AmCham EU's position on the Transatlantic Trade and Investment Partnership (TTIP)

Building the framework for strengthening the transatlantic partnership

14 March 2014

Executive summary

The American Chamber of Commerce to the European Union (AmCham EU) believes that a comprehensive and ambitious EU-US trade and investment agreement will enhance a growth-oriented investment climate in Europe and the United States that would benefit business, employment and all citizens on both sides of the Atlantic. This could, in turn, ensure that consumers have access to more innovative goods and services that are both lower in cost and delivered more efficiently. This effort has the ability to release the combined potential and vitality of the two markets to the benefit of all.

This position paper reflects the views of the AmCham EU membership, and will be updated as the negotiations evolve.

* * *

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 €1.9 trillion in 2012 and directly supports more than 4.2 million jobs in Europe.

* * *

POSITION PAPER

American Chamber of Commerce to the European Union (AmCham EU)
Avenue des Arts 53, B-1000 Brussels, Belgium
Register ID: 5265780509-97
Tel: +32 (0)2 513 68 92 | www.amchameu.eu

Secretariat Point of Contact: Adriaan Scheiris; adriaan.scheiris@amchameu.eu +32 (0)2 289 10 19

TABLE OF CONTENTS

1. Overarching principles for TTIP

The American Chamber of Commerce to the European Union (AmCham EU) believes that a comprehensive and ambitious EU-US trade and investment agreement will enhance a growth-oriented investment climate in Europe and the United States that would benefit business, employment and all citizens on both sides of the Atlantic. This could, in turn, ensure that consumers have access to more innovative goods and services that are both lower in cost and delivered more efficiently. This effort has the ability to release the combined potential and vitality of the two markets to the benefit of all.

Key horizontal principles for TTIP:

- **Regulatory cooperation and coherence**: A focus on enhanced cooperation in EU and US regulatory processes will create a more efficient regulatory environment and enable a consistent and certain operating environment for businesses.

- **Concept of broad mutual recognition**: While regulatory cooperation is a long-term priority, in some areas, mutual acceptance of regulations and standards is a shorter-term goal to explore within these discussions.

- **Elimination of tariffs**: Although tariffs are already low between the EU and US, they remain high for specific sectors and are still a tangible nuisance to economic actors. Moreover, with complex global supply chains, these tariffs simply act as an unnecessary cost to companies seeking to compete on equal terms with companies in emerging economies. EU and US negotiators should approach the removal of tariffs in a way that reflects companies' complex global value chains today and avoid allowing the process degenerate into a tit-for-tat negotiation.

- **Common regulatory impact assessment procedures**: Impact assessments of future regulations could benefit from a joint EU-US approach. Such qualitative and quantitative assessments, which would consider anticipated costs and benefit of the regulation and include public consultation mechanisms, would identify potential barriers to trade and investment upfront.

- **Common risk assessment procedures**: A shared approach to science-based risk assessment would provide clarity and confidence for both operators and consumers in EU and US markets and serve as a basis for closer scientific cooperation between regulators on emerging issues. Building on best practices in the EU and the US, common methods to assess data quality and common principles to conduct weight of evidence assessments should be established.

- **Coherence with international trade rules**: Designed to foster international trade and provide legal certainty, international trade rules allow enough regulatory flexibility to protect legitimate policy objectives (such as the protection of public health, the environment and national security). AmCham EU supports comprehensive trade agreements that reinforce the long-standing principles of the global rules-based trading system, including national treatment, non-discrimination and objective policy-making based on sound science.

- **Regulation based on sound science and consumer/environmental protection:** No trade agreement prevents governments from regulating in the interest of the general public. In fact, governments can, and do, regularly implement strict measures to protect the environment or

human, plant or animal health. These measures should be based on sound evidence, be non-discriminatory and not more trade-restrictive than necessary. If this is the case these measures should not conflict with international trade agreements.

2. Trade in Goods

a. Automotive

Challenges

- **Most automotive tariffs** are relatively low but there are still some 'peak' tariffs such as duties for trucks (25% in the US including light commercial vehicles and 22% in the EU). Passenger car tariffs are 2.5% in the US and 10% in the EU. Parts and components tariffs are on average 0-2.5% in the US and 4% in the EU.

- Although similar vehicles are sold in both the EU and the US, both markets apply different technical regulations, standards and testing requirements, including for wiper blades, headlights, light beams and seat belts to name just a few. These diverging requirements result in additional burden and cost for any manufacturer wishing to export vehicles to the other side of the Atlantic. According to the EU impact assessment, regulatory differences in the automotive sector act as a non-tariff barrier (NTB) and are equivalent to an ad valorem tariff of about 26%.

- Tariffs remain low in the **tyre sector** (around 4% on both sides), but given the very high trade volume, tariff elimination would have a significant impact on this sector.

Recommendations

- The most significant economic gains can be achieved through regulatory convergence, so the key objective should be to achieve a comprehensive agreement which includes mutual recognition/recognition of equivalence of existing EU and US technical regulations and standards.
- The EU and the US should agree to cooperate closely when developing new and future automotive legislation.
- Building on existing progress through the TEC, greater EU-US collaboration between national, regional and international standards setting organisations to support harmonisation of electric vehicle technical standards is encouraged (e.g., compatibility with smart grid communication methods; IT security and data protection; common billing methods, charging stations, plugs).

- The **elimination of all automotive tariffs**. Due to the high level of intra-company trade flows, tariff elimination would result in significant gains for automotive manufacturers on both sides of the Atlantic.

- The **elimination of all tariffs for the tyre sector**.

- **Regulations and standards** that are not compatible should ideally be **harmonised**.

b. Machinery and Electronics

Challenges

- **Diverging conformity and technical requirements regarding pressure equipment**. The US system for managing safety of design and manufacturing of pressure equipment is regulated at the state level, i.e. each state has regulations requiring compliance with the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code of Construction. State regulations neither permit nor recognise any other pressure equipment codes of construction or standards. Conversely, the European Union's CE Marking Directive, 97/23/EC for Pressure Equipment (PED) is set at EU level. Under the PED, manufacturers can use EU, international or industry-recognised standards (such as ASME) to design and manufacture to meet the PED criteria.

Recommendations

- The **management** of US pressure equipment conformity and technical requirements should take place **at the federal level**.

- The US system should **recognise EU, international and industry-recognised standards**. In this way, EU standards will be recognised in the US and vice versa.

c. Chemicals

Challenges

- For **chemicals**, EU import **tariffs** are 4.6% on average, while US import tariffs are at approximately 2.8%. This means that average tariffs on both sides are 3-4%. Significant intra-company trade costs result from duties paid on key inputs to the manufacturing process in the EU and US.

- Both the US and European economy (not only chemical sectors, but also downstream users) would benefit dramatically if there were greater regulatory coherence between EU and US authorities (see also chapter 8 on regulatory cooperation and chapter 9 on technical barriers to trade).

- Differences in **classifications and labelling** for chemical substances create additional costs for companies and government. Reducing or eliminating the need for dual classifications, where appropriate, would facilitate trade and reduce inefficiencies.

- Most **biocidal products** approved in the US do not comply with EU regulations, and vice-versa. This requires reformulation, additional efficacy testing, different toxicology tests, new supply chains etc. This lack of harmonisation results in higher costs and longer lead times, leading to fewer products available for commercial customers (serving hospitals and restaurants) and consumers. The additional cost for large companies exceeds several million euro and hinders SME activity.

Recommendations

- The EU and US should **eliminate all tariffs on chemical products**; this would increase competitiveness, augment availability of inputs for downstream manufacturing and save costs for American and European companies, especially SMEs and ultimately for consumers.

- **Aim for regulatory convergence and avoid technical barriers to trade (TBTs)** in the field of chemicals policy.

- Developing **common principles for information sharing, prioritising chemicals for review and evaluation, protection of commercial and proprietary interests and, coherence in hazard and risk assessment**, would dramatically improve the current transatlantic regulatory environment on chemical policy.

- **A harmonised approach to data assessment** would simplify the registration process, improve transparency and be more efficient for companies in both economies. Both governments should aim to develop common principles for data quality, including utility, objectivity (which includes reproducibility) and integrity.

- The EU and US should establish a framework for **mutual recognition of compatible regulations for chemicals risk management** that would allow maximum recognition of functionally equivalent approaches while respecting the relevant regulatory provisions in each region.

- The EU and US should **agree on objectives and governing principles for chemical regulation.** Such an agreement would help develop chemical assessment tools (hazard and exposure models and databases), as well as a common template and equivalent or compatible IT systems for chemical restrictions or ban requests, based for example on the UN Globally Harmonized System for Classification and Labelling (GHS).

- **Promoting greater coherence on classification and labelling** would reduce or eliminate the need for dual classifications, where appropriate. This would help facilitate trade and provide a level playing field for companies, while also supporting the cost-effective implementation of the GHS as a common classification inventory. Agreeing upon standardised templates to be used on both sides of the Atlantic will help to leverage all the work that has already been done without changing current statutory or regulatory requirements already in place in either jurisdiction.

- A mechanism should be created that would allow physic-chemistry, health and environment **data submitted under one regulatory regime** to be acknowledged under the other without re-submitting. This would avoid unnecessary animal testing and save costs for companies and public authorities, while accelerating efforts to protect consumers and the environment.

- By **harmonising EU-US regulation on biocidal products**, industry would be able to create products with a focus on performance and environmental footprint rather than meeting specific requirements in each jurisdiction.

New and Emerging Issues

- **New and emerging scientific issues** present the EU and the US with opportunities to align regulations and prevent divergence prior to their enactment.

- EU and US regulation to determine whether a substance is an **endocrine disruptor** should be based on a full 'weight of evidence' analysis of the relevant scientific data and a comprehensive hazard assessment, which requires both 'hazard identification' and a 'hazard characterisation'. **Endocrine disruptors** warrant a **case-by-case assessment** in **the regulatory approach**, with the possibility to establish safe thresholds for use.

- **Nanotechnologies** are considered the new industrial revolution, and could be the competitive industry of the future for the US and Europe. If the regulation framing this new technology and the materials and products it produces is too rigid, it could stifle its development. It is important that transatlantic regulations be set for this new technology. The global market for nanomaterials is estimated at a market value of €20 billion.

