.S. oil and gas companies have also faced lengthy delays in obtaining necessary permits from the Italian government for exploration and drilling.

Latvia: The judicial system in Latvia can present significant challenges to investors. Insolvency proceedings, for example, can take several years to resolve, and there have been reports of large-scale abuse by both insolvency administrators and bad-faith creditors who have manipulated the proceedings to seize control of assets and companies and to extract unwarranted settlements and fees. In a recent study, 76.8 percent of business owners said they believe insolvency proceedings in Latvia are not transparent and fair and 74.3 percent said they had encountered insolvency abuse. U.S. stakeholders have similarly voiced concerns about the duration of civil cases, while the nature and opacity of judicial rulings have led some investors to question the fairness and impartiality of some judges.

In 2017, Latvia enacted amendments to its Law on Land Privatisation in Rural Areas that, among other things, prohibit foreigners who are not permanent residents in Latvia from purchasing agricultural land. These amendments also require that any person wishing to purchase agricultural land possess a working knowledge of the Latvian language and be able to present in Latvian their plans for the future use of the land.

Poland: Financial service institutions and retailers have expressed concerns about recent tax measures directed at companies operating in those sectors. With respect to the retail sector, Poland in July 2016 adopted a new tax on companies engaged in the retail sale of goods, one that would impose progressively higher rates of taxation based on the size of a company's turnover. In June 2017, the European Commission ruled that the measure breached EU rules on state aid by unduly favoring certain companies over others, and Poland subsequently suspended implementation of the tax indefinitely. With respect to financial institutions, Poland in January 2016 imposed a new 0.44 percent tax on the assets of banks, consumer lending companies, and insurances companies. International ratings agencies expressed concern that the

tax, which was estimated to cost companies in the sector €1 billion ($1.1 million) in 2016, would reduce banks' ability to absorb shocks, hurt credit growth, and adversely affect Poland's economic growth. Similar concerns have also been raised with respect to proposals that would require banks holding mortgages denominated in Swiss Francs to convert these loans into local currency, or that would require these lenders to make mandatory contributions to a fund that would make payments to mortgage borrowers.

Romania: Uncertainty and a lack of predictability in legal, fiscal, and regulatory systems pose a continuing impediment to foreign investment in Romania. Many companies report experiencing long delays in receiving VAT refunds to which they are legally entitled, with deadlines stipulated by law for the processing and payment of refunds often not being respected.

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

GOVERNMENT PROCUREMENT

Government procurement is governed by EU public procurement directives. In 2014, the European Parliament approved revised directives addressing general public procurement and procurement in the utilities sector. The Parliament also approved a new directive on concessions contracts. Member States were required to transpose the new directives into national legislation by April 2016.

The directive on procurement procedures in the utilities sector covers purchases in the water, transportation, energy, and postal sectors. This directive requires open and competitive bidding procedures, but it permits Member States to reject 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 water (the production, transport, and distribution of drinking water); energy (gas and heat); urban transport (urban rail, automated systems, trams, buses, etc.); and postal services. Subsidiaries of U.S. companies may bid on all public procurement contracts covered by the EU directives.

The EU is a member of the WTO Agreement on Government Procurement (GPA). U.S.-based companies are allowed to bid on public tenders covered by the GPA.

The EU's lack of country of origin data for winning bids makes it difficult to assess the level of U.S. and non-EU participation. Nevertheless, a 2011 report commissioned by the EU noted that only 1.6 percent of total Member State procurement contracts were awarded to firms operating and bidding from another Member State or a non-EU country, demonstrating that in practice the value of direct cross-border procurement awards even among Member States was very small. The same study said that U.S. firms not established in the EU received just 0.016 percent of total EU direct cross-border procurement awards.

Member State Measures

Lack of transparency in certain Member State public procurement processes continues to be an almost universally cited barrier to the participation of U.S. firms. U.S. firms seeking to participate in procurements in Bulgaria, the Czech Republic, France, Greece, Hungary, Italy, Lithuania, Romania, Slovakia, and Slovenia have all proactively voiced concerns over a lack of transparency, including with respect to overly-narrow definition of tenders, language and documentation barriers, and implicit biases toward local vendors and state-owned enterprises. The Commission's 2014 EU Anti-Corruption Report asserts that Member

State public procurement is one of the areas most vulnerable to corruption.[14] Additional Member State-specific trade barriers to U.S. participation in public procurement processes are cited below.

