AmCham EU's reply to USTR's Request for Comments Concerning Proposed Transatlantic Trade and Investment Partnership

CONSULTATION RESPONSE

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1. Introduction

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. In tough economic circumstances, a comprehensive EU-US trade and economic agreement would provide a stable framework for trade facilitation and foster the creation of new jobs in both economies.

AmCham EU has been actively involved in providing input into the process that led to the announcement by the EU and US of the intention to negotiate a Transatlantic Trade and Investment Partnership (TTIP). We have provided input to both EU and US stakeholders. We look forward to continue this dialogue with all EU and US institutions.

AmCham EU's committees cover the following policy areas: Agro-Food, Competition, Consumer Affairs, Customs and Trade Facilitation, Digital Economy, Environment, Employment and Social Affairs, Financial Services and Company Law, Healthcare, Institutional Affairs, Intellectual Property, Security & Defence, Trade & External Affairs, Transport and Energy, Climate Change, EU Tax, Legal Affairs, Single Market and EU-US Relations.

2. General and product-specific negotiating objectives for the proposed agreement

AmCham EU very much welcomes the approach being taken by both the EU and US authorities towards this Partnership, and wishes to reinforce the point reflected by that title – that this is an agreement which is not a zero-sum game, but rather a joint effort to release the combined potential and vitality of the two markets to the benefit of citizens on both sides of the Atlantic. The discussion should therefore be approached not as a classic trade negotiation, but as a collaborative enterprise to seek regulatory convergence through identifying common approaches to the outcomes sought from regulations and standards

Non-tariff barriers; The parameters for negotiation of the TTIP rightly recognise that, given the relative complexity of regulatory convergence, this process will continue over a longer period. But, since non-tariff barriers make up a much greater proportion of the potential gains to be had from the TTIP, we would urge both sides to seek an agreement including both tariffs and substantial progress on regulatory convergence in as many areas as possible.

AmCham EU believes that the EU and the US proposed TTIP should adopt an ambitious approach to further integrate our economies, with the aim of boosting the transatlantic market and encouraging the creation of jobs and growth. We believe that the following horizontal priorities will work towards enabling this:

Regulatory Cooperation and Coherence: a focus on enhanced cooperation in EU and US regulations will create a more efficient regulatory environment and enable a consistent and certain operating environment for businesses. Implementation of key principles for regulatory cooperation applying to all sectors – as outlined in the EU-US 2002 Guidelines on Regulatory Cooperation and Transparency - should be an integral part of a comprehensive agreement, even if their application needs to be delivered through sector-specific mechanisms.

Concept of Broad Mutual Recognition: Whilst regulatory convergence is a long-term priority, in some areas, the concept of transatlantic mutual recognition of regulations and standards is a shorter-term goal to explore within these discussions. The EU and US share the common goal of ensuring citizens' health and safety, although different approaches are often taken to achieve this goal. We recognize that these differences are difficult to harmonise, as they often reflect fundamentally different cultural and legal approaches to public policy.

Common Impact Assessment procedures: Impact assessments of future regulations could benefit from a joint approach at EU-US level. The development of an impact assessment is an opportunity for stakeholders to join in a reflection on important policy questions and to promote shared analysis and thinking. The EU and US possess useful knowledge and experience across a diverse range of policies and sectors – this knowledge and expertise should be shared and tapped in the early stages of the regulatory process, within the impact assessment procedures.

A common impact assessment approach should identify potential barriers to trade and investment upfront. It should be inclusive and non-exclusive – the more stakeholders involved in the impact assessment process, the richer the process. Common principles should include an agreed standard for assessing trade vs. domestic economic impacts.

Common Risk Assessment procedures: A uniform approach to science-based risk assessment would provide clarity and confidence for both operators and consumers in EU and US markets. Different risk assessment procedures create barriers to entry in markets, cause confusion for consumers and by their nature, raise questions rather than provide answers to consumers looking for direction and guidance from "experts" in our regulatory regimes. Defining a common risk assessment approach would be one of the most valuable principles in creating a level playing field across the transatlantic economy.

We would recommend the establishment of a working group to define how common risk assessment procedures and tools could be developed to secure the appropriate high standards of safety and health.

A comprehensive process: A comprehensive process under the auspices of this agreement should not hinder or prevent dedicated, bespoke sector-specific processes from continuing or taking place in the future. A comprehensive agreement should not exclude (or otherwise discriminate against) sectors in either the market access provisions or the rules, including technical barriers to trade, investment and intellectual property rights.

AmCham EU does not underestimate the size of the task at hand, and therefore would endorse an approach where parallel discussions within other sector-specific forums continue to achieve maximum results in as short a timeframe as possible to deliver on the objective of jobs and growth. An EU-US agreement could provide for "roadmap" commitments on issues requiring longer-term negotiations and commitments.

EU-US bilateral economic, trade and regulatory dialogues: AmCham EU is supportive of the overall ambitions of the TEC process, and was encouraged by the statements made at the 2011 EU-US Summit and TEC meetings that underlined the need to develop an ambitious program for bilateral economic cooperation. In particular, we welcome the renewed momentum imprinted on the process, as well as the acknowledgment of the role that TEC can play as a cornerstone for transatlantic cooperation in the wider world.

Although the TEC has brought some positive results, these have not been numerous enough. Moving ahead, AmCham EU believes that that the TEC should serve as the political champion to ensure the necessary resources and political will to achieve a meaningful agreement. Its scope should be broadened to include all industry sectors, standardisation institutions and legislative branches. The TEC should not be allowed to become a forum for trade-offs or detailed negotiations. These changes would allow EU policy makers to work more closely with their Congressional counterparts, and result in a more coherent and representative consultative procedure.

Small and Medium Enterprises (SMEs): A basic point worth bringing out regarding negotiating any trade agreement, 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 opt out of 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 the first time for small companies to overcome many of the logistical difficulties (establishing commercial presence in markets etc.) which in the past would have rendered it impossible to create a global reach. This puts a new responsibility on regulators to ensure that their rules are not now the main obstacle to the global economy delivering efficiencies and consumer choice through greater SME participation which the simplification of those rules would help promote.

Furthermore, SMEs play a pivotal 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 pipeline for major companies. Investment in biopharmaceutical SMEs is seen as especially high risk due to the long and expensive development and approval procedures.

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
- Where creating a new businesses is facilitated
- Where there is increased flexibility in the labour market.

The Internet allows small businesses to overcome the difficulties they have faced in earlier decades in addressing customers across the world. The similarities in consumer taste and expectations between the US and EU, as well as wide knowledge of the English language in Europe, make the US and EU 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 actually are in breach of rules of which they may not be aware, could make a major difference to the volume of trade these companies could build up. Issues to do with IPR, SPS, differing product safety and other standards, as well, of course, as trade facilitation/customs procedures are obvious examples of where action could impact SMEs' ability to trade significantly.

3. Treatment of specific goods

a. Product-specific import or export interests or barriers

Residual tariffs on low-valued rum: 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 US and EU origin spirits are zero (with the exception of certain low-valued rums which are still subject to tariffs). We would request the elimination of residual tariffs on low-valued rum so that all tariffs on US and EU-origin spirits would be eliminated.

For chemicals, average EU import tariffs come to 4.6%, while US import tariffs are at approximately 2.8%, so average tariffs on both sides are between 3-4%. Elimination of these tariffs on goods, which mainly serve as input to the manufacturing process (see 3b), would lead to considerable cost savings.

As far as the tyre sector is concerned, tariffs are not very high (around 4% on both sides) but given the very high level trade flows, the sector would really make significant gains through tariff elimination.

For raw materials designated for use in the manufacture of any finished good that would qualify for duty free treatment in conjunction with an airworthiness certificate, average EU import tariff is between 3 – 5 % and the complex rules in the aviation sector don't allow for the issuance of an airworthiness certificate for raw materials used in the manufacture of aircraft or aircraft parts and components. The elimination of tariffs on raw materials used in the manufacture of aircraft or aircraft parts and components would alleviate the administrative burden for the economic operators in the aviation manufacturing sector since it would reduce the need to utilise complicated customs regimes such as inward processing relief, bonded warehouses, or by reason of their end-use to achieve the duty free treatment of these raw materials. Furthermore, it would enable small and medium-sized enterprises, which have hitherto been unable to use the special customs regimes mentioned above to become more competitive with larger enterprises operating in the aviation manufacturing sector.

b. Particular measures that should be addressed in the negotiations

Tariffs on components imported and re-exported to the US: High tariffs are applied to products made in the US and then exported to the EU, where they are used to create value added products – which are often re-exported to the US. This applies to manufactured goods and agricultural products, which support the EU industry's efforts for innovation, job creation and economic growth. Products which fall into this category could be identified and targeted for tariff reduction.

Duties paid on key inputs to the manufacturing process: Significant intracompany trade costs result from duties paid on key inputs to the manufacturing process in the EU and US e.g. in the chemicals industry. Full tariff liberalisation would lead to enhanced competitiveness and a greater ability to reinvest in manufacturing and R&D in the EU and US.

Pharmaceuticals: The TTIP should include a pharmaceuticals annex to address key barriers relating to government pharmaceutical pricing and reimbursement policy. The pharmaceutical annex included in the EU-Korea FTA is an appropriate basis with this regard.

The annex should include fundamental principles such as recognition of the value of pharmaceuticals in reducing other more costly medical expenditures and improving the lives of patients. It should also require policies that adequately recognise the value of and reward innovation. Such provisions should include, in particular, that price controls set by national governments should only apply to the extent that the medicinal products are purchased or reimbursed by the country concerned, and that reference prices for patented pharmaceuticals should only reference countries that are similar in terms of their socio-economic level, purchasing power, populations, disease burdens and health care systems. Prices should never be set by reference to prices in countries in economic crisis. The annex should also

address existing transparency concerns specific to pharmaceuticals such as ensuring that all criteria, rules and procedures that apply to the listing, pricing and reimbursement of products are transparent, fair, reasonable and non-discriminatory.

c. Approach to tariff negotiations

We recommend an elimination of tariffs covering all goods without exceptions and comprehensive tariff "elimination" in the broader context of comprehensive market access.

