



Organización Profesional – C.I.F. G-84309350

Avenida de Europa 20-B
Parque Empresarial La Moraleja
28108 Alcobendas (Madrid)

Tel: 91 490 96 11 – Fax: 91 490 97 33

www.asoprovac.com

En Madrid a 30 de Octubre del 2012

Consulta aspecto regulatorios EEUU

La evidente diferencia en los costes de producción explica la enorme desventaja competitiva entre USA y la Unión Europea, cuyo mercado interior se está erosionando en los últimos años.

Desde Asoprovac no estamos en contra de un acuerdo de libre comercio siempre y cuando partamos de idénticas reglas de juego. En caso contrario, se acrecentaría todavía más la diferencia entre producir carne en la UE y producirla en terceros países. Podemos citar como ejemplo de mayores costes en la UE los resultantes de la identificación individual y la trazabilidad, los programas de retirada de cadáveres, la cuestión de los OGM, la prohibición de utilizar harinas de carne, la prohibición de utilizar promotores de crecimiento (monensina, ractopamina o zilpaterol, entre otros), los costes de MER, los programas sanitarios, el bienestar animal, las exigencias medioambientales y los costes que conlleva cumplir con las regulaciones laborales vigentes en la UE.

Resulta preocupante ver como las políticas de la UE respecto a OGM, sanidad y bienestar animal, trazabilidad, etc., conforman un modelo de seguridad alimentaria que en teoría debe de proteger al consumidor, pero que realmente está dejando el abastecimiento interno de carne y otros productos animales en manos de terceros países que, evidentemente, no se plantean cumplir la política comunitaria en estas mismas materias.

1. Diferencia de estándares de producción de carne de vacuno:

- La UE está importando carne de vacuno estadounidense con unos estándares muy diferentes a los autorizados en la UE. Así, mientras el contingente de carne de vacuno americano cubre únicamente el programa “Non-Hormone Treated Cattle”, no cubre sin embargo, la utilización de muchas otras sustancias y técnicas de producción prohibidas en la UE.

1.1. Diferencias de estándares en seguridad alimentaria

- Utilización de promotores de crecimiento prohibidos en UE pero sin embargo autorizados en EEUU (por ejemplo, virginiamicina, bacitracina zinc, flavomicina y carbadox), estando únicamente cubierto este último por el programa nacional de control de residuos americano (NRP)¹.
 - Utilización de arsénico para alimentación animal¹
 - Utilización de alimentos para animales (maíz, soja...) a partir de organismos modificados genéticamente no autorizados en la UE o en periodo de evaluación para la alimentación del ganado.
 - A diferencia de la situación UE, numerosos antimicrobianos (penicilina, tetraciclina, macrolidos y sulfonamidas) y betagonistas (por ejemplo, ractopamina y zilpaterol) están disponibles sin receta médica. Esta realidad lleva consigo una mayor probabilidad de mal uso de los medicamentos veterinarios como lo demuestra el frecuente hallazgo de residuos no conformes de flunixinina por ejemplo, en las muestras tomadas para el NRP.¹
 - A diferencia de la UE, en EEUU han sido autorizados medicamentos veterinarios para alimentación de animales de abasto sin que hayan sido establecidos límites máximos residuales para su uso. Por ejemplo, la oxitetraciclina, la tilosina o la fumagilina no tienen tolerancia establecida para la miel.¹;
- Reglamentación en bienestar animal: según el Instituto de l'élevage francés, la actual normativa en bienestar animal supone un sobre coste del 5% para el coste total del transporte.
 - Reglamentación medioambiental, en particular la obligación de contar con estercoleros.
 - Destrucción de subproductos animales: «alto riesgo» ó de riesgo» es importante.
 - Identificación animal y trazabilidad: Inversiones en material y sistemas informáticos, gastos de funcionamiento: mano de obra y consumibles y Costes indirectos por la pérdida de productividad en la cadena de sacrificio y despiece

En definitiva, según el institut de l'élevage francés y estudio realizado por ASOPROVAC, todas estas medidas suponen un sobre coste a la carne UE de entre 1 -1,5 €/kg canal adicionales por animal.

¹ Final report of a mission carried out in the United States from 18 to 29 October 2010 in order to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products - DG(SANCO) 2010-8444 - MR FINAL)

2. Denominación comercial del contingente de carne vacuno:

Según normativa comunitaria, los actuales contingentes de carne de vacuno aprobados para la importación desde países terceros, reciben la denominación de “carne de vacuno de alta calidad” pudiendo ser así comercializados en mercado UE mientras que, idénticos cortes de carne de origen UE, no pueden denominarse de igual manera.

3. Veto de USA a la carne de vacuno europea:

Por otro lado existe, inexplicablemente un veto americano por EEB a la carne europea. Esta situación es absolutamente desconcertante si se tiene en cuenta la evolución de la enfermedad en Europa en comparación con la situación americana.

En conclusión partimos de situaciones de partida francamente desequilibradas y desde nuestro punto de vista, cualquier acuerdo de libre comercio en estas circunstancias sería francamente desafortunado y podría tener un impacto irreversible sobre la producción europea de carne de vacuno. Por tanto, a pesar de las expectativas de este acuerdo para otros sectores europeos, los intereses de la UE para el sector agrarios deben protegerse.

Spanish Federation of Associations of Producers and Exporters of Fruits, Vegetables, Flowers and Live Plants (FEPEX)

Statement

Public Consultation on EU-US High Level Working Group on Jobs and Growth

La evolución de las exportaciones europeas a EEUU, 105.109 Tm en 2009, 115.825 Tm en 2010 y 113.082 Tm en 2011, refleja la eficacia proteccionista de las medidas fitosanitarias impuestas a las exportaciones por este país.

La lentitud en la negociación de los procedimientos conjuntamente con la incertidumbre de sus resultados es un factor desincentivador para el acceso a este mercado, al menos en el caso de las frutas y hortalizas, ya que se requiere la aprobación o autorización previa específica por parte del Animal and Plant Health Inspection Service (APHIS) de USDA. Para ilustrar la lentitud negociadora basta con citar que actualmente seis Estados miembros de la Unión Europea, entre ellos España, están a la espera desde el año 2009 para la aprobación final del protocolo de exportación de manzanas y peras negociado entre la UE y EEUU. En el caso del albaricoque las negociaciones también se ralentizaron al señalarse el alto riesgo de este producto de introducir la Ceratitis en EEUU.

La especificidad de los protocolos establecidos, que recogen requisitos para determinadas áreas ó zonas geográficas además de otros relativos al transporte, control en origen y tratamientos de cuarentena, no facilitan el establecimiento de relaciones comerciales fluidas

Los protocolos en el sector de frutas y hortalizas generalmente contemplan el establecimiento de un registro de huertos y almacenes que están sujetos a inspecciones periódicas.

En el caso específico del tomate el protocolo existente (protocolo bilateral USA-España) contiene unos requisitos demasiado estrictos, debido a la *Tuta Absoluta*, que hacen prácticamente inviables las exportaciones españolas, que en el año 2009 fueron de 162 Tm y nulas en los años 2010 y 2011. Estas exportaciones deben cumplir con uno de los siguientes requisitos:

- 1.- Zona declarada libre de plaga.
- 2.- Programa de control.
- 3.- Tratamiento con Bromuro de Metilo.

En España no se pueden cumplir ni el primer ni el tercer requisito al no ser una zona libre de *Tuta absoluta* y no estar autorizado el bromuro de metilo en la UE. Únicamente se puede realizar el programa de manejo, que debe ser aprobado por el APHIS e incluye los siguientes requisitos:

- El tomate debe ser importado sin elementos de la planta (tallos, cálices, etc)

- El tomate destinado a USA debe ser cultivado únicamente en estructuras estancas que aíslen el cultivo de plagas y que además estén registrados en el APHIS.
- El invernadero donde se cultive el producto debe contener doble puerta o cualquier método que minimice la entrada de plagas y debe tener un grosor máximo de 1,6 mm.
- El invernadero debe contener trampas de feromonas (2 trampas/hectárea) con un mínimo de 2 trampas por invernadero.
- Las trampas deben estar en el invernadero, al menos, dos meses antes de la recolección y ser revisadas semanalmente.
- Las estructuras registradas para la exportación deben ser inspeccionadas por la NPPO u otro organismo designado durante el cultivo para observar presencia de *Tuta Absoluta*.
- Si durante 30 días en el periodo de recolección se capturan 2 T. absoluta en el invernadero o se encuentra 1 T. absoluta en el fruto o en el envío, todos los productos de ese invernadero serán suspendidos hasta que no exista riesgo.
- El programa de control de la calidad del APHIS será revisado o auditado por el NPPO. Todas las estructuras (invernaderos, centros de manipulación) deben ser aprobadas por el APHIS. Cuando una estructura se dé de alta o de baja se debe informar al APHIS. El APHIS realizará visitas periódicas a las instalaciones para controlar el programa.
- Después de la recolección de los tomates, éstos deben ser protegidos durante su transporte a la central y durante el tiempo de espera a ser envasados.
- Los tomates deben ser envasados antes de las 24 horas después de su recolección.
- La central hortofrutícola, cuando envase productos destinados a USA sólo puede aceptar producto de los invernaderos registrados en el programa.
- Los tomates destinados a USA deben ir protegidos (plásticos, etc.) y la protección debe llegar intacta a USA, de lo contrario el envío será rechazado.

De estos requisitos el que está señalado en rojo es el que más rechazo produce entre los productores, no por la dificultad de controlar la *Tuta*, que actualmente no es ningún problema, sino por la incertidumbre que produce.

VALASTRO Silvia (TRADE)

From: asoprovac@asoprovac.com
Sent: 30 October 2012 18:26
To: TRADE F3 SECRETARIAT; ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Cc: matilde.moro@asoprovac.com
Subject: EU and US call for input on regulatory issues for possible future trade agreement
Attachments: Consulta aspecto regulatorios EEUU.pdf

Dear Sirs,

Please see attached report with the answers of ASOPROVAC (Spanish beef cattle farmers association) in relation to the regulatory aspects between the EU and USA.

Yours sincerely

Javier Lopez

Director
ASOPROVAC

En Madrid a 30 de Octubre del 2012

Consulta aspecto regulatorios EEUU

La evidente diferencia en los costes de producción explica la enorme desventaja competitiva entre USA y la Unión Europea, cuyo mercado interior se está erosionando en los últimos años.

Desde Asoprovac no estamos en contra de un acuerdo de libre comercio siempre y cuando partamos de idénticas reglas de juego. En caso contrario, se acrecentaría todavía más la diferencia entre producir carne en la UE y producirla en terceros países. Podemos citar como ejemplo de mayores costes en la UE los resultantes de la identificación individual y la trazabilidad, los programas de retirada de cadáveres, la cuestión de los OGM, la prohibición de utilizar harinas de carne, la prohibición de utilizar promotores de crecimiento (monensina, ractopamina o zilpaterol, entre otros), los costes de MER, los programas sanitarios, el bienestar animal, las exigencias medioambientales y los costes que conlleva cumplir con las regulaciones laborales vigentes en la UE.

Resulta preocupante ver como las políticas de la UE respecto a OGM, sanidad y bienestar animal, trazabilidad, etc., conforman un modelo de seguridad alimentaria que en teoría debe de proteger al consumidor, pero que realmente está dejando el abastecimiento interno de carne y otros productos animales en manos de terceros países que, evidentemente, no se plantean cumplir la política comunitaria en estas mismas materias.

