

Consultation response

Response to the call for proposals for EU-US regulatory cooperation activities



AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled more than €2 trillion in 2018, directly supports more than 4.8 million jobs in Europe, and generates billions of euros annually in income, trade and research and development.

Executive summary

The American Chamber of Commerce to the European Union (AmCham EU) welcomes the opportunity to respond to the European Commission's call for proposals for EU-US regulatory cooperation. The transatlantic economy remains the largest, most prosperous and most innovative of its kind in the world – and it continues to grow. However, a number of challenges and opportunities are present in the bilateral EU-US economic relationship which require careful attention. The response we set out below is our *"A new agenda for transatlantic economic cooperation: recommendations from the US business community in Europe"*¹ position paper, published in November 2018. In this paper, we highlight a number of areas in which the EU and the US could work together in the short- and longer-terms to develop their economic ties, address global challenges and promote new global standards. We look forward to working with policymakers and stakeholders on both sides of the Atlantic in pursuit of this important goal.

Purpose of the paper

For over two decades, AmCham EU and the transatlantic business community have been at the forefront of efforts to enhance transatlantic cooperation, beginning with the Transatlantic Economic Council (TEC) established in 2007 and culminating in the launching of negotiations for a Transatlantic Trade and Investment Partnership (TTIP) agreement between the EU and the US in 2013.

Significant progress was made during the TTIP talks in identifying areas to deepen regulatory cooperation and remove barriers to trade and investment. The negotiations also had the added value of bringing the two regions closer together, united in a common goal to advance their shared values and interests globally. In recent times, ties between the EU and the US have been more uncertain, with a number of trade disputes arising that have caused disruption to the transatlantic partnership. The successful meeting between European Commission President Juncker and US President Trump held in July 2018, and the setting up of the high-level EU-US Executive Working Group (EWG) chaired by EU Trade Commissioner Cecilia Malmström and US Trade Representative Robert Lighthizer, has restored optimism that the two parties can re-establish a positive agenda.

In particular, the two parties have identified a number of areas in which they could potentially make progress in in the short term, including, but not limited to: sectoral cooperation in automotives, chemicals, energy, pharmaceuticals, medical devices, and emerging technologies; and cooperation to address unfair trading practices of third countries. In the longer-term, the two parties are scoping out the potential for a relaunch of broader trade talks, with the ultimate goal of removing all tariff and non-tariff barriers, enhancing regulatory cooperation, and reforming the global trading system to make it fit for the 21st century. To this end, we were greatly encouraged by the Council's approval of the negotiating mandates on conformity assessment and regulatory cooperation on Monday, 15 April 2019. We encourage both partners to start the talks, and stand ready to support during this process.

The purpose of this paper is therefore to outline key opportunities for deeper policy and regulatory cooperation, in both traditional areas as well as in new and rapidly-evolving fields. This document could provide useful input to EU and US policymakers in the context of the newly established EWG, and as the two sides begin their scoping work towards a broader EU-US trade agreement.

¹ *"A new agenda for transatlantic economic cooperation: recommendations from the US business community in Europe"*, AmCham EU, November 2018, http://www.amchameu.eu/system/files/position_papers/a_new_agenda_for_transatlantic_cooperation_november18_final.pdf.

The transatlantic economy

The transatlantic economy is responsible for around one-third of world GDP and directly supports 15 million jobs, as well as millions more in the supply chain. Meanwhile, both regions are highly profitable: Europe is the source of some 56 percent of earnings for US affiliates overseas. European firms also accounted for over half of foreign affiliate sales in the US, showing the extraordinary depth of the relationship.² The success of the EU-US economic relationship has been predicated on a common commitment to free trade, open markets and the rule-of-law. It has helped to ensure the prosperity and security of successive generations of Europeans and Americans, and remains a key driver of growth, innovation and opportunity.

In an age of increased competition and at a time when the rules of the international order are being challenged at every turn, increased transatlantic cooperation is more critical than ever. Analysis suggests that as much as 90 percent of global growth in the next decade will take place outside Europe, one-third of this growth in China alone.³ As these international actors become more powerful, they are increasingly challenging the rules, norms and standards that govern the international economy. Addressing the challenges posed by the rise of new economic actors and the proliferation of unfair trading practices is increasingly a priority of both the EU and the US, as well as like-minded countries such as Japan and other market economies. The time is now for the EU and the US to work together to help shape the global economy for the decades to come.

Micro-, small- and medium-sized enterprises (MSMEs)

It has been well-documented that small businesses stand to gain more than most from improved transatlantic cooperation. Unlike larger companies, they lack the resources to overcome the costly and burdensome barriers to trade that exist between the two regions.

