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AAF – CRA

October 31, 2012

Mr. Daniel Mullaney
Assistant U.S. Trade Representative for Europe and the Middle East
United States Trade Representative
600 17th Street NW
Washington, DC 20508

To whom it may concern
European Commission
Directorate General for Trade
Unit F3
Rue de la Loi, 200
1043 – Brussels

Dear Mr. Mullaney, dear Official in charge in European Commission DG Trade :

RE: EU and US call for input on regulatory issues for a possible future trade agreement

The Corn Refiners Association (CRA) and the European Starch Industry Association (AAF) are pleased to jointly submit these comments in response to the Federal Register notice of September 28, 2012, "Promoting US EC Regulatory Compatibility: Request for Comments" (USTR-2012-0028).

CRA is the national trade association representing the corn refining (wet milling) industry of the United States. CRA and its predecessors have served this important segment of American agribusiness since 1913. Corn refiners manufacture sweeteners, ethanol, starch, bioproducts, corn oil and feed products from corn components such as starch, oil, protein and fiber.

AAF is the trade association which represents the interests of the EU starch industry both at European and international level. Its membership comprises 24 EU starch producing companies, together representing more than 95% of the EU starch industry, and, in associate membership, 7 national starch industry associations.

As the EU and U.S. work to promote greater regulatory coherence through the High Level Working Group on Jobs and Growth and the U.S.-EU High Level Regulatory Cooperation Forum, AAF and CRA would like to present the following issues of mutual concern. Harmonizing regulations in these areas would improve efficiencies in trade.

I. Pesticides

The Federal Food Drug & Cosmetic Act has a "no threshold" approach to pesticides found in foods when that pesticide does not have a specific tolerance provided by the Environmental Protection Agency (EPA) or an exemption from the requirement of a tolerance. Specifically, Section 402(a)(2)(B) of the Federal Food, Drug, & Cosmetic Act deems a raw agricultural commodity or a processed food or feed to be adulterated and subject to FDA enforcement action if it contains either: a pesticide residue at a level greater than that specified by a tolerance or

food additive regulation; or a pesticide residue for which there is no tolerance, tolerance exemption, or food additive regulation.

Likewise, in the EU, in the absence of a specific maximum residues level (MRL) under EU Regulation 396/2005, a very low default MRL (10 ppb) applies and materials exceeding it cannot enter the EU food and feed chain. Pesticides tolerances/MRLs are set in each geography further to submissions by producers of pesticides and experience shows that the uses they support often differ across geographies, resulting in asymmetric tolerances/MRL between US and EU, thereby limiting the entry and sale of these foods in the U.S. or in the EU market.

US and EU should explore which initiative they might introduce in their respective procedures and regulatory standards to take into consideration the MRL/tolerance of the other party (e.g. prerequisites and feasibility of a mutual recognition approach). In a first step it is suggested that a joint US/EU working group would address practical prerequisites to meet the fundamental requirement underlying both the US and EU legislation that MRLs/pesticides tolerances must be set at a level that is sufficiently protective of human and animal health. In particular this working group should define standard methodologies to assess to which extent a mutual recognition process might increase exposure to acceptable/unacceptable extent.

II. Food and Feed Contaminants/Undesirable Substances

Both the U.S. and the EU maintain regulations to prevent consumer exposure to a broad array of food contaminants (also known in EU regulation as "undesirable substances"). In the United States these substances are regulated by the Food and Drug Administration and in Europe by DG Sanco.

The relevant regulation in the U.S. is found in Section 402(a)(1) of the Federal Food, Drug and Cosmetic Act. In Europe, contaminants are regulated under Commission Regulation (EC No 1881/2006 (food) and Directive 2002/32 EC (feed).

Consumers in both the United States and Europe consume a widely varied diet in comparison to other regions of the world where diets are often characterized by heavy consumption of a few staple crops. Both the U.S. and Europe also have advanced food processing industries. While there are differences in U.S. and European diets, such as the type of grain, oilseed and animal products consumed, overall exposure to foods that may contain minor amounts of contaminants such as heavy metals, mycotoxins and chemical contaminants is generally similar. However, standards for maximum or action levels for these contaminants are often different between the U.S. and EU regulations. These differences can lead either to direct disruptions in trade when a non-compliant product is detected, and to producers, ingredient suppliers and food manufacturers having to alter what would be efficient and economical sourcing practices to account for regulatory differences. Harmonizing these regulations as much as possible would contribute to greater efficiencies in trade.

In order to address these horizontal differences, under the guidance of the HLWG, the relevant U.S. and EU regulatory agencies should create a side-by-side inventory of contaminant levels in food and feed (whether they are maximum limits, action levels or guideline levels), including levels adopted by the FAO/WHO Codex Alimentarius Commission. This document could be used to identify the most important and economically-significant differences in U.S. and EU

contaminant regulations and be a basis for regulators to determine where harmonization is possible while still maintaining appropriate consumer protection in both regions.

III. Definitions for Food and Feed

There is a need to develop common definitions for food and feed products in the U.S. and the European Union. The EU is systematically reviewing and reauthorizing its food additives and flavorings; whereas the U.S. uses several mechanisms to set specifications for food and feed, including specifically listing in the CFR text, listing by state agriculture departments, or by reference to third party standard setting organizations like the Food Chemicals Codex (FCC) and Association of American Feed Control Officials (AAFCO). Definitions should insure harmonization.

These specifications are set by FDA/AAFCO in the U.S. and EFSA in the European Union. Relevant provisions are 21 CFR and AAFCO Official Publication and EU community new list of feed materials.

Efforts should be made by the U.S. and the European Union to establish common specifications, thereby harmonizing definitions to facilitate trade. One option to achieve this objective could be to publish a Federal Register notice (and an equivalent public notice in the European Union) inviting comments on items that should be prioritized for harmonization. The U.S. and the EU should harmonize already approved food additives and ensure equivalent specifications and standards moving forward for food and feed products. Such harmonization would facilitate increased trade and compliance; however, the process to achieve harmonization could take several years with significant stakeholder input. Although progress on this issue would likely be slow, an incremental process aimed at implementing harmonization would still yield meaningful results.

IV. Certification Programs

Various certification programs are required by food and feed regulatory agencies as a condition of import. However, some certifications may not be consistent, reciprocal, or even needed at this time. Certification programs are often introduced in response to a specific trade problem or emergency situation. Once instituted, these programs may be continued well after the specific problem has been resolved.

Food and feed imports into the United States and the European Union are subject to a wide variety of government-mandated certification programs as a condition of entry. These may be health-related (phytosanitary certificates) or related to product composition. A comprehensive list of EU-required certification programs for food and feed has been developed by USDA and contains the specific legislation/regulation in the EU mandating certification (http://www.fas.usda.gov/gainfiles/200810/146296188.pdf). We are not aware of a similar comprehensive list of U.S. certification requirements.

An examination by regulatory authorities can be conducted to determine if there are outdated requirements which could lead to reduced burdens on business operators and importation officials. Using the USDA inventory as a guide, the European Union could prepare a similar list of certificates which EU exporters are required to present in order to enter food and feed

products into the United States. Both sides could then review these comprehensive lists and identify outdated or unnecessary certification programs that could be eliminated by mutual agreement. Elimination of unnecessary or outdated certification programs would reduce paperwork burdens both for industry and the regulatory agencies involved.