As indicated above, even though trade tariffs are in almost all cases already low between the US and EU they are important for specific sectors and are still a tangible nuisance to economic actors. Moreover, with the complex supply chains almost all global products and services involve, these tariffs simply act as an unnecessary cost to companies seeking to compete on equal terms with companies in emerging economies. AmCham EU urges negotiators on both sides to approach the removal of tariffs in a way which reflects companies' complex global value chains today, and to avoid the process becoming a classic tit-for-tat negotiation. Where full removal of tariffs proves impossible, both sides should look carefully at generous zero-tariff quotas as an alternative.

4. Customs - rules of origin

Rules of Origin have for a long time been a hindrance to companies seeking to optimise the quality and competitiveness of their products, and an area in which the agreement of robust common disciplines 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 a cost burden on businesses and therefore consumers. This can put EU and US corporations competing with emerging market suppliers at a major disadvantage causing them to lose market share to them. Therefore, it will be important to make the establishment of an agreed upon set of coherent rules of origin a priority in the negotiations. This can also serve as a useful precedent for progress on a multilateral basis.

AmCham supports simplified and rational rules of origin that are easy for customs administrations to verify. Overall, the agreed rules of origin should contribute towards trade facilitation between the EU and US.

Rules of origin and "accumulation"

The current standard language used in US and EU FTAs does 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. [NB: The language allows trans-shipment provided the goods remain under constant Customs control.] Businesses increasingly uses regional hubs to consolidate shipments of non-country specific bottles, where country-specific back labels and tax stamps (where required) are applied.

Further, 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 United States and European Union (e.g., Central America, Colombia, Korea, and Mexico) will qualify for the preferential treatment accorded by any of the FTA partners.

Recommendation: The rules of origin should allow qualifying goods to undergo these minor processes without losing their preferential treatment. The TTIP should also include rules of origin that allow for accumulation.

5. Sanitary and phytosanitary measures and technical barriers to trade

a. Sanitary and phytosanitary measures

Plant Protection Products

Concerns on classification: 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 This has been substantiated by the European Crop Protection Association (ECPA) and CropLife America (CLA) (see Annex 2.1.).

The consequences of regulating chemicals by hazard classification and how this could be modified without compromising human health is possible by using established, science-based assessment criteria already successfully used in other areas of toxicology. The classification system needs to be 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 which would not occur at lower, more realistic, doses in people. Substances which have this effect can be clearly distinguished from those which 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.

- 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 implementation of the classification system by ECHA happens through its Risk Assessment Committee (RAC). This committee comprises independent experts from Member States in addition to members of the ECHA secretariat. This is a relatively new committee which, at present, is still developing its experience and capabilities in making sound science-based decisions on classification. The use of the above-mentioned criteria would provide the committee with a more objective framework for making the key classification decisions on carcinogenicity, reproductive and developmental toxicity.

Concerns on Trade & MRLs:

Different scientific approaches between the EU and the US in the setting of Maximum Residue Levels (MRLs) on plant protection products frequently lead to different MRLs for the same crop-substance combination. This produces avoidable trade barriers. If a plant protection product is not registered on a crop in the US and is detected on imported EU commodities, (even if it is well below the EU requirements), it will result in the rejection of that commodity. Although the crop-plant protection product combination has not been reviewed in the US, a simple risk assessment would identify whether such low residue levels could pose a risk to US consumers. Alternatively the US could follow other regulatory authorities such as the EU and set default MRLs.

Setting default 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.

Harmonisation of MRLs for the same crop-plant protection product combination would avoid such trade barriers.

Products in particular that will be discriminated against are simple processed commodities such as wine, flour, juice, oil etc. where the EU requirements do 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. In such cases the actual residue level in the RAC will not be known by EU growers/exporters because it will be below any reporting level used in the EU.

Please note also that 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 V on Important Tolerance Data Requirements states (see annex 2.2.).

Regulatory Divergence:
Furthermore, ECPA and CLA recently submitted joint comments to the White House Office of Information and Regulatory Affairs in the Office of Management and Budget, in which they highlighted some regulatory divergences already jeopardising future prospects for the TTIP, including concerns over the precautionary principle for science-based risk assessment and the need for greater harmonization in the "processes for establishing MRLs for pesticide residue" (see annex 2.3.).

Endocrine Disruption:
Endocrine disruption (ED) is high on the European Commission's political agenda as a number of associated regulatory deadlines are approaching under REACH, the Plant Protection Products Regulation (PPPR), and the Biocidal Products Regulation (BPR). These regulations require the European Commission to develop criteria for identifying endocrine disrupting chemicals (EDCs).

DG Environment is currently finalising a proposal for identifying endocrine disruptors. It is understood that this will be submitted for inter-service consultation in May 2013. In addition, guidance will be needed to ensure efficient and consistent interpretation of the criteria, across relevant areas of existing EU legislation. The legal requirements for regulatory action have triggered debate at both scientific and political levels. It is encouraging to see that a consensus now emerging on a number of important elements, including hazard identification and characterisation of EDs, a process which is also referred to as "hazard assessment".

Emerging Consensus
In general, all parties involved (the European Commission (DG ENVI), the European Parliament (EP), the European Food Safety Authority (EFSA) and the Commission's Endocrine Disruption Expert Advisory Group) are asking for a systematic and transparent set of criteria that will, based on the weight of evidence, be able to clearly identify those substances that can produce adverse effects via an endocrine mode of action (endocrine disrupters or EDs) and which therefore could have a harmful impact on health and the environment. This will ensure legal certainty for both the consumer (safety of products) and the producer of the product.

There would appear to be general agreement that the WHO /IPCS definition of Endocrine Disruptors should provide a basis for ED criteria, including the existence of a link between the endocrine mode of action and its potential for causing adverse effects (e.g. to be observed in laboratory animal studies).The evaluation used to show whether a substance meets the elements of the WHO/IPCS definition is known as hazard assessment.

In the current debate, two important stages of such assessment have been identified and discussed:

1) *Hazard Identification*

Identification of EDs is a process which should start with the identification of an intrinsic hazardous potential of substances.
According to IPCS, it refers to the identification of the type and nature of adverse effects that an agent has an inherent capacity to cause in an organism, system, or (sub)population. Hazard identification is agreed to be the first stage in hazard assessment, which the EP, as well as EFSA and Joint Research Centre make reference to in their reports.

2) *Hazard Characterisation:*

A number of stakeholders (including EFSA, and some Member States) have indicated that in order to identify EDCs within the regulatory context, it is also necessary to establish the specificity, severity and (ir)reversibility of the associated intrinsic hazard. This part of the process is known as hazard characterisation. Hazard characterisation is the second stage in the process of hazard assessment. The European Parliament in its report is asking for the criteria to be based on a comprehensive hazard assessment. Hazard identification and hazard characterization jointly form the hazard assessment, which should trigger regulatory action.

According to IPCS, hazard characterization is "The qualitative and, wherever possible, quantitative description of the inherent property of an agent or situation having the potential to cause adverse effects. This should, where possible, include a dose–response assessment and its attendant uncertainties.

Building on this Emerging Consensus
The objective of the future ED regulatory framework is to properly manage the risks of harmful substances safely, that is, to ensure that people and the environment are not exposed to substances which could cause them harm. Industry therefore argues that hazard identification should necessarily be combined with hazard characterization to focus regulatory attention on substances with characteristics which could endanger human and environmental safety. Importantly, this approach is necessary to fully interpret and implement the WHO/IPCS definition as a basis for European regulation, and make appropriate use of the scientific data available.

In order to identify, characterize and regulate EDCs efficiently, industry believes that it is necessary to consider important toxicological characteristics, including reversibility, lead toxic effect, severity, and potency. As no single characteristic, in isolation, is sufficient to characterize an ED, it is necessary to consider the full weight of relevant and robust scientific evidence (weight of evidence approach) when determining whether or not a substance should be characterized and eventually regulated as an EDC under relevant legislation.

The final criteria should enable authorities and manufacturers to appropriately perform comprehensive hazard assessments (identification and characterisation) before substances are identified as endocrine disrupters. Like other stakeholders, industry strongly believes both elements, hazard identification and hazard characterisation, should be included in the final criteria for the identification of endocrine disrupters[1].

Agricultural biotechnology crops; regulatory reform & alignment:

Ever since the commercial introduction of the first genetically engineered, or biotech, commodity crops in 1996, biotech varieties have transformed global agriculture, helping farmers become internationally competitive while reducing costs and promoting important environmental and sustainability goals.

While the adoption of biotechnology is impeded by regulatory obstacles in the European Union (EU), other countries' governments are spurring a biotech revolution. Already, the governments of Brazil and Argentina are in the process of rationalising and streamlining their regulatory systems. And some experts now believe that as many as half or more of the new biotech varieties introduced in the next four years will be registered first in these two countries.

Because of the additional regulatory scrutiny associated with the introduction of biotech plants, dozens of scientific bodies ranging from the U.S. National Academy of Sciences to the European Commission's Directorate General for Research have categorically stated that the biotech varieties now on the market are at least as safe for humans, animals, and the environment as conventionally bred plants. Nonetheless, cultivation and import approvals are taking longer in the European Union 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 – whether they are large or small firms, public sector institutions, or non-profit organizations – do not have confidence that their applications will be reviewed and acted upon in a timely manner. If instead, developers are able to secure more rapid approvals in other countries such as US, Canada, Brazil and Argentina, and reach the market first in those countries; European farmers will be put at an increasingly large disadvantage compared with their international competitors.