- Since the EU is currently reflecting on how to address **combined effects of chemicals**, there is an opportunity to seek early harmonisation of the EU and US regulatory approaches. An agreement on a common prioritisation methodology for identification of mixtures of concern and risk assessment methods building on international standards would greatly improve the predictability and efficiency of the measures for the benefit of industry and public health and the environment.

d. Medical Devices

Challenges

- **Border tariffs** on medical technology trade between the US and EU are not high. However, those that remain add costs to the free exchange of products between the two trading partners and ultimately increase costs to patients.

- The main challenge for the sector is the non-tariff barriers caused by a lack of regulatory convergence between the two sides of the Atlantic. This is a key obstacle to more efficient movement of medical devices between the EU and US, which could ultimately benefit patients on both sides.

Recommendations

- All **remaining tariffs** on medical devices should be **eliminated** upon the TTIP's entry into force.

- **Cooperation between the regulatory agencies** on both sides of the Atlantic is necessary to promote understanding and reduce unnecessary regulatory burdens. Rather than attempting comprehensive 'convergence' of these two systems, such as a mutual recognition agreement (MRA), it is better to focus on specific areas of 'convergence'. Previous efforts to conclude a workable mutual recognition agreement between the two systems failed after spending considerable time and resources. **Negotiations on medical technology should focus instead on specific areas where convergence is possible** and avoid negotiations that pressure either system to fundamentally change.

- TTIP should also include a **regular dialogue** between the US Food and Drug Administration (FDA) and DG SANCO, involving USTR and the US Department of Commerce, **to exchange information on regulatory measures under consideration** that could impact trade and determine areas for additional convergence.

- The **following areas** have been identified as areas where greater regulatory cooperation would facilitate trade, reduce market access barriers and strengthen the medical device industries on both sides of the Atlantic:
  - Mutual recognition of ISO 13485;
  - Single audit process;
  - Harmonised format for product registration submission;
  - A common way to trace products through a single unique device identification (UDI) process with interoperable databases; and
  - Development of common guidelines for health and social media.

- Because TTIP may possibly **set precedents in other markets**, provisions similar to those in KORUS and the Korea-EU FTA should be included in TTIP. For example, under the KORUS:
  - Article 5.2 indicates that the procedures, rules and criteria for setting reimbursement rates shall be fair, reasonable and non-discriminatory;
  - Article 5.2 states that reimbursement rates should be based on competitive market prices or, if not, the rates should recognise the 'value' of the medical device, allowing the manufacturer to provide evidence to that effect – including the ability to demonstrate the

rationale for increased rates. This provision does not indicate that the prices should be published or otherwise provided to anyone;

- Article 5.3 includes clear transparency provisions that allow the medical device industry to provide input into pricing decisions, to have access to 'all procedural rules, methodologies, principles and criteria' and guidelines used for pricing, and an independent review process; and
- Article 5.7 establishes a committee to monitor implementation and to promote collaboration.

e. Pharmaceuticals

Challenges

- **The value of innovative pharmaceuticals in reducing other more costly medical expenditures and improving the lives of patients is not recognised**. Price controls set by national governments should only apply to the extent that the medicinal products are purchased or reimbursed by the country concerned. Prices of medicines should in general be based on a variety of criteria, primarily the value of the product, patient benefits and physician requirements, its place in the national healthcare system, patterns of disease burden and willingness-to-pay. However, where governments decide to use external reference pricing for patented pharmaceuticals, they should only reference countries that have similar socio-economic levels, purchasing power, populations, disease burdens and healthcare systems.

- **There are differences in requirements** in some areas and a **lack of alignment between EU-US regulatory processes** in medicinal product approval standards. This includes **duplicate inspections** to manufacturing facilities by both the European Medicines Agency (EMA) and FDA (Federal Drug Authority), and **unnecessary administrative burdens** for companies, such as different approaches to retesting.

- **Confidential commercial information.** The current guidance and draft policy of the EMA would weaken safeguards intended to ensure the privacy of patients and other individuals identified in Marketing Authorisation Application dossiers. Non-clinical and clinical study reports submitted by an applicant to obtain marketing authorisation would be considered as non-confidential and could be released into the public arena either proactively by the EMA or upon request of a third party. This would undermine trust in the regulatory approval system, introducing risks of misinterpretation and misuse of clinical data into the process; and weaken incentives for companies to invest in biomedical research by disclosing companies' commercially confidential information. See also chapter 12 on intellectual property.

Recommendations

- **Prices** should not be set by reference to prices in countries currently in economic crisis.

- **Include a pharmaceuticals annex** to address key barriers relating to government pharmaceutical pricing and reimbursement policy. The pharmaceuticals annex included in the EU-Korea FTA could serve as an example. All criteria, rules and procedures that apply to the listing, pricing and reimbursement of products should be transparent, fair, reasonable and non-discriminatory. In addition, a transparent appeal process should be in place.

- **Avoid unnecessary duplication of inspections** through mutual recognition of good manufacturing practice inspections. If the FDA and the EMA shared inspection findings through mutual recognition of good manufacturing practice inspections, only one agency would need to visit each facility, saving inspection resources and reducing preparation time for companies.

- **Harmonise import procedures**, such as harmonisation of approaches to retesting.

- **Extend the existing parallel scientific advice pilot to allow sponsors the right to receive joint scientific advice** upon request for all medicines. Based on the lessons learned from the pilot launched in 2010 by the EMA, regulators should extend and modify the work between EMA and FDA on parallel assessment of quality by design applications to develop a process that is fit-for-purpose for all stakeholders.

- **Maintain data protection standards related to commercially confidential information**. 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. To maintain participation and investment in clinical trials, it is imperative that both the EU and US maintain uniform protection of patient privacy and confidential commercial information and trade secrets in their respective clinical trial and marketing application disclosure policies. Such protections are necessary to maintain incentives to invest in innovative medical research. Technical standards for implementation should be aligned to save additional cost.

- **Enhance compatibility on paediatric plans**. Include greater compatibility in the scope, content and timing requirements for submission of paediatric plans so that companies are able to prepare a single plan for simultaneous submission in both jurisdictions.

- **Drive higher standards at a global level on regulatory coherence**. Further cooperation on regulatory matters between the EU, US and third markets could help movement toward a globally harmonised regulatory system. This cooperation could include for instance coordinated GMP inspections in third countries. EMA and 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. Continued support for the International Conference on Harmonisation agenda would reduce regulatory burden and time to market for new products.

f. Cosmetics

Challenges

- **Different classification** of cosmetics and their **ingredients** as well as divergences in testing requirements (such as for sunscreens and colour testing) continue a costly and unnecessary barrier to trade that does not provide health benefits. Likewise, diverging **labelling provisions** result in extra costs without health benefits.

Recommendations

- **Mutual recognition of diverging classification** (e.g. tooth paste, anti-dandruff, antiperspirant, etc.) and of EU positive list materials (e.g. UV filters) would decrease complexity.

- The EU and US should **mutually recognise** the **labelling of ingredients** in cosmetics and sunscreens. The US should accept EU trivial names and should fully adopt INCI Nomenclature. For example, the US has a requirement that the term 'water' be used rather than 'aqua'. Such unnecessary requirements are costly and do not create added value for the consumer or consumer safety.

- The EU and US should **work together to ensure that the EU animal test ban is implemented in a way that avoids trade barriers** and allows for the continued marketing and trade of new and innovative cosmetic products in the EU.

- The EU and US should **harmonise and/or mutually recognise testing requirements**. The harmonisation and/or the mutual recognition of testing requirements would facilitate a single testing requirement for EU-US purposes permitting quicker marketing, reducing costs and creating synergies in the supply chains. Harmonisation of testing requirements would additionally create a strong signal towards international convergence.

g. Spirits

Challenges

- **Spirits** (HTS 2208) were included in the 'zero-for-zero' agreement that was negotiated as part of the Uruguay Round. Consequently, transatlantic tariffs on most EU and US origin spirits are zero, with the exception of certain low-valued rums, which are still subject to tariffs.

Recommendations

- **Residual tariffs should be removed**, such as those on low-valued rum, so that all tariffs on EU and US-origin spirits are eliminated.

3. Agriculture & Processed Agricultural Products

Challenges

- Both the European and American food and drinks sectors have been losing global market share over the last decade. Agricultural products are a key resource for this and many other sectors.

- **Tariffs** on agricultural and processed agricultural products have a negative impact on the competitiveness of EU and US companies. For example, **high tariffs** are applied to **agricultural products** from the US and exported to the EU, where they are often used to create val**u**e-added products that are then re-exported to the US. These high tariffs on intermediate products lead to price increases for consumers buying the final product. For products that are exported outside of the EU and US, such tariffs increase production costs thus undermining competitiveness.

- **Regulatory differences** are the other major source of unnecessary additional costs. Examples of particular relevance to agriculture and processed agricultural products are provided in chapter 10 on Sanitary and Phytosanitary Measures.

- The lack of expert consultation between EU and US agencies on data requirements, guidance and guideline development is a source of **regulatory divergence** that is potentially damaging to international trade.

- **Regulatory data protection** is an essential element for stimulating investment in research and development of crop protection products and animal health. The requirement to protect data from disclosure and unfair commercial use is recognised under article 39 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Recommendations

- **Tariffs** on agricultural and processed agricultural products which undermine the competitiveness of value added products should be eliminated. For example, components imported and then re-exported to the US should be identified and targeted for tariff reduction.

- **Immediate elimination of tariffs** and other import duties for **crop protection (CP) products** upon the entry into force of TTIP or a phasing out of tariffs and import duties in a short period, no more than three years.[1] An immediate elimination of tariffs and import duties would reduce the cost of goods sold and benefit the agroindustry and prevent consumer prices from rising.

- The tariffs rates for **seeds products** are a combination of ad valorem and specific duties, eliminating such tariffs would help reduce the costs of bringing seeds products in the US market. The elimination of duties should also include special duty rates, which are additionally levied once the seeds products are customs cleared.

[1] Taking as example the FTA signed by the EU and US with South Korea (one of the most modern FTAs signed by the two economic blocks), the United States eliminated tariffs on 91% of industrial products within three years, with an additional 4% in five years and all remaining tariffs (5%) within 10 years.

- **Regulatory Cooperation** should be institutionalized through the establishment of a formal platform to discuss regulatory matters with a view to:
  - reducing regulatory discrepancies and excess that cause unnecessary additional costs
  - enhancing the establishment and application of international standards.