V. Food Safety Modernization Act (FSMA) Implementation

There are two regulatory issues relating to the implementation of FSMA: pathogens and the creation of a Foreign Supplier Verification Program. Implementation and enforcement of FSMA falls under the jurisdiction of the U.S. Food and Drug Administration.

Currently, there is a lack of clarity of what constitutes a pathogen and what products need to be tested. Our customers often ask for specific "pathogen-free" batch-wise testing. However, pathogens are neither defined, nor is the batch-wise testing for any product requested. Testing of this type is unnecessary for starches and other dry products. This issue has arisen since the U.S. Food Safety Modernization Act (FSMA) went into effect.

The U.S. FDA and its European counterpart should start a dialogue on the issue of pathogens and testing standards and validation methods to encourage harmonization of standards. Greater consistency between guidelines in the United States and European Union will make it easier for CRA and AAF member companies and their customers to know when pathogen testing is necessary.

FSMA also requires the establishment of a Foreign Supplier Verification Program. U.S. importers must have a program to verify that imported food is produced in accordance with U.S. requirements. Although it is still developing its guidelines, FDA may require the following: monitoring records for shipments, lot-by-lot certification of compliance, annual on-site inspections, checking the hazard analysis and preventative controls of the foreign supplier, and periodically testing and sampling shipments.

As the regulation for the Foreign Supplier Verification Program is established, we would encourage the FDA to consider ways to implement it so that trade between the United States and the European Union is not hindered unnecessarily in the process of ensuring a safe food supply.

VI. Toxic Substances Control Act (TSCA) Reform

The Toxic Substances Control Act ("TSCA") imposes a number of recordkeeping and reporting obligations that are burdensome because of the difficulties that companies face in often having to track a small portion of overall production that is used for TSCA-regulated purposes. Most burdensome are the recordkeeping obligations under Section 8 (c) of TSCA and the reporting obligations under Section 8(b) of TSCA, notably Chemical Data Reporting ("CDR"). The food processing part of the industry is already heavily regulated by the Federal Food and Drug Administration ("FDA") and the overlapping regulation under TSCA results in duplicative and unnecessary additional paperwork. Food-derived substances have a long history of safe use and, accordingly, the existing TSCA recordkeeping and reporting obligations impose burdens and cost on our industry without a substantial health or environmental benefit.

TSCA reform should focus on the evaluation and appropriate management of high risk chemicals and provide incentives, rather than disincentives, for the development of safer chemicals. In that

regard, pre-manufacture review of new food-derived substances should be streamlined under Section 5 of TSCA in order to provide incentives for the industry to develop alternatives to traditional industrial chemicals. Any substances that are approved for use by the FDA should benefit from reduced data requirements and review time frames relative to traditional industrial chemistries. The new safety determination process for existing chemicals under Section 6 of TSCA should assign a low priority to food-derived substances because it is unnecessary to subject substances already evaluated by the FDA and found to be safe for consumption to a separate safety determination under TSCA. Consistent with the goal of providing incentives for the development of safer alternatives to traditional industrial chemicals, the recordkeeping and reporting obligations under the CDR should impose fewer requirements on FDA-approved food-derived substances.

By learning from each other, regulatory agencies and industry will avoid the significant and wasteful expenditures of time and money to reestablish what was clear at the outset, i.e. that sugars, food-grade gums, vegetable oils and fats, etc. are safe. To date, we understand the consortium working on vegetable oils and fats in Europe has spent in excess of 1.5 million euro to register 66 closely-related substances under REACH.

In conclusion, thank you for your consideration of these comments. We look forward to working with you on these issues to improve efficiencies in trade for our industry's products.

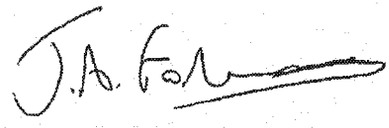
Sincerely,

Audrae Erickson
President

Corn Refiners Association

Jamie Fortescue
Managing Director

European Starch Industry Association



HAF-CRA

AdvaMed Recommendations for U.S. EC Regulatory Compatibility – October 31, 2012

Names of the relevant regulatory agencies in the EU and US	Issue / Citations to the relevant regulatory and/or statutory provisions for each jurisdiction	Description of the regulatory differences	Possible solutions for bridging these differences	Steps that the EU and/or the US should consider to address horizontal and/or sectoral differences	An assessment of the effects of enhanced regulatory compatibility the likelihood of these effects occurring, and the time period over which they would occur.
U.S. Food and Drug Administration (FDA) and the European Commission (DG Sanco)	FDA's proposed rule for a Unique Device Identification (UDI) System and Article 24 (row 237) of the EC's proposed regulation for medical devices	An initial comparison is difficult since Article 24 is a general outline of a possible framework whereas the US has a long and detailed rule under review. Based on what the EC has laid out, traceability appears to be a major objective of Article 24; unlike the FDA's proposed rule. The EU market is different from the US, i.e. gray market is not a concern in the US.	The EC and US should work together through the International Medical Device Regulators Forum (IMDRF) and bilaterally to ensure that there is regulatory compatibility for each region's UDI regime.	Both governments need to ensure that required data elements are aligned. Data transmission protocols are also critical.	We expect that that the FDA final rule will be in effect, at least for Class III products, well before the EC has a an enforceable law.

U.S. Food and Drug Administration (FDA) and EU Member State's competent authorities and Notified Bodies	The US and EU system for manufacturer inspections and audits	Currently the US FDA and Member State competent authorities conduct independent inspections of medical device manufacturer facilities.	Both sides should consider a single audit system that would allow the relevant authorities to share inspection reports and reduce duplicative audits and inspections.	NA	A single or mutual recognition system for company inspections and audits would facilitate information sharing between the EU and US and reduce the burden on both regulators and industry. Greater efficiencies on both sides would facilitate market access to innovative products. A mutual recognition system should be considered as the EU finalized its new regulations for medical devices and IVDs.
U.S. Food and Drug Administration (FDA) and EU Member State's competent authorities and Notified Bodies	The use and recognition of relevant standards such as ISO 14971 in the FDA review process and the EU's CE Mark process.	FDA recognizes the 14971 standard as written. The recent EU action to harmonize the standard with a revised interpretation rejecting the use of the ALARP principle ("as low as reasonably accepted") to determine the acceptable risk level is counter to	The EU should reconsider this action. Otherwise many products will potentially become unavailable in the EU as a result of having a more severe, and in some cases impossible requirement regarding setting an acceptable risk level for certain medical devices.	The EU could confer with either ISO TC 210 or with the US FDA regarding a resolution path to return to the previously-held interpretation.	This issue should be addressed quickly before the disparity of this new interpretation reduces the viability of the EU market for certain medical devices.

		internationally accepted practice.			