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
As explained in a recent briefing paper by public-sector scientists and farmers organisations, EU GMO Policies, Sustainable Farming and Public Research: "Two evaluation reports commissioned by

[1] Position developed by The European Chemical Industry Council

the European Commission show widespread dissatisfaction with the way in which the EU regulatory system for GMOs is implemented. The procedures for field trials and product approvals of Directive 2001/18 and Regulation1829/2003 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 every year the equivalent of over 15 million ha of GM crops to feed its livestock sector, resulting in a distortion of competition."[2]

Costs of regulations
According to research by EuropaBio, a trade association representing several AmCham EU member companies: "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 which the applicant companies have to present to EFSA. The 42approvals (including for imports) having been granted under this regulatory framework by April 2013 represent total costs to companies of between €210 and 300 million. This does not include the costs for the 74 GM products which were in different stages of the approval system in April 2013.

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. For example, for dossiers submitted in 1998, EFSA was still asking new questions in 2011. With equally thorough requirements, yet swifter approvals in other parts of the world, and an increasing backlog in Europe, the result is an uneven playing field for companies. Some ideas to improve this situation are being discussed."[3]

[2] http://greenbiotech.eu/wp-content/uploads/2012/06/Farmers-scientists-briefing-paper-EU-GMO-policies-2012.pdf, p. 7
[3] http://www.europabio.org/sites/default/files/position/europabio_socioeconomics_may_2011.pdf, p. 18

b. Technical barriers to trade

Transatlantic rules need to ensure transparency that regulations germane to the agreement are necessary to accomplish a legitimate objective (including in public health) and that germane regulations do not raise impediments to trade. An agreement that encourages a risk based approach for regulations, based on principles of sound science, risk assessment and risk management, and transparency is paramount.

Avoidance of new Non-Tariff Barriers (NTBs), in areas such as Data Privacy, Security, Cloud Computing and Nanotechnology: new NTBs should be avoided. This can be achieved by building greater procedural awareness once new legislations are introduced. Nanotechnology could benefit from transatlantic cooperation to increase environmental and consumer protection, whilst avoiding trade distortions and benefitting from its innovative uses.

Recent developments investigating an environmental label based on product footprinting would also set a worrying precedent. We strongly recommend deep collaboration among US and EU authorities on this issue to avoid creating new NTBs.

Diverging Manufacturing Medicinal products: If the Food and Drug Administration and European Medicines Agency 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. Secondly, an agreement on importation procedures e.g. harmonisation of approaches to retesting would reduce administrative burden for companies. Finally, continued support for International Conference on Harmonisation agenda would reduce regulatory burden and time to market for new products.

Diverging Conformity and Technical Requirements regarding Pressure Equipment: The US system for managing safety of design and manufacturing of pressure equipment is regulated at a US State level, i.e. each State has regulations requiring compliance with ASME Boiler and Pressure Vessel Code of Construction. US State level regulations do not permit, nor recognize, any other international or non ASME pressure equipment codes of constructions or standards to be used for pressure equipment acceptance in the US. Conversely, the European Union's CE Marking Directive, 97/23/EC for Pressure Equipment (PED) is at a Commission level. Under the PED, manufacturers can use EU, international, or industry recognized standards (such as ASME) to design and manufacture to meet the PED criteria.

Biocidal products: Most of the biocidal products approved in the US are not compliant with the EU regulations, and vice-versa. This requires reformulation, additional efficacy testing, different toxicology tests, new supply chain, etc. This lack of harmonisation results in higher costs and longer lead times leading to fewer products available for commercial customers (that serve hospitals and restaurants) and consumers. The additional cost for large companies exceeds several millions € and prevents development of SMEs.

Industry would gain the ability to formulate with a global mindset, with a focus on the performance of our products and the environmental footprint rather than meeting the specific requirements in each geography. Overall this would lead to better and cheaper biocidal products.

6. Transatlantic regulatory compatibility

There is a need for transatlantic regulatory cooperation in most if not all the industrial sectors. More specifically, a common approach for EU-US regulations and standards is needed for sectors like healthcare equipment; energy technology; transportation; and pharmaceuticals.

But there are challenges in harmonising standards between the EU and the US. To illustrate, self-contained breathing devices sold in the US must meet the standards and tests established by the National Institute of Occupational Safety and Health, a US government agency. However, if the devices are used in the fire service, they must meet tests and standards established by the National Fire Protection Association, a user and industry organisation. These standards are recognised in the EU; however the EN standards applicable to a product in the EU are not recognised in the US. The same can be said for gas detection devices. They would not be marketable if they did not meet Underwriters Laboratory (UL) standards.

In addition to the challenges to facing transatlantic commerce outlined above, it is also important to bear in mind that the US has a more unified market while the European market is more fragmented. Unlike the US, a number of national and in some cases local regulations in Europe act as barriers to trade and prevent Europe from having a Single Market. These barriers occur when member states are allowed to interpret EU Directives to suit national interests. This occurs with environmental requirements, as well as other national rules which distort trade within the internal market.

If the EU used Regulations rather than Directives this would establish more consistency. Limiting use of the term "Minimum Requirements" will reduce additional national requirements on a Member State by Member State basis. Much more needs to be done to remove barriers between EU Member States, so that market access is more similar in the EU and the US.

Manufactured products must also obtain various national certifications to trade across Europe. These certificates are required for products whether 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 quality of test results. Therefore the CE mark is not viewed 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.

To improve the value of the CE mark, stricter implementation of the technical assessment of the national notified bodies is needed. Ideally what is needed is a single certification scheme for products that do not fall under a specific EU Directive or Regulation (i.e. security products).

Chemical sector: The EU and US should establish mutual recognition of compatible regulatory regimes for the risk management of chemicals. Creating a mechanism that allows regulatory agencies to recognize that they have functionally equivalent approaches would avoid affecting each region's existing regulatory framework while allowing for the production, sale and use of chemicals that are lawful in one continent to also be lawful in the other.

Secondly, the EU and US should agree on objectives and governing principles of chemical regulation. Such an agreement would help develop chemical assessment tools (hazard and exposure models and databases), as well as on a common template and equivalent or compatible IT systems to submit registration dossiers.

Thirdly, a mechanism which would allow physico chemistry, health, and environment data submitted under one regulatory regime can be acknowledged under the other without re-submitting. This would

avoid unnecessary animal testing and save costs for companies and public authorities and accelerate efforts to protect the consumer and the environment

Cosmetics: Different classification of cosmetics and their ingredients is a costly and unnecessary barrier to trade that has no health consequences. Mutual recognition of diverging classification (e.g. dentifrice, anti-dandruff, antiperspirant etc) and of EU positive list materials (e.g. UV filters) would decrease such complexity.

Likewise, diverging labelling provisions result in extra costs without health consequences. The US and EU should mutually recognise the labelling of ingredients in cosmetics and sunscreens. The US should fully adopt INCI Nomenclature and end its requirement to use the term 'water' rather than 'aqua.' This requirement is a costly and very unnecessary exercise given the total lack of a health risk from using this ingredient.

Animal testing is currently being phased out in various regulatory jurisdictions, such as the EU. 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 cosmetics products in the European Union.

Restricted Materials: The US should enact a federal law modelled after the EU RoHS legislation. It should restrict the same materials at the same levels. Associated with the law are a number of conditions defining the categories of equipment covered by the regulation. Federal legislation should use the EU directive as a model but involve industry groups to help make the final decision. After the law is implemented there should be an effort to allow reciprocity between the EU and US for RoHS. There is no recommendation to model the China RoHS regulation but it should be revisited after it is in force in China.

Recycling Electronic Waste: The US should enact a federal law modelled after the EU WEEE legislation. It should require recycling of the same categories of electrical and electronic waste including consumer products such as TV's and computers. Associated with the law is a number condition defining the categories of equipment covered by the regulation. Federal legislation should use the EU directive as a model but involve industry groups to help make the final decision. Recycling should be at the state level with reporting to the federal level. After the law is implemented there should be an effort to allow reciprocity between the EU and US for WEEE.

Pharmaceuticals: Despite efforts made to increasingly harmonise standards for the approval of medicinal products, there are still differences in requirements in some areas and there is a lack of alignment between the EU and US regulatory processes. Further cooperation on regulatory matters between the EU, the US and third markets could help movement toward a globally harmonised regulatory system. This cooperation could include for instance coordinated Good Manufacturing Practice (GMP) inspections in third countries.

Standards established by EU and US regulators (EMA and FDA) are a model to regulatory agencies across the globe – harmonised requirements between the EMA and FDA will pave the way for harmonisation of global standards.

The EMA and FDA should work to increase compatibility and eliminate unnecessary inefficiencies in the regulatory field, while maintaining their high standards of protection for patients.

Alignment of regulatory processes and procedures as well as the elimination of duplicative testing requirements are key. Harmonisation is of importance in the below areas:

- Regulatory assessment of innovation and new manufacturing technologies;
- Good manufacturing practice (GMP) requirements, including guidelines on dedicated production facilities for particular products, such as high-risk products;

- Providing mutual recognition of each other's Good Clinical Practices inspections
- Granting sponsors the right to receive parallel scientific advice upon request for all medicines; and
- Based on lessons from the pilot, 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.

A further critical issue, requiring attention is the concerns EMA's recent guidance and policies that non-clinical and clinical study reports submitted by an applicant to obtain marketing approval should, contrary to years of precedent protecting such data from disclosure, generally not be considered confidential commercial information, and thus may be publicly released if requested by a third party. Inappropriate disclosure, such as proactive, indiscriminate disclosure of companies' non-public data submitted in clinical and pre-clinical dossiers and patient-level data sets, risk undermining a number of important goals..