Bulgaria: Stakeholders report that the public procurement process in Bulgaria is frequently discriminatory and unfair. There are persistent complaints that tenders are too narrowly defined and are tailored to a specific company. For example, a U.S. company seeking to sell nuclear fuel to Bulgaria's state-owned Kozloduy Nuclear Power Plant (KNPP) is facing substantial barriers imposed by KNPP and by Bulgaria's nuclear regulator. In order to participate in a 2018 procurement of nuclear fuel, Bulgaria's nuclear regulator would have to grant KNPP a license to use the fuel from the U.S. vendor. However, the regulator has refused to define the requirements for licensing KNPP to use the new fuel type, and KNPP's Board of Supervisors has refused to sign a contract that KNPP's management has reached with U.S. vendor to conduct the safety analysis that KNPP expected that it would have to provide the regulator. In contrast, in 2016 a Russian state-owned company, and the incumbent supplier to KNPP, was permitted to load a new nuclear fuel type prior to completing comparable tests. Without a process in place to license KNPP to use the nuclear fuel from the U.S. vendor and with short time remaining before the launch of the tender for KNPP's post 2020 nuclear fuel contract, the U.S. supplier will be unable to compete in the 2018 procurement.

France: France continues to maintain ownership shares in several major defense contractors (11.08 percent of Airbus, formerly EADS, shares; 14 percent of Safran shares and 21.9 percent of its voting rights; and 25.97 percent of Thalès shares). 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: U.S. firms have complained that 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. Additional complaints center on onerous certification and documentation requirements on U.S. firms.

Italy: U.S. firms continue to cite widespread corruption in procurements, especially at the local level. In 2012, the Italian parliament approved an anti-corruption bill that introduced greater transparency and more stringent procedures to the public procurement process. Law 69/2015, an additional anti-corruption law passed in 2015, has strengthened the powers of the National Anti-Corruption Authority (ANAC) and sanctions for offenses committed against the Public Administration became more severe. Law 69/2015 also inserted Article 322 ("Riparazione pecuniaria") in the Criminal Code, which provides for the restitution of assets illegally obtained by public officers. According to Transparency International Italia's October 2017 Anticorruption Report, Italian legislation to combat corruption is adequate, though enforcement remains weak. The report cites the lack of adequate whistleblower protection and the absence of laws regulating lobbying activities as key challenges for anti-corruption enforcement. However, a whistleblower protection law was approved by the Italian parliament in November 2017, shortly after the report's publication.

Poland: U.S. firms reported disappointment that "lowest cost" remains the main criterion Polish officials use to award contracts, often overlooking other important factors in bid evaluation, such as quality, company reputation, and prior experience in product and service delivery. Defense companies indicate that the Ministry of Defense uses statutory exclusions bypassing tendering procedures in signing contracts.

[14] Report from the Commission to the Council and the European Parliament, EU Anti-Corruption Report, February 3, 2014. https://ec.europa.eu/home-affairs/sites/homeaffairs/files/e-library/documents/policies/organized-crime-and-human-trafficking/corruption/docs/acr_2014_en.pdf.

Slovenia: U.S. firms report short timeframes for bid preparation, tendering documentation that is difficult to understand, and opacity in the bid evaluation process as major impediments. Slovenia's quasi-judicial National Revision Commission (NRC), which reviews all disputed public procurement cases, has 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 directed them to the NRC, which is not required to justify its decisions.

SUBSIDIES

Various financial transactions and equity arrangements throughout the EU raise questions as to the role of state funding in supporting or subsidizing private or quasi-private organizations, including in the manufacture of civil aircraft.

Beginning in June 2014, the Commission announced that certain transfer pricing rulings given by Member States to particular taxpayers may have violated EU restrictions on state aid. The EU initiated a series of state aid investigations primarily involving U.S.-headquartered companies. As the U.S. Department of the Treasury explained in a white paper dated August 24, 2016, the United States remains deeply concerned with the Commission's approach in these investigations. This approach is new, and departs from prior EU case law and Commission decisions. The Commission's actions also undermine the international consensus on transfer pricing standards, call into question the ability of Member States to honor their bilateral tax treaties, and undermine the progress made under the OECD/G20 Base Erosion and Profit Shifting project.