Source: https://www.federalregister.gov/articles/2012/09/28/2012-23613/promoting-us-ec-regulatory-compatibility

ACEA | European Automobile Manufacturers Association

THE SECRETARY GENERAL

Mr Jean-Luc DEMARTY
Director-General
Directorate-General for Trade
EUROPEAN COMMISSION
B-1049 BRUSSELS

Mr Daniel CALLEJA CRESPO
Director-General
Directorate-General for
Enterprise and Industry
EUROPEAN COMMISSION
B-1049 BRUSSELS

Brussels, 7 December 2012

Subject: AAPC/ACEA Joint Submission to the HLWG

Dear Mr Demarty,
Dear Mr Calleja Crespo,

Please find attached the "AAPC and ACEA Joint Submission in Support of Automotive Regulatory Harmonization in a European Union–United States Trade and Investment Agreement", as well as the joint AAPC/ACEA letter to the Commission and to USTR.

ACEA welcomed the interim HLWG report, which states that "… a comprehensive transatlantic trade and investment agreement, if achievable, is the option that has the greatest potential for supporting jobs and promoting growth and competitiveness across the Atlantic". ACEA fully concurs with that assessment and the merits of pursuing a bilateral trade agreement (ETP) between the United States (US) and the European Union (EU).

Our industry expects the initiation by the EU Commission of an impact assessment, the results of which, namely for our industry, should condition the launch of the negotiations of a deep and comprehensive ETP with the US.

An ETP with the US should be ambitious and address tariff and non-tariff measures in the automotive sector. The following key objectives should be achieved in the phase of negotiation: the elimination of tariffs and regulatory convergence as part of the full elimination of non-tariff barriers. Our industry's position is that tariffs should only be reduced/eliminated following a successful alignment of regulations (maximum in parallel), especially in the fields of safety and the environment.

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These negotiations should also lead to acceptable results on product liability rules, which remain a major concern and a prerequisite for the automotive industry in EU–US trade. In this regard, the mutual recognition of the US certification and EU homologation processes, along with their respective quality management processes, is fundamental. The procedure regarding mutual recognition of existing regulations and future technical harmonization should draw upon WP 29 UNECE ('58 and '98 agreement).

ACEA would appreciate it if the final HLWG report could include a reference to the AAPC/ACEA joint submission as we expect it to recommend the launch of the ETP negotiations.

It is our understanding that AAPC will send the AAPC/ACEA joint submission to USTR.

We look forward to cooperating with you on this important and challenging topic.

Yours sincerely,

Ivan Hodac

Encl.

cc: Mr Ignacio Garcia Bercero, Director, Directorate-General for Trade, European Commission
Mr Carlo Pettinelli, Director, Directorate-General for Enterprise and Industry, European Commission
Mr Damien Levie, Head of Unit, Directorate-General for Trade, European Commission
Mr Philippe Jean, Head of Unit, Directorate-General for Enterprise and Industry, European Commission

AAPC
AMERICAN AUTOMOTIVE POLICY COUNCIL

ACEA
European Automobile Manufacturers Association

AAPC and ACEA Joint Submission in Support of Automotive Regulatory Harmonization in a European Union-United States Trade and Investment Agreement

7 December 2012

Introduction

ACEA and the AAPC welcome the interim HLWG report, which states *"...a comprehensive transatlantic trade and investment agreement, if achievable, is the option that has the greatest potential for supporting jobs and promoting growth and competitiveness across the Atlantic"*, and fully concur with that assessment and the merits of pursuing a bilateral trade agreement between the United States (US) and the European Union (EU).

ACEA and AAPC call for an ambitious agreement addressing tariff and non-tariff measures in the automotive sector. The negotiations should use all possible tools available to achieve key objectives in parallel, which include:

- Tariff elimination, and;
- Regulatory convergence as a part of the full elimination of non-tariff barriers.

Although there is already a robust exchange of automotive trade and investment between the US and the EU, some policies and practices, including tariff and non-tariff measures, unnecessarily burden and impede that activity.

Addressing these measures in a bilateral trade agreement would help ensure that the auto sector gains the efficiencies that are expected to come from such a deal and would significantly contribute to economic growth on both sides of the Atlantic.

Greater auto regulatory harmonization between the EU and US would open the door for increased trade, lower costs, create jobs, and improve the international competitiveness of the industry on both sides of the Atlantic. This would strengthen the automotive industry and the economic contribution made in both regions.

Representing a market of almost 30 million annual vehicle sales, the transatlantic partnership would also set up the EU and the US as the worldwide standard setters and encourage third parties to adopt international regulations and avoid further auto regulatory fragmentation.

Today, significant differences exist in the prescribed test procedures and requirements between the US and EU regulations, although both effectively address the same motor vehicle safety and environmental challenges.

For over two decades, US and EU regulators have long promised to achieve global regulatory uniformity and to encourage a collaborative approach in testing and certification procedures by promoting greater acceptance of comparable regulations and health and safety-related measures.

Yet, there is little to show for these efforts. In the past fifteen years, only seven safety regulations[1] have been globally harmonized through participation in the United Nations Working Party 29 (UN WP.29).

The negotiation of a transatlantic trade agreement presents an opportunity to implement a regime that effectively breaks down regulatory barriers in the auto sector, while respecting US and EU sovereignty and without sacrificing vehicle safety or environmental performance.

Guiding Principles for Harmonization of EU-US Automotive Technical Regulations

In order for auto sector regulatory harmonization efforts to succeed, there must be:

- Strong and sustained political support at the highest levels of government, and the relevant regulatory authorities;
- Ambitious negotiating objectives fully supported by the relevant regulatory authorities and a commitment to achieve them in an accelerated time frame during the FTA negotiations;
- No net increase in US or EU regulatory requirements;
- No new third regulations (in addition to existing EU or US regulations);
- No net increase in vehicle production and certification costs.

ACEA and AAPC recommend that regulatory harmonization efforts pursue two paths concurrently:

1. Acceptance of existing regulations based on data driven analyses. The term "acceptance" for purposes of this paper, is meant to broadly cover the concepts of unilateral and mutual acceptance/recognition of US and EU automotive regulations. It could also draw upon UN WP.29 ('58 and '98 agreements) concepts, including equivalence and technical harmonization. ACEA and AAPC will subsequently provide additional details on their preferred approach.
2. When it is determined that a new regulation is needed (e.g. electric vehicles), promotion and facilitation of strong EU-US bilateral and multilateral cooperation to avoid the development of divergent regulations.

[1] Pedestrian safety, head restraints, door locks, safety glazing, electronic stability control, motorcycle controls and displays, and motorcycle braking systems.

Acceptance of Existing Regulations

The AAPC and ACEA propose that acceptance of existing EU regulations in the US, and vice versa, should be self-executing. Rather than attempt to analyze and then unify divergent requirements/testing procedures – exercises that have virtually paralyzed harmonization efforts to date – the focus should be a data-driven evaluation of a given regulation.

Acceptance of an existing regulation should be presumed recognizing the significant advancements that the regulations have provided in environmental and safety technologies in both the US and the EU, unless, within a defined time frame, the analysis of the data conducted by the responsible regulatory agency demonstrates that the regulation is deficient from a safety or environmental perspective.