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 U.S. and the EU maintain uniform protection of patient privacy and confidential commercial information and trade secrets in their respective clinical trial and marketing application disclosure programs. Such protections are necessary to maintain incentives to invest in innovative medical research.

Beyond the above initiatives, there are a number of areas to increase EU-US regulatory collaboration under the auspices of the ICH (International Conference on Harmonisation). These include:

1) Greater compatibility in the scope, content and timing of submission of paediatric plans should be sought, so that companies are required to prepare only a single plan for submission in both territories.
2) There should be greater collaboration on pharmacovigilance issues (including post-market testing and risk management requirements), as well as revising existing guidance to reduce the requirements for duplicative local bridging requirements.
3) The structural framework and methodology for benefit-risk assessments and on approaches to post-approval variation submissions for manufacturing changes should be harmonised.
4) The EU and US should establish a collaborative process for developing scientific and other regulatory guidelines for specific therapeutic areas.

7. Reduce unnecessary costs and administrative delays stemming from regulatory differences

Regulatory Cooperation and Coherence: We would recommend EU and US regulators adopt a broader consultation process, including of affected industries, at the earliest stages. This will help to identify differences and potential opportunities to further cooperate to ensure minimum competitive impact before regulation is proposed and implemented. We believe 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 by standardisation bodies is key. We strongly endorse the establishment of a separate working group between CEN/CENELEC and ANSI – this 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, 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.

Broad Mutual Recognition Clause: Mutual recognition of long-standing standards and regulations that cover similar technologies, for example, would be beneficial for both the EU and the US. 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. Mutual recognition of 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. Products such as pressure equipment, machinery and electrical equipment are an example of areas where mutual recognition should be encouraged. Examples include:

- Secure Trade: beyond the rapid implementation of mutual recognition of secure trade systems, i.e. C-TPAT and AEO schemes, there is a need to move towards implementing global WCO (and aligned AEO) standards, leveraging global principles of securing trade and ensuring tangible benefits for the businesses.
- Healthcare equipment: Unique Identification numbers on Healthcare products; Standards Adoption - harmonization/convergence; mutual recognition of regulatory approval, and medical device software.

Impact of Potentially Explosive Atmospheres Directive (ATEX) on US Component and Apparatus Manufacturers: In addition to meeting US requirements of the National Electric Code (NFPA 70) and related standards, for US manufactures to comply with ATEX requirements, they need additional resources and third parties to conduct product evaluations, tests and documentation, resulting in a significant increase in product costs and cycle times for product development and delivery. Many component manufactures choose not to obtain ATEX compliance for these reasons. Since many component manufactures in the US choose not to obtain ATEX, this requires the end-product manufacture to determine solutions that tend to be more expensive and complex in order to obtain certification of the final product.

Potentially Explosive Atmospheres: We would propose a cooperative US-EU committee be put together to do a comprehensive review of the requirements between ATEX and the NEC/UL standards to specifically identify any technical differences and to evaluate their impact related to the level of product safety. This comprehensive study, comparing requirements between NFPA 70 and ATEX would specifically identify if a gap exists between the technical requirements. Based upon this the committee could then develop a mutual recognition agreement to accept NEC/UL components and end-products into the EU.

Restricted Materials: The US does not have a federal RoHS regulation and some states are stepping in to implement their own regulation. The will cause us to manage one big regulation for the EU and up to 50 others for the US. Also, it must be remembered that there are lists of applicable equipment and exempted equipment for each regulation that could be harmonized. China is implementing their own version of RoHS which may include testing in China and already has a marking requirement for selected equipment. There is no marking requirement as of yet for EU RoHS but the updated regulation will make certain equipment have a CE mark. RoHS also bans the placing on the EU market of new electrical and electronic equipment containing more than agreed levels of certain materials.

Recycling Electronic Waste: There is an existing regulation in the EU (2002/96/EC) which is being re-written at the present time (WEEE). The US has no federal regulation and some states are implementing their own. As with RoHS above there are lists of applicable equipment and exempted equipment for each regulation that could be harmonized. There is also a mark required for equipment which would need to be harmonized. China WEEE is getting started with a limited list of equipment.

Consumer Goods: Differences between chemicals management regulations, i.e., U.S. TSCA, EU REACH, as well as multiple state specific regulations create a barrier to business . Protection of the consumer and the environment, as well as speedy access to market is hampered by conflicting regulation.

Chemicals Industry: While levels of protection of the chemicals management systems in the EU and US are comparable, the regulatory systems differ fundamentally in practice. Since 1990 efforts have been undertaken to improve convergence of regulation but these have not been very successful. The TTIP should stimulate regulatory agencies to step up cooperation and, where possible, encourage convergence of regulatory approaches and the mutual recognition of regulatory data. Developing common risk and science-based principles in these areas would help minimise costs to governments and industry, promote better cooperation and resource efficiency for regulators and help guide future work.

a) REACH/TSCA: The EU and US have separate chemicals management systems – REACH and TSCA – but both are based on a risk-based approach and are focused on delivering high levels of health, human safety and environmental protection. They are differing systems that share a common value and objective.
b) Overall regulatory cooperation in chemicals management: Developing common principles for information sharing, for prioritising chemicals for review and evaluation, for protection of commercial and proprietary interests and, as well as for coherence in hazard and risk assessment, would dramatically improve the current transatlantic regulatory environment on chemical policy., i.e. based on the weight of scientific evidence to ensure appropriate allocation of risk management resources. Furthermore, a harmonised approach to data assessment would simplify the registration process, improve transparency and toolsets; 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.

Pharmaceuticals: the EU and the US should develop a roadmap for full Mutual Recognition between EMA/EC and FDA for good practices inspections including GMP, Clinical Practices, Laboratory Practice, Distribution Practices, Vigilance Practices; and an option for companies to ask for coordinated assessments of NDAs/MAAs where joint scientific advice has been sought and adhered to. This optional coordinated assessment could apply to the entire NDA/MAA or to particular aspects of the file, notably quality aspects. A working group between the EU and US should be established to continue harmonisation and the establishment of proportionate requirements as science evolves. It should also address regulatory barriers that may arise following the conclusion of the process.

8. Customs cooperation between the United States and the EU

AmCham EU strongly urges US and EU leaders to facilitate transatlantic trade, through the modernisation of customs processes, raising and harmonising the de minimis threshold for customs duties and other taxes, harmonising US and EU borders, and establishing provisions for electronic pre-clearance and immediate release of time-sensitive shipments. These objectives will go a long way towards facilitating trade for the US and EU which will benefit businesses of all sizes wishing to operate internationally.

Customs Modernisation

AmCham EU encourages the US and EU to work together to develop truly modernised customs processes on both sides of the Atlantic. Of critical importance to those exporting to the EU is the implementation of centralised clearance or a "Single Window" for customs declarations. The EU and its Member States must 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. Businesses should be able to centralise their accounting for the 27 Member States, collect statistical data for the 27 Member States, conduct risk analysis for national prohibitions and restrictions of the 27 Member States, and pay of customs duties for the 27 Member States, all in one EU Member State.

AmCham EU is concerned by the adoption of different computer systems by different national administrations. The use of nationally based clearance agents which have developed appropriate interfaces to the customs computers of the 27 Member States is an inefficient means of operation. As it currently stands, customs clearance of import goods into the EU takes place in the Member State to which the goods are destined. The result is that companies operating in more than one Member State have to use at least one separate IT system per Member State, and have to meet the national procedural and language requirements in each of the individual Member States in which they operate. In the US and our other major competitors, one system, one set of procedures and one language are common.

If customs clearance for the imports destined to all 27 Member States, could be performed in one single Member State the savings to business would be vast. For a company operating in all 27 Member States, it would provide the opportunity to:

- Reduce the IT systems needed to complete customs clearance from 27 to 1;
- reduce the need for staff to speak the 22 official languages of the EU to the need to only 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
- use a single facility in the Union, 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. Raising the de minimis threshold to $800 (or a Euro equivalent) will liberate small and medium sized enterprises in particular from costly and administratively burdensome processes, increasing their capacity to trade internationally.

Border Harmonisation

A commercially meaningful Mutual Recognition program for Trusted Traders, for achieving a common approach on air cargo security regimes, and on the security of the international operations of air cargo carriers bringing shipments into the U.S. or EU from third countries: needs to be established:

- Trusted Trader Programs: The TTIP should establish a single online application process, which would be recognised by both the U.S. and the EU, and would harmonise 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.

- Air Cargo Security: AmCham EU urges leaders to develop a common U.S.-. EU approach to air cargo security, and believes that the US Air Cargo Advance Screening (ACAS) program would serve as the most appropriate basis for such cooperation.
- Data elements required for the ACAS program in the US i.e. shipper name & address, consignee name & 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.

The Provisions for Express Delivery Services: The express delivery sector currently faces one of the most antiquated and administratively burdensome regulatory environments. Increasing competition in international trade and the e-commerce trend have pushed express delivery services to the fore of services which support global supply chains, and AmCham EU believes that the US and EU should work together to promote a better understanding of the unique customs and trade facilitation needs of this sector.

We encourage the inclusion of provisions for electronic pre-clearance based on advanced data for goods moving in either direction across the transatlantic border. In addition, US and EU leaders should build on existing World Customs Organization guidelines for the immediate release of consignments for which necessary customs information has already been provided, and adopt a common position to facilitate the movement of such goods between the U.S. and EU.

VAT Border Tax: Differing national laws mean that it is not possible to use the Corporate Import Entity to affect the imports of the entire group's activities, as that entity cannot then recover the VAT as separate legal entities could. Pan-EU VAT protocols should be agreed.