- The EU and US should **continue to promote** minimum standards of 10 years for **protecting regulatory data** for crop protection products, and protection of confidential business information through free trade agreements with countries that have low level of regulatory data protection. The EU and US should consider the following:
  - Ensure a common approach to free trade negotiations, with all countries promoting a minimum 10 year standard for the protection of regulatory data;
  - A common framework for the protection of confidential business information of crop protection products to be included in TTIP;
  - Provide training to regulatory authorities to ensure protection of regulatory data against unfair commercial use; and
  - Ensure that article 39 of TRIPS is enforced in all WTO member countries.

4. Rules of Origin

Challenges

- Rules of origin can be inconsistent and complicate significantly the operations of companies seeking to optimise the quality and competitiveness of their products. This is an area were the agreement of robust common rules has been elusive. With **supply chains** becoming **highly integrated** and involving inputs from multiple suppliers and territories, this problem has become even more acute, and imposes unnecessary costs on businesses and consumers. This can put EU and US corporations competing with emerging market suppliers at a major disadvantage and lead to causing them to lose market share.

- The current rules used in EU and US FTAs generally do not permit **trans-shipment** or any processing or manipulation of exports in third countries before arrival in the importing country, other than loading and offloading of a vessel, except in certain circumstances and provided the goods remain under constant customs control. Businesses increasingly use regional hubs to consolidate shipments of non-country specific shipments, where country-specific labels and other specific requirements are applied prior to shipment to their final destination.

- Given the growing number of FTAs with common trading partners, '**accumulation**' is increasingly important to ensure that products that are produced wholly from qualifying inputs sourced from a number of countries that have FTAs with both the EU and US (e.g. Central America, Colombia, Korea and Mexico) will qualify for the preferential treatment accorded by any of the FTA partners.

- Due to the low prevailing duties in the EU and US, the cost of documenting when complying with robust rules of origin may often overwhelm duty savings. Thus, in order to realise the benefits of duty reduction under TTIP, simple, innovative rules of origin regime may be necessary.

Recommendations

- Make the **establishment of a set of coherent rules of origin** a priority in the negotiations. This can also serve as a useful precedent for multilateral negotiations.

- Rules of origin should allow qualifying goods to undergo minor processes without losing their preferential treatment. TTIP should also include rules of origin that **allow for accumulation with countries that already have an FTA with either partner**.

- For articles where tariff rates in both jurisdictions are low and the differences between them so small that trans-shipment of third-country goods for purposes of tariff reduction is economically impractical, the parties should provide for free circulation within the TTIP area after first importation or a rule of origin that requires only minimal processing. In effect, the parties should establish TTIP as a customs union for those articles where there exists, within a specified margin of difference, a common external tariff.

- Have the US **accept 'EU' as a valid preferential origin indication** would simplify reporting, systems and master data management and align it with other EU FTAs. This would have a similar effect as the mention of the ISO code of the individual EU Member State and would bring consistency on the origin indications for both non-preferential and preferential purposes.

- **Preferential rules of origin** for **crop protection (CP) products and seed products** might follow one or more of the following least rules:
  - Tariff shift or value content of 50–60 % calculated from free on board (FOB) price of the products. The base of calculation of the value content can follow the NAFTA model (FOB value), without excluding intangible costs, such as royalties, license fees;
  - Last country of formulation (CP products);
  - The possibility of a change of Chemical Abstract Service (CAS) number (CP products) might help to grant the origin of CP products. In some cases a chemical reaction does not trigger a tariff shift, but a change of CAS number, consequently a CAS number shift could be also an alternative;
  - Plants and plant products harvested, picked or gathered in that country or obtained by the use of plant cell cultures in that country (cell culture–based production operation);
  - Include diagonal cumulation (e.g. materials/active ingredients from other countries, such as Switzerland, Mexico and Canada), following the PANEUR-MED rules of origin model;
  - Increase the de minimis rule from 10% to 15% in order to use non-origin materials that are necessary for CP production, without losing the US or EU origin status; and
  - The possibility to make origin declaration (provided by authorised exporters) in the following commercial documentation: commercial invoice, pro-forma invoice, packing list, delivery notes, purchase order, transport documentation.

5. Services

Challenges

- **Services** are essential to enabling all international trade. In order to make, buy, move or sell products, services play an integral role. **High-tech services** enable research and development, and in many sectors, make up an important part of the final product itself. **Professional and financial services** provide the support needed for the development and sale of products, retail services provide the venue to the sale of products, and logistics and delivery services get products to and from the market.

- Electronic security services, where the customer is likely a business or household, do not threaten national security and should not be regulated as such. Member States have used **the security exemption** in the Services Directive **to erect trade barriers**.

- With regard to distribution services, **direct selling** companies are concerned about restrictions on the types of products than can be distributed in Europe through the direct selling channel. Some EU Member States prohibit or limit the ability of companies to sell **nutritional supplements** such as vitamins, botanical and herbal products through this channel, even though they are sold freely to consumers without a prescription or special certification.

- Despite their critical role in the development of modern, global supply chains, the **express delivery sector** (EDS) faces some of the most antiquated policy environments for doing business, including onerous regulations on cross-border transport, inefficient border clearance procedures and domestic regulations that distort fair competition.

Recommendations

- Developing a **common transatlantic framework** and opening markets to the provision of services will play a crucial role in enabling the transatlantic trading platform to meet both current and future demands.

- A 'negative-list' approach would be a good way forward to achieve greater liberalisation, while at the same time being future proof as it prevents new/evolving services of being excluded.

Trade in services

- In addition to the benefits for transatlantic businesses of all sizes, securing a comprehensive agreement on US-EU trade in services will allow the EU and US to play a leading role in the multilateral arena. TTIP provides the EU and US with an opportunity to **set global benchmarks**, both through the Trade in Services Agreement and other bilateral agreements.

Professional services

- Quick adoption of the **EU Intra Corporate Transferees Directive**.

- Both the EU and US0 should take additional steps to **facilitate short-term talent mobility**. When such mobility takes place on an intra-corporate basis, the benefits should apply to employees of the relevant EU or US based company regardless of the nationality of the employee concerned.

- Any agreement designed to facilitate short-term talent mobility must address procedural **and administrative aspects** as well as rights of access to the relevant market. For instance, the negotiations should result in a **fast track treatment for EU and US companies** when filing applications for intra-corporate transfers. Candidates from EU and US companies should be exempt from any quotas or labour market tests. Moreover, a standstill agreement should be put in place to ensure that no additional restrictions are put in place with respect to intra-corporate transferees falling within the scope of TTIP.

- Given that intra-corporate transferees are often highly specialised employees with unique experience and, consequently, are in high demand to work on numerous projects upon completing one project, they may soon embark on a second project after having returned to their country of origin for a short period of time. A 'waiting period' would deprive the employer of the intra-corporate transferee, and its customers of the ability to call upon the skilled transferee to perform valuable work on a second project in the same Member State for an artificially long period of time.

Electronic security services

- TTIP should include **market commitments for electronic security services**. This would allow for the deployment of innovative technology and professional response to protect life and property. Products are only as good as the quality of the design, installation, service, and monitoring of the electronic security system. Moreover, the benefits of commercial and residential electronic security services should not be restricted under the banner of national security.

- With regard to **licensing**, there should be rules to ensure transparency and non-discrimination in the issuance of licences and certifications. In cases where denial is due to cross-border issues, including ability to obtain insurance and local public safety restrictions, companies should have recourse via the European Commission.

Distribution services

- The goal should be **enabling EU and US service suppliers to compete** on the basis of quality and competence rather than nationality. The scope of TTIP should be comprehensive, permitting the coverage of all services, including direct selling distribution services.

- Sale of **nutritional supplements** should not be restricted based merely on the sales channel used by the company. Products that can be sold freely to consumers without a prescription or special authorisations should be also allowed for sale through direct selling channels.

Competitive delivery services

- **An annex for delivery services** that introduces market access measures, domestic regulation and the application of pro-competitive principles for the provision of competitive delivery services, including express delivery (EDS) and ancillary services, should be included in TTIP.
- In addition to trade facilitation and customs modernisation efforts as described in chapter 18 of this paper, the EU and US should **recognise the role of competitive delivery services** (CDS), defined as those services that collect, transport and deliver documents, printed matter, parcels, goods and other items in competition with one or more other suppliers.

- In the context of delivery services, TTIP should included **principles** that ensure:
  - An independent national regulatory authority;
  - The prevention of anti-competitive practices resulting from the abuse of dominant market power by a public service operator, e.g. state-owned and state-sponsored enterprises;
  - The prohibition of cross-subsidisation of commercial activities by operators where these activities are subsidised by monopoly-related profits, state funding, aid or other privileges;
  - The enforcement of transparent accounting by public service operators, ensuring the maintenance of separate accounts for monopoly and competitive services;
  - The equal application of customs and security procedures to all delivery-related activity; and
  - Competitive delivery service providers have non-discriminatory access to public postal services rates and infrastructure, and are not required to fund them as a condition of a license or authorisation to supply their services.

For **financial services**, please see chapter 6, for **digital services**, chapter 18.

6. Regulatory Cooperation in Financial Services

Challenges

Given that an estimated 80% of the economic benefits of a transatlantic trade agreement would derive from eliminating non-tariff barriers, maximising the potential of TTIP will require a comprehensive and ambitious approach to regulatory cooperation and convergence in all sectors including financial services.

Efficient and well regulated financial markets are a critical enabler of growth for the thousands of main street businesses, both large and small, who rely on them for funding, exports and risk mitigation. Ensuring that EU and US regulations are compatible will enhance this important strategic and economic relationship that brings jobs and economic growth to communities on both sides of the Atlantic.

Four specific issues act as a barrier to trade on EU-US financial services that need to be addressed as a matter of priority:

- **Extra-territorial application**: These measures can unnecessarily burden EU and US financial institutions with overlapping or even inconsistent regulation and discourage third-country investors from undertaking transactions that risk bringing them into the EU or US legal regime, thereby distorting economic decision making (e.g. the choice of counterparty) in a way that undermines market efficiency.

  Divergence in specific rules and definitions: Any divergence of between the EU and US will distort markets significantly, and uncertainty makes it more difficult and expensive for market participants to plan the significant investment that they need to make to secure compliance.

- **Divergent timelines for application**: Financial regulation is too important to be discussed ad hoc, at the very last minute, under market pressure. Given the differences between our market structures and legislative frameworks, it is inevitable that regulatory differences would occur; therefore it is critical to work together, at an early stage in the legislative process to ensure that we aim for consistent rule making. When consistency is not possible, the parties should work to mitigate unintended consequences.

