AMCHAM EU
AMERICAN CHAMBER OF COMMERCE TO THE EUROPEAN UNION
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

CONSULTATION RESPONSE

AmCham EU's response to the European Commission Public consultation on the future of EU-US trade and economic relations

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Background and Analysis

1. About you

To ensure that our public consultation is open and transparent DG TRADE will publicise all contributions on its website, unless respondents indicate that they do not wish their contributions to be made public. The consolidated report will similarly include a list of the names of all the organisations from whom DG TRADE has received contributions to this process.

1.1. Do you wish your contribution to be made public?*

Yes

1.2. Please state the name of your business/organisation/association?*

American Chamber of Commerce to the European Union

1.3. What is your profile?

Trade association representing business

1.6. What is your main area/sector of activities/interest

Other

1.7. If "Other", please specify

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 U.S. investment in Europe totaled €1.7 trillion in 2010 and directly supports more than 4.2 million jobs in Europe.

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.

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1.8. In which country are your headquarters located?

A Member State of the European Union

1.9. Please specify which country?

Belgium

2. Priorities for a forward-looking trade relationship with the United States

2.1. What should be the priorities of the future EU-US trade and economic relationship?

AmCham EU believes that the future EU-US trade and economic relationship 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 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.

• ***Broad Mutual Recognition Clause***: Whilst regulatory convergence is a long-term priority, 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 harmonize, 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.

• ***Common Risk Assessment procedures***: A uniform approach to 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.

• ***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.

2.2. How should the European Union pursue these priorities?

•***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. 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: rapid implementation of mutual recognition of secure trade systems, i.e. C-TPAT and AEO schemes, including moving 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.

• ***Common 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***: 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***: 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 fora 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.

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3. EU-US bilateral economic, trade and regulatory dialogues (e.g. Transatlantic Economic Council – TEC, High Level Regulatory Cooperation Forum – HLRCF)

3.1. Did the TEC, the HLRCF or other sector specific cooperation between the European Union and the United States bring satisfying results for your business in the past?

No

3.2. If the TEC, the HLRCF or other sector specific cooperation between the European Union and the United States has not brought satisfying results for you in the past, please explain why this has not been the case.

• Need for broadened scope, necessary resources, and political will to achieve meaningful agreement

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.

3.3. Are there any priority sectors on which economic cooperation should focus?

Yes

3.4. If there are priority sectors please explain, including specific areas or issues to be addressed.

AmCham EU's sectoral interests 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. In addition, AmCham EU's membership covers a wide range of industries and services companies, who will contribute additional expertise in supporting liberalization in their specific sectors.

4. Tariffs

4.1. Are you concerned by tariffs in your field of activity?

Yes

4.2. If you are concerned by tariffs, do these tariffs affect your ability to export/import or to do business in the US?

Yes

4.3. If tariffs affect your ability to export//import or to do business in the US, please explain.

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

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. The European Commission could identify some products which fall into this category and target them for tariff reduction.

Duties paid on key inputs to the manufacturing process: Significant intra-company 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 liberalization would lead to enhanced competitiveness and a greater ability to reinvest in manufacturing and R&D in the EU and US.

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.

4.4. If you are concerned by tariffs, what is the average tariff on your exports/imports?

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 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.

5. Non-tariff measures for industrial products

5.1. Are you concerned by unnecessary regulatory barriers for industrial goods in your field of activity in the European Union or the United States?

Yes

5.2. If you are concerned by regulatory barriers, please specify whether they arise from:

Technical regulations/ Standards/ Conformity asessment procedures/ Other

5.3. If other, please specify

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.

5.4. Describe the barriers of regulatory nature you are concerned about with as much detail as possible

• ***Technical barriers to trade***: Transatlantic rules developed in this context 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.

• ***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 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.

• ***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.

• ***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.

5.5. Indicate how and how much it impacts your business/activity. If possible, provide an estimate/quantification of the costs of the barriers

Consumer Goods: Differences between chemicals management regulations, i.e., U.S. TSCA and EU REACH, create a barrier to our business model which is to innovate for the world, look into worldwide supply of raw materials. Speed to market which is key in the Fast Moving Consumer Goods area is hampered.