Rather than wait for the conclusion of FTA negotiations and entry-in-force of the trade pact to initiate this regulations acceptance review process, ACEA and AAPC recommend that that process begin in earnest immediately in close cooperation with the industry in order to take advantage of the current increased existing political will and interest in these issues. In conjunction with this submission, AAPC and ACEA are presenting a preliminary and non-exhaustive list of regulations where regulatory convergence could be appropriate and beneficial (see Annex I). In the near term, ACEA and AAPC will identify a list of commercially meaningful auto regulations, to be addressed as priorities, for which ACEA and AAPC believe acceptance is appropriate. ACEA and AAPC propose that US and EU negotiators secure acceptance of these priority regulations during the course of the FTA negotiations based on data driven analyses.

Development of Common Future New Regulations

When a new regulation is needed, a joint EU-US auto regulatory harmonization process, that takes into account differences in US and EU auto regulatory development and implementation timelines, needs to be developed that promotes and facilitates the development and adoption of common future new regulations. Ideally, this process would include a mechanism to foster the development of common voluntary standards in the pre-regulatory environment. In developing this joint approach, the lessons and experience of the recent US-EU collaboration in developing an electric vehicle plug standard, and other voluntary agreements, should be heavily drawn upon.

Specifically, the development of each future new harmonized approach, should:

- Aim at strengthening the automotive industry in both regions towards the 21st century;
- Reduce complexity costs or administrative burdens while keeping needed flexibility;
- Have strong and sustained political support at the highest levels of government;
- Engage industry to work together to develop each harmonized approach;
- Provide a timeline to complete the development of each harmonized approach.

The outcome of this joint EU-US auto regulatory harmonization process should also be an agreement to help streamline and improve the efficiency of the current global auto regulatory development process (i.e. avoid as much as possible the introduction of options or exemptions under the GTR process of the UN WP.29 '98 Agreement or '58 Agreement).

In addition to the need to address divergent US and EU auto regulations, governmental consumer information (public domain assessments) testing and rating requirements in the US and EU, which also have a significant impact on transatlantic trade, are often divergent. The goal of consistency in these protocols would also contribute to enhanced cooperation and transatlantic trade opportunity.

Conclusion

ACEA and AAPC are excited about the opportunities for tariff reduction and regulatory harmonization presented by the negotiation of a bilateral trade agreement between the EU and the US. The objective of the EU—US negotiation should be to address auto NTBs and import duties. The EU-US negotiations, and in particular on the issue of regulatory harmonization should consider the role of consumer information (public domain) assessments and be seen also in the context of the global trade environment and lead to the extension of benefits to NAFTA partners.

To achieve these goals, there must be overwhelming and sustainable political will at the highest levels. Anything less and there is a significant risk that history will repeat itself and this harmonization effort will fail. ACEA and AAPC, as well as the EU and the US as a whole, cannot afford that result.

Annex I: Preliminary, non-exhaustive list of existing auto-related safety and environmental regulations where harmonization could be beneficial for the industry:

- **SAFETY**

Regulation (EU / US) - Comment
Front impact (ECE R94 / FMVSS 201 & 208) – unbelted & PAB suppression/low-risk deployment testing in US
Side impact (ECE R 95 / FMVSS 214) – GTR on PSI progressing; MDB testing will remain different
Rear impact (ECE R34 / FMVSS 301 303 & 305) - covered with fuel tank req. in EU for ICE and Hybrid vehicles
Pedestrian Protection (79/2009 EEC / -) – GTR established
Tyre pressure monitoring (ECE R64 / FMVSS 138) – EU covers safety & environment
Door locks and latches (ECE R11 / FMVSS 206) – GTR contains one option
Controls and Tell Tales (ECE R121 / FMVSS 101) – both broadly reference ISO
Braking incl. BAS, ESC, etc. (ECE R 13H / FMVSS 126 &105 & 106 & 116 & 121 & 135) – GTR on ESC contains options for methods
Lighting (ECE R48 & 7 & 6 & 4 & 23 & 31 & 37 & 38 & 77 & 87 & 91 & 98 & 99 & 112 & 119 & 123 / FMVSS 108 & Part 564)
Roof Crush Resistance (- / FMVSS 216)
Eject mitigation (- / FMVSS 226) – will drive unique side curtain designs in US even with PSI GTR
Steering effort (ECE R79 / -)
Audible warning (ECE R28 / -)
Electric safety (ECE R100 & 12 & 94 & 95 / FMVSS 305) – GTR on EVs progressing
Anti-theft (ECE R116 & 18 & 97 / FMVSS 114 & Part 541 and 543)
Seat strength and head restraints (ECE R17 / FMVSS 202a) – GTR in place for HR
Seat belt anchorages (ECE R14 & 16 / FMVSS 210)
Seat belt and restraint systems (ECE R16 & 44 / FMVSS 208, 209 & 213)
Defrost / demist (672/2010 / FMVSS 103)
Child restraint anchorage systems (ECE R14, 16 & 44/ FMVSS 225) – pull test in the US has a higher pull force
Wash / wipe (1008/2010 / FMVSS 104)
Heating system (ECE R122/ -)
Safety glazing (ECE R43 / FMVSS 205) – GTR in place (marking is different)
Tyres (ECE R30 & & 54 & 64 & 117 / FMVSS 109 & 110 & 119 & 120 & 129 & 139) - GTR progressing
Flammability of materials (ECE R118 / FMVSS 302) – only commonality is the horizontal burn test
Windshield Zone Intrusion (- / FMVSS 219)
Windshield Mounting (- / FMVSS 212)
Seat Assembly (ECE R 17 / FMVSS 209 & 210)
Seating System (ECE R17 & 80 / FMVSS 207)
Impact from Steering Control (ECE-R12 / FMVSS 203 & 204)
Warning Devices (ECE-27 & 65 & 13H & 13 / FMVSS 125)
Accelerator Control System (ECE R89 / FMVSS 124) – different scope between the regions
Power Operated Windows, etc. (ECE R21 / FMVSS 118)
Hood Latch System (- / FMVSS 113)
Rear Visibility (ECE R46 / FMVSS 111) – no warning on the mirrors; ECE includes indirect vision; rear view cameras and displays in the US
Transmission Shift lever, etc. (GSI from GSR / FMVSS 102)
Internal Trunk Release (- / FMVSS 401)
Event Data Recorder (- / Part 563)

Interior Fittings (ECE R21 / FMVSS 101)
Exterior Projections (ECE R26 / -)
Speedometer, reverse Gear (ECE R39 / State requirements)
Forward Vision (ECE R125 / -)
Rear, Side and Front under run (ECE R58, 73 & 93 / Part 393)
Tachographs (1360/2002 EEC / -)
Masses & Dimensions (92/121 EEC / -)
Certification Label / VIN Manufacturers Plate (19/2011 / Part 565)
Emergency towing hook (1005/2010 / -)
Couplings (ECE R55 / -)
Driver Distraction Guidelines (ESOP / Alliance guidelines) – US guidelines based on ESOP but distinct tests included
Quiet Car (RE.3 reference / NPRM)

- **ENVIRONMENTAL**

Regulation
Sound levels (drive by noise)
EMC
Recycling
RFI
Emissions Light / Med / Heavy duty - Tailpipe Criteria pollutants - Supplemental (MAC / Aggressive driv.) - Low Temp - Evaporative Emissions - OBD - Low temperature testing - NOx aftertreatment anti-tamper - Durability - Diesel Smoke - Real Driving Emissions
A/C systems - MAC working fluid - MAC testing
GHG emissions - Definition of GHG - Test cycle - Standards
Power
Right to repair / Repair maintenance info