EORI: The current inability of many Member States to utilise the EORI (customs ID) numbers of other Member States is in contravention of EU law. Member States should be required to comply with EU law (and WTO treaty obligations) regarding acceptance of the EORI numbers of other member states

Other Customs Procedures: The refusal to allow the import of items that don't carry the CE mark regardless of their final destination in some EU Member States (e.g. Italy) is of concern. We are alarmed by the detailed scrutiny by many Member States (particularly on the EU's eastern border) of individual declarations, rather than moving to the EU's preferred post-import validation mechanism. Transparent and readily-available guidance to national administrations regarding unacceptable practices and interpretations should be published, and rapidly updated as a result of verified notifications of new unacceptable practices.

Despite the common WTO valuation rules, the approach often varies between customs authorities on their application which can lead to border issues. There needs to be proper understanding of these rules across customs agencies to ensure a consistent approach. In addition, there are industry specific exceptions that may arise like in the pharmaceutical sector with clinical trials that need multi-country agreement.

9. Barriers to trade in services

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. 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.

As we encourage the adoption of EU Regulations and Directives improving the trade and services relations between the US and Europe, we notably support the quick adoption of the EU Intra Corporate Transferees Directive. The Directive was designed to facilitate short-term international movements of employees assigned to transfer knowledge and fill temporary skills gaps.

Given the specialised nature of the skills performed by Energy Services Personnel (ESP) to service the thousands of products in Europe, it is not economical to hire and train sufficiently skilled ESP in each country to respond to all situations. Barriers to movement of personnel in the energy sector lead to power outages and financial losses amounting to millions of euro daily to European utilities and consumers.

Furthermore, 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.

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

Financial Services

We believe that TTIP should be comprehensive and include a set of key principles for regulatory cooperation and convergence applying to all sectors, including financial services. Four specific issues act as a barrier to trade on EU-US financial services that need to be addressed as a matter of priority:

1) Extra-territorial application: These can discourage third country investors from undertaking transactions that risk bringing them into the scope of the legal regime of a jurisdiction that is not their own, distorting economic decision making (e.g. the choice of counterparty) in a way that undermines market efficiency.
2) Divergence in specific rules and definitions: In the central clearing of derivatives, the EU and US have yet to secure clear consensus on the question of scope, with ambiguity remaining about the treatment of FX products. Any divergence of application 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.
3) Divergent timelines for application: Greater attention needs to be paid to the timetables for the introduction of new rules stemming from the G20 and initiatives such as Basel III, to ensure that global markets are not disrupted by differentiated dates of application in different jurisdictions.

4) Reciprocity provisions: The proposed TTIP should expressly prohibit the inclusion of provisions in financial services legislation that requires 'reciprocal' action by the other regime before market access is granted. In the interim both sides should make a political declaration that it is their policy not to include such provisions in future legislation.

We call for the establishment of a coherent action plan for the Financial Markets Regulatory Dialogue, with ex ante identification of specific issues that will be addressed and of concrete success criteria. Mechanisms must be found for achieving greater political ownership of the Dialogue in both Washington DC and in Brussels, and in both the legislative and executive branches of government. Stakeholders should be involved more systematically, helping, for example, to establish the priorities for the action plan.

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. The proposed 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, we would encourage the EU and US authorities to 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 finalized.

We support the work of international rule-making bodies, and believe that these bodies should be strengthened by ensuring that they are adequately resourced, by ensuring both US and EU policymakers are appropriately represented on relevant committees, and through a public commitment from European and US policymakers that they will respect the conclusions of these international standard-setters when drafting rules in their own jurisdiction.

International convergence should become a more concrete part of the mandate of EU and US rule-makers. In Europe the European Supervisory Authorities should be expressly required to have international convergence as a key criterion for the Level 2 measures that they draft. The language on international issues in Article 1 of the Regulation establishing the European Securities and Markets Authority, for example, should be strengthened. As the eurozone Member States draw up plans for their new centralized supervisory arrangements, involving the ECB, the twin goals of preserving the EU single market and of international convergence should be hard-wired into the new arrangements.

Digital Economy Services

Much of the growth in global services trade has largely been enabled by the development of fast, efficient and cost-effective electronic communications networks, including the Internet, which has become "the global trade route of the 21st Century". Almost half of cross-border trade in services worldwide is enabled by information and communications technology (ICT) services and the share of electronically delivered services is increasing.

The group of services enabled by ICT extends far beyond computers and related services and telecommunication services. ICT-dependent services include financial analysis, engineering, research and development, insurance claims processing, design, education, publishing, medical services and journalistic work. Robust ICT networks and cloud computing allow knowledge and expertise to cross borders. As such, firms in many services industries are increasingly able to use data to more effectively serve customers around the world, reduce transaction costs and improve efficiency, resulting in economic growth, productivity and innovation.

Cross Border Data flows

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.

Restrictions on cross-border data flows could become a major barrier to trade in services: 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 of data flows from legitimate commerce are blocked or severely restricted. Common international legal principles and standards on privacy to maximize the potential of new and emerging technologies and the opportunities arising with global and ever-increasing data flows should be promoted.

The proposed TTIP needs to ensure cross-border data flows. Data flow commitments or non-binding agreements should be negotiated to complement cross-border services commitments and promote responsible and accountable treatment of data. This might be achieved through provisions in the EU-US trade agreement, balancing the need to protect data with the right to move data. The EU and the US need to work together to develop approaches to data security and protection that will instil confidence in, and reduce resistance to, cross-border data flows. It could reduce the government's perceived need to restrict data flows and provide greater opportunities for cross-border trade in services.

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 the 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 the US can set a positive example for how to enable strong growth and job creation in the digital economy.

Electronic Security Services

The EU adopted the Services Directive to create a single services market. However as only 15% of all services in the EU occur across member states, this illustrates that more needs to be done before a true single market exists.

We encourage the USTR to 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.

Legitimate commerce, such as electronic security services where the customer is likely a business or household does not threaten national security and should not be regulated as such. Although this isn't an issue in either the US or EU, member states have used the "security services" exemption in the Services Directive to place barriers to trade in electronic security services. This exemption is only meant for guarding and cash-in-transit. With US-EU commitments for free trade in electronic security services, it is hoped that the EU will require Member States to correctly define the exemption and implement the Services Directive correctly and remove internal barriers for this sector.

With regard to licensing, there should be rules to ensure transparency and non-discrimination in the issuance of licenses 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. Finally, regulations that are found to be barriers to legitimate cross-border activity should be eliminated or amended.

Distribution services

We support the goal of enabling U.S and EU service suppliers to compete on the basis of quality and competence rather than nationality. We appreciate that the scope of T-TIP will be comprehensive, permitting the coverage of all services, including direct selling distribution services.

With regard to Distribution Services, direct selling companies are quite 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. Sale of such products 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 authorizations should be also allowed for sale through direct selling channels.

Express Delivery Services:

Please refer to section 8 for AmCham EU's recommendations for Express Delivery Services.

10. Digital Economy issues

Additional trade commitments by all countries are also necessary to facilitate increased digital trade and electronic commerce. We believe that the European Union-United States Trade Principles for Information and Communication Technology Services, released on April 2, 2011, should form the basis of such 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.

Governments also should not restrict the ability of suppliers to supply services over the Internet on a cross-border basis. Additional principles require, among other things, transparent laws, regulations and procedures affecting ICT and trade in ICT services, independent regulatory authorities, and the authorization of competitive telecommunications services based wherever possible on simple notification by a service provider**.**

11. Investment issues

Regulatory stability/Legal certainty: Regulatory stability is one of the key factors that may, or not, encourage foreign investment in a region. US companies sometimes find it difficult to predict what the EU regulatory framework (in conjunction with national regulation) will look like over the short to medium term. The resulting legal uncertainty can be a deterrent to foreign investment in the EU.

An example of this is the EU's chemicals regulatory framework. Several pieces of EU environmental legislation overlap and there is potential for legal discrepancies in national implementation and long-term legal uncertainty for industry. AmCham EU has recently noticed examples of EU regulation that are not based on adequate scientific risk analysis or impact assessments.

Recently, the same substances have been subject to different EU regulatory approaches: the REACH Regulation, as a piece of framework legislation, analyses substances in several ways under its Evaluation, Authorisation and Restriction procedures;

- The Restriction of Hazardous Substances (RoHS II) Directive, a sector specific directive, regulates certain hazardous substances in electrical and electronic equipment (EEE) and its substance scope will be subject to assessment this year;
- The Water Framework Directive (WFD) identifies priority hazardous substances. A proposal was made for the inclusion of pharmaceutical substances in the scope, while DG Health and Consumers has only just initiated an investigation into the impact of pharmaceuticals on the environment.
- There is legal uncertainty over possible overlap between the Directive on the eco-design of energy-related products (ErP), the construction materials and F-gas regulations.
- Different legal terminology and definitions have been adopted between the above-mentioned RoHS II Directive and the Waste Electrical and Electronic Equipment (WEEE II) Directive.

Legal discrepancies and uncertainty because of overlapping legislation are barriers to investment. This inhibits the ability to innovate and compete, and may potentially have unintended consequences for consumers. A balanced and coordinated legal framework will accelerate business developments that meet citizens' needs and foster growth.

EU-US cooperation vis-à-vis international investment: AmCham EU welcomes the Joint Statement of Shared Principles for International Investment agreed to by the EU and US in April 2012. Both inward and outward investment are vital to getting the EU and US back onto the path of economic growth, job creation and prosperity. These principles which promote fair competition open, transparent, and non-discriminatory regulatory environments reflect the shared values of our societies and deserve close cooperation in addressing challenges thereto. AmCham EU calls on the European Commission and US to promote implementation of these principles in their member states and in all relevant multilateral and bilateral forums.

Inter EU-US investment: An agreement building upon the longstanding traditions of US and EU treaties and agreements and a strong investor-state arbitral mechanism should be endorsed. Investment and investor-state arbitration are strongly supported by the business community.