1. Diferencia de estándares de producción de carne de vacuno:

- La UE está importando carne de vacuno estadounidense con unos estándares muy diferentes a los autorizados en la UE. Así, mientras el contingente de carne de vacuno americano cubre únicamente el programa “Non-Hormone Treated Cattle”, no cubre sin embargo, la utilización de muchas otras sustancias y técnicas de producción prohibidas en la UE.

1.1. Diferencias de estándares en seguridad alimentaria

- Utilización de promotores de crecimiento prohibidos en UE pero sin embargo autorizados en EEUU (por ejemplo, virginiamicina, bacitracina zinc, flavomicina y carbadox), estando únicamente cubierto este último por el programa nacional de control de residuos americano (NRP)¹.
 - Utilización de arsénico para alimentación animal¹
 - Utilización de alimentos para animales (maíz, soja...) a partir de organismos modificados genéticamente no autorizados en la UE o en periodo de evaluación para la alimentación del ganado.
 - A diferencia de la situación UE, numerosos antimicrobianos (penicilina, tetraciclina, macrolidos y sulfonamidas) y betagonistas (por ejemplo, ractopamina y zilpaterol) están disponibles sin receta médica. Esta realidad lleva consigo una mayor probabilidad de mal uso de los medicamentos veterinarios como lo demuestra el frecuente hallazgo de residuos no conformes de flunixinina por ejemplo, en las muestras tomadas para el NRP.¹
 - A diferencia de la UE, en EEUU han sido autorizados medicamentos veterinarios para alimentación de animales de abasto sin que hayan sido establecidos límites máximos residuales para su uso. Por ejemplo, la oxitetraciclina, la tilosina o la fumagilina no tienen tolerancia establecida para la miel.¹;
- Reglamentación en bienestar animal: según el Instituto de l'élevage francés, la actual normativa en bienestar animal supone un sobre coste del 5% para el coste total del transporte.
 - Reglamentación medioambiental, en particular la obligación de contar con estercoleros.
 - Destrucción de subproductos animales: «alto riesgo» ó de riesgo» es importante.
 - Identificación animal y trazabilidad: Inversiones en material y sistemas informáticos, gastos de funcionamiento: mano de obra y consumibles y Costes indirectos por la pérdida de productividad en la cadena de sacrificio y despiece

En definitiva, según el institut de l'élevage francés y estudio realizado por ASOPROVAC, todas estas medidas suponen un sobre coste a la carne UE de entre 1 -1,5 €/kg canal adicionales por animal.

¹ Final report of a mission carried out in the United States from 18 to 29 October 2010 in order to evaluate the control of residues and contaminants in live animals and animal products, including controls on veterinary medicinal products - DG(SANCO) 2010-8444 - MR FINAL)

2. Denominación comercial del contingente de carne vacuno:

Según normativa comunitaria, los actuales contingentes de carne de vacuno aprobados para la importación desde países terceros, reciben la denominación de “carne de vacuno de alta calidad” pudiendo ser así comercializados en mercado UE mientras que, idénticos cortes de carne de origen UE, no pueden denominarse de igual manera.

3. Veto de USA a la carne de vacuno europea:

Por otro lado existe, inexplicablemente un veto americano por EEB a la carne europea. Esta situación es absolutamente desconcertante si se tiene en cuenta la evolución de la enfermedad en Europa en comparación con la situación americana.

En conclusión partimos de situaciones de partida francamente desequilibradas y desde nuestro punto de vista, cualquier acuerdo de libre comercio en estas circunstancias sería francamente desafortunado y podría tener un impacto irreversible sobre la producción europea de carne de vacuno. Por tanto, a pesar de las expectativas de este acuerdo para otros sectores europeos, los intereses de la UE para el sector agrarios deben protegerse.

**Spanish Federation of Associations of Producers and Exporters of Fruits, Vegetables, Flowers
and Live Plants (FEPEX)**

Statement

Public Consultation on EU-US High Level Working Group on Jobs and Growth

La evolución de las exportaciones europeas a EEUU, 105.109 Tm en 2009, 115.825 Tm en 2010 y 113.082 Tm en 2011, refleja la eficacia proteccionista de las medidas fitosanitarias impuestas a las exportaciones por este país.

La lentitud en la negociación de los procedimientos conjuntamente con la incertidumbre de sus resultados es un factor desincentivador para el acceso a este mercado, al menos en el caso de las frutas y hortalizas, ya que se requiere la aprobación o autorización previa específica por parte del Animal and Plant Health Inspection Service (APHIS) de USDA. Para ilustrar la lentitud negociadora basta con citar que actualmente seis Estados miembros de la Unión Europea, entre ellos España, están a la espera desde el año 2009 para la aprobación final del protocolo de exportación de manzanas y peras negociado entre la UE y EEUU. En el caso del albaricoque las negociaciones también se ralentizaron al señalarse el alto riesgo de este producto de introducir la Ceratitis en EEUU.

La especificidad de los protocolos establecidos, que recogen requisitos para determinadas áreas ó zonas geográficas además de otros relativos al transporte, control en origen y tratamientos de cuarentena, no facilitan el establecimiento de relaciones comerciales fluidas

Los protocolos en el sector de frutas y hortalizas generalmente contemplan el establecimiento de un registro de huertos y almacenes que están sujetos a inspecciones periódicas.

En el caso específico del tomate el protocolo existente (protocolo bilateral USA-España) contiene unos requisitos demasiado estrictos, debido a la *Tuta Absoluta*, que hacen prácticamente inviables las exportaciones españolas, que en el año 2009 fueron de 162 Tm y nulas en los años 2010 y 2011. Estas exportaciones deben cumplir con uno de los siguientes requisitos:

- 1.- Zona declarada libre de plaga.
- 2.- Programa de control.
- 3.- Tratamiento con Bromuro de Metilo.

En España no se pueden cumplir ni el primer ni el tercer requisito al no ser una zona libre de *Tuta absoluta* y no estar autorizado el bromuro de metilo en la UE. Únicamente se puede realizar el programa de manejo, que debe ser aprobado por el APHIS e incluye los siguientes requisitos:

- El tomate debe ser importado sin elementos de la planta (tallos, cálices, etc)

- El tomate destinado a USA debe ser cultivado únicamente en estructuras estancas que aislen el cultivo de plagas y que además estén registrados en el APHIS.
- El invernadero donde se cultive el producto debe contener doble puerta o cualquier método que minimice la entrada de plagas y debe tener un grosor máximo de 1,6 mm.
- El invernadero debe contener trampas de feromonas (2 trampas/hectárea) con un mínimo de 2 trampas por invernadero.
- Las trampas deben estar en el invernadero, al menos, dos meses antes de la recolección y ser revisadas semanalmente.
- Las estructuras registradas para la exportación deben ser inspeccionadas por la NPPO u otro organismo designado durante el cultivo para observar presencia de *Tuta Absoluta*.
- Si durante 30 días en el periodo de recolección se capturan 2 T. absoluta en el invernadero o se encuentra 1 T. absoluta en el fruto o en el envío, todos los productos de ese invernadero serán suspendidos hasta que no exista riesgo.
- El programa de control de la calidad del APHIS será revisado o auditado por el NPPO. Todas las estructuras (invernaderos, centros de manipulación) deben ser aprobadas por el APHIS. Cuando una estructura se dé de alta o de baja se debe informar al APHIS. El APHIS realizará visitas periódicas a las instalaciones para controlar el programa.
- Después de la recolección de los tomates, éstos deben ser protegidos durante su transporte a la central y durante el tiempo de espera a ser envasados.
- Los tomates deben ser envasados antes de las 24 horas después de su recolección.
- La central hortofrutícola, cuando envase productos destinados a USA sólo puede aceptar producto de los invernaderos registrados en el programa.
- Los tomates destinados a USA deben ir protegidos (plásticos, etc.) y la protección debe llegar intacta a USA, de lo contrario el envío será rechazado.

De estos requisitos el que está señalado en rojo es el que más rechazo produce entre los productores, no por la dificultad de controlar la Tuta, que actualmente no es ningún problema, sino por la incertidumbre que produce.

CEFIC-ACC RESPONSE TO EU AND U.S. CALL OF 7 SEPTEMBER 2012 FOR INPUT ON REGULATORY ISSUES FOR POSSIBLE FUTURE TRADE AGREEMENT

BACKGROUND

The June 12, 2012 report of the co-chairs of the EU-U.S. High Level Working Group on Jobs and Growth highlights the potential to create efficiencies in the transatlantic trade relationship by addressing regulatory barriers that may impede trade. Cefic¹ and ACC² believe that there exist important opportunities to expand and enhance chemicals trade across the Atlantic.

Two-way chemical trade between the EU and U.S (excluding pharmaceuticals), was valued at \$52 billion in 2011. Given that import duties on chemicals on both sides of the Atlantic are on average about 3%, the elimination of the industrial tariffs would entail savings for consumers of chemistry in the order of \$1.5 billion.

Beyond tariff liberalization, though, significant potential exists to enhance regulatory transparency and cooperation, streamline chemical regulatory reviews, and minimize the cost and burden to governments and industry alike. Indeed, enhanced regulatory cooperation can help eliminate unnecessary burdens on regional cross-border trade, reduce costs, foster investment, and promote certainty for business, the public, and economies. Perhaps most importantly, promoting regulatory cooperation should be expected to have a positive effect in job creation and maintenance on both sides of the Atlantic.

¹ Cefic, the European Chemical Industry Council, is both the forum and the voice of the European chemical industry. It aims at maintaining and developing a prosperous chemical industry in Europe by promoting the best possible economic, social and environmental conditions to bring benefits to society.

² The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$760 billion enterprise and a key element of the U.S. economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports.

The High Level Working Group has recognized that more effective approaches to chemical regulation can enhance the competitiveness of the EU and U.S. manufacturing industries and promote high standards for human health and environmental protection. The Working Group has committed to engage in a further discussion, including relevant sectors, to identify what policies and measures might be discussed, understand what work is already in progress, and establish a path forward that can complement a comprehensive trade agreement. The shorter-term objective is to identify the opportunities that exist for further discussion – and a full understanding of the advantages and disadvantages to further cooperation – rather than conclude agreements on specific outcomes.

INTRODUCTION

Cefic and ACC believe there are important opportunities to promote additional trans-Atlantic chemical regulatory cooperation. The principle, although a rather long-term issue, is simple: both sides agree to consult and to cooperate when adopting new chemicals regulations. If comparable regulations are adopted on both sides of the Atlantic the cost of compliance for industries could be reduced considerably through mutual recognition. Whilst not attempting the unreachable and recognizing the sovereignty of each side to legislate Cefic and ACC would suggest the following areas as a starting point in order to promote the longer term goal of regulatory cooperation:

Starting Point:

- Information sharing between the EU and U.S. government bodies, while ensuring appropriate protection of confidential commercial information.
- Prioritizing chemical substances for further review and assessment, including for classification.
- Alignment in chemical assessment processes, and enhanced understanding of risk management measures.
- Promoting alignment in classification and labeling and other regulatory requirements.

- A mandatory consultation process (including procedural safeguards so that each sides comments can be taken into account) when drafting new chemical regulations.

Long Term Goal:

- The adoption of chemical regulations that are comparable in effectiveness so that the concept of mutual recognition can be applied.