- **Reciprocity provisions**: TTIP should expressly prohibit each party from including in financial services legislation provisions that permit market access for a financial service only if the other party provides 'reciprocal' market access. In the interim, both sides should make a political declaration that it is their policy not to include such provisions in future legislation.

Recommendations

- TTIP should be comprehensive and **include a framework for regulatory cooperation and convergence** applying to all sectors, including financial services, based on the principles of undertaking joint work, parallel consultations and a commitment to examining existing rules with a view to determining the equivalence of outcomes.

- The introduction of legal mechanisms that permit market participants to meet their obligations in one jurisdiction by compliance with legal requirements set out in another is a welcome

development. TTIP should include an **express commitment to 'equivalence' or 'substitutive compliance'**, thereby creating an expectation that such regimes will be incorporated into European and US regulation. Pending the adoption of any such agreement, the EU and US authorities should make a public commitment that there is a 'presumption of equivalence', and to commit to a timeline to deliver this in all of the legislation and rules that are currently being finalised.

7. Investment

Challenges

- The European Union is the world's largest investor abroad and remains the largest recipient of FDI. Total US investment in the EU is three times higher than in all of Asia. EU investment in the US is around eight times the amount of EU investment in India and China together.

- **EU and US investments are the real driver of the transatlantic relationship**, contributing to growth and jobs on both sides of the Atlantic. In addition, it is estimated that a third of the trade across the Atlantic actually consists of intra-company transfers.

- **Regulatory stability** is one of the key factors impacting foreign investment. Legal and business uncertainty can be a deterrent to foreign investment. A balanced and coordinated legal framework will accelerate business developments that meet citizens' needs and foster growth.

- Before the Lisbon Treaty, the **EU Member States had negotiated some 1400 Bilateral Investment Treats (BITs)** - half of the world's BITs. Since the Lisbon Treaty, the Commission is responsible for negotiating investment agreements on behalf of the EU.

- Investment agreements are a long-standing and essential part of the system of checks and balances contributing to confidence for investors to invest in other countries than their home country. They are not an instrument for getting regulatory change, but a safeguard against arbitrary expropriation and discrimination.

- Dispute Settlement (ISDS) provisions in Bilateral Investment Treaties provide guarantees to companies that their investments will be treated fairly and on an equal footing to national companies. They enable European and American companies to invest around the world and companies of different origins to invest in Europe and America with confidence.

- The European Commission's decision to launch a consultation on the investment part of the TTIP negotiations is a welcome development and will give all stakeholders **the opportunity to comment on what should be an appropriate Investor-State Dispute Settlement (ISDS) mechanism between the EU and US.**

Recommendations

- The **Joint Statement of Shared Principles for International Investment** agreed by the EU and US in April 2012 is a welcomed development. Both inward and outward investments are vital to getting the EU and US back onto the path of economic growth, job creation and prosperity. These principles promote fair competition open, transparent, and non-discriminatory regulatory environments. They reflect the shared values of our societies and should be at the heart of the TTIP negotiations.

- The EU and the US should **promote implementation** of the EU-US Shared **Principles for International Investment** in their Member States and in all relevant multilateral and bilateral forums.

- TTIP should include horizontal and sector-specific measures to foster regulatory stability and legal certainty to attract new investment and protect investments made in the EU and the US.

- The importance of the inclusion of a comprehensive investment chapter in the agreement between the partners of the biggest bilateral trade relationship of the world needs to be stressed. This investment chapter should include ISDS provisions and no sectoral exclusions should be allowed.

- TTIP will have a considerable impact on rulemaking worldwide. **The EU and the US should seize the opportunity to set the standard and should agree on a state of the art investment chapter**.

- AmCham EU welcomes the European Commission's intention to issue a consultation on ISDS and will submit a response.

8. Regulatory Cooperation

Challenges

- There is a **need for transatlantic regulatory cooperation** in most if not all the industrial sectors. More specifically, a common approach to regulations and standards is needed for sectors like chemical policy, medical devices, energy technology, transportation and pharmaceuticals. Such a common approach would lead to important cost-reductions for companies, which in turn would benefit consumers.

- **Regulatory convergence is needed inside both trading partners**. Both in the US and in Europe, state or national and in some cases local regulations act as barriers to trade and prevent companies from benefitting from economies of scale.

- Manufactured products must obtain **various national certifications** to trade across Europe. These certificate**s are required for products whethe**r **they have a CE** mark or not. National notified bodies do not equally apply harmonised standard testing procedures for CE labelled products. This leads to inconsistencies in the quality of test results. Therefore the CE mark is not yet accepted as a uniform European quality mark and privately run national voluntary marks remain a de facto market requirement. As a result, industry is still obliged to adhere to multiple tests to obtain national certification for CE and non-CE marked products.

- **Unnecessary and expensive design changes to meet regional or national requirements** can cause US products to be uncompetitive in Europe, and European products to be uncompetitive in the US.

Recommendations

- The EU and the US **should continue to strengthen its consultation processes**. This will help to identify differences and potential opportunities to further cooperate and ensure minimum competitive impact before regulation is proposed and implemented.

- The EU and US should further demonstrate continued best practices through horizontal commitments to transparency, meaningful consultation of stakeholders and accountability in the draft regulatory stages.

- Agreeing on concrete processes **to foster mutual recognition and other forms of cooperation for regulations and standard setting should be a key priority**. This approach will allow the development of regulatory tools (databases, education) and also accelerate implementation/adoption.

- **Closer cooperation between standardisation bodies** is key. The establishment of a separate working group between CEN/CENELEC and ANSI is a step in the right direction that requires more focus to produce tangible results. Closer transatlantic cooperation on standards regarding product safety, smart meters, energy efficiency, pharmaceuticals, medical devices, bio-based products and other sectors should be further explored. Examples include:
  - The 'bridges principle', as agreed at the November 2011 TEC meeting, should be further developed and ultimately made mandatory;

  - Common e-mobility standards; and
  - Common principles and guidelines in risk and hazard assessment processes that would ensure a common scientific basis for regulatory decisions.

- **Mutual recognition of long-standing standards and regulations that cover similar technologies** would benefit both the EU and US. Mutual recognition of such high standards will stimulate growth for businesses, both large and small, on both sides of the Atlantic, as well as provide greater choice for consumers and suppliers.

- **To improve the value of the CE mark, stricter implementation of the technical assessment of the national notified bodies could be beneficial.** There could be a single certification scheme for products that do not fall under a specific EU directive or regulation (e.g. security products). The EU principle of Suppliers Declaration of Conformity could be recognised by the US, as well. Self-assessment could be used when appropriate.

9. Technical Barriers to Trade

Challenges

- Technical barriers to trade (TBTs) can prohibit new and emerging innovative technologies and industries from developing and flourishing. Transatlantic cooperation on environmental and consumer protection is vital to facilitate development of these new technologies and existing goods on the market.

Recommendations

- In order for new emerging and innovative technologies and industries to develop and flourish, the **introduction of TBTs should be avoided**. Technologies and horizontal industry developments, such as cloud computing, data privacy and security, and nanotechnology, which are in different stages of development and introduction, cannot fully develop their potential if their growth is being limited by TBTs.

- New emerging and innovative technologies and industries could benefit from **transatlantic cooperation to increase environmental and consumer protection, while avoiding trade distortions** and would benefit consumers on both sides of the Atlantic.

- Transatlantic rules **need to ensure transparency** that regulations relevant to the agreement are necessary to accomplish a legitimate objective (including in public health) do not raise impediments to trade.

- An agreement that encourages a **risk based approach for regulations**, using the principles of sound science, risk assessment and risk management, and transparency is paramount.

- Any future product **environmental impact label** based on a life cycle analysis should remain voluntary in the absence of any robust data and methodology. In addition, EU and Member State measures s not fragment trade, be non-discriminatory and proportionate to the objective being pursued.

- We recommend the creation of a **cross sector information sharing agreement to explore the impact of product information translation for industrial products exported into the EU**. We recommend the development of a **memorandum of understanding** to define the options and expectations for industrial product language translations.

- We recommend the creation of EU-US sector partnerships to **create transparent methods** that are secure from reprisal for US manufacturers and **notified bodies** to inquire and obtain support on regulatory and technical questions to ensure consistent application of the requirements between all parties.

10. Sanitary and Phytosanitary Measures

Challenges

Agricultural biotechnology: regulatory reform and alignment

- Because of the additional regulatory scrutiny associated with the introduction of biotech plants, dozens of scientific bodies ranging from the US National Academy of Sciences to the Commission's DG Research have categorically stated that the biotech varieties on the market are as safe for humans, animals and the environment as conventional plants. Nonetheless, **cultivation and import approvals are taking longer in the EU compared to the rest of the world**.

- **The significant time lag in EU authorisations has created a pool of asynchronous approvals that threaten the sustainability of commodity trade imports into the EU**. Despite this, the EU remains reluctant to implement measures that would allow for pragmatic and meaningful thresholds for low level presence (LLP) in food and feed, and for adventitious presence (AP) in seeds of those biotech products previously evaluated and authorised in third countries.

- **Developers of new biotech crop varieties fear that their applications in the EU are not being reviewed and acted upon in a timely manner**. Developers are able to secure rapid approvals in other countries such as US, Canada, Brazil and Argentina, and reach the market first in those countries, putting European farmers at a disadvantage compared to their international competitors.

- The same is true for innovative veterinary medicines. To address emerging disease and performance challenges, veterinary medicines increasingly employ biotechnology. **The EU's regulatory burdens and legislation on animal drugs could serve as trade barriers and disincentives to develop products for very important health, animal welfare and environmental challenges.** This could not only impacts trade but could also removes important disease management options from EU Member States and places EU farmers at a competitive disadvantage to farmers in other countries.

- European agricultural producers and biotechnology R&D companies alike are deeply concerned by the **lack of the regulatory certainty** to continue investing in the EU with confidence.

The functioning of the EU regulatory framework

- **The procedures for field trials and product approvals of Directive 2001/18 and Regulation 1829/2003 are not functioning as they are designed**, because routinely the legal timelines are exceeded. In addition, in several EU Member States, the cultivation of one or both of the EU approved GM crops is banned without scientifically sound justification as the European Food Safety Authority (EFSA) has stated on repeated occasions. At the same time, the EU imports the equivalent of over 15 million ha of GM crops per year to feed its livestock sector, resulting in a distortion of competition.[1]

[1] http://greenbiotech.eu/wp-content/uploads/2012/06/Farmers-scientists-briefing-paper-EU-GMO-policies-2012.pdf, p. 7

Costs of regulations

- The **average cost for having GMOs approved in Europe** has been estimated at €7-10 million per event. These costs mainly accrue from the large number of studies that the applicant companies must present to EFSA.