Government Support for Airbus

Over many years, 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 and 100 percent of the development costs (launch aid) of all Airbus aircraft models and have provided other forms of support, including equity infusions, debt forgiveness, debt rollovers, marketing assistance, and research and development funding, in addition to political and economic pressure on purchasing governments.

The EU aeronautics research programs are driven significantly by a policy intended to enhance the international competitiveness of the EU civil aeronautics industry. Member State governments have spent hundreds of millions of euros to create infrastructure for Airbus programs, including €751 million ($843.8 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 ($204.5 million) to create the AeroConstellation site, which contains additional facilities for the A380. After having given the Airbus A380 more than $5 billion in subsidies, the relevant Member State governments have also provided launch aid in comparable amounts for the new Airbus A350 XWB aircraft.

Airbus SAS, the successor to the original Airbus consortium, is owned by the Airbus Group, 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 accompanied a reorganization of the company's ownership structure, resulting in the governments of France and Germany each owning up to 11 percent of the shares, the government of 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 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. The WTO compliance panel issued its report on September 22, 2016, finding that the EU Member States had not withdrawn the past subsidies conferred by $17 billion in past launch aid to Airbus, and that the launch aid of nearly $5 billion for the A350 XWB was also contrary to WTO rules. The EU appealed that finding to the WTO Appellate Body.

Government Support for Airbus Suppliers

Member State Measures

Belgium: The Belgian federal government coordinates with Belgium's three regional governments on the funding of Non-Recurring Costs to be financed by Belgian manufacturers in order to be able to supply parts to Airbus. The Belgian Government has, in this context, decided in 2000 to set aside a budget of €195 million ($178.9 million) for Belgian industrial participation in the A380 program and in 2008, a budget of €150 million ($220.6 million) for Belgian industrial participation in the A350 XWB program. Belgium has always stated that these were refundable advances, partially covering nonrecurring costs in accordance with the European regulations. Both in 2006 and in 2009, the Commission initially disputed that view, but later acquiesced. Only industrial research or experimental development projects linked to the A350 XWB and A380 programs can be (partially) financed through reimbursable loans in accordance with European regulations. For the A380-program, the average intervention level is 47 percent and for the A350 XWB program, 54 percent. These interventions are not considered grants but reimbursable advances based on sales forecasts for each aircraft. This constitutes as such a risk-sharing between the related companies and the Belgian Government. Statistics indicate that the total reimbursement level is more than 60 percent of the total sum of state interventions for all the Airbus-programs, excluding the most recent ones (A380, A350 XWB, and A400M), where production started relatively recently. This level is also influenced by elements outside the control of the Belgian authorities (*e.g.*, Airbus stopped the production of A340 much earlier than initially planned).

Eurostat, the Commission's statistical unit, notified the Belgian government in 2014 that these amounts should not be considered as reimbursable advances but subsidies, because they were never totally reimbursed. Beginning in 2016, Belgian federal and regional governments were supposed to include the Airbus interventions as subsidies in their budgets, but that has not been the case to date.

For the A350 XWB and A380 programs, the price distortion resulting from Belgian subcontractors is estimated to be a minimum of €370 million ($411.1 million). For the A400M program, the Belgian federal government in 2016 agreed on a €45 million ($50 million) grant for the 2017-2020 period.

France: In addition to the seed investment that the French government provided for the development of the A380 and A350 XWB aircraft, France provides assistance in the form of reimbursable advances for the development by French manufacturers of products such as airplanes, aircraft engines, helicopters, and onboard equipment. In February 2013, the government confirmed €1.4 billion ($1.9 billion) in reimbursable advances for the A350 over the period 2009-2017 and a similar scheme for the helicopter X6 to be built by Airbus Helicopter. The government's 2018 budget includes €170.6 million ($191.7 million) in reimbursable advances for aeronautical/aviation products, up from €164 million ($184.3 million) in the 2017 budget. French appropriations for new programs include €102.7 million ($115.4 million) in support

of research and development in the civil aviation sector in 2018, up from €68.2 million ($76.6 million) in 2017.