COOPERATION IN CHEMICALS MANAGEMENT

Europe's regulation on Registration, Evaluation and Authorization of Chemicals (REACH) and the U.S. Toxic Substances Control Act (TSCA) take very different approaches to the manner of regulating the manufacture, use and distribution of chemicals, however both systems have risk assessment as a fundamental element. REACH came into force in Europe in 2007, replacing a regulatory system first developed in the 1960's and developed over the last 40 years. TSCA was first enacted in 1976 and has similarly developed over the years. Although TSCA has not been substantially amended since, several proposals to modernize the statute have been introduced in the U.S. Congress and some level of amendment seems likely over the next few years.

Notwithstanding the differences in the chemical regulatory systems, there are fundamental elements for their efficient and effective operation. These include the data and information on which regulatory decisions are based, the processes for identifying priority substances for review and evaluation, how hazards and risks are characterized, and the need for transparency of information and rules to protect commercial and proprietary interests. Developing and agreeing on principles in these areas would help guide future cooperative work.

1. Principles for Information Sharing

In Europe, a considerable amount of information will be made publicly available, largely through the European Chemical Agency's (ECHA) web-based platform. The U.S. Environmental Protection Agency (EPA) has been taking steps to make additional information on chemicals

publicly available, including by declassifying some prior claims for confidential business information (CBI).

The ability to share information is expected to be even more critical in the future. In addition, the ability to share information on the interpretation of that information will shape regulatory decisions (and transatlantic chemicals trade) for decades to come. The emergence of new assessment technologies such as computational toxicology threatens to outpace the ability to interpret the data in a regulatory context or put the information into a meaningful risk-based context. The significant investment companies make in generating information on chemicals raises important questions about the protection of Confidential Business Information (CBI) and commercial interests. It is vital that the EU and the U.S. fully explore the opportunities to cooperate to promote access to this information, as well as the regulatory consequences of applying that information.

Basic principles for information sharing include:

- Promotion of appropriate government access to useful chemical data and information, with appropriate protections against and sanctions for unlawful or inadvertent disclosure.
- Recognition of legitimate commercial interests in the appropriate protection of information (including chemical hazard, financial and ownership data) should be recognized.
- Use of Robust data summaries as an important mechanism to allow increased access to and transparency in information without jeopardizing commercial interests. The approach was successfully employed in the U.S. and ICCA/OECD efforts to ensure screening information data for high production volume (HPV) chemicals.
- A discussion on the apparent barriers to information sharing across the Atlantic.

The EU and US should explore opportunities to promote appropriate government access to information whilst recognising legitimate commercial interests in appropriate protection of information.

2. Principles for Prioritizing Chemicals for Review and Evaluation

Chemical regulatory programs in the EU and the U.S. do not appear to be well coordinated in terms of priority and the opportunities for burden-sharing between government agencies. An explicit objective of transatlantic regulatory cooperation in the chemicals sector should be to minimize the potential for duplication of effort (by both governments and industry) in chemical testing, assessment and evaluation. Common principles on approaches to prioritization for chemical assessment could help encourage work and burden sharing by either governments or industry. An understanding of how substances are prioritized for review, what use and exposure patterns prompt concern, and what information is currently available to support the review and assessment could dramatically reduce the potential for duplication of effort and streamline and expedite reviews.

General principles for prioritization processes to identify chemical substances for further review and assessment should include:

- Prioritization processes should apply a science- and risk-based approach, considering both the degree of hazard and extent of exposure potential in setting priorities.
- Information on the use and exposure patterns that prompt the need for additional review should be transparent and public, consistent with the need to protect sensitive commercial information.
- Prioritization processes should leverage existing, available data and existing hazard classification frameworks already in use across industry and agreed by regulators, such as the Globally Harmonized System for Classification and Labelling (GHS).
- Relevant science advances should be incorporated and accounted for in prioritization programs, where there is broad acceptance in the scientific community (e.g. improvements in how persistence and bioaccumulation considerations are addressed).
- Prioritization process should allow for the use of significant new information, to ensure prioritization decisions remain current.
- Substances identified as priorities should be subject to further evaluation and assessment, rather than immediate risk management measures.

- Prioritization screening and ranking processes should provide for public review and comment with an opportunity to submit additional relevant data and information.
- As resources are limited, prioritization should fully consider both the probability of the occurrence and the consequences arising from risks, so that attention is given to the most significant issues affecting human health and the environment.

Common science- and risk-based approaches to prioritisation for chemical assessment could help encourage work and burden sharing and minimise duplication of efforts for both government and industry.

3. Principles for Coherence in Chemical Assessment Processes: Common Scientific Basis for Regulatory Decisions

A basic building block for chemicals management is information about the hazards of chemicals. Developing common principles, practices and guidelines in assessment processes will help assure a common scientific basis for regulatory decisions across the regions.

The role and impact of chemical assessments cannot be overstated. Scientific determinations serve as the foundation of effective chemical management regulatory programs. High quality, reliable science is the foundation for protecting health and the environment, instilling public confidence in regulatory systems, encouraging innovation, and fostering transatlantic competitiveness. It is critical that chemical assessments meet appropriate benchmarks for objectivity, transparency, and scientific accuracy so that all stakeholders can have confidence in their use for regulatory decision making, product development decisions, and consumer choices. Fundamental principles to promote a firm scientific foundation for chemical assessments include:

- Exploration of common data formats as one means to promote cooperative approaches to assessment.

- Chemical assessments should rely on the best available scientific data and methods, and employ consistent, objective methods and models to derive realistic determinations at environmentally relevant levels of exposure.
- Development and application of consistent, transparent criteria for evaluating data and selecting studies used in assessments, to ensure that their quality, relevance and reliability can be evaluated.
- Assessments should be tailored to chemical-specific datasets, knowledge of mode of action and biological effects, and should assess the overall weight of the evidence, giving the greatest weight to information from the most relevant and highest quality studies.
- Review of the assumptions and default approaches that underlie assessment programs. Reliance on outdated default values should be minimized. Today scientists and health professionals have an advanced understanding of how the human body works, and the way chemicals interact with the body and the environment at different levels of exposure.
- Hazards and risks must be objectively characterized and presented in a manner understandable to stakeholders and risk managers. Assessments should include central estimates and ranges and not simply rely on theoretical maximum exposure estimates to characterize potential risk.
- Assessments must provide full disclosure of key information. When assumptions are used in lieu of data, the assumptions must be disclosed along with the justification for their use. The impact of each assumption on the evaluation should be clearly stated.

A common basis for and understanding of how chemical hazards and risks are assessed will help enhance regulatory cooperation, while leaving to relevant governments the decision of how and when to apply the assessments in regulatory decisions.

Enhanced cooperation in hazard and risk assessment can also help ensure a common understanding in several critical science policy areas:

- Design and Data Acquisition. Transparency in the design of chemical assessments will help promote broad understanding of the key issues that are to be assessed and the specific methods, assumptions, and evaluation procedures that will be utilized. Input from the research community and stakeholders should be part of this activity, so that the most up-to-date data can be obtained and the most relevant methods can be considered and used.
- Data Evaluation. Transparent, consistent and scientifically objective data evaluation protocols should be used to evaluate studies.
- Data Integration and Weight of Evidence. All assessments must be based on a clear and consistent framework that takes into account and integrates all relevant data and information and gives the greatest weight to information from the most relevant and highest quality studies.
- Ensuring discussion of and reliance on accepted international standards and definitions developed by recognized organizations. At minimum common-accepted definitions will help reduce trade barriers, increase regulatory certainty and ensure objectivity and transparency. For instance: the WHO definition on endocrine disruptors should be used by both partners as a starting point for future regulatory activities.
- Regulatory requirements in Europe impose constraints on animal testing to meet data generation requirements. Where such test data are generated in order to fulfill legal requirements in the U.S., these data should be accepted by EU public authorities, and vice-versa. Recognition of specific data also with respect to marketing authorisations would reduce the potential for duplication in effort, streamline and expedite chemical assessments.
- Upcoming regulatory activities: First step: agree on definitions and assessment criteria. Long term goal: adopt regulations that are comparable in effectiveness and apply mutual recognition. Example: Can both sides agree on a transatlantic definition for nano-materials?

Common principles, practices and guidelines in chemical assessment procedures will help assure a common basis for regulatory decisions across the regions.

4. Trade Secrets/Confidential Business Information (CBI)

Trade secrets and CBI are critical assets and key indicators of competitiveness. The chemical management systems in both the EU and the U.S. are intended to make information on chemicals more transparent, particularly to the public. Wording on this is included in legislation like REACH. A key set of common principles for enhanced transparency in chemical management could have important benefits for both business and governments. More detailed principles for the protection of trade secrets / CBI could help ensure consistent protection for critical information, consistent enforcement of rights to protected information, and would foster the useful exchange of information between regulatory authorities.

Enhanced transparency in chemical management could have important benefits for both business and government and more detailed principles for the protection of trade secrets/CBI would foster the useful exchange of information between regulatory authorities.

5. Classification and Labelling/Implementation of International Convention

Approaches to harmonised classifications must be based on common principles as stipulated in the Globally Harmonized System (GHS) in conjunction with considerations of other factors such as the following: weight of evidence; substance identity (e.g., impurities, composition, form and physical state) and an assessment of data accuracy and quality. Companies should have the opportunity to question a specific classification and its relevance.

The chemical industry supports a review of the potential for harmonised classifications. The benefits of harmonised classifications could include (1) supporting/promoting cost-effective GHS implementation; (2) avoiding duplication of effort; (3) applying expert systems to maximize resources and minimize costs; (4) promoting harmonization/consistency in classification; (5) providing a reference for self-classification by manufacturers; (6) facilitating international trade;

and (7) improving safety for workers and others through consistent and harmonized communications on chemical hazards and practices to follow for safe handling and use.

The well-developed chemical regulatory systems in the EU and the United States were the model for the Rotterdam Convention on Prior Informed Consent, an international agreement aimed at ensuring importing governments had appropriate information on the regulatory status of the shipments in the country of origin. The EU and the US should explore the extent to which it can harmonize the list of chemicals for which they provide export notifications, and whether there is any need for of value from such notifications for chemical transatlantic shipments.

The chemical industry supports a review of the potential for harmonised classifications based on common principles as stipulated in GHS in conjunction with considerations of other appropriate factors.

Harmonisation of the implementation of the PIC Convention could be explored and in particular the value of notifications for chemical transatlantic shipments.

SHORT TERM IMPLEMENTATION PATH

1. Implement the 2002 Guidelines on Regulatory Cooperation

A commitment by the EU and U.S. governments to fully implement the 2002 EU-U.S. Guidelines on Regulatory Cooperation and the “Common Understanding of Regulatory Principles and Best Practices” of 2011 would be a key first step in promoting more open, efficient chemical regulatory environments. Full and detailed implementation of the guidelines – including interactive consultation with affected industry would be invaluable to removing unnecessary barriers and inefficiencies for chemical industry and our customers.

The 2002 Guidelines specifically refer to regular consultation and an exchange of data and information, including information on planned new regulations. Full implementation of the Guidelines would help promote more efficient Trans-Atlantic chemical regulation by:

- Enhancing the quality of technical regulation
- Minimizing the potential for divergence in regulation due to interpretative or technical misunderstandings
- Increasing predictability and certainty in the development and implementation of chemical regulation
- Inviting relevant stakeholders on either side of the Atlantic to participate in appropriate rulemakings
- Promoting transparency by disclosure and access to the research and analysis that support chemical regulation
- Providing a means to engage the expertise of government and industry experts in a dialogue
- Promoting increased public understanding of chemical regulation.