- **Indirect costs result from unpredictable timelines**, which can take up to 13 years for GM cultivation applications and 47 months for import applications, as well as frequent, sometimes retroactive, changes in the requirements.

Plant Protection Products

- **The system being used by ECHA to classify chemicals as carcinogenic or reproductive toxicants** based only on hazard criteria under the EU Classification, Labelling and Packaging (CLP) regulation in combination with cut-off criteria under Regulation 1107/2009 leads to the **loss of valuable existing active substances/products and new innovation without any health and environmental safety benefits**.

- **Current toxicity testing guidelines require chemicals to be tested at very high doses**, which are many orders of magnitude above any feasible human exposure. As a result, chemicals that can be used safely can be placed in the same category as chemicals that cannot be used safely because they pose a high risk to the user.

- **A network of EU legislation relies on classification**. This downstream legislation includes laws protecting consumers and workers, as well as rules on biocides, plant protection products and waste. Therefore, the consequences of classification are greater than just a hazard label in that certain classifications are exclusion criteria from the regulatory process. In the case of plant protection products, **inappropriate classification of chemicals as carcinogens or reproductive or developmental toxicants can lead to an inability to register or re-register a plant protection product** under regulation 1107/2009.

- The current classification system will have no positive impact on public safety but would cause serious harm to the chemicals industry, the agricultural sector and the development of a sustainable, knowledge-based bio-economy.

- With chemicals that do not pose a risk to the user but that are included in the most hazardous category, the system could lose credibility and will not be properly applied where needed. There could be a massive disincentive to innovate, causing chemical companies to disinvest or become uncompetitive thus stifling the development of the knowledge-based bio-economy. This would impact European farmers the most as they would be deprived of certain crop protection technologies simply based on hazard classification. This would also raise consumer food prices at a time many consumers are struggling to make ends meet.

Concerns on trade and MRLs

- **If a plant protection product is not registered for a crop in the US and is detected on imported EU commodities** (even if it is well below EU requirements), **it will result in rejection of the imported EU commodity.**
- **Products discriminated against** in particular are simple processed commodities such as wine, flour, juice and oil, for which the EU does not require a processing study because residue levels in the raw agricultural commodity (RAC) are so low. The same applies to pesticides with residues in the RAC of <0.01mg/kg.

- Many regulatory issues pertaining to **pesticides** could benefit from greater regulatory cooperation between authorities in the EU and US. The focus should be in particular on three areas of high importance:
  - Science-based risk assessment as the foundation for regulatory;
  - Maximum residue levels (MRLs) and the need for greater harmonisation in the processes for establishing MRLs for pesticide residues; and
  - Protection of intellectual property, in particular, confidential business information.

- The EU's interpretation of the Codex Alimentarius standards for residues of veterinary medicines or food hygiene products distorts trade between the EU and US on a wide range of products, including poultry, pork and beef.

- Although the EU's regulatory framework is risk-based, the use of hazard-based cut-off criteria in the EU will **hinder international trade**. The planned re-evaluation of Regulation 1107/2009 is an opportunity to reassess the use of hazard-based criteria and its influence on international trade.

- **Differences** among national systems for setting, maintaining, revising and enforcing **Maximum Residue Levels (MRLs)** can lead to multiple types of non-tariff trade barriers without improving consumer safety. They can restrain trade in agricultural produce, food and feed commodities and grains, complicate crop production decisions by growers at the field level and prevent access to certain crop protection technologies. The effect is an unnecessary increase in crop production costs without enhancing human and environmental protection.

<u>Recommendations</u>

Agricultural biotech crops

- The EU and US should work cooperatively to eliminate the risk for serious risks to trade disruptions via:
  - Driving for efficient, timely, science-based and effective implementation of existing laws and regulatory framework for biotech approvals of pending and future products;
  - Seeking a viable joint mechanism for accountability/dispute resolution;
  - Defining a workable threshold for low level presence of not yet authorised biotech traits in conventional seeds;
  - Extending the technical solution in commodity trade to include food; and
  - Regulatory cooperation on a harmonised approach towards new plant breeding techniques.

Plant Protection Products

- The EU and the US should **work together on a classification system based on risk assessment** rather than hazard and hazard-based exclusion criteria, such as:
  - Most hazardous substances only cause harm above a certain minimum dose, and this principle is already used successfully in the CLP regulation to classify damage to specific target organs using the STOT (specific target organ toxicity) criteria;
  - In most cases, tumours, reproductive or developmental effects in animals result from dosing at high doses by mechanisms that would not occur at lower, more realistic, doses in people. Substances that have this effect can be clearly distinguished from those that can cause effects at realistic doses in people;
  - When the possibility of effects at lower doses in people can be excluded, **the STOT criteria should be used for carcinogenicity, reproductive toxicity and developmental toxicity**;
  - Similar principles are already used to classify mixtures containing substances classified for carcinogenicity, reproductive and developmental toxicity; and
  - No changes to current CLP regulation (Regulation (EC) No. 1272/2008) would be required to implement this change, but revision of the CLP Guidance documentation would be required.

- The use of the above-mentioned criteria would provide ECHA's Assessment Committee with a more objective framework for making the key classification decisions on carcinogenicity, reproductive and developmental toxicity.

Trade and Maximum Residue Levels (MRL)

- **Science-based risk assessment** should remain the foundation for regulatory decisions, and should not be overtaken by precautionary regulations that are disproportionate to the uncertainties that may be present in impact assessment. These precautionary rules are often discriminatory and lack predictability and transparency.

- A **uniform approach to risk assessment** would provide clarity and confidence for both operators and consumers in both markets. Opportunities for **cooperation** include:
  - Endocrine disruptors;
  - Nanotechnology;
  - Common position on low-dose effects; and
  - Pollinators.

- **Setting US default MRLs at the limit of quantification** would facilitate the import of products with very low residues of substances that are not registered in the US. This would avoid requests for import tolerances for residues that may be present at traces but below the level of quantification.

- The **harmonisation of MRLs for the same crop-plant protection product combination should be ensured**.

- The US **should follow its own 'NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities**' produced by the US Environmental Protection Agency contained in chapter five on important tolerance data requirements.

- The EU and US should intensify their **cooperation**, overcome existing barriers and send a strong signal to third countries, such as OECD member countries and other trading partners:
  - A **uniform approach to risk assessment** in the regulation of crop protection products would provide clarity and confidence for both operators and consumers in EU and US markets. Defining a common risk assessment approach would be one of the most valuable principles in creating a level playing field across the transatlantic economy;
  - **Harmonisation of MRL settings** will reduce costs through the entire food chain;
  - Further **protection of intellectual property and confidential business information** will foster a climate of innovation; and
  - Integrate a system for pre-approval and confidential scientific consultation and the recognition of a food safety standards of newly approved veterinary medicines by the other entity.

- The EU and US should create **greater harmonisation** to the **WTO SPS Agreement and Codex Alimentarius standards**. Similar to crops and pesticides, science-based risk assessments could be a beneficial area for a foundation of regulatory convergence.

- The EU should be encouraged to respect international **joint reviews** in which it engages with other trading partners.

- **The EU and the US should co-operate regarding**:
  - Regulatory processes for setting MRLs;
  - Timelines for the MRL setting process;
  - Data requirements;
  - The regulatory rationale and calculations to derive numeric values for the MRLs;
  - Crop grouping;
  - The residue definition for MRL enforcement;
  - Recognition of codex MRLs; and
  - Submission formats.

  As a first step, the EU and US should establish a specific working group responsible for overcoming any differences among these issues.

11. Public Procurement

Challenges

- **Schemes that encourage public procurement entities to buy locally** (such as Buy America) distort trade and investment, increase the cost of goods to public agencies and limit competition.

- Trade defence instruments designed to force reciprocal liberalisation of public procurement markets can be useful but could have unintended negative effects if not designed properly.

- Although there are merits to equipping the EU with new instruments to promote free trade and open public markets, there are **concerns in some aspects of the European Commission's proposal for a European public procurement reciprocity instrument**. The automatic exclusion of US bidders in sectors where the EU has taken reservations in international agreements is particularly worrying. According to this proposal, US companies would be a priori excluded from some public EU tenders in strategic sectors like water, airports and urban transport, and this exclusion would be decided automatically, without a verification of the existence of a lack of reciprocity (while in cases where countries which have not negotiated an agreement with the EU are at stake, a full enquiry would be conducted). This process would amount to a clear discrimination against countries like the US that have negotiated public procurement agreements with the EU.

Recommendations

- The EU and the US should continue to work together on **opening public procurement markets** for all goods and services included the WTO Government Procurement Agreement (GPA) **at all levels**; including all US states.

- **Provisions like buy national schemes (i.e. Buy America) should not apply between the EU and US**. The expenditure of central government funds or credits by sub-central entities should not be conditioned on the purchase of local goods or services.

- If properly drafted and implemented, TTIP could deepen competitiveness, provide access to each other's markets and eventually enhance procurement markets globally.

- Work in this area should not **side step the WTO Government Procurement Agreement (GPA)**, but instead reinforce and support expanding the application of the GPA to more countries.

- The objective should be to ensure that the EU and US have access to public procurement contracts in other countries, and lead to an overall improvement of procurement markets globally and to help prevent the isolation of EU or US domestic markets.

- At a time when the EU and US should be cooperating to resolve issues, the measure proposed by the EU in its public procurement reciprocity would be a step backward. TTIP should address and resolve such issues.

12. Intellectual Property

Intellectual property rights are a critical protection for the technological and creative innovation that underpins the competitiveness of the EU and US economies today and tomorrow. There is concern that the global framework of protection and enforcement of the IPRs is being undermined. TTIP is an important opportunity to unequivocally reaffirm both sides' commitment to the highest standards of IPR protection and reject any calls for a lowering of international IP protection standards.

Challenges

- Combatting **trade in counterfeit and pirated goods**: Illegal online activities are harming consumers who buy counterfeit products, legitimate content providers, trademark owners and good manufacturers, and are also undermining trust in e-commerce and the Internet as enablers for progress and economic growth.

- Preventing **attempts by third countries to weaken IP protection** in their own respective countries and in the multilateral forums. A number of major emerging economies will continue to erode EU and US competitiveness by failing to effectively enforce IP rights in their countries, or in some cases, not doing so in order to build national champions and advance an IP theft-based industrial policy.