AdvaMed
Advanced Medical Technology Association

October 31, 2012

To:

Boris Bershteyn
Acting Administrator
Office of Information and Regulatory Affairs

Jean-Luc Demarty
Director General
Director General for Trade

Daniel Calleja Crespo
Director General
Director General for Enterprise and Industry

Ambassador Miriam Sapiro
Deputy U.S. Trade Representative
Office of the U.S. Trade Representative

The Advanced Medical Technology Association (AdvaMed) would like to thank the European Commission and the U.S. Government for the opportunity to share its views on how to promote greater transatlantic regulatory compatibility. AdvaMed welcomes both governments' stated goal of reducing excessive regulatory costs, unjustified regulatory differences, and unnecessary red tape while respecting each other's right to protect public health, safety, welfare, and the environment. During this critical time for both our economies, we also share the view that greater transatlantic regulatory compatibility will help businesses to grow, create jobs, and compete globally.

The medical technology industry creates the medical devices and diagnostics that are central to modern health care. Not only is medical technology a source of life-enhancing and life-sustaining treatments and cures, as a major manufacturing industry, it is a driver of current and future economic growth in the U.S. and Europe. The future potential for global economic growth driven by medical technology is great. World-wide markets for medical technology will expand dramatically as populations age in countries around the globe and as hundreds of millions of people in countries like India and China enter the middle class and demand access to modern, quality health care. Given the huge potential of this sector, it is critical that the U.S. and the European Union make this sector a priority as bilateral mechanisms are developed to promote regulatory compatibility and enhance economic cooperation.

The European Commission and U.S. Government already participate in multilateral efforts to promote regulatory harmonization through forums such as the International Medical Device Regulators Forum (IMDRF) but more can be done bilaterally to ensure that our governments achieve their regulatory objectives in a more effective and efficient manner. In particular, we urge both governments to work together as the European Commission develops new regulations for medical devices and in vitro diagnostics, to identify specific where greater regulatory convergence would reduce the regulatory burden on US and European manufacturers and regulators, speed up the pace of innovation and bringing technologies to patients in a timelier

AdvaMed
Advanced Medical Technology Association

manner. With this in mind, AdvaMed prepared the attached matrix with specific recommendations for regulatory cooperation between the EU and US in the medical device sector.

Thank you for your consideration and we look forward to working with both Governments on this initiative.

Yours truly,

Steve Ubl Serge
President and CEO
AdvaMed

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AESGP CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

AESGP and CHPA response to the
EU-US call for industry input on regulatory issues for possible future EU-US trade agreement

The Association of the European Self-Medication Industry (AESGP) and the Consumer Healthcare Products Association (CHPA) welcome the EU-US call for input on regulatory issues for a possible future EU-US trade agreement.

AESGP and CHPA acknowledge the significant role of the High Level Working Group on Jobs and Growth in the further development of EU-US relations and welcome the group's interim report conclusions. The two associations especially commend the intention to develop in the context of EU-US dialogue "concrete action plans to reduce unnecessary regulatory costs and promote regulatory compatibility".

AESGP and CHPA would like to use the occasion of this consultation to raise for consideration in the future EU-US dialogue the following issues relating to the self-care sector:

a. Market Exclusivity

Currently, the EU offers only a one year exclusivity period for relevant scientific work in the context of the reclassification of an ingredient from prescription to non-prescription status or with regard to a new indication for a known substance. The limited exclusivity period presents a barrier to free trade as it does not provide adequate time to recoup the investment needed to fulfill the relevant EU regulatory obligations.

In comparison, the US practice of granting 3 years data protection promotes innovation and opens up the self-care market to investment. It results in significant public health and economic benefits. Therefore harmonisation with the US provision should be sought for the periods of data protection provided in the EU.

Relevant EU legislative/regulatory provision	Relevant US legislative/regulatory provision
Directive 2001/83/EC *Article 10* 5. In addition to the provisions laid down in paragraph 1, where an application is made for a new indication for a well-established substance, a non-cumulative period of **one year of data exclusivity** shall be granted, provided that significant pre-clinical or clinical studies were carried out in relation to the new indication.	Federal Food, Drug, and Cosmetic Act (21 USC 301 et seq.) 21 USC 355(c) and 355(j) (using parallel language for contents of new drug applications, and abbreviated new drug applications, respectively; subsection (b) language shown below) (Waxman-Hatch Act) [I]f an application submitted under subsection (b) of this section for a drug, which includes an active ingredient (including any
Article 74a Where a change of classification of a medicinal	ester or salt of the active ingredient) that has been approved in another application approved under subsection (b) of this section, is approved after September 24, 1984, and if such application

product has been authorised on the basis of significant pre-clinical tests or clinical trials, the competent authority shall not refer to the results of those tests or trials when examining an application by another applicant for or holder of marketing authorisation for a change of classification of the same substance for **one year** after the initial change was authorised. **AGENCY:** European Commission	contains reports of new clinical investigations (other than bioavailability studies) essential to the approval of the application and conducted or sponsored by the applicant, the Secretary may not make the approval of an application submitted under subsection (b) of this section for the conditions of approval of such drug in the approved subsection (b) application **effective before the expiration of three years from the date of the approval** of the application under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. (iv) If a supplement to an application approved under subsection (b) of this section is approved after September 24, 1984, and the supplement contains reports of new clinical investigations (other than bioavailabilty 1 studies) essential to the approval of the supplement and conducted or sponsored by the person submitting the supplement, the Secretary may not make the approval of an application submitted under subsection (b) of this section for a change approved in the supplement **effective before the expiration of three years from the date of the approval** of the supplement under subsection (b) of this section if the investigations described in clause (A) of subsection (b)(1) of this section and relied upon by the applicant for approval of the application were not conducted by or for the applicant and if the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. **AGENCY:** FDA

b. Manufacturing Audits

Both FDA and European authorities (the European Medicines Agency and member state medicines agencies or other national competent authorities) require audits of pharmaceutical manufacturing facilities.

These audits, which are based on comparable standards and essentially pursue the same goals, are duplicative and thus cause unnecessary cost and redundancy. It is recommended to substantially increase the joint acceptance of audits performed by partner authorities, or acceptance of the documentation gathered by partner authorities during audits.

Relevant EU legislative/regulatory provision	Relevant US legislative/regulatory provision
The principles and guidelines for GMP are stated in two Directives: • Directive 2003/94/EC for medicines and investigational medicines for human use; • Directive 91/412/EEC for medicines for veterinary use. **AGENCY:** EMA, national competent authorities.	Basic authority for inspections is described in 21 USC 374. **AGENCY:** FDA

c. Foreign Data Acceptance for Marketing Authorisation Applications

FDA frequently does not accept bibliographic data for marketing authorisations, and instead requires new data to be generated on medicinal products in US patients, despite considerable safety and efficacy databases being available from European or other patient groups. However, US patient data is readily accepted as a basis for European Marketing Authorisation applications.