2. Commit to and Exchange Regulatory Impact Analysis

A significant benefit of greater regulatory cooperation is business certainty. In particular, the EU and U.S. should commit to adopting only those chemical regulations that are consistent with health and environmental policy objectives, with the least economic impact on competition and the least regulatory burden.

A commitment to assess the impact of chemical regulatory proposals would be a useful first step to enhanced regulatory cooperation. Such a commitment would not jeopardize the sovereign rights of governments on both sides of the Atlantic to identify, develop and implement regulatory priorities. Indeed, the impact assessment could help identify further opportunities to cooperate, build government and public trust in the respective systems, and perhaps identify opportunities to share appropriately the burden of government chemical assessment and oversight.

Conducting regulatory impacts assessments on chemical regulatory proposals would identify those measures that exceed a threshold of economic impact agreed by the Parties. At a minimum, the assessments should identify:

- The problem and policy objective intended to be addressed, including a description of the need for regulatory action and the magnitude of the problem.
- The regulatory alternatives considered in proposing a regulatory solution, consistent with the policy objective, whether non-regulatory and/or voluntary means have been considered or are appropriate, consistent with domestic or regional law. The costs and benefits of the alternatives should be addressed, including specifically the costs and benefits for two-way Trans-Atlantic trade.
- Where feasible and appropriate, a demonstration that the recommended regulatory alternative maximizes net benefits, including qualitative benefits, and an explanation why the recommended approach is preferred over other alternatives.
- The best available scientific, technical, economic, and other information upon which the proposal is based.

- The existence of potentially conflicting requirements arising from the chemical or other regulatory programs, or other applicable international consensus standards that might affect the need for a regulatory outcome.

Nothing in a chemical regulatory impact analysis should require the disclosure of confidential information, including information that would compromise a financial or commercial interest if disclosed, or if it is prohibited by law.

A commitment by each Party to periodically review significant chemical regulatory measures for their impact on Trans-Atlantic trade would also be an important commitment to identifying such measures and ensuring that they are as effective as possible in achieving the desired policy objectives. This would allow, for example, a periodic review of the state of transatlantic chemical trade, the impact of new and emerging technologies, and how improved regulatory cooperation could enhance the effectiveness of the regulatory programs.

Importantly, this approach would permit the EU and the U.S. to recognize the value of enhanced regulatory alignment with respect to chemicals, and could serve as a useful model for extension to other goods and service sectors.

First steps to promote more open, efficient chemical regulatory environments could include a commitment to fully implement the 2002 Guidelines for Regulatory Cooperation and a commitment to assess the impact of chemical regulatory proposals.

EXPECTED POSITIVE EFFECTS OF ENHANCED COOPERATION AND VALUE ESTIMATE

It is difficult to quantify the savings that would result from the above proposals. However, addressing the opportunities for regulatory cooperation in these areas can help minimize the potential for duplication of effort by government and industry, create efficiencies by ensuring high-quality, reliable information is the basis for decision-making, enhance the value of trans-Atlantic chemicals trade and offer guidance to the rest of the world in setting justifiable and usable regulation. Developing and agreeing on principles in these areas would help guide future cooperative work and set the stage to leverage all the efficiencies and effectiveness possible.

Improved cooperation in chemical regulation could also have the important ancillary benefit of minimizing the potential for duplication or inconsistency in the regulatory requirements applied by member government or subsidiary government bodies.

Additional trans-Atlantic chemical regulatory cooperation could minimise the cost and burden to government and industry alike by, as a first step, agreeing principles in five fundamental areas.

KADINOVA Desislava (TRADE)

From: TRADE F3 SECRETARIAT
Sent: 25 January 2013 17:10
To: TRADE DOCUMENT MANAGEMENT
Cc: TRADE F3 SECRETARIAT
Subject: 9/ Association of German Banks comments on EU-US call for input on regulatory issues for possible future trade agreement
Attachments: Stn-Un-2012-10-30-Association of German Banks comments on EU US call for input on regulatory issues for possible future tra.docx

Please, register email and attached document,
thanks

From: tobias.unkelbach@bdb.de [<mailto:tobias.unkelbach@bdb.de>]
Sent: Tuesday, October 30, 2012 2:07 PM
To: TRADE F3 SECRETARIAT; ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Cc: Gabriele.Spieker@bdb.de; WP IN Sekretariat@bdb.de
Subject: Association of German Banks comments on EU-US call for input on regulatory issues for possible future trade agreement

Ladies and gentlemen,

Please find attached the above-mentioned comments by the Association of German Banks.

Yours Sincerely,

Tobias Unkelbach,

Director International Affairs
 Association of German Banks

(See attached file: Stn-Un-2012-10-30-Association of German Banks comments on EU US call for input on regulatory issues for possible future tra.docx)

Mit freundlichen Grüßen
 Dr. Tobias Unkelbach

Direktor
 Bankenverband
 Wirtschaftspolitik und Internationale Beziehungen
<http://www.bankenverband.de>

Telefon: +49 30 1663 - 1110
 Telefax: +49 30 1663 - 1199

Comments

Association of German Banks

30 October 2012

EU and US 7 September 2012 call for input on regulatory issues for possible future trade agreement

Contact:

Tobias Unkelbach

Director

Telephone: +49 30 1663-1110

Fax: +49 30 1663-1199

tobias.unkelbach@bdb.de

Ref. BdB: J 19.1, U 2.4

Prepared by Un/Bu

Association of German Banks
Burgstraße 28
10178 Berlin | Germany
Telephone: +49 30 1663-0
Fax: +49 30 1663-1399
www.bankenverband.de
USt.-IdNr. DE201591882

Ladies and gentlemen,

The Association of German Banks represents the interests of the privately owned banks in Germany in the field of banking and economic policy.

We are writing this comment letter to express our support for including financial regulation issues in any negotiations on a comprehensive EU-US agreement to further liberalise transatlantic trade and investment.

The US remains the most important financial market outside the EU. For German banks, US rules – whether legislation by Congress, regulation by US authorities or case law – are highly important.

The recent “regulatory wave” in response to the financial crisis means that EU-US and global (G20, FSB, Basel Committee, IOSCO, etc.) coordination of financial market regulation is essential.

Differing financial system structures and legal traditions will not allow identical rules. It will therefore be paramount to apply principles of national treatment (i.e. competitive equality) and recognition of comparable home-country standards when regulating US operations of EU banks (and vice versa). The more we align rules internationally, the more likely such recognition will be.

By contrast, we would not like to see US regulators applying standards to our banks that are extraterritorial, duplicative or discriminating.

Unfortunately, we have quite a number of such concerns regarding the on-going implementation of the Dodd-Frank Act (DFA) by relevant US authorities, although final versions of the respective implementing rules are still pending and may, ideally, take our concerns into account.

- As regulators and banking associations from the EU, Germany as well as other countries have stated, the October 2011 Volcker Rule implementation proposal is much too extraterritorially burdensome for non-US banks and discriminates against issuance of non-US government bonds.
- We look forward with interest to the Fed’s proposed rules regarding application of the prudential requirements for SIFIs under DFA Section 165 to non-US banks. In any event, the Fed should recognise home-country regulation (incl. implementation of FSB/Basel rules) of non-US banks (or at least factor in their real impact on the US system) when implementing prudential requirements for non-US bank SIFIs under DFA.

- The June 29 (Federal Register: July 12) 2012 CFTC proposal on cross-border aspects of DFA derivatives rules is overly extraterritorial (by broadly defining "US persons" and subjecting non-US banks' worldwide dealings with them to its rules) and gives non-US banks too little time to adapt their compliance systems to the US standards, although the latter are still not properly detailed(!). In addition, while we lauded the CFTC in our comment letter for its "substituted compliance" approach in principle, we warned that it should not unilaterally extend US rules globally just because comparable EU derivatives rules are not yet finalised and recommended basing such recognition of (upcoming) EU standards on a MoU between the CFTC and EU authorities and using a principle-based approach to recognition rather than a rule-by-rule comparison. While the CFTC's October 12th no-action letters are helpful, they still leave the key issues unresolved.
- The so-called "swap desk push-out" provision (forcing US branches of non-US banks to give up derivatives business if they want to keep their access to the Fed discount window) is discriminatory (US-incorporated banks may retain most of such business). Ideally, DFA should be amended to remedy what is recognized to be an unintended oversight (bill H.R. 1838, as passed by the House Financial Services Committee, would accomplish this, but still lingers in the House and would have to be accepted also by the Senate). Failing such an amendment, the Fed should mitigate the discrimination of non-US banks in line with the legislative intention. We also observe that any discriminatory application of the swap desk push-out provision to US branches of foreign banks would violate the basic principle of national treatment and equality of competitive opportunity which is enshrined in US banking law and the General Agreement on Trade in Services and would also not be compatible with any future EU-US integration agreement. The need for resolution on the swap desk push-out provision (Section 716 DFA) is ever-more pressing in view of the approaching July 2013 effective date.

Against this background, we would very much welcome it if the following financial regulation principles could be agreed on as part of a negotiated EU-US economic integration agreement.

- Inclusion of the principle of national treatment and equality of competitive opportunity (cf. GATS). The principle of national treatment should be achieved in the agreement for GATS modes 3 and 4 of banking and security services (commercial presence and temporary movement of personnel) and possibly also with regard to such services providers' access to financial infrastructure (e.g., exchanges, payment and clearing systems, central bank facilities). It might also be extended to some cross-border business (e.g., with sophisticated client groups not in need of investor protection by their home jurisdiction). Methodically, negotiations on financial and other services could be based on the four GATS modes of delivery. As the US tries to negotiate services in the Trans-Pacific Partnership with a negative list approach, this, rather than the less stringent GATS approach, should be the standard for EU-US talks as well. It would allow most minor barriers to trade and investment to be dismantled upon entry into an agreement and focus political capital on trimming the exceptions in substance and over time.

- Mutual recognition of comparable regulation between relevant EU and US financial regulators should be encouraged. This should be supplemented by ex-ante consultation mechanisms between relevant financial regulators on both sides of the Atlantic. Such consultation mechanisms should help in finding comparable rules and ensuring their mutual recognition.
- Use of international standards by bodies such as the G20, FSB, Basel Committee and IOSCO as the basis for US and EU financial regulation should be encouraged. This would facilitate determination of comparability and recognition by regulators.

We feel that an economic integration agreement which included such principles of financial regulation would strongly contribute to avoiding fragmentation of financial markets due to insufficiently coordinated regulation with its protectionist or extraterritorial side-effects.

While we highly value the on-going financial market policy cooperation between the US and the EU through the US-EU Financial Markets Regulatory Dialogue (FMRD), we believe that inclusion of the above principles could strengthen the FMRD's efforts to achieve consistent regulatory reform. Any negotiations on a transatlantic agreement should, in the field of financial services, include the parties to the FMRD.

The Association of German Banks would be willing to further contribute to the terms and objectives of negotiations on a transatlantic agreement as soon as such negotiations are agreed to in principle.

KADINOVA Desislava (TRADE)

From: TRADE F3 SECRETARIAT
Sent: 25 January 2013 17:14
To: TRADE DOCUMENT MANAGEMENT
Cc: TRADE F3 SECRETARIAT
Subject: 10/ BUSINESSEUROPE contribution to public consultation on regulatory issues for possible future trade agreement
Attachments: Regulatory Coop Component of EU-US Agreement - BE USCC Joint FINAL Oct 2012.pdf

Please, register email and attachment,
Thanks

From: Catella Eleonora [<mailto:e.catella@businessseurope.eu>]
Sent: Wednesday, October 31, 2012 3:27 PM
To: TRADE F3 SECRETARIAT
Cc: ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Subject: BUSINESSEUROPE contribution to public consultation on regulatory issues for possible future trade agreement

Dear Sir, dear Madam,

Please find attached the BUSINESSEUROPE-U.S. Chamber of Commerce joint submission to the Public Consultation by European Commission – DG Trade on regulatory issues for possible future trade agreement.