- Addressing **increasing requests for compulsory technology transfers licensing and/or disclosure of trade secrets** as a condition of market access, especially in the field of healthcare and green technologies (see also chapter 21).

- Preventing **theft of valuable knowledge and information** (trade secrets): Knowledge and information has become increasingly valuable and also increasingly targeted for theft by domestic competitors and, in some cases, foreign entities and governments.

- Adapting the **discrepancies of the patentability provisions in the EU and US** that induce significant financial costs.

- Addressing **inefficiencies in the EU patent system**: Building on the European patent system to foster quick adoption of an EU-wide patent enforcement system, reducing the need for 28 separate litigation actions.

- The current and **proposed policies of the European Medicines Agency (EMA) regarding marketing application data disclosure** can jeopardise the privacy of patients, integrity of regulatory systems and incentives to invest in research in the biopharmaceutical sector that could benefit patients. Failing to protect confidential commercial information contained in regulatory submissions is inconsistent with the EU's treaty obligations contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Recommendations

Several key issues should be tackled to strengthen the intellectual property (IP) framework both in Europe and in the US, which in turn would strengthen the protection of IP rights globally. We would propose the following solutions to meet these challenges:

- **Develop a shared strategy at the international level on the IPR enforcement**: The right to use the delivery of a shared strategy should promote the strengthening of local cooperation between the EU and US diplomatic services in third countries.

- Consideration should also be given to enhancing **IP protection for industries that invest heavily in R&D or are heavily reliant on brand equity** and are critical to the future competitiveness of the EU and US.

- **Commitments** to achieve these shared objectives could include:
  - An agreement between the EU and US **to cooperate, where appropriate, in addressing third country violations of TRIPS**. The EU and US should jointly support a lifting of the moratorium on 'non-violation, nullification and impairment' cases under TRIPS. A lifting of the moratorium is timely given efforts by some WTO members to adopt policies that effectively deprive other members of the benefits due to them under TRIPS.
  - A commitment to **preserve the high IPR norms reflected in EU and US bilateral, regional and international agreements**. A commitment to **greater EU-US alignment in the context of multilateral dialogues and negotiations on IPRs. Both governments should strive to more closely coordinate their approaches to IP-related matters.** As a step towards achieving this objective, the parties should seek to ensure that trade and IPR experts in both countries are consulted on all TRIPS-related matters and that bilaterally coordinated approaches are developed where possible. This would ensure that commitments taken elsewhere do not undermine important IP norms in the EU and US systems, including the commitments set forth in TRIPS.

- **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**. Both the EU and the US are developing new tools to combat illicit trade of counterfeit products online. These tools should be compatible and accessible for trademark owners and operators across the EU and the US. Such efforts should be aligned with shared transatlantic principles on online freedom of expression.

- **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. As knowledge and information become increasingly valuable and increasingly targeted for theft by domestic competitors and, in some cases, foreign entities and even governments, mechanisms to protect trade secrets become essential. TTIP should include strong protections for trade secrets, which should be done through expressly recognising trade secrets as intellectual property, in line with TRIPS articles 1.2 and 39. Governments could also consider ways they could work together to promote adequate and effective trade secret protections in third countries. This could be achieved through the inclusion of robust trade secret protections in bilateral and multilateral instruments pursued by each government, for example. These instruments should also require that remedies be available for theft of trade secrets even where actions in furtherance of that theft occur abroad

- **Protect confidential commercial information and ensure that practices that undermine intellectual property are appropriately addressed.** For instance, there is concern that the current and proposed policies of the European Medicines Agency (EMA) regarding marketing application data disclosure jeopardise the privacy of patients, integrity of regulatory systems,

and incentives to invest in research in the biopharmaceutical sector that benefits patients. Failing to protect confidential commercial information contained in regulatory submissions is inconsistent with the EU's treaty obligations contained in TRIPS. The US should raise trade-related concerns with these EMA policies in the context of the TTIP discussions, and the EU to remedy these policies expeditiously in order to support public health, patient privacy, preserve the integrity of regulatory systems and respect intellectual property rights, including confidential commercial information.

- **Patents**
  - Facilitate quick adoption of an EU-**wide patent enforcement system** obviating the need for 28 separate litigation actions. In this context, a mechanism to provide increased predictability in patent enforcement for pharmaceuticals, enabling patent challenges to be resolved before potentially infringing products reach the market, should be adopted as a priority.
  - A commitment to cooperate on **improving the efficiency and effectiveness of the patent system at the global level** is essential. Commitments could include, for example, restrictions on the granting of permanent injunctions in cases where the relevant party's courts are still considering the validity of the underlying patent.
  - Post-patent scenarios for genetically-modified events in plant products should be clarified during TTIP negotiations to avoid trade disruption and ensure that competition and innovation in **the biotech seed industry** are facilitated.

- **Data exclusivity** for pharmaceuticals: authorities should seek to 'level up' regulatory data protection to the higher standard currently available in either regime (in healthcare, 8+2+1 years for small molecules; 12 years for biologics). The regulatory data protection period following reclassification of a medicinal product from a prescription to non-prescription status should likewise be levelled up (to 3 years).

- **Ensure that measures are balanced, efficient and proportionate with an evidence-based approach to avoid diminishing the value of IPRs.** As a matter of principle and to establish a benchmark for future free trade agreements with other countries, the EU and US should agree not to impose limitations, other than those necessary to protect public health, on the use of trademarks.

- **Expand the geographical indications list to include products that are of significant value or that are commonly exported:** We recognise that the EU and US take different approaches to protect geographical indications (GI, or 'distinctive products' in the United States). The primary internationally traded spirits of greatest economic interest to the EU and US are already mutually protected (e.g. Scotch whisky, Irish whiskey, cognac and bourbon), but some leading categories are not specifically protected (e.g. Irish cream, Swedish vodka, Polish vodka). We would suggest that the parties consider expanding the list of protected GIs, but caution that any expansion should prioritise those products that are of significant value or that are commonly exported.

- **Develop greater customs harmonisation through the creation of an integrated EU customs rapid alert and information exchange system:** This would facilitate further transatlantic intelligence sharing and the risk analysis. Adequate resources should be made available to customs to allow them to carry out their role effectively and bear down on the

trade in counterfeit goods. Increased cooperation between the EU and US in collaboration with all actors in the custom system is also necessary.

- **To ensure continuous discussions on these key issues as they evolve, from an institutional point of view in Europe we would propose to:**
  - **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. For example, this coordination would be enhanced through the emergence of an EU counterpart to the US Intellectual Property Enforcement Coordinator.
  - **Create an IP working group within the European Parliament:** A structural change as above at the Commission should be complemented in the Parliament through the creation of an IP caucus that could engage its longstanding counterpart in the US Congress.

13. Trade and Sustainable Development

a. Environmental issues

Challenges

- Industries in the EU and US realise there is a comparative advantage in reducing energy consumption and resource use. This agenda cannot be driven to the fullest, and across transatlantic supply chains, because of **non-trade barriers and divergent definitions** of what is 'green production', 'green public procurement', or of what is 'sustainable' as in the case of biomass.

Recommendations

- **Increased regulatory cooperation** on defining the key elements of a sustainable economy, and making sure that what is sustainable is mutually recognisable in Europe and in the US would allow companies to drive the energy and resource efficiency agenda by taking full advantage of economies of scale at the dimension of the transatlantic market.

- EU and US trade negotiators need to continue take the lead on **eliminating world tariffs and non-tariffs barriers** that affect trade in energy and resource efficient technologies. They need to lead by example and eliminate these barriers.

- To promote resource efficiency and sustainable development, the EU and US should adopt common language to treat **remanufactured goods** like new goods. They should also address market access barriers that can arise when third countries apply used goods importation measures to remanufactured goods or classify remanufactured goods as used goods for customs purposes.

- Greater **collaboration** between the EU and US **in international organisations** such as ICAO, the IMO and of course the UNFCC would of course help drive the sustainability agenda. However, we believe that this 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.

- The **environment chapter** should:
  - Promote standards based on industry best practice that allows market access and considers the growing economy while ensuring minimal impact on the environment;
  - Identify key areas of cooperation and alignment that will result in an approach that balances consumer needs with business capabilities;
  - Promote a universally agreed definition of sustainability measures for products. This would form the basis for incentives (tariff relief) to accelerate their development; and
  - Promote sustainability information to be available to designers at the time when they make product decisions.

b. Labour issues

Challenges

- A positive working environment allows workers to thrive, enhances competitiveness, productivity and prevents additional economic costs for employers and society. Progressive companies in the EU and US have therefore developed workforce policies that support their employees in their work and lives, including innovative practices in workforce diversity, employee well-being and leadership development. The legislator plays a role in setting complementary standards in certain areas.

- Both the EU and US have comprehensive legislation covering a wide range of policy areas such as gender equality, health and safety at work, work-life balance, non-discrimination, consultation and rights of workers to ensure that minimum working conditions are met.

Recommendations

- Encourage the EU and US to focus their efforts on ensuring the effective implementation of current legislation on working conditions at their respective level.

- A balanced approach based on existing legislation and **sharing good practice** is an effective way to improve quality of work for the employees and competitiveness for the employers of the EU and US.

- The EU and US need to facilitate better links between business and **education**, improve access to and harmonise key features of the labour markets, promote higher education and training in key enabling technologies and boost overall skills training and re-skilling.

- TTIP should improve the **movement of people** by facilitating work visas, by improving entry provisions and by extending the Global Entry Program. Focus should also be put on intra-company transferees, long-stay visas, 'visa waivers' and work permits for spouses. In addition, the agreement should enhance the mutual recognition of professional qualifications.

14. Competition Policy

Challenges

- **State-owned enterprises** (SOE) can be manipulated to serve as agents for practices that would be disciplined if undertaken directly by the governments that control them. This can be manifested as behaviour that is undertaken otherwise than in accordance with commercial considerations.

Recommendations

The EU and US should continue to advocate for sound competition policy and its enforcement across the global antitrust community, in particular with respect to the following three key principles:

- **Enforcement of antitrust laws must be based on a sound analytical framework and on determinations of what is best for consumers**. These need to be firmly grounded in economic principles and objective criteria that take dynamic efficiencies into account and that foster competitive markets, innovation and investment. A sound and objective analytical framework is critical in preventing the use of antitrust laws to promote protectionist or other policies that undermine well-functioning competitive markets.