SMEs are already heavily integrated into the transatlantic economy. However, a variety of challenges exist that restrict and sometimes prevent SMEs from doing business across the Atlantic altogether. A 2014 European Commission report found that small companies face numerous barriers to transatlantic trade, including:

- Compliance with complex technical and customs regulations;
- Lack of access to information or resources;
- Barriers to public procurement; and
- Unnecessary differences in regulations between the two regions.⁴

In a rapidly evolving marketplace, which presents as many opportunities as it does challenges for small businesses, it is essential that the EU and the US place SMEs at the heart of their liberalisation efforts. It should in particular be emphasised that the needs, opportunities and challenges for small and large businesses in the transatlantic economy are interconnected. Larger companies create ecosystems in which small companies can grow and thrive, enabling them to develop products and services for use by larger enterprises and utilising the scale that these companies offer. In turn, large companies rely on smaller companies in order to deliver the high-quality goods and services their customers expect. In a dynamic economy, the success of small and large companies are inextricably linked.

² Hamilton, Daniel S., and Quinlan, Joseph P., 'The Transatlantic Economy 2019: Annual Survey of Jobs, Trade and Investment between the United States and Europe,' Washington, DC: Center for Transatlantic Relations, 2019.

³ European Commission, 'Trade, Growth and Jobs: Commission contribution to the European Council,' February 2013, http://trade.ec.europa.eu/doclib/docs/2013/april/tradoc_151052.pdf.

⁴ European Commission, 'Commission report shows that SMEs stand to make significant gains from the Transatlantic Trade and Investment Partnership (TTIP) between the EU and the US,' 20 April 2015, http://europa.eu/rapid/press-release_IP-15-4802_en.htm.

An agenda for improved policy and regulatory cooperation

As part of efforts to reach an ambitious and comprehensive free trade agreement between the EU and the US under TTIP, the two parties' negotiators and regulators made significant progress in highlighting and, in many cases advancing opportunities for enhanced transatlantic cooperation. In a variety of sectors, opportunities to improve the way we do business with each other were identified and practical solutions proposed.

While the EU and the US could not finalise a TTIP agreement, in some cases the work that was done has already led to tangible outcomes – such as the EU-US Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMPs) for pharmaceuticals, which came into effect in November 2017.⁵ With the establishment of the EU-US EWG, the two parties have an opportunity to build on these achievements, take advantage of the current momentum in EU-US talks, and work towards a new and improved economic relationship.

To this end, the American business community in Europe has identified the following areas which could help re-establish a positive agenda for policy and regulatory cooperation:

Horizontal priorities

1. Market access

Free trade is fundamental to our prosperity and is essential to expanding economic growth and improving the standards of living for people across the globe. Both parties should work together to eliminate barriers to free trade and facilitate the global movement of goods and services, information, capital and investment in a rules-based free trade and investment system.

- a. **US tariffs and countermeasures:** US businesses continue to urge the removal of US tariffs on EU imports of steel and aluminium and EU countermeasures, which are restricting opportunities for businesses, driving up costs and acting as a tax on consumers. More broadly, an escalation of trade disputes between the EU and the US could have profound consequences for stability and security and would also put pressure on the rules-based global economic system. In particular, US industry strongly cautions against the introduction of US tariffs on imports of EU autos and auto parts, whose economic impact could be as much as ten times that of the steel and aluminium tariffs⁶ and would surely invite EU countermeasures which would further worsen the economic impact.
- b. **General tariff reductions:** Tariffs between the EU and the US are generally low but remain stubbornly high in certain sectors. During the TTIP negotiations, the EU and the US agreed to eliminate 97 percent of all remaining transatlantic tariffs. Pressing ahead with these reductions would enhance competitiveness and send a message that both sides are committed to free trade and open markets.

2. Regulatory cooperation

AmCham EU members have long recognised the value of regulatory cooperation as a means of unlocking new opportunities for businesses and consumers globally. In TTIP, AmCham EU strongly supported efforts to improve

⁵ European Commission, 'Annex to the Commission Decision on determining the Union position for a Decision of the Joint Committee set up under Article 14 of the Agreement on Mutual Recognition between the European Community and the United States of America, in order to amend the Sectoral Annex on Pharmaceutical Good Manufacturing Practices (GMPs)', 1 March 2017, http://trade.ec.europa.eu/doclib/docs/2017/february/tradoc_155398.pdf.

⁶ Trade Partnership, 'An Accident Waiting to Happen? The Estimated Impacts of Tariffs on Motor Vehicles and Parts, Trade Partnership,' 29 May 2018, http://tradepartnership.com/wp-content/uploads/2018/05/232_Auto_PolicyPaperFINAL.pdf.

regulatory harmonisation, which carried the promise of up to 80 percent of all economic gains from a transatlantic agreement.⁷ The potential for enhanced cooperation today remains as potent as ever.