Best regards,

Eleonora Catella
 Trade Adviser
 International Relations
BUSINESSEUROPE
 Av. de Cortenbergh 168, B-1000 Brussels
 Phone: +32(0)22376565
 Fax: +32(0)22311445
e.catella@businessseurope.eu
 Visit our [Global Trade webpage](#)

BUSINESSEUROPE



100 Years Standing Up for American Enterprise
U.S. CHAMBER OF COMMERCE

Regulatory Cooperation in the EU-US Economic Agreement

U.S. Chamber of Commerce and BUSINESSEUROPE

Introduction and Summary:

The United States and European Union are the world's largest economies, each producing about \$15 trillion in goods and services a year. They are also one another's largest trading partners, with two-way trade in goods and services approaching \$1 trillion annually.

Despite the depth and breadth of this commercial relationship, differences in regulation are overwhelmingly cited as the primary obstacle to enhanced trade between them. An exhaustive study of these differences in 23 different sectors¹ estimates that reducing even half of these divergences would lead to GDP increases for the EU and US of over \$200 billion per year, with exports increasing substantially in both. Many of these regulatory differences are 'unnecessary,' as the U.S. and EU, democratic societies with comparable levels of income and wealth, strive to provide similar levels of consumer, environment and investor protection; that is, their regulatory outcomes are similar, even if procedures and details differ.

The European Union and the United States should adopt a uniquely ambitious approach to regulatory issues in the context of a comprehensive transatlantic trade and investment agreement, with the purpose of enhancing regulators' efficiency and thus effectiveness in fulfilling their domestic regulatory mandates. In particular, in addition to strong and binding technical barriers to trade (TBT) and sanitary/phyto-sanitary (SPS) provisions, the EU and US should agree on regulatory cooperation provisions that will:

- Establish a **clear goal** of having counterpart US and EU regulators determine where their regulatory regimes aim for compatible regulatory outcomes, such that a product or service that can be sold in one market can be made available for purchase in the other; and
- Provide **new tools and a governing process** to guide regulatory cooperation on both a cross-cutting and sector-specific basis, which will help address divergences in both the existing stock of regulations and in future regulatory measures.

Obviously, a determination that specific regulatory approaches are compatible can come only after intensive study and establishment of full trust and confidence between counterpart regulators. This will take time and a US-EU agreement should allow for this, creating an 'evergreen' process with a continuous agenda for advancement. Further, in some sectors, the goal of full recognition may not be feasible or even desirable, but the process of studying the issue will likely lead to other

¹ ECORYS Nederland BV, *Non-Tariff Measures in EU-US Trade and Investment – An Economic Analysis* (2010).

benefits, such as simplification of reporting or data sharing requirements, elimination of duplicative testing, simplification of conformity assessment procedures, etc. Finally, the scope of coverage for regulatory cooperation should include financial regulations.

The U.S. Chamber of Commerce and BUSINESSEUROPE have developed the following proposal to elaborate how a regulatory component could be developed by describing the provisions that should be included in the agreement, including:

- **Preamble** which affirms the importance and benefits of regulatory cooperation to enhancing regulator efficiency and effectiveness, while recognizing their mandate to protect their consumers, investors and environment;
- **Regulatory Principles** that emphasize and endorse regulatory best practices both accepted and agreed by the US and EU;
- **Regulatory Outcomes** that establish a clear goal of compatible regulatory regime determinations for regulators to strive towards;
- **Transatlantic Regulatory Tools** including transparency, information and data sharing, confidentiality, processes for identifying proposed measures with a significant impact on transatlantic trade, and a new Regulatory Compatibility Analysis procedure;
- **Institutional Provisions** to establish an oversight body to address cross-sectoral issues, promote best practices, and oversee an ‘evergreen’ process of enhancing regulatory compatibility; and
- **Preserve Regulator Decision-Making Authority** to maintain respect for sovereignty.

Preamble

Although FTAs generally avoid chapeaux to individual chapters, it is, however, important that a US-EU agreement break from this mode in regard to how it approaches regulation. A US-EU agreement charting a course for regulatory cooperation for regulators in both markets must be guided by a unified vision in order to sustain a continuous high-level commitment. It would also signal to third countries the importance the US and the EU place on high quality, least trade restrictive approaches to regulation. The unique level of ambition in a US-EU agreement requires a clear statement of how deep EU-US regulatory cooperation benefits consumers, investors and the environment by allowing regulators to devote scarce resources to enforcement against higher-risk jurisdictions, without diminishing their ability to regulate or achieve their regulatory mandate. This will give U.S. and European citizens greater confidence in traded products and services even as it helps regulators ensure optimal allocation of their scarce resources. It would also ensure business have better predictability, and that small and medium sized businesses in particular are better able to engage in transatlantic trade.

Regulatory Principles

Here the text of an agreement is relatively straightforward. It essentially would draw from the various core regulatory best practices that are embodied in US and/or EU administrative law. It would also reaffirm and formalize work already done in the June 2011 *Common Understanding on*

Regulatory Principles and Best Practices and April 2002 *Guidelines on Regulatory Cooperation and Transparency*, developed bilaterally between the US and the EU.

Much of this has arguably already been negotiated between the two parties, therefore, its inclusion would be easy and it would serve:

- To make the regulatory component of the overall agreement comprehensive.
- As a model for other trade negotiations for how regulatory best practices have linkages to the same market liberalization goals that serve as the impetus for trade negotiations.
- Demonstrate a commitment from both the US and EU to go beyond any level of regulatory coherence or cooperation in current or in-process trade agreements.

Regulatory Outcomes

The US-EU agreement should create a clear goal that encourages regulators to evaluate the body of regulation and corresponding conformity assessments governing various sectors to determine to what degree each regulatory framework delivers compatible regulatory outcomes. Once this is determined, regulators can implement a 'sliding scale' of regulatory cooperation enhancements to maximize the desired level of coherence, which can include full recognition.

The creation of the mandate in the agreement and corresponding implementing legislation should help ensure any statutory barriers to cooperation are removed. Where compatibility of regulatory outcome is acknowledged, regulators would grant recognition of products and services found to be in compliance with either regulatory regime. These decisions would need to be evidence based – unlike traditional trade negotiations, decisions should not be based on tradeoffs.

This process should be oriented to allow stakeholders as well as regulators to identify entire sectors and regulations within sectors that are potentially ripe for a compatibility evaluation. Such a component will add a proactive requirement directing and empowering regulators to seek full recognition, as well as a process by which regulators would be required to respond to stakeholder-identified opportunities to examine compatibility – neither of which currently exists in the EU or the US. Further, embarking on the exercise of examining compatibility can yield benefits even if the regulators are unable to arrive at full recognition. For example, regulators can increase efficiency by enhancing mutual reliance through information and resource sharing or removal of duplicative testing and reporting requirements. Examining compatibility can identify barriers or other issues preventing progress and lead to the development of the pathways needed to arrive at full recognition, if desirable.

This process will also support regulatory reform in both the US and the EU, which is increasingly putting a premium on conducting ex-post assessments or look-backs of existing regulation; the best approach to these assessments is still very much in its infancy. However, an agreement that directs regulators to explore whether regulatory frameworks in the US and the EU achieve compatible outcomes ties together and enhances the current ex-post assessment trend and would aid in the development of a greater capacity and ability to assess how regulation is working in what is often a globalized market.

Transatlantic Regulatory Tools

Working within the existing EU and US regulatory promulgation process, an agreement would adopt new procedures that create a formal consultative role between the US and the EU for select regulations consideration by either Party to be ‘significant.’ These ‘significant’ regulations can be defined to cover issues of key importance to conducting business on either side of the Atlantic or to understanding how a regulatory mandate (e.g. health or safety) is being met when the regulated good or service will be traded across the Atlantic.

Possible factors that might trigger the formal consultative role are:

1. Where regulation will impact goods or services where the volume of such bilateral trade or investment is significant.
2. Any new regulation or change relevant to a sector where an existing regulatory cooperation arrangement between the EU and the US will be impacted.
3. Regulation is being considered in an emerging policy area or developing sector that has great potential for growth.

Regulatory Compatibility Analysis (RCA)

An important element of this process relates to the right of each side to be consulted early in the domestic regulatory process. This is particularly relevant given the apparent structural differences in the US and EU legislative and regulatory systems. These different structures will require some innovative thinking on how stakeholders, and regulators, on both sides can provide meaningful input into the process, where justified.

Such an approach is highly possible, in fact, in the 1980’s the Administrative Conference of the United States (ACUS) made two recommendations endorsing a process call “regulatory negotiation” which put stakeholders at the table with regulators to essentially co-write regulation. Similarly, the EU has a longstanding policy to promote regulatory cooperation, and where possible convergence, with its major trading partners. This discussion paper posits a modified hybrid international version of the existing ACUS recommendations and the realization of the EU’s regulatory cooperation ambitions.

Further, while, arguably, some consultation already occurs, an agreement would serve to add a well articulated and developed methodology to elevate and formalize those efforts. The formalization will create a cohesive system between regulators and also assure continuous progress.

In particular, the agreement would develop a process and methodology for consultation called a Regulatory Compatibility Analysis (RCA). An RCA should be overseen by OIRA or Sec Gen level, and for financial services in the newly created Financial Stability Oversight Committee (FSOC) in the US and the Sec Gen or other appropriate venue for the EU.

RCA Methodology

The agreement should also spell out a RCA methodology to use as a baseline for avoiding unnecessary divergence of new regulations. The RCA is meant to inform regulators' final decision and is not meant to be determinative.

Much consultation with regulators and stakeholders will need to be done to properly calibrate this methodology. But as a rough starting point, some questions to be considered as part of the methodology include, but are not limited to:

1. What are the costs/savings to the private sector (if any) of complying with a single set of regulations compared to the costs of complying with two or more sets of divergent regulations?
2. What are the budgetary savings to the two regulatory authorities of developing, inspecting, and enforcing two sets of regulations compared to one?
3. How much is transatlantic trade likely to increase as a result of the lower transaction costs from the elimination of the divergent rules?
4. How much would estimated benefits increase if regulatory spillover benefits to the transatlantic partner are included in the benefit estimates?
5. Would there be a change in the regulatory alternative recommended if the net-benefits are increased relative to the baseline of divergent regulations?
6. What are the quantitative and qualitative benefits of a transatlantic regulatory alternative compared to the domestic-oriented regulation?
7. Whether existing measures have become unnecessary or outdated by reason of changed circumstances, such as fundamental changes in technology and if the requirement can be removed or redeveloped more effectively through a cooperation activity.

Information Sharing

For many industries there is an enormous amount of data required by regulators as part of conformity assessment or product approval processes. However, this information is often business sensitive. The agreement should contemplate ways to incentivize and structure, perhaps on an industry by industry basis, information sharing arrangements that give both regulators' and stakeholders' confidence in data sharing, while addressing any other hindrances to open communication and information sharing. Further, the agreement should include harsh penalties for the release of confidential business information outside of a regulator-to-regulator context. Such assurances would be helpful to encourage industry to sign confidentiality waivers.