12. Competition-related matters

The US and the EU 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:

1) 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. Companies acting globally should not have to tailor their worldwide product offerings and marketing plans, given the welfare-enhancing efficiencies these bring, to satisfy the most demanding competition agency which fails to respect international comity norms.
2) 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 US and the EU should also stress that there is value in not simply rejecting investigations, but also in having the confidence to publish decisions not to pursue investigations, where the authority has concluded that a practice does not violate the competition rules.
3) 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.

13. Government procurement issues

Although we see the merits of equipping the EU with a new instrument to promote free trade and open public markets, AmCham EU is very concerned by some aspects of the European Commission's proposal for a European public procurement instrument. The automatic exclusion of US bidders in sectors where the EU has taken reservations in international agreement 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, urban transport etc., 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 which have negotiated public procurement agreements with the EU.

At a time when the EU and US should be cooperating to resolve such issues, we believe that this measure would signify a step backwards; and would hope that the proposed TTIP addresses and resolves such issues.

AmCham EU would welcome further work between the EU and US on opening public procurement markets at all levels; including all US states. Provisions like buy national schemes (i.e. Buy America) should not apply between the EU and the US. If properly drafted and implemented, an agreement between the EU and US 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.

14. Environmental issues

Industries in North America and Europe realise there is a comparative advantage in reducing energy consumption and the use of resources. 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', what 'green public procurement' is, or what is 'sustainable ' as in the case of biomass. In order to avoid that new green regulations turn into new non-tariff barriers, negotiators should devise coordinated EU-US approaches. This is especially the case for future initiatives related to resource efficiency and environmental footprint methodologies.

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.

Since the introduction of the first genetically engineered, or biotech, commodity crops in 1995, biotech varieties have transformed global agriculture, helping farmers become internationally competitive, reducing costs and promoting important environmental and sustainability goals. Environmental benefits gained from bio-diversity allow for increased productivity in the field due to higher levels of pollinators and higher productivity levels allow pressure to be taken off scarce resources.

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 from day one of the implementation of the proposed TTIP.

To promote resource efficiency and sustainable development, the EU and the 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 measures to the importation of used goods 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 US and EU authorities. Pragmatic progress on setting globally recognised standards, and on mutual recognition would unleash an economic potential which would amplify the message put forward by the EU and the 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 upon definition of sustainability measures for products. This would form the basis for incentives (tariff relief) to accelerate their development.
- promote the development and use of design tools that allow sustainability information to be available to designers at the time when they are making product decisions.

15. Labour issues

We encourage the EU and the US to focus their efforts on ensuring the effective implementation of current legislation on working conditions at their respective level. A positive working environment allows workers to thrive, enhances competitiveness, productivity and prevents additional economic costs for employers and society. Progressive companies in the US and the EU 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 the 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. 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 the US.

The EU and US need to ensure the free movement of people within the two continents; facilitate better links between business and education; improve access to and harmonize key feature of the labour markets; promote higher education and training in key enabling technologies and boost overall skills training and re-skilling.

Europe's and America's aging populations can also represent a market opportunity for certain sectors, in particular healthcare, pharmaceuticals, medical and nutrition products, tourism and leisure, which should be encouraged to innovate to meet changing demand patterns.

16. Trade-related intellectual property rights issues

AmCham EU is concerned that the global framework of protection and enforcement of the IPRs is currently under serious threat. The TTIP is an important opportunity to unequivocally reaffirm both sides' commitment to the highest standards of IPR protection and reject calls for a lowering of international IP protection standards.

More specifically, EU and US companies are confronting the challenges of:

- Combating trade in counterfeit and pirated goods: Illegal online activities are harming consumers, who buy counterfeit products , legitimate content providers, trade mark owners and good manufacturers, and are also undermining trust in e-commerce and into the internet as an enabler for progress and economic growth;
- Preventing attempts by third countries to weaken IP protection in their own respective countries and in multilateral forums: without a shared strategy that is based on enhanced cooperation and coordination, a number of major emerging economies will continue to erode EU and US competitiveness by both failing to 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;
- Adapting to the discrepancies of the patentability provisions in the EU and the US which induces very significant financial costs; and
- Addressing increasing requests for compulsory technology transfers licensing and/or disclosure of trade secrets as a condition of market access in the field of healthcare and green technologies (see also section 18).
- Inefficiencies in the EU Patent System: Building on the European Patent System to foster quick adoption of an EU-wide patent enforcement system (similar to the US federal court model that applies across all 50 states) obviating the need for 27 separate litigation actions
- Data Exclusivity: establishing a 15-year data exclusivity requirement to protect innovative products.
- Trade Secrets: Develop and implement trade secret laws to ensure a high level of trade secrets protection covering process technology that secures U.S. and European companies competitive advantage.
- 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. The TTIP should include strong protections for trade secrets. The governments also could consider ways in which 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

AmCham EU is of the opinion that several key issues should be tackled to strengthen the IP framework both in Europe and in the US, which would strengthen the protection of IP rights globally.

First of all, 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. Such a structural change 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.

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. Effective protection and enforcement of IP rights are essential. The EU and US should keep promoting the importance of intellectual property protection and enforcement measures. Because the EU and US both have very high levels of intellectual property protection, albeit with different mature systems, an IP chapter in the context of an EU-US agreement is sui generis. Focus should be on enhancing cooperation in third country markets and at the international level, as well as on discrete issues where the differences between the two systems lead to substantive differences in protection and enforcement.

In addition, we should seek to maintain and promote robust IP frameworks and effective levels of intellectual property protection in the European Union and the United States, ensuring that practices that undermine intellectual property are appropriately addressed. For example, we are extremely concerned 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 the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The United States should raise trade-related concerns with these EMA policies in the context of the TTIP discussions, and the EU should 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.

Furthermore, on patent and data protection issues several principles could guide the discussions between EU and US counterparts to strengthen the coordination of their policies:

- Greater alignment of patent term restoration to compensate for excessive patent examination periods and for regulatory delays;
- Adoption of patent enforcement systems that allow for early resolution of patent disputes before an infringing product is launched on the market; and
- Seeking to 'level up' regulatory data protection to the higher standard currently available in either regime (8+2+1 years for small molecules; 12 years for biologics).

At the international level, there is a need for a shared strategy based on enhanced cooperation and coordination. Such a strategy would help to avoid a number of major emerging economies continuing to erode EU and US competitiveness by failing to enforce IP rights in their countries, or in some cases, not doing so in order to build national champions and advance domestic industrial policy. The delivery of a shared strategy should promote the strengthening of local cooperation between the EU and US diplomatic services within the third country. IPR enforcement mechanisms should lead to timely and effective enforcement.

EU-US enforcement cooperation could be enhanced by greater customs harmonisation, such as through the creation of an integrated EU customs rapid alert and information exchange system that 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.

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.

Finally, even in the face of health and environmental concerns, governments should take care not to diminish the value of IPRs, for example by eliminating the ability of manufacturers to distinguish their products from their competitors (ref to plain packaging). They should look for balanced, efficient and proportionate measures with an evidence-based approach.

Geographical Indications

We recognise that the United States and European Union 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 European Union and United States are already mutually protected (e.g., Scotch whisky, Irish whisky, 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.

17. Emerging challenges in international trade

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 whom we negotiate further bilateral agreements to seek similar carve-outs for themselves, to the detriment of US and EU interests.

We welcome the objective of both the US Government and the European Union to address global emerging challenges such as localisation requirements and forced technology transfers.

Some examples of global challenges:

- 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. The 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.

- Global rules to prohibit regulations that require technology transfer**.** The EU and the 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.

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

Some examples of global challenges:

- *Addressing 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 complexity of global supply chains. The TTIP should include a chapter with agreed language on avoiding such measures between EU and US but which can also then be re-used in their respective bilaterals with other trading partners and in other venues.

- *Global rules to Prohibit Regulations that Require Technology Transfer* – The parties also should set global principles on preventing forced technology transfer through broad compulsory licensing, disclosure of sensitive information as a condition of market access, or otherwise.

18. ANNEX

a. Annex 1: Energy

Mutual Recognition of EU-US Standards and Regulations

US businesses that design and manufacture to long standing US national standards and codes have difficulty entering the EU market place when similar EN and EU Member State standards and regulations do not align Unnecessary and expensive design changes and redundant testing to meet regional or national requirements can cause US products to be uncompetitive in Europe. The same is true of EU products trying to access the US market. Mutual recognition agreements (MRA) on standards and regulations that cover similar technologies would be beneficial for both the EU and US. An even greater benefit would be derived from these MRAs: if the EU and US have harmonised their regional/national standards with similar international standards, and countries outside of either these regions adopt international standards, then it follows that either EU or US standards covered under MRAs would also be accepted.

Technical Regulations and Standards Cooperation with Third Countries

The US had been successful in leading and influencing third countries to adopt and or accept US technical regulations and standards for many products and industries. Specific successes include in the global acceptance of the US FAA's aviation and FDA's food and drug regulations and standards. For products that do not have federal regulations like for pressure equipment, structural design, machinery, and electrical equipment, the US has had strong global presence and third country acceptance of US based standards like the American Society of Mechanical Engineers (ASME) Boiler and Pressure Vessel Code, the NFPA NEC 70 for electrical, and the International Building Code (IBC) for structures. Today acceptance of US regulations and standards are being replaced by the acceptance of European regulations and standards, which is causing US-EU and US-third country barriers to trade.

The EU has been very successful in the past decade in influencing the adoption of EU product technical regulations, directives and standards by countries outside the European Economic Area through the European Neighbourhood Policy and other outreach initiatives, extending to Africa, the Middle East and Asia. This has accelerated the EU's ability to trade between more countries with little to no technical barriers. Despite the EU's efforts to harmonise their regulatory and standards approaches with other countries, there are still no mutual agreements between the EU and US for such products as pressure equipment, machinery, structural design, products used in explosive atmospheres, general electrical safety, etc., largely because there are too many technical and regulatory compliance approach differences between the two.