- a. **Removing discriminatory or unnecessary barriers:** A variety of non-tariff barriers (NTBs) still exist on both sides which curtail opportunities and benefits for companies, consumers and citizens. In some cases, unnecessary NTBs can be removed relatively easily – particularly in areas where progress was already made in TTIP, such as in auto safety regulations, electronic labelling provisions and mutual recognition of manufacturing practices for pharmaceuticals. Discriminatory barriers in areas such as services, investment and public procurement should also be removed as a matter of priority; always respecting the unique regulatory systems of both regions and the right to regulate in the public interest.
- b. **Enhancing common rules and setting global standards:** Regulatory cooperation between the EU and the US should be aimed at creating a more efficient regulatory environment and, where possible, enhancing common standards between the EU and the US. In turn, transatlantic standards-setting can raise the bar globally, helping to export the EU and US' high standards to other regions.
- c. **Cooperation for mutual benefit:** Efforts to enhance transatlantic economic ties should be seen through the prism of win-win cooperation for both the EU and the US. Both parties should be negotiating in good faith, finding compromises where necessary and aiming to bring value for each side. Positive results in the EU-US Working Group could set the stage for larger trade talks and also lead to further results at the global level, as well as reinforcing transatlantic stability and prosperity.

3. The WTO and the global trading system

The multilateral trading system, underpinned by the World Trade Organization (WTO), has helped to open up international markets, raised standards globally, and continues to act as a crucial guarantee for governments and companies in global markets. Where the system requires reform, it is crucial that the EU and the US, with like-minded partners such as Japan, take the lead and work to ensure that it is fit for purpose in the 21st century.

- a. **Reinforcing the rules-based order:** It is important that the EU and the US, as the architects of the modern global trading system, are vocal in their strong support for the WTO, encourage the robust application of global trade rules, engage on key emerging issues and advance an action-oriented agenda, and work constructively in the pursuit of sensible reforms which reinforce and enhance the existing framework.
- b. **Addressing unfair trading practices:** Both the EU and the US agree on the urgent need to confront unfair trading practices of third countries. Joint cooperation, as opposed to unilateral actions, will be most effective in achieving these important goals, and will also engender goodwill at the bilateral level.
- c. **WTO agenda:** The EU and US should work together to promote necessary reforms in the negotiation procedures that will allow progress on critical issues impacting commercial trade.
- d. **WTO dispute settlement:** The Dispute Settlement Mechanism ensures that the rules set by the WTO are enforceable. The EU and the US must make unblocking the current stalemate in the appointment of Appellate Body judges an absolute priority.

⁷ The World Trade Institute, 'TTIP and the EU Member States,' 2016, https://www.wti.org/media/filer_public/03/b8/03b803d4-e200-4841-9c58-f6612f4a7316/ttip_report_def.pdf.

Sectoral priorities

1. Agriculture

Transatlantic cooperation in the field of agriculture will be essential to meet the challenges posed by a rapidly growing population and rising demand for food products. As leading producers and manufacturers, the EU and US should work closely to level the playing field and seek common production standards at the international level, addressing key issues of regulatory divergence which threaten competitiveness and investment.

- a. **Agricultural biotechnology:** There is a significant time lag in EU authorisations for the introduction of biotechnology plants and other bio-inventions, in comparison to other countries including the US. Both parties should work cooperatively to eliminate risks of trade disruptions by driving for timely, science-based and effective implementation of existing laws for biotech approvals of products. We also encourage further dialogue in relation to the regulatory treatment of innovative plant breeding which can have an impact on the acceptability of needed sources of raw materials in the European market while and at the same time contribute to innovation at local level.
- b. **Pesticides:** The discrepancy of maximum residue levels (MRLs) between EU and origination areas including the US is a growing risk for the trade and local European industries. Many issues pertaining to pesticides could benefit from greater regulatory cooperation between authorities in the EU and US. There is a clear need for greater harmonisation in the processes for establishing maximum residue limits (MRLs) for pesticide residues. The two parties should both promote science-based risk assessments as the basis for their regulatory frameworks and cooperation.
- c. **Food and feed safety:** The EU and US should in the first instance explore increased cooperation between their respective bodies and agencies, to further strengthen existing dialogue and exchanges of information. In particular, these bodies and agencies should work closely to explore better alignment of food and feed safety requirements and standards.
- d. **Sustainability:** Both parties should strive to reach a common understanding and common language by harmonising diverging definitions of sustainability. Greater collaboration between the EU and US in international organisations such as the International Civil Aviation Organization (ICAO), the International Maritime Organization (IMO) and the UN Framework Convention on Climate Change (UNFCCC), would also help drive the sustainability agenda. Such collaboration would be most fruitful after greater regulatory collaboration between EU and US authorities. Pragmatic progress on setting globally recognised standards and mutual recognition would unleash an economic potential that would amplify the message put forward by the EU and US in international organisations.