Transparency

Provisions should also be drafted to:

1. Provide for a central registry of all regulatory cooperation agreements between both the US and EU, as well as between either the US or the EU and a respective trading partner.

2. Create transparency and stakeholder engagement guidelines to govern any US-EU bilateral dialogue. (e.g. US-EU Investment Dialogue, Financial Markets Regulatory Dialogue, Energy Dialogue, IPR Dialogue).

Institutional Provisions

An oversight/implementation group(s) will be needed to manage and provide political oversight of the regulatory cooperation obligations included in the agreement. Accommodations need to be made so that any oversight group appropriately addresses the challenges on the US side presented by independent agencies and structural differences of financial versus non-financial regulatory bodies. Similar corresponding accommodations would need to be made on the EU side. An oversight body would:

1. Develop methods to govern and coordinate both inter and intra-governmental communications.
2. Oversee and manage the RCA and sector compatibility evaluation processes.
3. Finalize concrete and feasible timeframes for regulators to achieve certain objectives and keep a publicly available 'scorecard' to track progress. Even if full recognition cannot follow a preset timeframe or be achieved at all, the oversight body should still set 'small victories' to improve compatibility on regulatory actions, like information and resource sharing.
4. Periodically, at preset intervals, examining existing and newly developed recognition arrangements to ensure enforcement and implementation of regulatory changes are in fact interoperable (particularly when faced with mismatched authorities, i.e. US federal agency, EU Member State, sub-federal/sub-EU/sub-national regulation, failures of regulatory compliance).
5. Work with stakeholders to ensure they are engaged at regular intervals during a RCA or compatibility examination.
6. Develop outreach to make sure SMEs and NGOs are actively engaged.
7. Develop procedures to conduct, where and when relevant, joint/transatlantic scientific analyses of risk to facilitate common understanding between regulatory agencies across the Atlantic.

Preserve regulator decision-making authority

This agreement must not undermine the sovereign right to regulate or force the hand of regulators in determining the final form a regulation takes. In order to recognize this the agreement must preserve a regulator's right to regulate even after new tools like a regulatory comparability assessment has been employed, but also:

1. Reserve the right for regulators to reject an individual product/service (at anytime, if available by sector) from the scope of coverage afforded by a regulatory cooperation/recognition arrangement (a "veto" authority). When this is done regulators should be required to notify their counterpart and provide rationale.
2. Provide for the unconditional immediate suspension and, after consultation, termination within a short period of time (say 90 days) of any regulatory cooperation/recognition arrangement.



BritishAmericanBusiness

75 Brook Street, London W1K 4AD
Tel: 020 7290 9888 Fax: 020 7491 9172

52 Vanderbilt Avenue 20th Floor, New York, NY 10017
Main line: 212 661 4060 Fax: 212 661 4074

Website: www.babinc.org

1 November 2012

European Commission
Charlemagne Building
Brussels, B-1049
Belgium

Dear Sir,

CONCRETE SUGGESTIONS ON HOW TO MAKE REGULATORY REGIMES MORE COMPATIBLE ACROSS THE ATLANTIC

We are writing to you on behalf of BritishAmerican Business and the British-American Business Council ('BABC') to provide our response to the call for input on regulatory issues for possible future trade agreement between the EU and the US.

BritishAmerican Business (www.babinc.org) is the leading transatlantic business organization, committed to promoting an open and competitive transatlantic business environment for our member companies to build their international business. Our International Advisory Board (list att'd) includes the Chairmen and CEOs of more than 100 leading multinational companies. We also participate in (and provide the Secretariat for) the British-American Business Council (BABC), the largest transatlantic business network, which has more than 20 chapters and 2,500 member companies based in major business centers throughout North America and the UK.

Further to our earlier response (which is attached) to the Consultation carried out by DG Trade on the future of EU-US trade and economic relations earlier in the year, we have conducted a further consultation of our members following your invitation and would make the following summary additional points in relation to compatibility of regulatory regimes:

1. We are convinced by the evidence (e.g. OECD and ECORYs) that the single most worthwhile pro growth focus for EU US economic cooperation should be on regulatory cooperation.
2. We are aware of the legacy of, at best, modest success with past efforts to deliver additional economic value through convergence initiatives. We do however applaud the upstream project focus recently adopted through the Transatlantic Economic Council process, and the continuing stream of deliverables being produced such as with mutual recognition of trade facilitation processes (AEO – CT –PAT)

3. We have these practical suggestions to deliver economic value add, most of which, given the nature of the instruments under discussion, call for political action as a precondition for increasing business momentum:
- a. A political agreement and statement that in purpose, fact and intention the levels of protection and public good delivered through different combinations of law, regulation and standardization processes in the EU and the US are functionally equivalent. Evidence* shows that both in the US and the EU risk is essentially priced at the same level through society, suggesting that businesses, consumers and citizens already believe in that equivalence. We have seen no evidence for example that US consumers are more or less likely to rent automobiles in Europe or vice versa, which might be expected if there were truly different perceptions of, for example, auto safety.
 - b. Agreement that this political declaration be a governing principle for all contacts between executive, regulatory and technical communities, and that the agreement represents the will of the people over and above the competence of intermediary authorities.
 - c. Agreement to pursue sign off to that effect from all relevant non signatory actors, at sub federal, national European, regulatory and technical norm setting communities using soft or hard power as appropriate.
 - d. Agreement that no spheres of economic activity should be excluded, so for example ensuring that a principle presuming functional equivalence also applies as a presumption for rule equivalence determinations in financial market regulatory cooperation.
 - e. Agreement to convene regulatory agencies and technical norm setting communities in support of existing processes such as the Transatlantic Economic Council and the High Level Regulatory Cooperation Forum, with agreement based on prior agreement of a specified set of actors against a roadmap for increasing depth of coordination, starting where necessary with structured information exchange and comparative cooperation on independent running initiatives and rule making and progressing to common planning, specification and execution of norms, particularly under so called 'upstream conditions'.
 - f. Agreement on a set of preconditions to be fulfilled by stakeholder communities where necessary to enable delivery at c, d or e above, to be communicated via the Transatlantic Business, Consumer and Legislator dialogues. Specifically in the business context, preconditions should set out sectoral organizations implicated.
 - g. Agreement on a number of key sector leadership initiatives and on roadmaps for each of those sectors, based on existing submissions from those sectors.

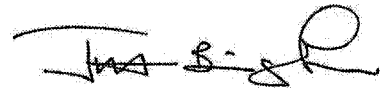
We are also enclosing two commentaries that we received (from BT Group and the Confederation of British Industry (CBI)) that we felt were particularly thoughtful and constructive and which we are happy to amplify.

We look forward to continue to work constructively with you, as you move this initiative forward.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Richard Fursland', with a stylized, flowing script.

Richard Fursland CBE
CEO
BritishAmerican Business and
The British American Business Council

A handwritten signature in black ink, appearing to read 'Jeffries Briginshaw', with a stylized, flowing script.

Jeffries Briginshaw
Managing Director/London
BritishAmerican Business

Evidence

OECD

2 See “The benefits of liberalising product markets and reducing barriers to international trade and investment:

The case of the United States and the European Union”, OECD Economics Department Working Paper No. 432, May 2005.

ECORYS

3 See “Non-Tariff Measures in EU-US Trade and Investment – An Economic Analysis”, ECORYS, Berden, K.G., Francois, J., Tamminen, S., Thelle, M., Wymenga, P., December 2009

EVIDENCE ON COMPARATIVE RISK TOLERANCE IN SOCIETY

4 The Reality of Precaution: Comparing Risk Regulation in the United States and Europe edited by Jonathan B. Wiener, Michael D. Rogers, James K. Hammitt and Peter H. Sand RFF Press (December 2010) (quoted in Determining Compatible Regulatory Regimes between the U.S. and the EU by John F. Morrall III, 2011).

Response from BT Group plc

A. Innovation agenda

1. Higher economic and jobs growth across the Atlantic will be best served by a relentless focus on ensuring a common and pro-innovation approach to regulation in emerging new areas. Regulation should be based on 'light touch' principles capable of implementation in a similar or mutually compatible way in the EU and USA. These core principles (such as between the EU and US, and US and Japan, on ICT policies and ICT regulatory principles) would obviate the need for long term major harmonisation or Treaty-based efforts. There may too be scope for combined efforts in pre-competitive R&D between Government led or funded programmes; and in shared best practice on funding models. All this could act to reinforce a joint EU/US effort with third markets e.g. BRICS, Japan. The innovation areas which seems most suitable for such a mutual effort are:

- * nanotechnology and related areas
- * cloud computing norms, data privacy and transborder data flows
- * smart grid and e-mobility norms
- * cyber security

2. Divergences of approach in the EU and US in the key regulatory area of data protection and data privacy may have a chilling effect on innovation and on new business models. The draft EU Data Protection Regulation is particularly worrisome and needs careful thought and attention. Whilst the draft Regulation has worthy harmonisation aims, the 'devil is in the detail' and the global market for data and transborder data flows means that this is an area which must be subject to a joint approach by the EU and US (which global impact) rather than precipitate effort on one side or the other.

3. The EU and US should also try to address material existing problems of regulatory or standards divergence, particularly in the high tech area, which are causing substantial competitive imbalances between EU and US businesses. 'Quick wins' would include aligning the EU approach to wholesale regulated access to communications networks and the US approach to 'special access'. This would cut the costs of ICT to businesses nationally and transatlantically;

B. Governance and institutional agenda

The US and EU should work together to improve transatlantic and global governance in at least the following areas:

- * to an extent consistent with existing Treaty obligations, the EU (DG Trade) and USTR should set up a joint trade policy task force to work on common approaches to developing enhanced trade opportunities in BRICS, Mexico and elsewhere. This should have explicit business consultation built in
- * the existing high level regulatory cooperation dialogue and the TEC process should be more transparent and more long term in planning and in agenda-setting. It suffers from lack of strategic and secretariat resource on both sides of the Atlantic
- * all measures of transatlantic regulatory significance agreed under the new Accord must be capable of passing tests of (a) the net impact of the measure, taken alone AND cumulatively with related sector or horizontal measures, must be pro-competitive and enhancing of jobs and growth; and (b) unless explicitly not relevant, the measure must be drafted and implemented so as to be 'e-commerce friendly' or 'internet ready'

* the EU and US should reaffirm their joint commitment to the current arrangement for internet governance (ICANN/IGF etc.) and ensure that the internet eco-system remains open to innovation and commerce globally, and that any constraints (such as on grounds of national or global security, or for the protection of children, or the detection of crime) are 'minimum necessary' measures and ideally harmonised as between US and EU at least on a principles level basis