• ***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 agreement should stimulate regulatory agencies to step up cooperation and where possible convergence of regulatory approaches and mutual recognition of regulatory data compliance.

• ***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.

5.6. Indicate what would be the benefits of its removal

• ***Chemicals***: the most value-added would be to focus on more efficient and effective operation of the chemical regulatory systems in the EU and the US, to include common principles for information sharing, for prioritising chemicals for review and evaluation, and for coherence in hazard and risk assessment. A harmonised approach to data assessment would simplify the registration process, improve transparency and be more efficient for companies to develop their application dossiers in both economies.

• ***Biocidal products***: 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.

• ***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.

5.7. Please indicate to which level of government the regulatory obstacles relate

US Federal / EU level regulation /US States / EU Member State regulation

5.8. What should be the European Union priorities to address the reported barriers? For instance, if the reported barriers are related to divergent regulatory or standardisation approaches in the EU and the US, could you please indicate how, in your opinion, greater compatibility/convergence of the EU and US regulations and standards in your field of activity could be achieved?

• ***Joint impact assessments of future regulations***: 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 at the early stages of the regulatory process, within the impact assessment procedures.

• ***Avoidance of new NTBs, in areas such as Data Privacy, Cloud Computing and Nanotechnology***: new NTBs should be avoided, particularly in areas such as Data Privacy and Cloud Computing. This can be achieved by building greater procedural awareness once new legislations are introduced. Nanotechnology could benefit from transatlantic cooperation to achieve the same level of environmental and consumer protection, whilst avoiding trade distortions and benefitting from its innovative uses.

• ***Chemical sector***: The EU and US should establish mutual recognition of compatible regulatory regimes for control 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 control laws, 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.

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• ***Pressure equipment***: We support regulatory cooperation between the United States and the European Union that would help reduce unnecessary divergences between the European Pressure Equipment Directive and the US ASME Boiler and Pressure Vessel Code requirements. We recommend the development of an EU-US pressure equipment sector committee to explore the option to align particular regulatory and technical measures between the PED and ASME taking into account the differences between the regulatory structures. We also support the option of creating equivalency arrangements between the US and EU for the pressure equipment sector.

• ***Restricted Materials***: The US should enact a federal law modeled after the EU RoHS legislation. It should restrict the same materials at the same levels. Associated with the law is 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 modeled 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 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. 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.

6. Sanitary and phytosanitary obstacles

6.1. Are you concerned by unnecessary sanitary and phytosanitary regulatory obstacles?

Yes

6.2. If you are concerned by sanitary and phytosanitary regulatory obstacles, please specify from where they arise:

Non-processed plant products/ Processed products

6.3. For non-processed animal products (multiple answers possible):
N/A

6.4. For non-processed plant products (multiple answers possible):

Divergences of Federal standards compared to EU standards/ Divergences of State/local standards within the US/ Setting up of import requirements

6.5. For processed products:

Divergences of Federal standards compared to EU standards/ Divergences of State/local standards within the US

6.6. If "Other", please specify.

N/A

6.7. Please explain the sanitary or phytosanitary obstacles in detail.

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 is scientifically questionable and results in a distorted estimate of the risk related to the use of the plant protection product.

Current toxicity testing guidelines require chemicals to be tested at very high doses, which are many orders of magnitude above any feasible human exposure. 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 it also has a direct effect on the management of associated risks. 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 European 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 European chemicals companies to disinvest or become uncompetitive and stifling the development of the Knowledge-Based Bio-Economy.

Concerns on Trade and Maximum Residue Levels (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, resulting in avoidable trade barriers.
If a plant protection product is not registered on a crop in the US, if it is detected on imported EU commodities, even if 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 at such low residue levels it could pose a risk to US consumers. Alternatively the US could follow other regulatory authorities such as the EU and set default MRLs. Setting a default MRL at level of quantification only allows import of crops treated with substances that are not registered or evaluated provided that a residue is below the default MRL. However, generally this allows only the use of these plant protection products in the very early growth stages of the crop. For all other uses is in general a so-called import tolerance required, meaning that data needs to be generated and submitted to the authorities for obtaining an MRL above the level of quantification.