The US practice represents a barrier to free trade by unnecessarily discriminating against companies who have complied data based on clinical trials conducted in the EU. It creates the need for clinically unnecessary and therefore ethically questionable duplication of clinical trials, leading to increases in the costs and time required to gain Marketing Authorisations. As long as data meet FDA's clinical standards, there is no justification for these no to be accepted.

Relevant EU legislative/regulatory provision	Relevant US legislative/regulatory provision
-	**FDA regulations governing the conduct of clinical trials describe good clinical practices (GCPs) for studies with both human and non-human animal subjects** 21 CFR Part 312 [Docket No. 2004N–0018] Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application **AGENCY:** FDA

AESGP CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

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About:

AESGP

The Association of the European Self-Medication Industry (AESGP) is the representation of manufacturers of non-prescription medicines, food supplements and self-care medical devices in Europe.

CHPA

The Consumer Healthcare Products Association (CHPA) represents the manufacturers and distributors of non-prescription, over-the-counter (OTC) medicines and dietary supplements in the US.

KADINOVA Desislava (TRADE)

From: Alex Burgalés <alejandro.burgales@afme.es>
Sent: 05 November 2012 09:42
To: ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Cc: TRADE F3 SECRETARIAT
Subject: Consulta aspectos regulatorios HLGW

Dear All,

Sorry for the delay in answering your request of information.

Regarding the trade barriers in USA, the most important one is the need of obtaining the UL product certification. For their products the CE mark is enough when entering our markets. The procedures to obtain the UL certification mark are costly and some of our companies have the feeling that they take longer than needed.

Our sector is the Low Voltage Electrical Equipment.

Best regards,

Álex Burgalés Director Comercial

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De: Rojo Virseda, Maria Rosa [mailto:MRRojo@comercio.mineco.es]
Enviado el: lunes, 22 de octubre de 2012 17:24
Para: ACEXPIEL ; ACEXPIEL 2 ; AEC; AEC (E. Coquillat); AEFJ; AEFJ 2; AEMZU ; AFEC; AFEMMA; AFHSE; AFM; AFME; AFOEX; AFYDAD; AGRAGEX; AGRAGEX (A. Madina); AGRUCÓN; AILIMPO; ALMENDRAVE; AMEC; AMETIC (Virginia) ; ANAIP; ANAIP (Dirección) ; ANFAC (Administración); ANFAC (d.economico); ANFAC 2 (Secretaría); ANFACO; ANFACO (Dirección); ANFACO 3 (M.Aymerich); ANFALUM (Dirección); ANFALUM (Pomatta) ; ANFALUM (Secretaría); ANFFE; ANIEME; ANIEME 2 ; ANMOPYC; ANMOPYC (Director); ARMERA; ARMERA (Dirección); ASCER (A.M.); ASCER (general) ; ASCER (Michel Toumi); ASCER(G.B.); ASEBIO; ASEFI (Director); ASEFMA; ASEFMA (Director); ASEMESA; ASEPRI ; ASEPRI (Administración); ASEPRI (Dirección); ASEPRI (Documentación) ; ASOLIVA; ASOLIVA (Dirección); ASPAPEL (general); ATA; CAUCHO; CAUCHO (Economica) ; CCAE (Administración); CCAE (Director) ; CCAE (general) ; CCAE (Subdirector); CÍTRICOS; CITRICOS (J.Perez); CLUBEX; COFEARFE (general); COFEARFE (Valencia); CONFECARNE; CONFECARNE 2; CONFEMADERA ; CONXEMAR ; CONXEMAR (Madrid); CONXEMAR (Tere) ; cristina.cofearfe; EDITORES; EDITORES 2 (COMEX); EDUESPAÑA; FAMO; FAPAE; FAPAE (Directora) ; FDP ; FDP (Monserrat Barberá); FEAD; FEAD 2; FEDAI DEC; FEDAI DEC 2; fedejerez@fedejerez.com; FEIQUE
Asunto: Consulta aspectos regulatorios HLGW

Estimados amigos:

La UE Y EE.UU lanzaron en el mes de septiembre pasado una consulta pública conjunta para solicitar propuestas concretas sobre compatibilidad regulatoria a ambos lados del Atlántico. La consulta tiene por objeto identificar aquellas diferencias regulatorias que dificultan el comercio y reducir los costes adicionales que supone la aplicación de distintas normas y estándares.

Esta consulta finaliza el próximo 31 de octubre y se desea saber si esa Asociacion o su homóloga europea han participado o van a participar en la mencionada consulta y en caso afirmativo, si nos pueden enviar sus aportaciones y/o las de la Asociacion europea, ya que esa información es fundamental para conocer las barreras a las que se enfrentan en el comercio con los EE.UU.

Toda la información sobre la consulta se encuentra en el siguiente enlace:

http://trade.ec.europa.eu/consultations/?consul_id=170

Muchas gracias por vuestra colaboración. Un cordial saludo,

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AMCHAM EU

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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27 September 2012

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.

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.

• ***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.

For further information please see Annex 1.

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.

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

<u>For further information please see Annex 2.</u>

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.

For further information please see Annex 3.

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?

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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.

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.

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?

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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

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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Annex

Annex 1: Energy

Mutual Recognition of EU-US Standards and Regulations

US businesses which design and manufacture to long standing US national standards and codes have difficulty entering the EU market place when similar EN and EU member national standards and regulations don't align, e.g. EU PED and US ASME B&PV code. 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 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 harmonized their regional/national standards with similar international standards, and countries outside of either these regions accept or have adopted international standards for their economies, then it follows that either EU or US standards covered under MRAs would also be accepted.

Technical Regulations and Standards Cooperation with Third Countries

Historically 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. We see specific success in the global acceptance of the US FAA's aviation and FDA's food and drug regulations and standards approach over the years for these industries. For products that do not have Federal regulations like for pressure equipment, structural design, machinery, and electrical, the US in years past 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 rapidly replaced by the acceptance of European regulations and standards which is directly causing a US-EU and US-Third Country barrier to trade for these products.

The European Union in the past decade has been very successful in influencing the adoption of EU product technical regulations, directives, and standards by Countries outside the European Economic Area (third countries) through their European Union Neighborhood Policy and other outreach initiatives. The EU has been able to achieve adoption and mutual recognition of their regulations and standards in Africa, Middle East, and Asia. Due to the growing acceptance and adoption of European technical regulations and standards it has accelerated the EU's ability to trade between more countries with little to no product technical barriers. Despite the EU's efforts to harmonize their regulatory and standards approaches with other countries, today there still are 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 coorperation with third countries, the US and EU should first work on identifying and promulgating mutual regulatory and standards acceptance for such product like pressure equipment, structural, electrical, equipment used in potentially explosive environments, and machinery. This is not a simple task as the US and EU manage these requirements at different judicial levels (Federal versus State) and the standards that are recognized 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 a Manufacturer to ensure the product has 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 product Manufacturers are forced to conduct immunity testing in order to export to the EU. This testing which can double or triple testing costs as 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. The Electromagnetic Compatibility Directive is not considered to be for safety (per Recital 10 of the Directive).

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. 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.

We recommend a mutual recognition agreement be considered and 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 level of testing.