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 ($110.3 million) destined for the French aeronautical sector. The equity fund's objective is to support the development of small and medium sized subcontractors that supply the aeronautical sector. The Aerofund III equity fund was launched in 2013 with a fundraising target of €300 million ($400 million) and an objective of becoming the leading aerospace industry investment fund in Europe.

Germany: Between 2010 and 2015, the German government provided Airbus with a €1.1 billion ($1.5 billion) loan package for the new A350 XWB wide-body jet. The loan runs until 2031 and covers deliveries of 1,500 aircraft. In addition to the A350 XWB loan package, Airbus continues to receive funds from the German government's aeronautics research program for a number of projects. In its last coalition agreement (2013), the German government pledged further support for the aeronautics program.

Spain: On October 23, 2015, Spain's government authorized the Ministry of Industry, Energy and Tourism to grant ALESTIS Aerospace aid amounting to €19 million ($21.1 million) for its participation in the development program of the Airbus A350 XWB. Aid corresponds to the schedule for 2013, which was not paid initially because the company was bankrupt at that time. Measures taken in connection with ALESTIS ensure the successful outcome of its participation in the A350 XWB program, which is considered strategic for the aviation industry in Spain. In 2015, the industry had a turnover of €9.7 billion ($10.8 billion) and directly employed approximately 54,400 people.

In the case of Airbus commercial programs, ALESTIS supplies parts and components for the A380, A330, A320, and A350 XWB aircraft, 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 employs approximately 1,600 people.

CUSTOMS ADMINISTRATION

Notwithstanding the existence of customs legislation that governs all Member States, the EU does not administer its laws through a single customs administration. Rather, there are separate agencies responsible for the administration of EU customs law in each of the 28 Member States. Institutions or procedures are not currently in place to ensure that EU rules and decisions on classification, valuation, origin, and customs procedures are applied uniformly throughout the Member States. (The Binding Tariff Information program provided for by EU-level law, but administered at the Member State level, does provide for advance rulings on tariff classification and country of origin.) EU rules do not 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.

In some cases, where the customs agency of a Member State administers EU law differently, or disagrees with the Binding Tariff Information issued by another Member State, the matter may be referred to the Customs Code Committee (CCC). The CCC consists of Member State representatives and is chaired by a Commission representative. Although a stated goal for the CCC is to help reconcile differences among Member States and thereby help to achieve uniformity of administration, in practice its success in this regard has been limited. The CCC and other EU-level institutions do not provide transparency in decision-making or opportunities for participation by traders, which might make them more effective tools for achieving the uniform administration and application of EU customs law.

In addition, the EU lacks tribunals or procedures for the prompt review and EU-wide correction of administrative actions relating to customs matters. Instead, review is provided in the tribunals of each Member State; the rules regarding these reviews vary from Member State to Member State. 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 CJEU. Although the judgments of the CJEU apply throughout the EU, referral of a question to the CJEU is generally discretionary, may take many years, and may not afford sufficient redress. Thus obtaining corrections with EU-wide effect for administrative actions relating to customs matters is frequently cumbersome and time-consuming. The United States has raised concerns regarding the uniform administration of EU customs law with the EU in various forums, including in the WTO DSB.

The Commission has sought to modernize and simplify customs rules and processes. The Union Customs Code (UCC), adopted by the Commission in 2013, entered into force in 2016. While the UCC contains a number of procedural changes, the key element of a harmonized information technology infrastructure has yet to be completed; Member States continue to use different data templates. Full implementation of harmonized customs systems is not expected to be complete before the end of 2020.

The Commission has published delegated and implementing acts on the procedural changes set forth in the UCC. These include Delegated Regulation (EU) 2015/2446, Delegated Regulation (EU) 2016/341, and Implementing Regulation (EU) 2015/2447. In April 2016, the Commission published another implementing decision (2016/578) on the work program relating to the development and deployment of the UCC's electronic systems.

The United States will continue to monitor the UCC implementation process, focusing on its impact on the consistency of customs treatment under EU customs law.

BARRIERS TO DIGITAL TRADE

In May 2017, the European Commission issued a "Mid-Term Review" document, describing work to date on the Commission's Digital Single Market (DSM) strategy, intended to eliminate barriers to digital trade within the EU. The Commission has tabled 24 legislative proposals for the DSM, but only six of those proposals have successfully completed the trilogue process with the European Parliament and European Council. As the EU continues its work on the DSM, the United States encourages the Commission to ensure predictable and consistent market conditions, which will support growth in transatlantic trade and investment. The effects of the proposed EU rules on innovative services and digital trade will be of particular interest to the United States. The well-intentioned goal of creating a harmonized single market for digital trade in the EU, if implemented through flawed regulation, could seriously undermine transatlantic trade and investment, stifle innovation, and undermine the Commission's own efforts to promote a more robust, EU-wide digital economy.