Not having a default USA MRL increases costs for agrochemical companies because they have to go to the expense of applying for a US import tolerance for products with very low residues (e.g. below 0.01 mg/kg). Levels of detection at 0.005 mg/kg do not necessarily reflect direct pesticide use as they could have been picked up from packing lines or cases, spray drift or soil carryover.

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6.8. How should the European Union address the specific obstacles?

Plant Protection Products: The consequences of regulating chemicals by hazard classification and how this could be modified without compromising human health

It is possible to correct this by using established, science-based assessment criteria already successfully used in other areas of toxicology.

-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 is 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: Setting default US default MRLs at the limit of quantification would facilitate 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 trade hurdles.

Agricultural biotechnology crops; regulatory reform & alignment: Governments and EU institutions are urged to implement the current regulatory system in the way they themselves designed it, i.e. science based, transparent, predictable and with respect for legal time frames and the legal criteria for decision making, and upholding the freedom of choice for farmers.

There is a need for increased and regular participation by European farmers and farmers' organisations in the national and EU-wide dialogues regarding the regulatory framework for GMOs. This would contribute to a better-informed debate, particularly regarding the practical experiences with regulatory procedures for commercial cultivation, notifications, co-existence measures, and the like. It would also help the debate on actual socioeconomic and environmental impacts from GMO cultivation.

Europe is dependent on grain imports, most of which are GM. A slow approval process and trade barriers in Europe make imports of GM products more expensive and could result in major trade disruptions.

Many new crops are rapidly being developed and authorised around the world. According to the European Commission's Joint Research Centre, the number of commercial GM crops is set to increase to 120 or more by 2015. As new crops are released, which may include salt tolerant, drought tolerant, nitrogen efficient and nutritionally enhanced varieties, it seems unlikely that the EU can reasonably continue with its current approach.

6.9. What are the priority agri-food sectors on which food safety/animal health/plant health regulatory dialogue should focus?

We would recommend focusing on:

- Plant protection products
- Maximum Residue Levels (MRLs)
- Agricultural biotechnology crops

7. Customs procedures, border enforcement and trade facilitation

7.1. Are you concerned by current practices in customs procedures and border enforcement?*

Yes

7.2. If you are concerned by current practices, please specify which practices?

• ***Centralised clearance***: 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 States to which the goods are destined. The result is that companies operating in more than one Member States 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.

• ***EORI***: The current inability of many Member States (MS) 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.

• ***VAT as a 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.

• ***Secure Trade***: The EU Authorised Economic Operator [AEO] and the US Customs-Trade Partnership against Terrorism [C-TPAT] systems have significantly different focus and priorities, reducing the tangible benefits to licensed companies. The US system only reviews imports, not exports – which differs from the EU side and still requires duplicative processing by companies.

• ***Regulatory Reform and Harmonization***: In the US, there is a lack of regulatory coordination between customs/ Customs-Trade Partnership against Terrorism (C-TPAT) regulations and other programs/initiatives. Despite complying with C-TPAT certification, import self- assessment (ISA) requirements and advanced electronic filing, businesses can face delays because of the lack of alignment with import/export requirements by US regulatory agencies. An interagency task force to leverage the Customs Department's efforts to align and facilitate import certification, and to develop secure channels to ensure efficient regulatory certification processing and to work more closely with other involved regulatory agencies, should be established.

• ***Common Supply Chain Security approach***: The EU-US mutual recognition of air cargo security regimes (1 June 2012) avoids duplication of processes and procedures. The application process for Air Carriers to benefit from this agreement has been lengthy, does not cover all the processes, for a set term only (1 year) and can be revoked at any time. This process needs to be simplified, with no fixed term allowing mutual recognition to be based wholly on compliance to EU requirements and no more. This will help ensure a stronger, more resilient and sustainable security system.

• ***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.