In order to promote cooperation with third countries, the US and EU should first work on identifying and adopting mutual regulatory and standards acceptance for such products like pressure equipment, structural, electrical equipment used in potentially explosive environments and machinery. This is not a simple task as the US and EU manages these requirements at different judicial levels (federal versus state) and the standards that are recognised for compliance are very different. It is recommended that these industries in the US and EU work together to find common ground to at least accept both methods.

2004/108/EC Electromagnetic Compatibility Directive, Immunity Requirements

The European Union CE Marking Directive 2004/108/EC for Electromagnetic Compatibility contains requirements for manufacturers to ensure products have been assessed for immunity and emissions. In the US, electromagnetic compatibility is governed by the Federal Communications Commission (FCC) and only has requirements for emissions - not immunity. In order to comply with the

2004/108/EC Directive, US manufacturers are forced to conduct immunity testing in order to export to the EU. This testing can double or triple testing costs compared with an identical product that is sold in the US. In fact, US product safety standards generally do not contain requirements for EMC testing, as electromagnetic compatibility is not viewed as a safety factor in the same way as other disciplines like electrical and mechanical factors.

Even in the absence of immunity regulatory requirements, manufactures generally include a level of immunity within the product as part of the normal development cycle to ensure customer satisfaction. Only for specific industries and applications are immunity requirements specified, and this is to satisfy customer requirements, not legal regulations.

Relaxing the immunity requirements for general industry would better enable trade and only specific instances, such as products used in a high hazard application, should require immunity requirements. A hazard based approach should be used, similar to other CE marking directives.

AmCham EU recommends a mutual recognition agreement be considered and that US products be allowed for general use within the EU market, with the possible exception being specifically for a high hazard application where a risk assessment requires such levels of testing.

Smart Grids

We strongly believe that technical standards can accelerate innovation and investment in emerging technologies. Policymakers from both the US and the EU also recognise these benefits, and, independently, have taken steps to support the accelerated development of smart grid technical standards. However, additional action is needed to encourage transatlantic cooperation in standards development, with a focus on harmonisation that improves market access and creates economies of scale for technology solutions providers. Specific recommendations are:

- Encourage EU participation in the US NIST Smart Grid Interoperability Panel (SGIP) Priority Action Plans (PAP). The PAPs bring together subject matter experts from relevant standards development organisations (SDOs) to address gaps where new standards are needed, or to coordinate between existing complementary standards.
- Create opportunities for SGIP representation on the EU Joint Working Group, established to advise the European Commission on European requirements related to the standardisation of smart grids, as well as within the three European SDOs (CEN, CENELEC, ETSI) that make up the EU Joint Working Group.
- Designate a single set of testing and certification specifications for harmonised technical standards, providing the consistency and clarity needed to support continued investment by utilities and other stakeholders. After NIST, the EU Joint Working Group and relevant SDOs have agreed upon the specifications, the testing for conformity and interoperability, and the certification for compliance, can be conducted by qualified regional organisations.
- Support 'dual-logo' arrangements for IEEE and IEC standards. There is an immediate need for collaboration on security and related standards, as diverging approaches have emerged among the various regions and SDOs. More broadly, the US and EU should encourage NIST and the relevant North American SDOs (IEEE and ANSI) to adopt the IEC smart grid architecture as the model architecture for all current and future work on smart grid standards.

Oil and Gas Exploration

Oil and gas exploration occurs in all regions of the world including US and EU Member States. Various national regulators create applicable regulations and performance standards are not consistent between different nations. Variations in standards can make it difficult to deploy best available control technology across the globe in an efficient and cost effective manner.

We believe that consistent global standards are the best way to ensure the deployment of best available technology to oil and gas exploration in challenging and environmentally sensitive environments. We respect the right of every nation to employ regulations that they believe best serve the interests of their particular nation. That said, we recommend governments to use available multinational forums such as API, ISO or the International Regulators Forum (IRF) to develop consistent and transparent regulatory requirements. Development of global offshore drilling standards will ensure that industry can focus on the best technologies rather than a wide range of local requirements for different technologies.

Emissions

The US and the EU 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 contain some significant areas of divergence. For instance, within the EU, there is an emerging new requirement for NOx emissions for liquid fuel gas turbines that exceeds the capabilities of existing technologies without imposing performance and operability limitations. For its part, the United States is moving past the EU with the adoption of regulations to limit mercury emissions from coal-fired power plants.

Both of these examples could affect the potential for exports from the US to the EU. If the EU were to proceed with the implementation of its new NOx rules, it could hamper the ability of US manufacturers to service certain segments in the EU market. Similarly, if the EU were to initiate new requirements for mercury emissions in line with what is being developed in the US, it could open up a new export opportunity in the EU where US manufacturers are highly competitive. We recommend a high-level dialogue between the relevant US and EU authorities to review the full range of emissions requirements and to explore whether such requirements can be rationalised in a way that enhances US access to the EU market without compromising the environment.

European Product Language Translation Requirements for Industrial Products

The European Union product safety CE Marking Directives, like the Machinery Directive and Pressure Equipment Directive, contain requirements for product information such as manuals, warning signage and electronic information (eg. computer screen information) to be translated into the official language of the Member State where the product will be placed into service. Today there are 23 official EU Member State languages. These requirements are to ensure the safe use, operation, maintenance and disposal of products in each Member State where the general public still communicates and operates in their official local language.

US industrial product manufacturers are often forced by law to provide products to their customers in national languages even if the European user does not want the product in the local. Since the requirements for translation are mandated at a regulatory/directive level, manufacturers are not permitted to contractually agree to a different language in lieu of providing the product in the national language. This general approach to product translation requires US manufacturers of industrial products, including SMEs, to unnecessarily spend millions of dollars annually to comply. This requirement imposed on industrial products has caused many US manufacturers not to be competitive in the European market.

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.

Regulatory and Technical Transparency for CE Marking Compliance

The EU New Approach Framework created a specific regulatory and technical role for pre-New Approach European regulatory and independent inspection agencies to become 'Notified Bodies'. Notified Bodies have to be assessed and approved to be competent to perform the required duties as specified in each respective Directive for their role. As a result, the ten-year-old New Approach Framework has been reliant on Notified Bodies having competency and expertise in understanding, interpreting and guiding US manufacturers to meet the regulatory and technical requirements of the Directive. European trade associations are another source for information but access is limited or cost prohibitive. Moreover, advice from a trade association is less desirable than advice from a Notified Body.

Notified Bodies serve as US manufacturer's single source for regulatory and technical support, guidance and certification to the Directive's requirements. Over the past ten years, not only have US manufacturers been working with inconsistent services provided by Notified Bodies, they also have been subjected to escalating and unreasonable service fees. The use of Notified Bodies to meet Directive regulations has directly contributed to higher product cost and longer product lead times, discouraging SME US manufacturers from even entering the EU market.

In 2008, the European Commission responded to the negative European stakeholder feedback that highlighted concerns with Notified Bodies' regulatory (conformity assessment) and technical competency by passing the New European Legislating Framework (NLF) Regulation 765/2008. Even though the new NLF will eventually impose competency requirements on Notified Bodies, it does not address or provide a transparent means for manufacturers to challenge and or obtain regulatory and or technical resolution on issues where there are discrepancies between Notified Bodies.

The Notified Body framework created under the New Approach continues to be a barrier to trade for US manufacturers exporting to the EU. In order to negate this effect, we recommend the creation of US-EU 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. This support should come from the Directive Committees to ensure consistent application of the requirements between all parties.

Wind Turbine Safety Standards

The European Normative EN 50308 has been in use by the international wind industry to identify requirements for the safe design, operation and maintenance of wind turbines. The requirements in this normative standard are specific to wind turbine design and provide consistent direction for all turbine and component manufacturers. In contrast, the US OSHA requirements for Environmental, Health and Safety are not specific to wind turbine design and are subject to a wide variety of interpretation by manufacturers and US authorities having jurisdiction.

We support regulatory cooperation between the US and the EU that would help reduce unnecessary divergences in regulation and in standards used in regulation. We recommend the development of a mutual recognition agreement or other appropriate approaches to better define the options for safe design of wind turbines.

Electric Vehicles

US policymakers and regulators should encourage greater EU-US collaboration between national, regional and international standards setting organisations to support harmonisation of electric vehicle technical standards (e.g., compatibility with smart grid communication methods; IT security and data protection; common billing methods, charging stations, plugs). Harmonised technical standards can accelerate innovation and investment in emerging technologies, improve market access and create

economies of scale for technology developers, thereby allowing US companies to be more competitive globally and increase exports.

Environmental Products Regulations: Battery Recycling

There is a battery directive in the EU (2006/66/EC) that has specific rules for material content and recycling. The US has some guidelines for lithium batteries but nothing consequential at the federal level and state level.

The EU's directive prohibits the placing on the market of certain batteries and accumulators containing mercury or cadmium. It also promotes a high level of collection and recycling of waste batteries and accumulators.

The US should enact a federal law modelled after the EU's battery legislation and it should require recycling of the same categories of batteries as the EU directive. The types of batteries and labelling requirements for US federal legislation should use the EU directive as a model, but involve industry groups to help make the final decision. Recycling should be at the state level with reporting to the federal level.

b. Annex 2: Agricultural biotechnology crops: regulatory reform & alignment

Annex 2.1. Plant Protection Products

The impact of reducing pesticide use to zero would be dramatic – Europe would suffer an approximate loss of 50% of food crop from pests and diseases without the intervention of pesticides. CropLife America state that up to 40% of the world's potential crop production is already lost annually because of the effects of weeds, pests and disease – these crop losses would be doubled if existing pesticide use was abandoned. Pesticides are even used in organic agriculture, so the bio sector would also suffer considerably.