- **Procedural fairness must be firmly ingrained in competition law enforcement systems. This requires a process that is fair, predictable and transparent**. In particular, systems should include effective internal review to ensure early identification and closure of cases that are not well-founded in fact, law or economics. This will also reduce the likelihood of enforcement action that legislates on the 'fringes', which may create considerable legal uncertainty for activities not on the fringes. The EU and US should have the confidence to publish decisions not to pursue investigations, where the authority has concluded that a practice does not violate the competition rules.

- **Local enforcement actions must take into account global antitrust developments and respect international comity norms, so that decisions do not have extraterritorial impact beyond the jurisdiction of the agency**. Where there are multiple investigations, remedies imposed in one jurisdiction should not affect the ability of other agencies to address concerns in their own jurisdictions. In addition, divergent approaches affect legal and commercial certainty; companies operating in a global economy need to know conduct that is deemed legitimate in one jurisdiction will not be struck down as anticompetitive in another, in the absence of evidence of that conduct having a direct, substantial and reasonably foreseeable anticompetitive impact on consumers in the latter jurisdiction.

- The competition chapter of TTIP should include disciplines on the use of SOEs to accomplish conduct not in accordance with normal commercial considerations policies that would not be permitted if undertaken directly by the governments that control them. These disciplines should build upon those contained in recent trade agreements such as KORUS and should include specific requirements that SOEs' conduct business in accordance with anticorruption laws and to adopt industry-standard policies and processes to prevent illicit behaviour. SOEs that engage in illicit behaviour should be obligated to pay damages directly to private-sector entities of the other party that are injured by that behaviour

15. Trade-related Aspects of Raw Materials and Energy

Challenges

US liquefied natural gas (LNG) exports

- Estimates of US natural gas resources have grown rapidly in recent years, primarily due to technology unlocking shale gas deposits once considered inaccessible or uneconomic to exploit. LNG exports from the US would give Europe the opportunity to further diversify its natural gas supplies. **Arbitrary restrictions on natural gas exports** undermine US efforts to promote free trade globally.

Fuels Quality Directive (FQD)

- **The assignment of a higher GHG value for oil sands-derived crude and fuels that are derived from oil sands crude (as proposed by the European Commission) constitutes a trade barrier** against US fuel imports and would have a significant impact on the competitiveness of the EU refining industry.

Raw materials

- For raw materials used in goods that would qualify for duty-free treatment in conjunction with an airworthiness certificate, the average EU import tariff is between 3 and 5%. Furthermore, complex rules in the aviation sector do not allow an airworthiness certificate to be issued for raw materials used in the manufacture of aircraft or aircraft parts and components.

Emissions

- The EU and US maintain highly complex and far-reaching regulatory regimes for emissions of conventional pollutants such as nitrogen oxides, sulphur dioxide, carbon monoxide and particulate matter. **At the national level in the US, and at the regional level in the EU, these regimes are generally in alignment but also show divergences**.

Recommendations

US liquefied natural gas (LNG) exports

- The freedom to import and export products benefits partners on both sides of a trading relationship, expanding wealth and raising standards of living. The **EU should insist** with the US that:
  - The free trade of oil and natural gas, is no different than the thousands of other products that are produced in the US and exported globally on a daily basis; and
  - That the US Department of Energy should expeditiously evaluate and act upon pending LNG export applications within the bounds of current law and public interest requirements.

Fuels Quality Directive (FQD)

- The Fuels Quality Directive proposal will not contribute to reducing global GHG emissions; the differentiated feedstock will not stay in the ground and will be reallocated to other (non-EU) markets.

- The FQD will require the creation of a chain of custody to track back the feedstock of origin of any fuel sold in the EU market. The reporting will be inaccurate and practically impossible to verify, opening the door to misrepresentation and fraud. It will create a disproportionate administrative burden – in terms of complexity - for Member States and for fuel suppliers.

- The trade relationships with important trading partners, notably the US and Canada, will be strained, since the differentiation in crude feedstock imposed by the EU may be considered arbitrary and legally challengeable. It may also lead to retaliatory measures against EU industry.

- A **single EU GHG default value for crude refined** in the EU should be supported.

Raw materials

- The **elimination of tariffs** on raw materials used in the manufacture of aircraft, or aircraft parts and components, would reduce the administrative burden for economic operators in the aviation manufacturing sector since it would reduce the need to use complicated customs regimes, such as inward processing relief, bonded warehouses. Furthermore, it would enable small and medium-sized enterprises, which have so far been unable to use the special customs regimes mentioned above, to become more competitive.

- **TTIP should address questions of access to raw materials**. It should include provisions to prohibit export duties and taxes as well as any other export restrictions on raw materials including rare earths and conflict minerals. Both sides should agree to enhance their cooperation to achieve sustainable supply of raw materials (including conflict minerals) and remove existing trade barriers in raw materials. They should also continue their cooperation in bodies such as the WTO and the OECD.

Emissions

- We recommend a regular **high-level dialogue between the relevant EU and US authorities to review the full range of defined and upcoming emissions requirements** and to explore whether such requirements can be rationalised in a way that further enhances transatlantic alignment and harmonisation without compromising the environment.

16. Customs and Trade Facilitation

Challenges

- **Transatlantic customs modernisation** will be a critical element of the TTIP's success in a number of ways. Customs control the flow of goods traded across borders, and in many cases it is these controls that determine whether or not companies, particularly small and medium-sized companies, engage in trade beyond their national borders in the first place. Furthermore, the fast evolving world of e-commerce puts the framework of international trade to the test every day of the year, making speedy and efficient customs procedures more important than ever.

- A critical point for TTIP negotiators to consider is that **inefficient customs procedures** could easily diminish the positive impact of progress made in tariff and non-tariff barrier aspects of the TTIP on the transatlantic economy.

Recommendations

- Customs and border security administrations in the EU and US should accelerate their **collaborative efforts** on improving the terms of **mutual recognition** of the EU Authorised Economic Operator programme and the US Customs and Trade Partnership Against Terrorism (AEO-C-TPAT), and **aligning** air cargo security programs such as US ACAS and EU PRECISE, to ensure that transatlantic customs continue to set the highest standards for the efficient and secure movement of goods.

- Following the successful conclusion of the Trade Facilitation Agreement at the World Trade Organization in December 2013, a **transatlantic standard for customs modernisation** that goes above and beyond these new multilateral commitments should be developed. This can be achieved by:
  - Identifying a common set of import and export data elements for customs and security purposes, and establishing a 'single window' through which importers and related parties can electronically submit all information to comply with customs and other government agency data requirements;
  - Raising and harmonising the 'de minimis' threshold for low value shipments; and
  - Harmonising processes for customs clearance with a goal of the immediate release of goods upon arrival.

- **TTIP should include a mechanism that promotes the mutual recognition of Binding Tariff Information (BTI)** to receive and solve BTI conflicts or any other differing interpretation of HS classification under certain conditions. This mechanism can actively work along with the World Customs Organisation. We consider that the different HS Nomenclature (8-10 digits) and BTI procedures currently in place might lead to different HS classification **for the same products.**

- Combined with the successful completion of cooperation on AEO/C-TPAT and ACAS/PRECISE, these efforts will help to cement a modern and robust customs framework to allow goods to move safely and seamlessly between the U.S. and EU.

- The EU principle of **Suppliers Declaration of Conformity should be recognised by US authorities.**

Development of a 'Single Window' for Transatlantic Customs

- The EU and US should work together to develop truly **modernised customs** processes on both sides of the Atlantic. It is of critical importance:
  - To companies exporting to the EU that a centralised clearance or a 'single window' for customs declarations is implemented;
  - That the EU and its Member States meet their commitment to implement a viable centralised clearance or procedure as set out in the Union Customs Code, without amendments before implementation and within a reasonable timeline; and
  - That economic operators are able to deal with one customs administration where they are established for the 28 Member States, collect statistical data for the 28 Member States, conduct risk analysis for national prohibitions and restrictions of the 28 Member States, and pay of customs duties and VAT for the 28 Member States, all in one EU Member State.

- If customs **clearance** for imports destined for all 28 Member States could be performed in one Member State, the savings to business would be vast. For a company operating in several Member States, it would provide the opportunity to:
  - Reduce the IT systems needed to complete customs clearance from multiple to one;
  - Reduce the need for staff to speak several official languages of the EU to speak the language of the single Member State in which customs clearance would take place;
  - Release goods from customs at the first point of arrival in the EU, allowing for direct distribution of goods in free circulation to customers and optimise the supply chain; and
  - Use a single facility in the EU and centralise the customs intelligence, instead of multiple facilities.

Harmonised US Customs Clearance

- The creation of an **interagency task force** in the US could build on the Department of Homeland Security's efforts to align and facilitate import certification, and develop secure channels to ensure efficient regulatory certification processing for imports from the EU and elsewhere.

Raising the De Minimis Threshold for Customs Duties

- Trade facilitation can also be achieved by raising and harmonising the **de minimis threshold** for customs duties and other taxes between the US and the EU. Substantially raising the de minimis threshold will liberate small and medium sized enterprises from costly and administratively burdensome processes, increasing their capability to trade across the Atlantic.

Provisions for Immediate Release

- The EU and US should **work together to promote a better understanding** of the unique customs and trade facilitation needs of express delivery services sector.

- We encourage the inclusion of provisions for electronic release based on advanced data for goods prior to arrival. In addition, EU and US leaders should build on existing **World Customs Organization guidelines for the immediate release** of consignments for which customs information has already been provided, and adopt a common position to facilitate the movement of such goods between the EU and US.

Improving the Terms of Border Harmonisation

- A commercially meaningful **mutual recognition programme for trusted traders** needs to be established to achieve common approach on air cargo security regimes and the security of the international operations of air cargo carriers shipping to the EU or US from third countries:
  - **Trusted trader programmes**: TTIP should establish a single online application process that would be recognised by both the EU and US, harmonising the information required. AEO and C-TPAT status holders should benefit from zero or minimal requirement for the submission of data for risk analysis for security purposes. In addition, holders of AEO and C-TPAT status should be allowed to use their procedures to the benefit of their SME customers, and should benefit from a progressive incentive scheme for long-term adherents;
  - **Advanced air cargo information for security risk assessment**: As both the EU and US are expecting to develop regulatory requirements on advanced air cargo information, a common EU-US approach should be developed; the US Air Cargo Advance Screening (ACAS) programme could serve as the most appropriate basis for such cooperation.
  - Data elements required for the ACAS programme in the US, such as shipper name and address, consignee name and address, description, piece count, weight and country of origin, should be the basis for the harmonisation of their requirements for advanced data for security purposes.