7.3. If you are concerned by customs procedures and border enforcement, what are the estimated additional costs for your business (in percentage of the exports/imports) resulting from of customs procedures and border enforcement?

Centralised clearance: It is impossible to estimate the savings that will accrue to business if customs clearance for the import of shipments destined for all 27 Member States, could be performed in one single Member State. For a company operating in all 27 Member States currently, it would provide them with 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.
-Use a single facility in the Union, instead of multiple facilities

7.4. If you are concerned by customs procedures and border enforcement, what should be the European Union priorities to address the issue?

The EU and its Member States must meet their commitment to implement a viable centralised clearance procedure as set out in the Modernised 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 member state.

A uniform international system of standardised customs processes, efficient customs clearance and mutual recognition of customs and security related standards should be developed:

1.Harmonised requirements for advanced data for security purposes, to the extent that they accept the results of the risk analysis carried out as export as sufficient to meet the needs of the importing country.

2.Data elements required for the ACAS program in the US - 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.

3.AEO and C-TPAT status holders should benefit from zero or minimal requirement for the submission of data for risk analysis for security purposes.

4.Holders of AEO and C-TPAT status should be allowed to use their procedures to the benefit of their SME customers.

8. Protection of Intellectual Property Rights

8.1. Are you concerned by problems of protection and enforcement of intellectual property rights in your field of activity?*

Yes

8.2. If you are concerned by problems of protection and enforcement of intellectual property rights, please explain the problems you encounter.

AmCham EU is concerned that the global framework of protection and enforcement of the IPRs is currently under serious threat. More specifically, EU and US companies are confronting the challenges of:

• **Combating trade in counterfeit and pirated goods**: especially online, but also in other areas like agricultural chemicals and medicines. Illegal online activities are harming consumers, legitimate content providers and good manufacturers, and are also undermining trust in e-commerce, one of the key contributors to 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 pharmaceuticals and green technologies**.

8.3. Are you concerned by problems of protection for Geographical Indications or trademarks in your field of activity?

Yes

8.4. If you are concerned by problems of protection for Geographical Indications or trademarks, please explain the problems you encounter.

The value of trademarks is being undermined by Government interventions in markets in some jurisdictions which prejudice the investment that has been made in brands. More specifically, two main issues should be addressed:

In the field of tobacco products, there are government policies reducing or eliminating the ability of manufacturers to distinguish products from those of competitors through "plain packaging". Even in areas where health or environmental concerns exist, the mandated elimination or diminishment of trademarks creates a dangerous precedent for other industries. Other well defined policy alternatives and an evidence-based approach should be taken into consideration.

There is a severe problem of counterfeiting in the European Union. According to the commission's press release of 24 July 2012, EU Customs detained in 2011 almost 115 million products suspected of violating intellectual property rights (IPR) compared to 103 million in 2010. The number of intercepted cases increased by 15% compared to 2010. The value of the intercepted goods represented nearly €1.3 billion compared to €1.1 billion in 2010, according to the Commission's annual report on customs actions to enforce IPR. The top categories of articles stopped by customs were medicines (24%), packaging material (21%) and cigarettes (18%). Products for daily use and products that could be potentially dangerous to the health and safety of consumers accounted for a total of 28.6% of the total amount of detained articles, compared to 14.5% in 2010. These figures are very worrying and underline the need to maintain and increase the efforts being made to fight counterfeiting which acts against the interests of both industry and consumers.

8.5. If you are concerned by problems of protection and enforcement of intellectual property rights, including Geographical Indications and trademarks, what should be the European Union priorities to address the issues?

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 and are critical to the future competitiveness of the EU and US. Effective protection and enforcement of IP rights are essential for the continued development of innovative pharmaceuticals. The EU and US should seek to harmonise and align intellectual property protection and enforcement measures. In the context of a comprehensive trade agreement, industry would seek to secure a comprehensive IP chapter with standards equivalent to the EU. In addition, consideration should be given to the incorporation and enhancement of the existing IP Dialogue within the institutional framework of the enhanced relationship.