Data Localization

The free flow of data has been critical to the continued growth of digital trade. The United States monitors and works to eliminate data localization requirements, which are unfortunately a growing global trend. Current EU law restricts the transfer of the personal data of EU citizens outside of the territory of the EU, except to countries that the EU has determined provide adequate data protection under EU law or that have met other specific requirements, such as the use of standard contract clauses or binding corporate rules.

The United States remains concerned that the implementation and administration of current and proposed EU law (*e.g.*, the General Data Protection Regulation, or GDPR) create disproportionate barriers to trade, not only for the United States, but for all countries outside of the EU. Although the United States has received a determination of partial adequacy from the EU (see discussion of the EU-U.S. Privacy Shield below), there are many other countries, including Japan, Korea, and India, that have expressed interest in obtaining an adequacy determination to facilitate the exchange of data with the EU. Restrictions on the flow of data have a significant effect on the conditions for the cross-border supply of numerous services and for support to the functionality embedded in trade in intelligent goods (*i.e.*, smart devices). The EU has so far found only a handful of countries to provide adequate data protection under EU law, which means that suppliers in the large majority of EU trading partners must rely on other arrangements or criteria to transfer data with suppliers in the EU. Moreover, legal challenges in the EU continue to create uncertainty around the transfer of data for U.S. and other foreign companies. As of the end of 2017, two legal challenges had been filed directly against the Privacy Shield in the EU's General Court (lower court). The use of standard contract clauses are also under judicial review in Ireland and expected to be referred to the CJEU.

Privacy Shield

On July 12, 2016, the United States and the EU concluded the EU-U.S. Privacy Shield Framework (the "Framework"), which provides U.S.-based organizations a mechanism to comply with EU data protection requirements when transferring personal data from the EU to the United States in support of transatlantic commerce. The Framework replaced the U.S.-EU Safe Harbor Framework of 2000, following an October 2015 CJEU ruling striking down the Commission decision that found Safe Harbor adequate under the EU's 1995 Data Protection Directive. As of January 2018, over 2,600 U.S. companies had completed their certification to the Privacy Shield.

The first annual review of the Privacy Shield was held in Washington, D.C., in September 2017. U.S participants included officials from the Department of Commerce, the Federal Trade Commission, the State Department, and other federal agencies. The European Commission's Directorate General for Justice led the EU delegation, with active participation from a select group of Member State DPAs, representing the Article 29 Working Party (a committee of Member State regulators). The White House issued a statement reaffirming the Administration's support for the program, and the participants issued a joint statement expressing the shared interest in the success of the Framework and a commitment to continue collaboration. On October 18, 2017, the Commission released its report on the first annual review of the functioning of the Framework. The report concludes that the Framework continues to provide an adequate level of privacy protection under EU law and the necessary structures have been established to ensure the functioning of the Framework.

Proposed EU Regulation on the free flow of non-personal data

On September 13, 2017, the Commission released a proposal for a regulation on a framework for the free flow of non-personal data within the EU. The proposed regulation focuses on non-personal data, *i.e.*, data that is outside the broad scope of the GDPR. The proposal would prohibit data localization requirements within the EU, unless they are justified on the grounds of public security. The proposal also includes provisions concerning data portability. The EU and United States share the goal of ensuring that there is a free flow of data in the transatlantic and global economy. In fact, the United States strongly encourages the EU to examine barriers not only within the EU, but also between the EU and the rest of the world.

General Data Protection Regulation

The GDPR will take effect on May 25, 2018, replacing the 1995 Data Protection Directive (DPD). The Commission and Member State DPAs are expected to issue a number of implementing measures before

May 2018, including some addressing elements of the GDPR explicitly left to Member States to determine (*e.g.*, age of consent). In addition, Member States must adopt legislation that repeals the national laws that implemented the DPD. The United State will be monitoring this work closely.

