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.