Public consultation on the future of EU-US trade and economic relations

About you	
Do you wish your contribution to be made public? -single choice reply-(compulsory)	Yes
Please state the name of your business/organisation/association? -open reply-(compulsory)	Confederation of British Industry (CBI)
What is your profile? -single choice reply-(compulsory)	Other
If "Other", please specify. -open reply-(compulsory)	
National business and employers' association	
What is your main area/sector of activities/interest (up to 3 answers possible)? -multiple choices reply-(compulsory)	Other
If "Other", please specify. -open reply-(optional)	
The CBI is the UK's leading business organisation, speaking for some 240,000 businesses of every size that together employ around a third of the private sector workforce. We represent all sectors, including agriculture, automotive, aerospace and defence, construction, creative and communications, financial services, IT and e-business, management consultancy, manufacturing, professional services, retail, transport, tourism and utilities.	
In which country are your headquarters located? -single choice reply-(compulsory)	A Member State of the European Union
Priorities for a forward-looking trade relationship with the United States	
What should be the priorities of the future EU-US trade and economic relationship? -open reply-(compulsory)	
<p>The EU and US already has a strong trading and economic relationship. Bilateral trade in goods alone totalled €444.7 billion in 2011, which means that the United States is still the EU's largest trading partner for goods, just ahead of China. Trade in commercial services is also very significant, with combined exports and imports totalling €257.6 billion in 2010. The UK-US economic relationship is particularly well developed. To demonstrate, the US is easily the UK's largest individual export destination. Furthermore, according to ONS data, the UK and US are by far the largest individual foreign investors in each other's economies. In 2010, the stock of US inward FDI to the UK stood at over £200 billion, almost double the stock of just 10 years earlier. A pro-active strategy with the US is required to maintain the strength and depth of the UK-US economic relationship. Looking at trade specifically, tariffs are already relatively low between the EU and US. This means that negotiations with the objective of boosting transatlantic trade should prioritise trade in services, as well as a variety of regulatory barriers to trade in both goods and services. This is not to say that tariff elimination is not important. The benefits from this alone would be significant due to the large quantities of goods traded between the EU and the US (even in those sectors where the applied tariff is already near zero or significantly below the average US tariff of around 5%). However, with the services economy responsible for over 75% of UK GDP, and with the US and the UK confirmed as the top two exporters of commercial services in this year's WTO World Trade Report, it is imperative that advancing the transatlantic services economy and reducing regulatory barriers to all forms of trade should be high on the agenda in order to maximise the economic benefits to both economies.</p>	
How should the European Union pursue these priorities? -open reply-(compulsory)	
The CBI is of the view that the launch of broad, ambitious negotiations resulting in new commitments that are delivered together as a single package is the most workable option of those that we have considered. It is not important to us whether this is done under the banner of an FTA or a functionally equivalent term. It is imperative that a negotiating framework is adopted that guarantees a positive	

outcome with results, as a protracted or even a failed negotiation could have serious consequences for future market access negotiations, whether they be at the bilateral, plurilateral or multilateral level. Any approach taken should lead to mutual benefits in terms of market access for industry players on both sides.

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

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?

-single choice reply-(compulsory)

No

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, in your opinion, not been the case.

-open reply-(compulsory)

Although TEC has helped achieve a few notable successes, most recently with the AEO/C-TPAT mutual recognition agreement in May, the overall results cannot be considered 'satisfying'. A targeted agenda focusing on upstream technologies has helped to focus discussions, but to date, the TEC process has still failed to deliver results of substantial economic significance to the EU and US. There is a clear lack of transatlantic common rules across the full range of sectors. The HLRCF and the overall TEC process should be more transparent with improved long-term planning and agenda setting. The launch of FTA negotiations would be an opportunity to continue the groundwork that has been done in TEC to deliver agreements of significance particularly on regulatory issues. Regulation should be based on 'light touch' principles capable of implementation in a similar or mutually compatible way in the EU and US.

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

-single choice reply-(compulsory)

Yes

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

-open reply-(optional)

The on-going scoping work should clarify where further commitments are realistic and possible. We welcome the involvement of industry and sectoral organisations at an early stage to help with this work. We have indicated our support for a comprehensive Free Trade Agreement (or functionally equivalent term) between the EU and the US that includes ambitious commitments on tariffs, trade in services, IPR protection, regulatory convergence, public procurement and investment.

Tariffs

Are you concerned by tariffs in your field of activity?

-single choice reply-(compulsory)

Yes

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

-single choice reply-(compulsory)

Yes

If tariffs affect your ability to export/import or to do business in the US, please explain. -open reply-(compulsory)

Tariffs between the EU and US are generally quite low, though they are still detrimental to UK-US trade. Even where tariffs are very low, there are significant gains to be had from eliminating them completely. For some industrial sectors in the UK, tariff elimination is particularly important to secure. For instance, in the chemicals sector, where the average import duty in both the EU and US is low at around 3%, it has been estimated that tariff elimination could save more than €500 million a year for intra-company trade alone given the high value of chemicals traded across the Atlantic (€54 billion of transatlantic chemical trade in 2011, 35-40% of which was

intra-company trade). This is a significant saving. Where higher tariffs occur, clearly the gains from duty elimination are even greater. There is no reason why industrial tariffs should continue to endure between the EU and US given the mature relationship between the two economies.

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

-open reply-(compulsory)

We represent all sectors (a 2010 ECIPE study estimated that the average weighted applied tariff on goods traded was 4.8% in the US and 6.7% in the EU).

Non-tariff measures for industrial products

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

-single choice reply-(compulsory)

Yes

If you are concerned by regulatory barriers, please specify whether they arise from (multiple answers possible):

-multiple choices reply-(compulsory)

Technical regulations - Standards - Conformity assessment procedures

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

-open reply-(compulsory)

See 5.8.

Indicate how and how much it impacts your business/activity. If possible, provide an estimate/quantification of the costs of the barriers. -open reply-(compulsory)

With relatively low average tariffs in force, regulatory barriers are generally regarded as being the most significant issue that is holding back deeper economic integration between the EU and US.

Indicate what would be the benefits of its removal.

-open reply-(compulsory)

See 5.8.

Please indicate to which level of government the regulatory obstacles relate (multiple answers possible)? -multiple choices reply-(compulsory)

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

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?

-open reply-(optional)

Under the auspices of different forums, the EU and US has been working on ways to address long-standing regulatory barriers and to come forward with best practices to minimise regulatory divergences in the future. In this regard, as part of the TEC process, the High-Level Regulatory Co-operation Forum has been successful in reaching agreement between the EU and US on a Common Understanding on Regulatory Principles and Best Practices. We welcome this understanding, and stress that the commitments made therein should become binding within the context of FTA discussions. In particular, transparency is critical and industry should be consulted as a matter of course prior to the proposal of new regulations that could impact transatlantic trade. With this in mind, all new regulation should pass much stricter tests of consumer need and business impact in order to really push forward a competitive transatlantic marketplace. In general, the CBI will be looking to ensure that a clear process is outlined when developing regulation for new technologies or when amending regulation for existing technologies to ensure collaboration on both sides of the Atlantic. Clearly the ability to address longstanding regulatory barriers within what we believe should be a swift negotiation process will be a significant

challenge and depends both on the issues at stake and the current level of co-operation between the regulatory bodies in the sectors concerned. As a result, the Commission should continue its scoping work with industry and regulatory bodies to clarify what may and may not be possible. As a general point, we believe there should be early moves to harmonise proportionate rules, regulations and standards in emerging new technology areas, building on TEC work in fields including smart grids, e-vehicles, nanotechnology, cloud computing and ICT. A common pro-innovation approach to regulation in emerging technologies is of fundamental importance. However, in addition to this, we would like to see concrete results for mutual recognition of functionally equivalent regulations where they exist. In some sectors, such as automotive, there is also scope to push for the harmonisation of technical standards (UNECE and FMVSS), which would undoubtedly support the development of a truly transatlantic marketplace. Trade in other sectors such as electrical goods, chemicals, ICT and engineering would all benefit from stronger regulatory co-operation in their respective fields. Regulatory commitments should be fully implemented and held to account.

Sanitary and phytosanitary obstacles

Are you concerned by unnecessary sanitary and phytosanitary regulatory obstacles?

-single choice reply-(compulsory)

Yes

If you are concerned by sanitary and phytosanitary regulatory obstacles, please specify from where they arise (multiple answers possible):

-multiple choices reply-(compulsory)

Processed products

For processed products (multiple answers possible):

-multiple choices reply-(compulsory)

Insufficient or lack of transparency of import requirements and of which Federal competent authority is responsible. - Divergences of Federal standards compared to EU standards - Divergences of State/local standards within the US - Setting up of import requirements - Approval facilities - Inspections and controls at border inspections post

Please explain the sanitary or phytosanitary obstacles in detail. -open reply-(compulsory)

There have been some longstanding SPS issues between the EU and US. The negotiations should be an opportunity to see whether there is scope to find solutions to such issues, such as import restrictions on milk and uncooked meat products, and to consolidate progress where it has been made, such as on the beef hormones dispute. However, at the same time, particularly contentious issues should not be allowed to halt overall progress with the talks. In particular, the UK food and drink industry will be looking carefully at implementation of the Food Safety Modernisation Act (FSMA). With the newly introduced 'Foreign Supplier Verification Program', it is important that the procedures already implemented by food exporters (e.g. the HACCP control system) are accepted in forthcoming guidelines for EU products. Furthermore, there should be bilateral agreement with the US on the equivalence of EU internal inspections given FDA's call for an increase in the number of controls in foreign production plants. Separate plans to introduce sanitary import permits for products containing less than 2% of eggs are also a concern as many products could be closed off from the US market. Furthermore, the fact that many state and municipal authorities in the US demand specific safety or environmental requirements creates issues for exporters. Not only may they be inconsistent with each other, but they may also be additional to federal level requirements.

How should the European Union address the specific obstacles? -open reply-(compulsory)

See 6.7

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

-open reply-(compulsory)

See 6.7

Customs procedures, border enforcement and trade facilitation

Are you concerned by current practices in

Yes

customs procedures and border**enforcement?** -single choice reply-(compulsory)**If you are concerned by current practices, please specify which practices?** -open reply-(compulsory)

The CBI welcomes and supports the recent agreement to mutually recognise AEO and C-TPAT trusted traders. Trade negotiations should lock in this agreement with commitments to fully monitor and implement it. Furthermore, the EU should explore opportunities for further reduced requirements for those companies that do hold AEO certification. However, in spite of this agreement, we are still concerned that new US legislation on 100% cargo screening at foreign ports prior to shipment to the US does the opposite of 'trade facilitation' and should be repealed fully. This should be addressed in negotiations. As new security programmes and initiatives are developed, more effort is needed to harmonise standards to prevent future divergence in requirements. The EU and US should work towards implementing uniform international principles of standardised customs processes, efficient customs clearance, and mutual recognition of customs and security related standards. The launch of EU-US negotiations would create an opportunity to assess possible options to develop more effective customs clearance systems and procedures within the EU. This is a complex issue as new requirements could have the unwanted effect of increasing costs for European companies. Nevertheless, it is essential to look at ways to make customs procedures more efficient, and all sectors stand to gain from improved trade facilitation. Another issue to look into is the fact that the "de minimis" value threshold for the imposition of duties and customs requirements is lower in the EU than it is in the US. Furthermore, the US Senate has recently been pressed by domestic industry groups to raise the US threshold significantly further from \$200 to \$1000, which would offer clear benefits for low value shipments. Reaching a higher, common threshold would be to the benefit of both economies, particularly for SMEs.

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? -open reply-(compulsory)

See 7.2

If you are concerned by customs procedures and border enforcement, what should be the European Union priorities to address the issue? -open reply-(compulsory)

See 7.2

Protection of Intellectual Property Rights**Are you concerned by problems of protection and enforcement of intellectual property rights in your field of activity?** -single choice reply-(compulsory)

Yes

If you are concerned by problems of protection and enforcement of intellectual property rights, please explain the problems you encounter. -open reply-(compulsory)

We call for strong IPR regimes, including protection of trade secrets for rights holders that extends beyond WTO TRIPS requirements. The reform in US patent law to the 'first to file principle' is one step towards harmonisation, though there is clearly a long way to go. The EU and US should use this initiative as an opportunity to promote the highest levels of IPR protection given the lack of adequate protection that is afforded in many significant third countries. The EU and US should take the lead to fight against counterfeiting and piracy.