Smart Grid

We strongly believes that technical standards can accelerate innovation and investment in emerging technologies. Policymakers from both the United States (US) and the European Union (EU) also recognize 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 harmonization that both 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 organizations (SDOs) to address gaps where new standards are needed, or to coordinate between complementary standards that already exist for a given application.

- Create opportunities for SGIP representation on the EU Joint Working Group, established to advise the European Commission on European requirements related to the standardization 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 harmonized 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 organizations.

- 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. Applicable regulations are promulgated by various national regulators and performance standards are not consistent between different nations. Variations in standards at times 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 which they believe best serve the interests of their particular nation. Within this construct, we recommend governments to use available multi-national 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 United States and the European Union maintain highly complex and far-reaching regulatory regimes with respect to emissions of conventional pollutants such as nitrogen oxides, sulfur dioxide, carbon monoxide, and particulate matter. At the national level in the United States, 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 gas turbines operating on liquid fuels 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 rationalized in a way to enhance 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 like manuals, warning signage, and electronic information (ex. 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 over 25+ official European 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 European exported products to their customers in National languages even if the European User does not want the product in the local National language. 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 SME's to unnecessarily spend millions of USD 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 European Union 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 10 year old New Approach Framework has been reliant on Notified Bodies having competency and expertise in understanding, interpreting, and guiding US Manufacturer's 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 requirements. Over the past 10 years, not only have US Manufacturer's been working with inconsistent services provided by Notified Bodies, they also have been subjected to escalating and unreasonable Notified Body service fees. The use of Notified Bodies to meet Directive regulations has directly contributed to higher product cost and longer product realization lead times which has discouraged SME US Manufacturer's from even entering the EU market.

In 2008, the European Commission responded to the negative European stakeholder feedback that had highlighted concerns with Notified Bodies' regulatory (conformity assessment) and technical competency by promulgating 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 Manufacturer's and Notified Bodies to inquire and obtain support on regulatory and technical questions. This support should come from the Directive Committee's 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 United States and the European Union 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

U.S policymakers and regulators should encourage greater EU-US collaboration between national, regional, and international standards setting organizations (SSOs) to support harmonization of EV ecosystem technical standards (e.g., Compatibility with smart grid communication methods; IT security and data protection; common billing methods, charging stations, plugs). Harmonized 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

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.

Covered Equipment – The 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.

Recommendation: The US should enact a federal law modeled after the EU battery legislation. It should require recycling of the same categories of batteries as the EU directive. The types of batteries and labeling requirements for the 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.

Environmental Products Regulations: Registered Materials

Registered materials – EU has the REACH regulation to handle chemical substances imported into or manufactured in the EU (2006/121/EC). There is an extensive registration process for these materials. There is also a list of candidate list substances whose content in an article is regulated and subject to being banned. This list is updated on a regular basis. There is no US REACH on any level. The regulation also contains requirements for an updated material safety data sheet, beyond what is required in the US – CLP in the EU vs. Hazard Communication Std in the US.

Recommendation: It is not recommended that the US implement a REACH like regulation. Given that the material safety data sheet requirements included in OSHA's Hazard Communication Standardregulation are now being updated to comply with the Globally Harmonized System (GHS) for Classification & Labeling, the classifications in the U.S. will be very similar to the CLP requirements in the EU. This will make it easier to provide safe use data in a CLP like format for materials exported to the EU. There are no recommended actions beyond the implementation of GHS in the U.S.

Annex 2: Agricultural biotechnology crops: regulatory reform & alignment

Background

Ever 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 while reducing costs and promoting important environmental and sustainability goals.

While the adoption of biotechnology is impeded by regulatory obstacles in both the European Union (EU), other countries' governments are spurring a biotech revolution. Already, the governments of Brazil and China are in the process of rationalizing 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, and review of new products are not made quickly enough in the European Union.

The significant time lag in EU authorisations has created a pool of asynchronous or asymmetrical 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 Brazil and China, and reach the market first in those countries, European farmers will be put at an increasingly large disadvantage compared with their international competitors.

Additionally, global food insecurity threatens our rapidly growing world population.

European agricultural producers, and biotechnology research & development companies alike are deeply concerned by the shaky future of this innovation in the EU. Due to signals from the EU government, stakeholders such as these lack the regulatory certainty to continue investing in the EU with confidence in its regulatory system.

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.

- 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.1

[1] Comments from CropLife America to United States Office of Science and Technology Policy. Request for Information: Building a 21st Century Bioeconomy. [Docket No. 2011-26088] 76 FR 62869. October 11, 2011.

Functioning of the current EU regulatory framework

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

The cost of regulation

According to research by EuropaBio, a trade association representing several AmCham 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 30 approvals (including for imports) having been granted by April 2011 represent total costs to companies of between €210 and 300 million. This does not include the costs for the 73 GM products which were in different stages of the approval system in April 2011.

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

Please see below an extract from the EU GMO Policies paper:

[A] regulatory proposal currently under discussion is...the transformation of EFSA guidance into a Regulation.

With regard to the draft proposal for transforming the EFSA guidance into a Regulation, all stakeholders involved in the development, production, import and/or processing of GMOs are of the opinion that such a regulatory change would seriously affect the efficiency of the EU authorization process and consequentially lead to further trade disruptions in the future.

Recommendations from EU GMO Policies paper:

1. As was emphasised in a recent G20 statement, governments and EU institutions are urged to target R&D programmes on key constraints in agricultural production.

2. Research institutes and farmers organisations are called upon to collaborate in further developing the survey database of crops, constraints, and biotechnological approaches, to facilitate exchange of information and experiences.

3. 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.

4. Research institutes and farmers' organisations are called upon to engage with the general public and policy makers in a dialogue about the current urgent challenges in agricultural production, and of the role that modern biotechnology can play in helping to find solutions for the current challenges.

5. 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.

6. Similarly, public-sector scientists should have a continued and more prominent role in current and future discussions on biotechnology in the EU. Our survey has demonstrated the range of "second generation" traits under investigation in public sector research organization and universities – going well beyond insect resistance and herbicide tolerance – all of which could have a major positive impact on farming practices, and food quality and safety. As the

EU wishes to move towards a "Knowledge Based Bio-Economy", this type of advanced research should be actively supported."4

Recommendations from EuropaBio:

1. Wherever they are allowed to, millions of farmers choose to cultivate GM crops. They derive socio-economic benefits from their use. If farmers did not get a suitable return, they would not continue to cultivate GM.

2. Higher productivity on the same amount of land is an important contribution to sustainable agriculture. Other large scale environmental benefits of GM crops have been proven and documented widely.

3. European farmers choose to cultivate GM crops where they are allowed to and where they benefit from their use. With EU cultivation limited mainly to Bt maize, it is clear that the main benefits are limited to regions most affected by the target pest, the European corn borer.

4. European farmers are missing economic opportunities worth between €443 to €929 million each year.

5. 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.

6. 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.

7. Socio-economic factors cannot be taken into account when approving GM crops.5

[4] http://greenbiotech.eu/wp-content/uploads/2012/06/Farmers-scientists-briefing-paper-EU-GMO-policies-2012.pdf, pp. 10-11

[5] http://www.europabio.org/sites/default/files/position/europabio_socioeconomics_may_2011.pdf, p. 18

Annex 3: Intellectual Property

A comprehensive Transatlantic Trade and Investment Agreement creates an important opportunity to build upon past U.S.-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 U.S. and EU economies, a Transatlantic Agreement could serve as a vehicle to tackle issues of common concern with respect to efforts to erode longstanding international intellectual property norms.