CropLife America estimate that crop protection products preserve upwards of $45 billion of produce worldwide each year. Failure to protect our crops would have enormous implications on the global economy, and would seriously impact on food security. Earth will be home to an estimated 9 billion people (around 2 billion more than today) by the year 2050. We are already struggling to feed 7 billion – can we feed 9 billion without effective crop protection measures? The FAO estimates that, even with improved food distribution, food production will need to increase 70% by 2050 to cope with a 40% increase in world population.[4]

Annex 2.2. Concerns on Trade and MRLs

Hereafter is a quote from chapter V of the "NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities" produced by the US Environmental Agency. It outlines the Important Tolerance Data Requirements:

"A. General Information The product chemistry, residue chemistry, and toxicology data requirements in this section apply to the establishment of import tolerances/MRLs in Canada and the United States. The import tolerance/MRL petitioner may not need to conduct new studies to fulfill the data requirements. Interested parties may support a new import tolerance/MRL in the U.S. and Canada with studies developed for a registration in another country, and/or for a Codex MRL, provided that the petitioner is able to demonstrate to both countries the applicability of the studies to the requirements in this document. The petitioner or other interested parties may consult with the two countries before submitting the existing studies. All studies must be formatted in accordance with requirements of the country to which the package is being submitted. Canada and the U.S. strongly recommend that petitioners attach a copy of the study evaluation by the registering country or by Codex to the study report as an appendix.

If a Codex MRL has been established, Canada and the U.S. may conduct a more limited review of the residue chemistry data under certain conditions. Canada and the U.S. are more likely to adopt MRLs similar to Codex MRL levels if MRLs for the pesticide are already established on other commodities with a contemporary robust database. Standard data and review requirements would be applied where exposure and/or risk to any subpopulation from the pesticide is high. An EPA-specific detailed description of how the U.S. may consider Codex MRLs as they relate to data requirements can be found in Unit VIII of the U.S. Import Tolerances Guidance document (65 FR 35069).

The data requirements that are most significant for import tolerances/MRLs are for Field Trials (Canadian Regulatory Directive 98-02, Residue Chemistry Guidelines, and Canadian DACO Guideline No. 7.4.1; U.S. Guideline No. 860.1500) and the adequacy of the Toxicology data for those pesticides not already registered for a particular use in Canada or the U.S. For registered pesticides,

[4] http://pesticideinformation.eu/2010/03/16/a-week-without-pesticides-musical-gnomes/

the field trials are typically the most significant data requirements for establishing a new tolerance/MRL. See Section V. D. 1. of this document for further information."[5]

Annex 2.3. Regulatory Divergence

Comments submitted by European Crop Protection Association (ECPA) and Crop Life America (CLA) to the US-EU High Level Regulatory Cooperation Forum dated 10 April, 2013 on regulatory divergences between EU and US:

"Many regulatory issues pertaining to pesticides could benefit from greater regulatory cooperation between pesticide regulatory authorities in the EU and the US. Our comments focus on three broad topics of high importance:

1) Science-based risk assessment, as the foundation for regulatory decisions, must not be taken over by the precautionary principle;
2) Maximum Residue Levels (MRLs) and the need for greater harmonization in the processes for establishing MRLs for pesticide residues

…Risk assessment and management is increasingly divergent. One notable examples of beneficial regulatory convergence is the reasonably similar regulatory data protection policies in the US and EU.

Current examples of regulatory divergence have broad potential for intermediate and long-term damage to international trade in agricultural commodities. Because of the potential for adverse influence on crop protection, ignoring or downplaying their importance now will make future corrective action that much more difficult.

- Increasingly frequent application of the precautionary principle in the assessment of pesticides in the EU.
- The anticipated suspension of uses of neonicotinoid insecticides, in contradiction of the weight of scientific evidence and of established administrative procedures;
- The use of hazard based cut-off criteria in the EU; for example consideration to categorize chemicals as endocrine disruptors in the absence of a risk assessment and ignoring evaluation of solid scientific data, both which are essential processes in the currently evolving U.S. policy on endocrine disruptors; and
- Lack of expert consultation between EU and US agencies on data requirements, guidance, and guideline development."[6]

Annex 2.4.

According to the trade association CropLife America

- Globally, over 900 million people – one-sixth of the world population – suffer from malnutrition. Agricultural output has to double in the next 20-30 years in order to feed the world's population, which the United Nations predicts will grow by 1.7 billion more people by 2030. To meet the global challenges of food production and security, high-yield production of biotech crops using crop protection products will continue as the primary agricultural practices.

- The early adoption of crop protection products and the recent rapid adoption of biotech crops have advanced modern agriculture through use of no/reduced tillage production systems and integrated pest management. The approaches provide both economic and environmental benefits including reduced soil erosion and improved soil moisture levels.

[5] NAFTA Guidance Document on Data Requirements for Tolerances on Imported Commodities in the United States and Canada (December 2005). http://www.epa.gov/oppfead1/international/naftatwg/guidance/nafta-guidance.pdf

[6] ECPA-CLA final comments to the US-EU High-Level Regulatory Cooperation Forum dated 10 April, 2013

- The crop protection industry makes a significant investment in research and development. Intensive scientific research and robust investment in technology during the past 50 years helped farmers double food production without a change in the footprint of total cultivated farmland. Crop protection is one of the most research-intensive industries in existence, with companies investing about 12% of their turnover in research and development (R&D). The top 10 plant science companies invest an estimated $3.75 billion in R&D per year to discover, conduct tests to ensure safety and develop new products.

    - Industry estimates that average research and development costs for one new crop protection product to reach commercialization are $256 million (a 40% increase in the U.S. and Europe over the past decade), and that the process takes an average of ten years (CLA and European Crop Protection Association, 2010. The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000 and 2005-2008. R&D Expenditure in 2007 and expectations for 2010. Final Report, January 2010).

- The rigorous science-based regulation of crop protection and agricultural biotechnology serves as the foundation for the safe use of these technologies. These regulatory processes, and subsequent policies, must continue to be grounded in science if we are to approve new products and advance modern agriculture.[7]

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

c. Annex 3: Intellectual Property

The TTIP offers an important opportunity to build upon past US-EU collaboration vis-à-vis third countries in promoting strong intellectual property rights. Given the influence of the transatlantic economy and the mutual importance of intellectual property to the US and EU economies, the TTIP could serve as a vehicle to tackle issues of common concern with respect to efforts to erode longstanding international intellectual property norms.

The US and EU are home to innovative industries that are heavily dependent on intellectual property rights (IPRs). Both markets have similarly robust protections for intellectual property, albeit through different systems, and both have been proponents of the WTO Agreement on the Trade Related Aspects of Intellectual Property Rights and of strong intellectual property provisions in other bilateral, regional, and international agreements. Advancing these protections in third countries and in multilateral organisations is a shared goal of the US and the EU.

The US and EU are already collaborating towards this objective. The Transatlantic IPR Working Group's Action Strategy, for example, commits both the US and EU to take steps to encourage third countries and multilateral organisations to better protect IPR, including through 'active complementing of each others' bilateral efforts working with third countries and exchange of information about . . . events that provide opportunities to advance these objectives', and the creation of 'bilateral IP networks in [the others'] Embassies/Delegations in relevant third country capitals to facilitate information sharing, delivery of complementary and/or joint messages as appropriate'. The 2007 Transatlantic Economic Council's Framework for Advancing Transatlantic Economic Integration reiterates and expands on these commitments.

The TTIP could include mechanisms that build upon the IPR Working Group and TEC commitments. US and EU innovative companies in key sectors such as clean technology, medical devices, aerospace and defence, and computing, software and the cloud have a global footprint; government cooperation in the area of IPRs should mirror that economic reality. Strengthening economies in the US and Europe will succeed only if both governments look beyond their borders to endorse and promote strong IP regimes that foster innovation.

Commitments to achieve these shared objectives could include:

- A commitment to preserve the IPR norms set forth in the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). TRIPS remains an important of the international intellectual property regime. In recent years, however, some have sought to circumvent or weaken its fundamental protections. An explicit agreement between the US and EU to cooperate, where appropriate, in addressing third country violations of TRIPS merits consideration. Equally important, the US and EU 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 the U.S. and EU bilateral, regional, and international agreements. Many of these agreements reflect the most up to date IP protections and enforcement tools. Yet, just as with the TRIPs agreement, in recent years there has been an effort to weaken or roll back this important progress. An express agreement between the U.S. and EU to cooperate, where appropriate, to address third country practices that deny important IP protections and enforcement tools shared by the U.S. and EU systems.

- A commitment to greater US-EU alignment in the context of multilateral dialogues and negotiations on IPRs. TRIPS, and IP protection more broadly, has become a topic of consideration in many forums. Several multilateral organisations have focused recently on

the intersection of IP and other public policy objectives. While the US and EU often have consistent positions on these issues, both governments should strive to more closely coordinate their approaches on IP-related matters. As a step towards achieving this objective, the parties should ensure that trade and IPR experts in both countries are consulted on all TRIPS-related matters regardless of the forum and that bilaterally-coordinated approaches are developed where possible. This will help to ensure that commitments taken elsewhere do not undermine important IP norms in the US and the EU systems, including, the commitments set forth in TRIPS.

A commitment to cooperate on improving the efficiency and effectiveness of the patent system at the global level is essential. The TEC framework already highlights the importance of cooperation to enhance the effectiveness of the patent system, and the US and EU have taken important steps forward toward furthering this objective. Building upon these successes, both governments could take further steps toward cooperation by promoting greater international harmonisation in patent litigation systems. 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.