2. Automotives

During the TTIP negotiations, significant progress was made in identifying the way forward towards closing the wide gap in the differences between the US auto safety standards (FMVSS) and the ones used in the EU (UNECE). The automotive sector was one of the sectors that was mentioned in the joint EU-US report of January 2017 assessing the progress made in the TTIP negotiations. The report reads: *‘Our regulators had detailed discussions on specific approaches to achieve more compatible automotive safety and enhance both bilateral co-operation and in the framework of the UNECE 1998 Agreement’.*

- a. **Regulatory convergence:** Welcoming the announcement of Presidents Juncker and Trump in July 2018 to launch a new EU-US standards dialogue, we request that the regulators on both sides of the Atlantic, NHTSA and DG GROW, pursue auto regulatory convergence in the following three areas:
 - i. Harmonisation of several pending auto safety regulations, as well as future auto regulations;
 - ii. Improve and strengthen the UN WP.29 Global Technical Regulation (GTR) process; and
 - iii. Coordination of research and regulatory development for auto regulations.

- b. **Quick wins:** A number of short-term opportunities could be achieved in the aforementioned area of **auto safety regulations** where discussions on expedited harmonisation are already advanced, namely on seatbelt interlock, adaptive driving beam (ADB) and advanced emergency braking systems for passenger cars.
- c. **Emerging technologies:** Regulators should further cooperate on new technologies such as automated vehicles and connectivity with the aim of achieving more convergent regulations in the future.

3. Chemicals

- a. **Co-operation in prioritisation of chemicals for assessment and assessment methodologies:** Common prioritisation principles and burden sharing for assessments of high priority chemicals and, where appropriate, categories of substances (e.g. substance evaluation under REACH and high priority targeted risk assessments under the current TSCA and safety determinations under a modernised TSCA). Recognition of each other's data and studies and harmonized standards and methodologies for hazard and risk assessment are necessary for effective burden sharing.
- b. **Scientific cooperation to give advice on chemicals assessment including on new and emerging issues of transatlantic relevance:** A formalised process to discuss and agree on basic standards and definitions for emerging regulatory issues. To achieve this goal, several options are possible.
- c. **Cooperation on new and emerging issues:** A mechanism for early and close cooperation on emerging scientific issues with regulatory relevance.
- d. **Promoting alignment in Classification and Labelling:** A mechanism in place for further aligning classification and labelling based on GHS, reducing or eliminating the need for dual classifications; promoting reciprocity for classification and labelling across the Atlantic and promoting the UN Global List of Classified Chemicals as a common classification inventory.
- e. **Enhanced information sharing and protection of confidential business information (CBI):** Development of a mechanism for data and information sharing between governments, while respecting the different regulations. This could include discussions on common data formats, robust summary exchange and common approaches to global platforms for data sharing (such as EU IUCLID). This would need to include adequate safeguards to ensure the protection of commercial and proprietary interests.

4. Climate

Climate change is a global issue that requires global solutions. International cooperation is important to advance realistic environmental objectives while minimising impacts on economic growth and competitiveness.

- a. Both parties should work to align on transparent, predictable **climate policies** based on a cost/benefit analysis, and allow market prices and open competition to determine the solutions and investments necessary to achieve objectives at the lowest cost to society.
- b. Climate policy should be predictable and trustworthy to incentivise investors to invest in low-carbon technologies. There is huge potential for **innovation and growth** in a wide range of sectors, from energy generation and supply, to transport and construction. To efficiently encourage these developments, further cooperation is needed to support investment in emerging technologies, while ensuring sufficient investment opportunities and economy of scales for on-the-shelf technologies.

5. Cosmetics

- a. **Removal of technical barriers:** The removal of existing technical barriers to trade which relate mainly to regulatory divergences would significantly facilitate access to the markets by reducing industry costs related to the formulation, marketing, labelling and facilitating of supply chain management.

- b. **Harmonisation and/or mutual recognition of testing requirements:** Divergences in testing requirements lead to increased costs for companies that often have to go through different testing methods to enable marketing of the same product both in the EU and the US. The harmonisation and/or the mutual recognition of testing requirements would facilitate a single testing requirement for EU-US purposes permitting quicker marketing, reduce costs and creating synergies in the supply chains. Harmonisation of the testing requirements would additionally create a strong signal towards international convergence.
- c. **Harmonisation and/or mutual recognition of labelling requirements:** The divergence between the EU and US regulatory systems with respect to labelling requirements of products that are safe creates an enormous burden on companies. This is particularly true where regulations requiring the same formula need to be analysed or presented differently. Alignment of certain labelling requirements on both sides of the Atlantic would lead to a reduction in costs due to simplified logistics with respect to labelling and packaging. More importantly it would improve the level of clarity for customers, thereby enhancing consumer understanding and easy recognition amongst a mobile consumer base which could only benefit from harmonisation of labelling.