The U.S. and EU are home to innovative industries that are heavily dependent on intellectual property rights (IPRs). Both markets have been proponents of the WTO Agreement on the Trade Related Aspects of Intellectual Property Rights, and have similarly robust protections for intellectual property. Advancing these protections in third countries and in multilateral organizations is a shared goal of the U.S. and the EU.

The U.S. and EU are already collaborating towards this objective. The Transatlantic IPR Working Group's Action Strategy, for example, commits both the U.S. and EU to take steps to encourage third countries and multilateral organizations to better protect IPRs, 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.

A Transatlantic Agreement could include mechanisms that build upon the IPR Working Group and TEC commitments. U.S. and EU innovative companies in key sectors such as clean technology, medical devices, aerospace and defense, and computing, software and the cloud, today have a global footprint; government cooperation in the area of IPRs should mirror that economic reality. Strengthening economies in the U.S. 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 remains the foundation of the international intellectual property regime. In recent years, however, some have sought to circumvent or weaken its fundamental protections. An express agreement between the U.S. and EU to cooperate, where appropriate, to address third country violations of TRIPS merits consideration. Equally important, the U.S. 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 greater U.S.-EU alignment in the context of multilateral dialogues on IPRs. TRIPS, and IP protection more broadly, has become a topic of consideration in many fora. Several multilateral organizations have focused recently on the intersection between IP and other public policy objectives. While the U.S. and EU often have consistent positions on these issues, both governments should strive to more closely coordinate their approaches on TRIPS-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 fora and that bilaterally coordinated approaches are developed where possible. This will help to ensure that commitments taken elsewhere do not undermine international IP norms and the commitments set forth in TRIPS.

- A commitment to strengthen and better harmonize protections for trade secrets. 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 Transatlantic Agreement 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.

- A commitment to cooperate to improve the efficiency and effectiveness of the patent system at the global level. The TEC framework already highlights the importance of cooperation to enhance the effectiveness of the patent system, and the U.S. and EU have taken important steps forward towards furthering this objective. Building upon these successes, the Parties could take further steps towards cooperation by promoting greater international harmonization in patent litigation systems. [Commitments here 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.]

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

25

31 October 2012

Daniel Calleja Crespo
Director General
Directorate General for Enterprise and Industry
European Commission
Brussels

RE: Call for input on regulatory issues for possible EU-US trade agreement

Dear Mr Calleja Crespo,

As you may be aware, the American Chamber of Commerce to the European Union (AmCham EU) has been following the development of the EU-US High Level Working Group on Jobs and Growth since it was established in November 2011. AmCham EU is supportive of an ambitious approach to further integrate the EU and US economies, with the aim of boosting the transatlantic market and encouraging the creation of jobs and growth. Regulatory cooperation and coherence are fundamental building blocks in this aim, and we welcome the opportunity to provide input through this public consultation. We are aware that a number of sector-specific associations have undertaken to provide detailed examples of potential areas for regulatory cooperation. To complement these, we wish to highlight several key regulatory features which we would hope to see in any future EU-US agreement.

Improving regulatory cooperation makes economic sense. It is estimated that aligning half of relevant non-tariff barriers and regulatory differences between the EU and US would boost EU GDP by up to €122 billion and US GDP by up to €41 billion by 2018.[1] The US and EU have similar, although not identical, health, safety and quality concerns for the goods and services made available to their citizens, and in a period of far-reaching economic austerity programs, finding ways to achieve more with fewer resources is critical. Regulatory cooperation through the sharing of information and experience would allow scarce resource to be used more efficiently.

In addition to creating a more efficient regulatory mechanism, an enhanced focus on cooperation in EU and US regulation will enable a consistent operating environment in which small, medium and large businesses in the broadest range of sectors can thrive. The 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.

In order to achieve greater regulatory cooperation and coherence, we would recommend the following changes to current practice:

[1] Hamilton, Daniel S. And Quinlan, Joseph P. 'The Transatlantic Economy 2011 Annual Survey of Jobs, Trade and Investment between the United States and Europe', Center for Transatlantic Relations (2011) p.11.

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- The adoption of a **broader consultation process, common impact assessments and common EU and US risk assessments, with broad stakeholder involvement**: cooperation on these procedures will help to identify potential barriers to transatlantic trade and investment during the early phases of the policy making process, and ensure the highest health, safety and quality standards. Common principles and guidelines in risk and hazard assessment processes would ensure a common scientific basis for regulatory decisions. Such an approach would be particularly welcome to overcome sanitary and phytosanitary trade barriers.

- **Agreement on concrete processes to foster mutual recognition**: and other forms of cooperation for regulations and standard setting should be a key priority. AmCham EU supports the development of a broad mutual recognition clause, supporting high standards, and avoiding unnecessary and expensive adaptation to meet varying regional requirements. Examples include (i) secure trade systems such as C-TPAT and AEO schemes and (ii) unique identification numbers on healthcare products.

- **Closer transatlantic cooperation on standards regarding product safety, smart meters, energy efficiency, bio-based products and other sectors** should be further explored. Examples include (i) The 'Bridges principle', as agreed at the November 2011 TEC meeting. This should be further developed and ultimately made mandatory. (ii) Common e-mobility standards, and (iii) 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.

AmCham EU appreciates the challenges of regulatory harmonisation, particularly in the case of entrenched differences in cultural and legal approaches to policy making; however we are encouraged by the efforts of EU and US leaders to build a suitable framework for cooperation, and identify workable solutions to current challenges. Please find attached our recent submission on the future of EU-US trade and economic relations, which highlights a number of examples across a broad range of sectors of possible areas for EU and US regulatory cooperation. We look forward to continuing our dialogue with you over the coming months.

Yours sincerely,

Michelle Gibbons
Chair, EU-US Task Force
American Chamber of Commerce to the European Union (AmCham EU)

CC: Boris Bershteyn, Acting Administrator, Office of Information and Regulatory Affairs, Jean-Luc Demarty, Director General, Directorate General for Trade, European Commission, Ambassador Miriam Sapiro, Deputy U.S. Trade Representative, Office of the U.S. Trade Representative.

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

31 October 2012

Jean-Luc Demarty
Director General
Directorate General for Trade
European Commission
Brussels

RE: Call for input on regulatory issues for possible EU-US trade agreement

Dear Mr Demarty,

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Michelle Gibbons
Chair, EU-US Task Force
American Chamber of Commerce to the European Union (AmCham EU)

CC: Boris Bershteyn, Acting Administrator, Office of Information and Regulatory Affairs, Daniel Calleja Cerspo, Director General, Directorate General for Enterprise and Industry, Ambassador Miriam Sapiro, Deputy U.S. Trade Representative, Office of the U.S. Trade Representative.

AMCHAM EU

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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Secretariat Point of Contact: Aylin Lusi aylin.lusi@amchameu.eu +32 2289 1033

27 September 2012

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.

AMCHAM EU

CONSULTATION RESPONSE

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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.

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.