Furthermore, on patent issues several principles could guide the discussions between EU and US counterparts to strengthen the coordination of their policies: (I) Patent term restoration to compensate for excessive patent examination periods and for regulatory delays; (II) Parties should adopt patent enforcement systems that allow for early resolution of patent disputes before an infringing product is launched on the market; (III) Parties should seek to 'level up' regulatory data protection to the higher standard currently available in either Party (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 to avoid that a number of major emerging economies continue 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 an IP theft-based industrial policy.

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 will further transatlantic sharing of intelligence and the development of 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 are harming consumers, legitimate content providers and manufacturers' goods, there should be increased cooperation between the EU and US in collaboration with all actors in the internet ecosystem. Such efforts should be aligned with the online freedom of expression principles shared on both sides of the Atlantic.

Finally, where health and environmental concerns are at stake, the governments should not just propose eradication of IPRs 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.

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9. Trade in services

9.1. Are you concerned by barriers to trade in services in your field of activity?

Yes

9.2. If you concerned by barriers to trade in services, which ones are the most important ones? Please clarify whether:

They derive from local regulation being applied differently to you compared to domestic firms/ They discriminate against cross-border service provision
They affect your ability to establish physical outlets in the country and supply services through these outlets/ They affect the price of the services you provide/ They have other restrictive impacts

9.3. If "Other", please specify.

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 uneconomical 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 euros 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.

9.4. Please describe the barriers in detail.

A: Financial Services

The volume and complexity of the issues to be addressed in the financial services sector are better suited to a bespoke process amongst EU and US rule-makers than an FTA. However, we believe that a set of key principles for regulatory cooperation and convergence applying to all sectors, including financial services, should be an integral element of an FTA, even if their application needs to be delivered through sector-specific mechanisms. 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*: any comprehensive EU-US FTA that is negotiated 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.

B: 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.

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 if they block or severely restrict data flows. 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.

9.5. If you are concerned by barriers to trade in services, please indicate to which level of government the obstacles relate (multiple answers possible)?
US Federal / EU level regulation

9.6. If you are concerned by barriers to trade in services, what are the estimated additional costs (in percentage of the exports/imports) for your business resulting from the barriers to trade in services?

-

9.7. If you are concerned by barriers to trade in services, how should the European Union address these restrictions to trade in services?

A: Financial Services

1. 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.

2. 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. Any horizontal EU-US agreement 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.

3. 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.

4. 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.

B: Digital Economy

A comprehensive EU-US agreement 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.

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The prospect of a bilateral EU-US agreement 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 service providers and multinational businesses to move data around the world so that they can manage their businesses and server their customers most efficiently. 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.

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10. Investment

10.1. Are you concerned by barriers to direct investments in your field of activity?

Yes

10.2. If you are concerned by barriers to investment, please describe the barriers in detail.

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. AmCham EU is committed to working with the European Commission, Parliament and Member States to ensure that new legislative proposals are consistent with existing EU regulation. A balanced and coordinated legal framework will accelerate business developments that meet citizens' needs and foster growth.

10.3. If you are concerned by barriers to investment, please indicate to which level of government the regulatory obstacles relate?
US Federal / EU level regulation

10.4. If you are concerned by barriers to investment, what are the estimated additional costs for your business (in percentage of the investment) resulting from the barriers?

-

10.5. If you are concerned by barriers to investment, how should the European Union address the issue?

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 fora.

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.

11. Public Procurement

11.1. Are you concerned by restrictions in public procurement in your field of activity?

Yes

11.2. If you are concerned by restrictions in public procurement, please explain the restrictions.

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 any EU-US agreement reached addresses and resolves such issues. AmCham EU will soon circulate a new position paper on the recent EU proposal.

11.3. If you are concerned by restrictions in public procurement, please indicate to which level of government the obstacles relate (multiple answers possible)?

US Federal / EU level regulation

11.4. If you are concerned by restrictions in public procurement, what are the estimated additional costs/forgone revenue for your business resulting from these restrictions?

N/A

11.5. If you are concerned by restrictions in public procurement, what should be the European Union priorities to address the issue?