6. Customs and trade facilitation

In today's highly interconnected global economy, it is essential that the EU and the US encourage transatlantic trade facilitation based on the principles of free trade and utilising the latest technologies:

- a. Harmonise and **simplify customs clearances** processes, improve transatlantic **customs clearance efficiency** for private shipments, rely more **on advanced data mechanisms** to pre-clear goods and reduce costs, facilitate the submission and processing of documentations via **Single Window** and create sector-specific '**fast lane**' processing pilot projects;
- b. **Raise the de minimis** threshold for customs duties and other taxes to \$800 (or a Euro equivalent), liberating businesses of all sizes – and in particular SMEs – from costly and administratively burdensome processes, increasing their capacity to trade internationally;
- c. Work towards electronic pre-clearance based on advanced data for goods moving in either direction across the transatlantic border (**Mutual Recognition for Trusted Traders programs (C-TPAT and AEO)**. Leaders should build on the existing World Customs Organization guidelines for the immediate release of consignments for which necessary customs information has already been provided, and adopt a common position to facilitate the movement of such goods between the EU and the US.
- d. **Liberalisation of Preferential Rules of Origin (ROO):** One of the objectives of FTAs is to promote regional labour and overhead through manufacturing, packaging and distribution investments. Flexible rules for 6 digit tariff shifts, other than simple processing, are essential for investment opportunity and FTA ease-of-use.
- e. **Verification of preferential origin:** Verifications should be conducted by the exporting party even if requested by the importing party. Sharing sensitive data and costs will impede the use of FTAs.
- f. **Trans-shipment through a Non-Party Country:** Products should maintain their preferential status independent from the transportation route.
- g. **Transition towards electronic labelling for indicating compliance:** While compliance markings differ across regions, indicating compliance should be further harmonised through the adoption of electronic labelling. Electronic labelling significantly reduces manufacturers' operational burden that results from the requirement to physically alter the labelling on the devices before entering the market.

7. Digital economy

Nowhere is transformation more evident and more disruptive than in the digital economy. To take full advantage of the enormous potential of the digital revolution, it is critical that the transatlantic regulatory environment adequately reflects the needs of businesses and consumers and provides unencumbered opportunities for digital businesses of all sizes – from start-ups to SMEs to multinational companies. New technologies are also under constant development and new threats are also emerging at an equally rapid rate. Key priorities include:

- a. Establishing the **Privacy Shield** agreement as a long-standing mechanism for international data transfers;
- b. Enabling cross-border **data flows** and opposing forced data localisation requirements in future mutual trade and investment agreements;
- c. Barring **forced technology transfers**, including access to source code, algorithms and encryption keys when accessing new markets from trade and investments agreements and ensuring technology choice;
- d. Supporting the development and use of **global standards** to ensure a global scale in cybersecurity, smart grids, smart cities, intelligent transportation, Internet of Things (IoT), advanced manufacturing and 5G;
- e. Ensuring **interoperability** frameworks and economies of scale for IoT and cloud in order to maximise the potential of these technologies;
- f. Maintaining the EU-US **cybersecurity** dialogue. In particular, provide a common framework using a risk-based approach on cybersecurity and leveraging consensus-based and international standards e.g. any future EU security certification should draw consensus-based standards and existing international practices;
- g. Providing common guidelines on ethics in the area of **artificial intelligence (AI)**.
- h. Achieving interoperability between the US Cloud Act and the EU e-evidence proposals through an EU-US Agreement on **law enforcement access to electronic evidence**.

8. Energy

In the context of the transition to a low-carbon economy, cooperation between the US and the EU on energy policy will be more important than ever. The continuation of close dialogue with the US on both an ad-hoc basis, and through the EU-US Energy Council, will also be critical.

- a. **Energy security:** The safe and continuing supply of energy into Europe is critical to the region's economic competitiveness and to continuing to attract inward investment. It is important that the EU works closely with its partners to keep global energy markets open and transparent, and cooperation between the EU and US should form a basis for efforts to this end on the global stage.
- b. **Energy efficiency:** Improvements in energy efficiency will be one of the most effective tools to reduce energy dependency, particularly in the building sector, while providing a competitive advantage to both economies. We take note of the US-EU Energy Council's proposal in 2016⁸ to look into alignment of test and measurement procedures and the convergence of minimum energy performance standards (MEPS), and hope further progress can be made in this area. Both parties should also work closely together to exchange best practices and promote global cooperation.

⁸ Delegation of the EU to the US, 'Joint Statement: US-EU Energy Council,' 4 May 2016, https://eeas.europa.eu/delegations/united-states-america/2817/joint-statement-us-eu-energy-council_en.