Under the GDPR, the Commission and Member State DPAs can impose fines of up to 4 percent of annual global revenue on firms that breach the new data protection rules. For multinational corporations, such fines could amount to billions of dollars. The GDPR also introduces joint liability for controllers (the company that controls the processing of personal data) and processors (generally contractors hired by the controller to provide services using the data). Under the DPD, only the controller was liable for data breaches. Many companies are concerned that joint liability would require them to monitor other companies' data protection practices, which would increase administrative costs and burdens. Such monitoring requirements could make controllers and processors transfer more personal data more frequently between them, thereby increasing potential vulnerabilities to unauthorized disclosure. The new regulation also requires companies to have a data protection officer or a representative present in the EU. It adds new requirements for accountability, data governance, and notification of a data breach.

In addition, the GDPR provides expanded rights to EU data subjects, including data portability and more stringent consent requirements. The GDPR also codifies the 2014 decision of the CJEU that imposed a right for EU citizens to demand that search engines remove information that is inaccurate, inadequate, irrelevant, or excessive for the purposes of data processing ("right to be forgotten"). Companies have continued to express concern over the "right to be forgotten" and its potential to infringe on free speech and to restrict access to information of legitimate public interest.

The GDPR will create a new European Data Protection Board. The Board will be tasked with minimizing disparities in implementation and enforcement between individual Member State DPAs, and it will be entrusted to resolve disputes between DPAs. The GDPR includes provisions intended to minimize the bureaucratic hurdles of dealing with DPAs in multiple Member States by allowing EU residents to file complaints with the DPA in their home country and to allow companies to deal only with the DPA in the Member State where the company has its primary establishment. While U.S. companies welcomed the goals of this initiative, some have expressed disappointment that the proposed mechanism may be too complex and cumbersome and may still leave too much room for DPAs to take divergent approaches in different Member States.

France. The French DPA (CNIL) ordered one U.S. search supplier to remove information under a "right to be forgotten" matter from all its domains on a worldwide basis. The CNIL order was appealed to the State Council, France's highest administrative court, and in July 2017 the State Council referred the matter to the CJEU, noting the scope of the right to be de-listed posed several serious difficulties with respect to the interpretation of EU law. If CNIL's order is upheld, France and presumably other Member State DPAs would maintain that they have the authority to restrict what non-EU businesses and individuals would be able to access on the Internet. This could set a worrisome precedent, empowering governments to apply their domestic law extraterritorially on the Internet, and would create significant market uncertainty for businesses worldwide.

Interactive Computer Services

Aggregation Services

Over the past several years, certain Member States have adopted copyright-related measures requiring remuneration or authorization for certain content associated with online news aggregation services. Specifically, the measures require news aggregators, which provide short excerpts ("snippets") of text from

other news sources and/or images, to either remunerate those other sources or obtain authorization for their use. One Member State has also introduced a similar measure with respect to digital images.

Additionally, as described above, the European Commission proposed a new neighboring right for press publishers that is under discussion as part of the Directive on Copyright in the DSM (COM(2016) 593 final). The Commission recommends expanding the reproduction right and making available right to press publishers with respect to the digital use of their press publications. Although certain U.S. and EU stakeholders, particularly from the publishing industry, have supported this proposal, online news aggregators, including but not limited to U.S. service suppliers, have raised concerns regarding the potential impact of this proposed directive, in part because of their experiences with the German and Spanish laws described below.

These measures are intended to address publishers' and visual artists' challenges in adapting to the digital marketplace. U.S. stakeholders have expressed a range of competing views on these issues. Measures that disproportionately affect only one group of foreign-based service suppliers in the digital ecosystem may exacerbate those challenges to the detriment of all participants in the marketplace. These measures and proposals warrant careful monitoring in light of the interests and concerns of these stakeholders.

Spain: A 2014 amendment to the Spanish intellectual property law (Article 32.2), which took effect in 2016, imposed upon commercial news aggregators a mandatory compensation regime for the use of fragments of news publications. News aggregators are required to remunerate publishers via a rights management organization for the use of "non-significant fragments" of their news publications. The remuneration rate is negotiable via the collective management organization but there are no means by which a covered news publisher can waive this right or independently license directly with a news aggregator should it so desire (*e.g.*, if the news publisher wishes to allow readers to find and access such publications through such aggregators). Faced with this measure, at least one leading U.S. supplier suspended its news aggregation service in the Spanish market. A 2015 economic study conducted for the Spanish Association of Publishers of Periodical Publications (AEEP) predicted that the amendment would raise barriers to entry for Spanish publishers, would decrease innovative access online for users, and could cost publishers an estimated €10 million ($11.1 million) per year, with a disproportionate impact on smaller publishers (although publishers have not yet had to pay).