AmCham EU would welcome further work between the EU and US on opening public procurement markets. 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.

12. Competition issues

12.1. Are there fields where the European Union should seek to increase cooperation with the United States?

Yes

12.2. If there are there fields where the European Union should seek to increase cooperation with the United States, which fields?

Yes

Anti-trust/ Mergers/ Liberalisation

12.3. What should be the European Union priorities?*

The European Union 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 Commission 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. Facilitating the participation of small and medium sized enterprises (SMEs) in the transatlantic market place

13.1. In your view/experience, which of the sections in this questionnaire are of particular importance to SMEs? Please explain why?

In principle the entire questionnaire. A basic point worth bringing out in the strategy the Commission adopts to 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. More than 70% of the biotechnology companies in the EU employ less than 50 people. Venture capital and EU funding are fundamental if SMEs are to flourish in Europe and so promotes economic growth and lay a foundation for innovation and development of new medicines. However, the current economic situation has a negative impact on venture capital in Europe, particularly in comparison to the US and Asia. 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.

13.2. In your view/experience, how could SMEs better benefit from economic opportunities in transatlantic trade and investment relationships?

As set out in our answer to 13.1, 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.

The Regulation on European Venture Capital Funds should be implemented without delay to help facilitate better access to finance for SMEs across Europe. EU funding instruments (Particularly the EIB) should be made more accessible to biopharmaceutical SMEs and a short term investment vehicle should be developed to increase risk capital. The EU Framework Programme for Research should be more attractive for biopharmaceutical SMEs and unnecessary administrative and cost barriers should be addressed.

14. Impact on Consumers

14.1. In your view, would the elimination of barriers to trade and investment between the EU and the US have an effect on Consumers?

Yes

14.2. If yes, what impact do you expect?

Lower Prices/ Larger choice of products / Other

14.3. If "Other", please specify

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.

15. Environmental Impact

15.1. Do you expect impacts on the environment in the context of an enhanced EU-US trade cooperation?
Yes No Do not know / Not applicable

15.2. What impacts on the environment in the context of an enhanced EU-US trade cooperation do you expect?

Positive on: Air pollution/ Water pollution/ Ground pollution/ CO2emissions/ Impact on bio-diversity/ Other

15.3. If "Other", please specify

Industries in North America and Europe realise there is a comparative advantage in reducing energy consumption and 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 is 'green public procurement', 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 ecological 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.

15.4. Given the importance of commitments on environmental protection as underlying elements for international economic relations, how could the European Union and United States cooperate to further promote the adherence to and the strengthening of international principles, rights and agreements on environmental protection?

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 a possible EU-US FTA.

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 standards setting, 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.

16. Social Impact

16.1. Are you concerned by (trade-related) problems of protection or enforcement of labour and social rights in the United States or the EU in your field of activity?

Yes

16.2. Please explain

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.

16.3. Do you think that the level of employment in the European Union or United States respectively could be affected, positively or negatively in the context of an enhanced EU-US trade cooperation?

Positively in the EU and US

16.4. Do you think that wage levels in the European Union or United States respectively could be affected, positively or negatively in the context of an enhanced EU-US trade cooperation?

Do not know / Not applicable

16.5. Do you think that labour standards in the European Union or United States respectively could be affected, positively or negatively in the context of an enhanced EU-US trade cooperation?

Do not know / Not applicable

16.6. Given the importance of commitments on labour rights and decent work as underlying elements for international economic relations, how could the European Union and United States cooperate to further promote the adherence to and the strengthening of international recognised principles, rights and agreements on labour and decent work?*

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 labor 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.

17. Other issues

17.1. If there are any other issues that are not mentioned in this questionnaire that you would like to address, please use the space below to set them out.

If the enhanced relationship between the EU and US evolves to include pursuit of a comprehensive trade agreement, it 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 recognize the value of and reward innovation e.g. in setting prices. 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.

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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 U.S. investment in Europe totaled $2.2 trillion in 2010 and directly supports more than 4.2 million jobs in Europe.

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