9. Environment

Stronger transatlantic cooperation on environmental issues, such as waste policy, sustainability reporting and due diligence measures, would greatly reduce the burdens that companies face when operating in both the EU and the US. Greater convergence in these matters promises efficiency gains and cost reduction for industry with strengthened transatlantic business ties. It would also send a strong positive signal that European and American businesses are at the vanguard of corporate citizenship.

- a. **Transnational challenges:** Many environmental issues are dominated by their transnational nature, such as marine litter etc. The only effective means of finding a solution in these cases, is to promote greater international cooperation, based on science, in venues such as the UN, G20 or G8. Any approach needs to be comprehensive, looking at the entire life cycle from product generation through to the valuation of waste materials.

10. Financial services

AmCham EU is a longstanding supporter of a strong and constructive transatlantic financial services regulatory cooperation. We welcomed the coordinated response by the G20 to the financial crisis of 2008, recognising that international coordination of regulatory reform is the most effective way to deliver financial stability and high common standards, and provides market participants with regulatory stability and certainty to operate.

The creation of the enhanced Joint EU-US Financial Regulatory Forum ('the Forum') in 2016, which built on the successes of the Financial Markets Regulatory Dialogue (FMRD) established back in 2002, demonstrated the continued willingness and importance attributed to such cooperation. Regular exchanges between the regulators of the world's foremost financial centres have helped to enhance understanding, improve efficiency and promote competitiveness on both sides of the Atlantic. Within the framework of this ongoing dialogue, there are a number of key issues which should be addressed to maintain and enhance this cooperation:⁹

- a. **Equivalence:** The hard-fought equivalence agreement between the European Commission and the Commodity Futures Trading Commission (CFTC) on Central Counterparty (CCP) recognition is a case in point. Regulators should focus on improving coordination at an earlier stage in the policy development process and include coordination of timetables for implementation; in the absence of coordinated timetables, regulators should consider how to establish a recognition regime that will work amongst jurisdictions at different stages of implementation. A mutual recognition or equivalence regime that is outcomes based should also be pursued. Meanwhile, jurisdictions should not aim for line by line equivalence that risks market disruption and fragmentation that stifle growth. Finally, we should also recognise that discussions are taking place in the context of Brexit – equivalence determination toward the UK should be sufficiently robust from an EU perspective; it is also equally important in the transatlantic context.
- b. **Extraterritoriality:** We have grown increasingly concerned about the divergence in approach between authorities in the US and the EU. Extraterritoriality has appeared into many pieces of financial services legislation, such as rules governing the securities markets and derivatives clearing over the past few years. The result has been increased risk of fragmentation of global markets, with market participants facing substantial uncertainty, overlapping and sometimes conflicting regulation, and some choosing to withdraw from certain markets completely. For instance, the globally inconsistent implementation of Basel III has received much attention, as have the various proposals on ring-fencing. Keeping the important transatlantic and global financial markets in mind while implementing the next iteration of prudential and resolution tools will be key to its success.

⁹ The views expressed on this subject are set out in more detail in a dedicated position paper issued in 2016. AmCham EU, 'Building a Transatlantic Capital Markets Union': http://www.amchameu.eu/system/files/position_papers/amcham_eu_paper_on_a_transatlantic_cmu.pdf, 3 June 2016.

- c. **Third-Country issues:** Third-country regimes and the related supervisory and regulatory practices determining third-country treatment are a crucial pillar of the EU's financial services policy. However, today, as Brexit negotiations unfold, EU policymakers are considering the future of EU regulatory cooperation with third-country jurisdictions. Brexit may also mean an inevitable fragmentation of financial markets, bringing risks to financial stability and increased costs for investors and issuers. We believe that open markets are inextricably linked to Europe's ambition to become more globally competitive.

Authorities on both sides of the Atlantic should look to set an example to governments across the globe and return to the cooperative spirit of the G20 process. Decision-makers should refrain from pursuing unilateral initiatives, which can lead to tit-for-tat retaliatory action, reducing the capital available and in turn threatening the recent upturn in the global economy.

11. Healthcare

Further cooperation on regulatory matters between the EU, US and third markets could help movement toward a globally harmonised regulatory system. The European Medicines Agency (EMA) and US Food and Drug Administration (FDA) standards are a model for regulatory agencies across the globe and harmonised requirements between the EMA and FDA would lead to the harmonisation of global standards:

a. Pharmaceuticals:

- i. The Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP) inspections for pharmaceuticals was an important outcome that demonstrated the potential for robust transatlantic regulatory cooperation in healthcare. By removing the need for duplicative inspections, it is set to deliver improved outcomes for companies and patients by facilitating the global sourcing of pharmaceuticals and active ingredients while maintaining high standards for patient safety. We support the progress made on the MRA to date. As well as supporting a successful conclusion of the process for including all EU Member States in the agreement, we would welcome efforts to expand its scope to include areas not currently covered by the MRA, for example vaccines and Advanced Therapy medicinal products (ATMPs).
- ii. Better alignment of paediatric scientific approaches between EU and US would reduce duplication and streamline medicines development for children, reducing the time and costs of conducting trials resulting in a global approach to the effective and efficient development of medicines for paediatric patients.
- iii. Mutual recognition agreement in the area of Good Clinical Practice (GCP): Clinical research is global. An MRA in GCP would reduce duplication of inspections and conserve both regulatory authority and industry resources that could be used in other ways to oversee or reduce risk. As both EMA and FDA operate under harmonized ICH¹⁰ GCP standards and have already significant experience in collaboration, the agreement of a formal MRA would be a logical next step. Varying levels of convergence and sharing are possible with an MRA, such as has recently been implemented for GMP inspections between the US and EU, being the pinnacle option..
- iv. Science and technology are rapidly presenting new opportunities in the development and use of medicines, so aligned approaches are important. Therefore it is important to prioritise upstream discussions between EU and US on evolving science and technology (e.g. for new sources of evidence) to support the development of medicines and their assessment.

¹⁰ The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use

- v. Establishment of a harmonised approach to post-approval variation submissions for CMC (chemistry, manufacturing and control) changes as enhanced harmonisation would facilitate the management of supply and limit disruption risks to the supply chain that could potentially lead to shortages of essential medicines.
- b. **Medical devices:** The transatlantic medical technology industry is the most advanced in the world. However, the non-tariff barriers caused by a lack of regulatory convergence between the EU and US create an obstacle to more efficient movement of medical devices across the Atlantic, which could ultimately benefit patients on both sides. Cooperation between the regulatory agencies on both sides of the Atlantic is necessary to promote understanding and reduce unnecessary regulatory burden. Rather than attempting comprehensive convergence of these two systems, such as an MRA, it is better to focus on specific areas of ‘convergence’ including: a single audit process; harmonised format for product registration submission; and a common way to trace products through a single unique device identification (UDI) process with interoperable databases.
- c. **AMR:** The fight against Antimicrobial Resistance (AMR) requires global action and a “one health” approach, advocated by policymakers on both sides of the Atlantic. The establishment and ongoing work of the Transatlantic Taskforce on AMR (TATFAR) represents an important step in strengthening international cooperation in the fight against AMR. Transatlantic cooperation between public and private partners in the EU and US has helped to revitalise the antibiotic pipeline, including the clinical development of new antibiotics supported by the Innovative Medicines Initiative (IMI) in the EU and by the Biomedical Advanced Research and Development Authority in the US.
We urge stakeholders on both sides of the Atlantic to work together to shape and promote the right policies against AMR. These include: antibiotic stewardship; improved and more coordinated surveillance mechanisms; strong healthcare-associated infection prevention policies to enable a reduction of incidence of infection through effective hygiene and infection prevention interventions; full recognition of the value and increased uptake of vaccines as a key element to reduce use of antibiotics, as well as recognition of medical technologies (such as medical devices, in-vitro diagnostics, e-health and m-health) to improve prevention, control and monitoring. Finally, and equally important, we urgently need new sustainable and predictable economic models and incentives for antibiotic, vaccine and diagnostic research and development (R&D) in order to secure appropriate investments for the future.
- d. **Digital health:** The EU and US have made important steps in collaboration on eHealth IT, and recently updated the roadmap for their Memorandum of Understanding on transatlantic cooperation on eHealth/Health information technologies. In order to benefit public health in the long run, data disclosure policies must preserve patient privacy; respect the integrity of regulatory systems; protect intellectual property and conform to legislation, international treaties, and current national practices in patent law.

12. Investment

The EU and the US have long championed the cause of free and fair investment at home and abroad. These efforts have helped make the two regions the most economically attractive places in the world to do business.

- a. **Investment climate:** For a century, the EU and the US have been standard bearers for an open, rules-based global economy. However, in recent times there has been increasing evidence of protectionism on both sides of the Atlantic, mirroring trends globally. It is essential that the two parties continue to promote open investment markets and provide fair access for EU and US companies to each other’s markets. Doing so will ensure the ongoing competitiveness of both economies. It will also encourage similar practices globally and could help arrest any backsliding towards protectionism elsewhere.

- b. **Investment protection:** The debate around investment protection and the Investor-to-State Dispute Settlement (ISDS) mechanism in TTIP highlighted the need for a modified approach to this issue to satisfy concerns raised by civil society. AmCham members continue to believe that investment protection provisions should apply equally to all sectors relevant to an investment in either the EU or the US. Continued dialogue on comprehensive investment protection, as part of the international dialogue on ISDS, should be actively encouraged. Such an approach would provide companies with renewed confidence to invest globally, guaranteeing that their investments are treated fairly and on an equal footing with national companies. Given the potential for overlapping processes, it is essential that investor protection provisions are enforceable globally.