Germany: A 2013 German law ("Leistungsschutzrecht für Presseverleger") creates a neighboring right for press publishers that permits news publishers and news aggregators to negotiate terms of individual licenses (including the option to opt out of requirement payment under the law). It does not apply to "short extracts" of news publications. Implementation of the German law has reportedly been less disruptive than in the case of the Spanish measure, and at least one leading U.S. supplier obtained a royalty-free license from a German collecting society for the display of short extracts of news publications. There are continuing stakeholder concerns regarding the legal uncertainty created by the law and its effect on innovative businesses in Germany.

France: In July 2016, France passed the Freedom of Creation Act, a set of measures designed to bolster suppliers of cultural products through subsidies and other governmental interventions. The so-called "thumbnail amendment" in the Freedom of Creation Act, found in Article 30, requires "automated image referencing services" to remunerate French rights collecting societies for the right to "reproduce and represent" an image. Individual artists or photographers cannot opt out of this licensing regime. France's main copyright collecting societies have pursued negotiations for the payment of royalties for the reproduction of photographs and images in thumbnails with foreign search engines and social networks.

Other Issues

Geo-blocking

The Commission defines geo-blocking as a market segmentation practice whereby traders treat their customers differently, based on the Member State in which they reside or are located, by applying different contract terms, directing them to different websites, or offering different prices, usually based on the customer's IP address, physical address, or nationality, or on the issuer of the customer's credit or debit card. The final regulation to bar unjustifiable "geo-blocking" will take effect on December 3, 2018. The regulation sets forth disclosure requirements for businesses that engage in geo-blocking or re-routing to justify these practices. U.S. businesses that rely on market segmentation or exclusive distributor agreements as part of their overall strategy have expressed concerns that the pricing transparency requirements will make it possible for EU consumers to purchase goods and services from any Member State, potentially interfering with the freedom to contract. For example, a Swedish consumer would be able to price compare across the entire EU and bypass the exclusive Swedish distributor of a product, potentially obtaining the product at a lower price from a distributor in another Member State market.

Creative industries are strongly opposed to what they see as another attack on territorial licensing, and this aspect of the proposal has been contested by some Member States. The Commission affirmed in an official statement that its first evaluation of the regulation "will take account of the increasing expectations of consumers especially of those that lack access to copyright protected services." The European Parliament's Internal Market Committee also included a provision to consider the inclusion of all audiovisual services three years after the law's entry into force.

Cross-Border Contract Rules

In December 2015, the European Commission tabled legislative proposals on contract rules on the supply of digital content (*e.g.*, streaming music) and on contract rules on the online sale of physical goods (*e.g.*, buying a camera online). The two proposed directives are still going through the legislative process. The European Parliament lead committees adopted the final Parliament amendments to the proposed text on supply of digital content, opening the way for trilogues with the Commission and the Council, once the latter finalizes its own amendments. The other proposal addressing contracts for the online and other distance sales of goods is still under debate by the relevant committees and working groups in Parliament and Council.

The proposals seek to address concerns over a perceived relative lack of legal remedies in certain cases, such as for "defective" digital content purchased online. Specific provisions include expanding the cases in which vendors may rely on their own national laws when selling to other EU markets and improving coordination and monitoring for infringement of consumer protection rules.

It is not yet known whether, and to what extent, greater regulatory harmonization would be beneficial for U.S. online providers selling in the EU. The Commission's proposal to create "harmonized EU rules for online purchases of digital content" should reduce burdens for all sellers, including U.S. providers. In particular, this should help smaller players to scale up in the EU, requiring fewer resources to manage legal differences between markets. It is not clear, however, what impact regulatory harmonization in the final directives will have on other aspects of cross-border electronic commerce, potentially burdening providers of digital content. These include possible new rules affecting contracts between such providers and users, remuneration for damage done by "defective" digital content, and data portability requirements.