VAT Border Tax

- **Pan-EU VAT** protocols should be agreed.

Authorised Exporter

- In order to confer preferential treatment, the origin of the goods must be proven by importers. In that sense, **the status of authorised exporter should be regulated in TTIP** in order to make origin declarations in commercial documentation, such as packing lists, commercial invoices, pro-forma invoices, delivery notes, purchase orders and transport documentation.

Establishment of a Customs Valuation Committee

- TTIP should **designate a special customs valuation committee on both sides of the Atlantic to address technical discrepancies with regard to customs valuation issues**. Importers and exporters should have the possibility to directly or indirectly communicate customs valuation issues that are affecting customs clearance.

Inclusion of Free Trade Zones

- **Customs operations and commercial transactions through free trade zones should not be excluded from TTIP**. Free trade zones give the possibility to reduce costs in the supply chain and promote the development of key industries with trading partners.

Permitting the Drawback Procedure

- Following the model of the EU–South Korea FTA, **the drawback procedure (refund of duties) should be permitted in TTIP**. There should be a possibility for the refund of import duties on intermediate products processed under and outward-inward processing procedures that do not enjoy a tariff reduction or elimination.

17. Small and Medium Sized Enterprises (SMEs)

Challenges

- A basic point about any trade agreement, either bilateral or multilateral, is that while larger corporations can generally live with the inconvenience (and cost, not just to themselves, but cumulatively to the global economy) of compliance with conflicting national rules, and can do business globally, smaller companies cannot devote the resources to solving these difficulties, and will simply refrain from exporting. This is a missed opportunity: SMEs employ by far the largest proportion of the workforce in almost all economies of the Western world. The Internet makes it possible for small companies to overcome many of the logistical difficulties (establishing commercial presence in markets etc.) that in the past would have made it impossible for them to have a global reach. Regulators must therefore ensure their rules do not become the main obstacle to the global economy. **Simplified trade rules would deliver efficiencies and consumer choice through greater SME participation**.

- Furthermore, **SMEs play a critical role in creating innovative new medicines and other related life science technologies** (e.g. diagnostics and instruments), as larger biopharmaceutical companies are increasingly relying on external R&D, mostly performed by SMEs. These externally-initiated programmes now represent as much as 30% to 50% of the research and development pipeline for major companies. Investment in biopharmaceutical SMEs is seen as especially high risk due to the long and expensive research & development, and approval procedures.

- The Internet allows small businesses to overcome obstacles that previously stood between them and their customers around the world. The similarities in consumer taste and expectations between the EU and US, as well as the widespread knowledge of the English language in Europe, make the EU and US natural markets for SMEs in each territory. Certainty that the goods and services which SMEs could offer across the Atlantic do not run up against regulatory problems or turn out to be in breach of rules they may not be aware of would allow these companies to dramatically increase the volumes they trade. Issues to do with intellectual property rights, sanitary and phytosanitary measures, **differing product safety rules and other standards, as well, of course, as trade facilitation/customs procedures, are obvious examples of where action could significantly increase SMEs' ability to trade.**

Recommendations

- A business friendly **environment must be friendly to both large companies and SMEs**. Multinationals depend on SMEs as suppliers, or as service providers, and both grow and produce wealth together. **SMEs, just as any other business, need an environment in which**:
  - There is as little administrative burden as possible;
  - The cost of doing business is reasonable;
  - Creating a new businesses is facilitated; and
  - There is increased flexibility in the labour market.

18. Information Technology – Digital Economy

Challenges

- There is a **growing trend to install a patchwork approach to the digital economy**. One specific example is the blocking of data flows by forcing localisation of data centres and other prescriptive regulations. This would unnecessarily increase costs for businesses, either large or small, and harms competitiveness. As the group of services enabled by ICT extends far beyond computers, related services and telecommunication services, this will have a significant and wide impact on the broader economy. While governments might make cross-border services market access commitments in trade agreements, those commitments would be undermined and would provide no benefit to multinational service providers if data flows from legitimate commerce is blocked or severely restricted.

- There are various **other emerging challenges** that the digital economy is faced with such as forced technology transfers and other forced localisation requirements.

Recommendations

- TTIP should include language **enabling cross-border data flows and oppose forced data localisation requirements** to enable future mutual trade and investment. Governments should **not restrict the ability of suppliers to supply services over the Internet on a cross-border basis**.

- TTIP should include specific language supporting the development and use of **international standards**.

- The prospect of a TTIP presents an important **opportunity for the world's two leading services economies to establish a model agreement and rules to enable the global digital economy**, ensuring the ability of their legitimate service providers and multinational businesses to move data around the world so that they can manage their businesses and service their customers most efficiently. This model language should clearly prohibit the adoption or continuation of requirements for local data storage, the use of local servers or other local sourcing or local content restrictions that similarly restrict cross-border data flows and limit the growth of digital trade and electronic commerce.

- The EU and US should **follow through on their pledge to implement the EU-US Trade Principles for ICT Services** and should also seek to incorporate the OECD Internet Policy Principles in any agreements that they negotiate with each other or with other parties. Together, the EU and US can set a positive example for how to enable strong growth and job creation in the digital economy. The **EU-US Trade Principles for Information and Communication Technology Services, released on 2 April 2011, should form the basis of additional trade commitments**. These principles require that governments should not limit foreign direct investment or prevent service suppliers from other countries electronically transferring information internally or across borders, or require ICT service suppliers to use local infrastructure or establish a local presence in order to supply services.

- The EU and US should **support ambitious global tariff reduction agreements such as the Information Technology Agreement (ITA)** and agree to on remove any remaining tariffs.

- **TTIP should be a 21st century agreement and therefore provide coverage for evolving IT services**: Trade commitments must cover evolving IT services so that commitments do not become obsolete with advances in technology. Otherwise, trade agreements will become an impediment to innovation. A 'negative-list' approach would be a good way forward to achieve this goal, assuming liberal treatment for all services that are not specifically listed as an exception.

- The **avoidance of restrictions on cross-border data flows** is particularly important to digital trade and not only in the context of digital economy services as such but also as an underpinning for various other sectors that rely on such global data flows. Countries should permit cross-border data flows and external data management, storage and access (including the ability to use cloud-based technologies) both within a firm and in its operations with customers.

19. Emerging Challenges in International Trade

Challenges

- The US and the EU need to address global emerging challenges such as localisation requirements and forced technology transfers. Examples of global challenges include:
  - **Forced localisation requirements**. Governments are increasingly requiring the localisation of R&D, IP and/or manufacturing within their borders as a condition of market access or to qualify for trade distorting incentives. This is unrealistic given the complex global supply chain of multinational technology companies. TTIP should include a chapter with agreed language on avoiding such measures between the EU and US that can also be re-used in bilateral agreements with other trading partners and in other venues; and
  - **Regulations that require technology transfer**. The EU and US should also set global principles on preventing forced technology transfer through broad compulsory licensing, disclosure of sensitive information as a condition of market access, or otherwise.

Recommendations

- What the EU and US agree will almost inevitably **set a benchmark for** either bilateral **agreements with third countries** interested in maintaining their access to both markets and, in due course for what we hope will be a resumption of active multilateral negotiations in the WTO. It will therefore be important to **avoid as far as possible inserting major exceptions from the free trade principles underlying this agreement in the individual sectors covered by it**. Such provisions could provide an excuse for third countries with which further bilateral agreements are negotiated to seek similar carve-outs for themselves, to the detriment of EU and US.

- A comprehensive 21st century agreement should also find ways to leverage joint strengths. **Strong joint language within TTIP on how to address these challenges will send a strong signal** and could also be leveraged in future trade discussions with third parties.

- **Avoidance of product-specific restrictions:** No trade agreement prevents governments from regulating in the interest of the general public. In fact, governments can, and do, regularly implement strict measures to protect the environment or human, plant or animal health. Provided they are based on sound evidence, non-discriminatory and no more trade restrictive than necessary, such measures do not conflict with international trade agreements. Accordingly, we do not support any product-specific references under the application of GATT Article XX or any other provision of the TTIP or other existing or future trade agreements. Product-specific exemptions are unwarranted and unnecessary. Any product-specific exemption will invite arbitrary decision-making and will call into question the basic principles of democracy and rule of law. A priori blocking the recourse to the dispute settlement system for specific products denies them the normal due process and equality before the law accorded by current trade rules and principles that underpin existing legal and democratic systems. Product-specific exclusions undermine broad business and agriculture interests in a longstanding and respected system of trade rules, and raise larger issues of concern for those in business and agriculture who rely upon certainty and objectivity in global trade policy.

20. Corruption and Bribery

Challenges

- Lack of public awareness of the **costs of corruption to society and business.**

- **Corruption hampers our economies** by artificially increasing the cost of goods and services, distorting competition and deterring investment. Its effects can be felt through the entire supply chain, distorting markets and competition, increasing costs to firms, penalising smaller companies that cannot afford to compete on these terms and firms with high integrity that refuse to do so.

- A recent **EU study of corruption in EU Member States** concluded: 'In some Member States, shortcomings exist regarding the supervision of state-owned companies where legislation is unclear and politicisation impedes merit-based appointments and the pursuit of the public interest. Moreover, there are insufficient anti-corruption safeguards or mechanisms to prevent and sanction conflicts of interest. There is little transparency regarding the allocation of funds and, in some cases, purchase of services by these companies'.

Recommendations

- **Increase public awareness on the cost of corruption to society and business.**

- Develop and establish programmes for action to significantly reduce corruption and therefore boost the competitiveness of the EU and US economies.

- TTIP should **include a chapter calling for the elimination of corruption and bribery**. The wording could be as follows:
  - The Parties shall cooperate in seeking to eliminate bribery and corruption and to promote transparency in international trade. They are committed to seeking avenues in relevant international fora to address bribery, corruption, and transparency and to build on anti-corruption efforts in these fora.[2]

- Anti-corruption measures are a significant matter of compliance and corporate responsibility. **Business also calls on governments to devote increased resources to ensure appropriate measures are in place and that authorities respond effectively to violations.**

- TTIP should provide that SOEs must conduct business in accordance with anti-corruption laws and adopt industry-standard policies and processes to prevent illicit behaviour. SOEs that engage in illicit behaviour should be obligated to pay damages directly to private-sector entities of the other party that are injured by that behaviour.

[2] Article 22.5 on Anti-Corruption, Australia-United States Free Trade Agreement:https://www.dfat.gov.au/fta/ausfta/final-text/chapter_22.html