13. Intellectual property

Intellectual property rights provide critical protection for the technological and creative innovation that underpins the competitiveness of the EU and US economies today and tomorrow. A strong transatlantic commitment to IPR enforcement and cooperation is important to prevent any lowering of international IP protection standards.

- a. **Further enhance a shared strategy at the international level on IPR enforcement:** Delivering a shared strategy should promote the strengthening of local cooperation between the EU and US diplomatic services in third countries.
- b. **Ensure compatibility of tools to combat illicit trade of counterfeit products online:** As illegal online activities harm consumers, legitimate content providers and manufacturers, there should be increased cooperation between the EU and US in collaboration with all Internet actors.
- c. **Protect trade secrets by inclusion of robust protections:** A commitment to strengthen and better harmonise protections for trade secrets both within the EU and US and in third countries.
- d. **Establish an EU counterpart to the US Intellectual Property Enforcement Coordinator:** Specific EU-US coordination could be furthered through the development of enhanced coordination on IP issues at the EU ministerial and parliamentary levels.
- e. **Advance discussions regarding broader territorial reach of patents and trademarks:** businesses on both sides of the Atlantic are forced to file patent applications in both locations and then to validate European patents in certain European countries, which is very costly. Moreover, as obtaining protection in every European country is prohibitively expensive, the cost-effective decision not to protect throughout Europe encourages infringers to conduct activities in countries in which protection was not acquired. Enabling businesses to obtain patents enforceable in the U.S and throughout Europe would help combat infringement. The same applies for trademarks.

14. Security and defence

The transatlantic partnership remains vital in the current global environment in which security threats are increasingly complex and rapidly evolving. In this context, AmCham EU welcomes the strong momentum gained by defence in the EU's Global Strategy and codified by the European Defence Action Plan (EDAP) and its flagship proposal to establish a European Defence Fund (EDF). A more assertive and resilient EU policy in the field of security and defence is instrumental to reinforce NATO and therefore achieve collective security and maintain transatlantic cooperation.

However, in light of protectionist rhetoric from both sides of the Atlantic, AmCham EU would like to remind EU and US law- and policymakers of its core recommendations:

- a. Maintaining and supporting **strong and advanced Defence Technological and Industrial Bases** on both sides of the Atlantic;

- b. Ensuring that **impediments to Transatlantic Defence Technological and Industrial Cooperation (TADIC) are reduced** while the foreign policy and national security interests of the EU, its Member States and the US continue to be protected;
- c. Ensuring reciprocal **openness and accessibility** of defence and security markets;
- d. Promoting the **adoption of best available technologies**, irrespective of their origins, and learning from global experiences to provide the best available level of protection to European and US citizens;
- e. Collaborating in the **standardisation and certification of emerging technologies** such as cyber, artificial intelligence, autonomous systems etc.

15. Transport

The transport sector is fundamentally international and strong transnational policy cooperation is required. In other words, maintaining an international level playing field goes hand in hand with finding global solutions for global challenges, crucial for the environment and competitiveness of Europe.

- a. **Aviation:** The revision of the European Aviation Safety Agency (EASA) Basic Regulation offers an opportunity to pursue a more harmonised approach with the Federal Aviation Agency (FAA) alongside alignment with ICAO. EASA should work closely with the FAA to promote regulatory convergence and global harmonisation.
- b. More broadly, we encourage further **liberalisation of international air service** to develop an open and flexible global aviation system that delivers increased market access and operational flexibility for airlines and greater choice as well as greater choice and lower fares for travellers.
- c. **Climate:** measures to address aviation and shipping emissions are best taken through cooperation with key partners at the international level such as ICAO and IMO, rather than through regional solutions.
- d. **Logistics:** Interoperability of logistics standards should be a priority.
- e. **Automotives:** See dedicated section on automotives.

Conclusion

The EU and the US are historic allies and partners, sharing a common history and united by shared values and interests. The value of this relationship is particularly evident in the enduring strength of the transatlantic economy and the stability and prosperity it brings. However, EU-US ties are currently being tested in new and complex ways. New challenges are emerging in the bilateral relationship, at the same time that powerful new economies are gaining prominence and contesting the norms and standards of the liberal economic order.

Managing these challenges will be crucial and will require strong political leadership. It is essential that the two parties build on the achievements made during the TTIP negotiations and work constructively to develop a positive new agenda for transatlantic cooperation. This paper, which underscores the continued potential of deepened economic ties, is part of a broader effort by the business community to maintain and strengthen the EU-US relationship for the years to come. AmCham EU looks forward to working with policymakers and stakeholders on both sides of the Atlantic in pursuit of this important goal.