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

-single choice reply-(compulsory)

Yes

If you are concerned by problems of protection for Geographical Indications or trademarks, please explain the problems you encounter. -open reply-(compulsory)

See above.

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?

-open reply-(compulsory)	
See above.	
Trade in services	
Are you concerned by barriers to trade in services in your field of activity? -single choice reply-(compulsory)	Yes
If you concerned by barriers to trade in services, which ones are the most important ones (multiple answers possible)? Please clarify whether: -multiple choices reply-(compulsory)	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
If "Other", please specify. -open reply-(optional)	
Please describe the barriers in detail. -open reply-(compulsory)	
See 9.7	
If you are concerned by barriers to trade in services, please indicate to which level of government the obstacles relate (multiple answers possible)? -multiple choices reply-(compulsory)	US Federal / EU level regulation - US States / EU Member State regulation
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? -open reply-(compulsory)	
See 9.7	
If you are concerned by barriers to trade in services, how should the European Union address these restrictions to trade in services? -open reply-(compulsory)	
<p>Services are highly important in the context of transatlantic trade. According to the WTO's World Trade Report 2012, the US and the UK are the top two exporters in world trade of commercial services, with a combined share of 20.5% of global services exports in 2011. The CBI would strongly welcome horizontal commitments from both sides to improve market access and national treatment in all services modes and to remove remaining equity caps for investment. Both the EU and US should not be able to retract from the current level of openness. We support a negative list approach to services coverage, where any exceptions to the rule have to be explicitly spelt out. Within the context of these negotiations, we will also be looking carefully to ensure that significant sector specific priorities are accounted for. A range of barriers to UK-US services trade in sectors including legal services, engineering, electronic communications, the internet economy, transport (all modes, including aviation) and financial services (including banking and insurance) have already been put forward to the Commission. Rather than repeat these priorities, we would like to stress that ambitious, meaningful results in these areas will be necessary to get anywhere close to the 0.5% increase in EU GDP figure written in the July 2012 Commission progress report on external sources of growth. Regulatory barriers are particularly relevant in the context of services negotiations. While Section 5 of this consultation focuses on NTBs for industrial products, general principles such as close consultation with industry at the pre-regulation stage and high levels of transparency are equally important in the context of services regulation. Behind-the-border barriers to services do not only appear due to the existence of distorted regulation, but also because of the lack of appropriate pro-competitive regulation in the market. For example, the EU has non-discriminatory and transparent wholesale access rules for electronic communications services in place, which does not align with the US approach to 'special access'. This has led to competitive distortions in the US, the EU and the global network services market. A further area of importance that we would like to stress is in the field of data privacy and protection.</p>	

Negotiations should protect the free flow of data between the EU and US as well as the interoperability of their data privacy and protection regimes. This is crucial in boosting the confidence of consumers and businesses alike to engage in transatlantic e-commerce. The adoption of strict and unnecessarily divergent approaches to data privacy and protection should be avoided. A joint approach would be far more beneficial to drive forward innovation and new business models. Further general problems have been reported relating to the predictability of the US visa regime. Given the high degree of regular business travel between the US and US, a fast-track registered traveller process would be welcomed. In addition, while overall the investment climate is very positive for UK businesses, some British companies with a commercial presence in the US have reported general issues with the litigation culture, which has led to payoffs for the sake of simplicity. This is clearly a structural problem which transatlantic negotiations alone would not be able to address, but nevertheless, it is a significant factor that reduces investor confidence in the US, particularly for SMEs and mid-sized businesses that may not have significant legal teams to fight dubious claims at their disposal.

Investment

Are you concerned by barriers to direct investments in your field of activity? -single choice reply-(compulsory)

Yes

If you are concerned by barriers to investment, please describe the barriers in detail. -open reply-(compulsory)

One notable example concerns the current restrictions that limit investment in US airlines by EU citizens/entities and vice versa. This prevents consolidation in the industry, creating inefficiencies and fragmentation.

If you are concerned by barriers to investment, please indicate to which level of government the regulatory obstacles relate (multiple answers possible)? -multiple choices reply-(compulsory)

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

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?

-open reply-(compulsory)

N/A

If you are concerned by barriers to investment, how should the European Union address the issue? -open reply-(compulsory)

We welcomed the shared principles on International Investment that emerged from the TEC process and were announced on 10 April. We consider that a very ambitious investment agreement consistent with these principles and containing an EU-US investor-state arbitration mechanism with timeframes could form part of the negotiations.

Public Procurement

Are you concerned by restrictions in public procurement in your field of activity? -single choice reply-(compulsory)

Yes

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

-open reply-(compulsory)

GPA commitments do not cover all US States. Furthermore, the general clauses of the GPA do not apply to 'Buy America' provisions. Within the EU, there has been intense pressure to close off the EU's public procurement market to create a 'level playing field' with other markets including the US which are not deemed to be 'open'. This led to a proposal from the European Commission in February 2012 which would give contracting authorities and Member States the ability to close off public procurement contracts to overseas companies including bidders from the United States. We are of the view that this recent proposal is not the best way to boost access to the US public procurement market, and are concerned of the potential implications for the EU's overall trade relations with a number of key trading partners. However, against this backdrop, it is particularly important that negotiations do result in significant public procurement commitments from the US. Evidence does suggest that there is lots of scope for the US to reduce protection in this area at both federal and state level, including the elimination of local content requirements, and as a result, this should be a priority for the EU in the negotiations.

<p>If you are concerned by restrictions in public procurement, please indicate to which level of government the obstacles relate (multiple answers possible)?</p> <p>-multiple choices reply-(compulsory)</p>	<p>US Federal / EU level regulation - US States / EU Member State / local level regulation</p>
<p>If you are concerned by restrictions in public procurement, what are the estimated additional costs/forgone revenue for your business resulting from these restrictions?</p> <p>-open reply-(compulsory)</p> <p>N/A</p>	
<p>If you are concerned by restrictions in public procurement, what should be the European Union priorities to address the issue?</p> <p>-open reply-(compulsory)</p> <p>Negotiations should look to open up the US public procurement market to the highest degree possible, going beyond GPA commitments in terms of coverage, including purchases made at the sub-federal and local level with reduced thresholds. There should be binding transparency rules for award process and national treatment, clear decision making criteria, clear deadlines in the selection and decision making process, and a neutral arbitration board which deals with complaints.</p>	
<p>Competition issues</p>	
<p>Are there fields where the European Union should seek to increase cooperation with the United States? -single choice reply-(compulsory)</p>	<p>Yes</p>
<p>Anti-trust</p> <p>-single choice reply-(compulsory)</p>	<p>Yes</p>
<p>Mergers</p> <p>-single choice reply-(compulsory)</p>	<p>Yes</p>
<p>Liberalisation</p> <p>-single choice reply-(compulsory)</p>	<p>Yes</p>
<p>State Aid</p> <p>-single choice reply-(compulsory)</p>	<p>Yes</p>
<p>What should be the European Union priorities? -open reply-(compulsory)</p> <p>Discussed elsewhere in consultation.</p>	
<p>Facilitating the participation of small and medium sized enterprises (SMEs) in the transatlantic market place</p>	
<p>In your view/experience, which of the sections in this questionnaire are of particular importance to SMEs? Please explain why?</p> <p>-open reply-(compulsory)</p> <p>We think that Sections 5 on regulation, Section 7 on trade facilitation, Section 9 on trade in services, and Section 11 on public procurement are particularly important for SMEs. On services trade specifically, SMEs typically do not have the resources to establish offices overseas, which puts extra importance on the cross-border provisions.</p>	
<p>In your view/experience, how could SMEs better benefit from economic opportunities in transatlantic trade and investment relationships? -open reply-(compulsory)</p> <p>See above.</p>	
<p>Impact on Consumers</p>	
<p>In your view, would the elimination of</p>	

barriers to trade and investment between the EU and the US have an effect on Consumers? -single choice reply-(compulsory)	Yes
Lower Prices -single choice reply-(compulsory)	Yes
Higher prices -single choice reply-(compulsory)	No
Larger choice of products -single choice reply-(compulsory)	Yes
Smaller choice of products -single choice reply-(compulsory)	No
Other -single choice reply-(optional)	Yes
If "Other", please specify. -open reply-(optional)	
It is important that business consumers as well as end consumers benefit from more competition, quality and lower prices in a transatlantic marketplace. There are regulatory and non-regulatory distortions which particularly affect the business-to-business market segment and this often risks being overlooked by policymakers and government administrations.	
Environmental Impact	
Do you expect impacts on the environment in the context of an enhanced EU-US trade cooperation? -single choice reply-(compulsory)	Do not know / Not applicable
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? -open reply-(compulsory)	
The EU and US should work closely together with a view to reaching a global agreement on aviation emissions, using ICAO as one possible route. The CBI supports the inclusion of aviation in the EU ETS as a stepping stone towards a global deal, but the current increasingly political debate has the potential to affect trade. It is therefore of paramount importance that a solution be found through constructive dialogue and negotiations.	
Social Impact	
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? -single choice reply-(compulsory)	No
In the EU: -single choice reply-(compulsory)	Positively
In the US: -single choice reply-(compulsory)	Positively
In the EU: -single choice reply-(compulsory)	Positively
In the US: -single choice reply-(compulsory)	Positively

In the EU: -single choice reply-(compulsory)	No change
In the US: -single choice reply-(compulsory)	No change
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? -open reply-(compulsory)	
See above.	
Other issues	
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.	
-open reply-(optional)	
The EU and US should also set up a joint trade policy task force to work on common approaches to develop enhanced trade and investment opportunities in the BRICs and other key emerging markets. Business consultation should be fundamental to this work.	
Your comments ... -open reply-(optional)	



BritishAmerican Business

75 Brook Street, London W1K 4AD
Tel: 020 7290 9888 Fax: 020 7491 9172

52 Vanderbilt Avenue 20th Floor, New York, NY 10017
Main line: 212 661 4060 Fax: 212 661 4074

Website: www.babinc.org

27 September 2012

The Director General
Directorate General Trade
European Commission
Charlemagne Building
Brussels, B-1049
Belgium

Dear Sir,

PUBLIC CONSULTATION ON THE FUTURE OF EU-US TRADE AND ECONOMIC RELATIONS

We are writing to you on behalf of BritishAmerican Business and the British-American Business Council ('BABC') to provide our response to the Public Consultation on the Future of EU-US Trade and Economic Relations which was launched following the Interim Report of the High-Level Working Group (HLWG) on Jobs and Growth delivered in June 2012.

BritishAmerican Business (www.babinc.org) is the leading transatlantic business organization, committed to promoting an open and competitive transatlantic business environment for our member companies to build their international business. Our International Advisory Board includes the Chairmen and CEOs of more than 100 leading multinational companies. We participate in (and provide the Secretariat for) the British-American Business Council (BABC) which has more than 20 chapters and 2,500 member companies based in major business centers throughout North America and the UK.

To ensure that we provide you with the most accurate and comprehensive possible response to this Consultation, we have consulted our members in writing and convened a special meeting on and around this issue with our members in London on September 18th under the title "Agenda for Growth, the EU and US – Partners for the 21st Century?". As a business organization, dedicated to representing the views and interests of our members, we find the questionnaire to be an insufficient structure and format to communicate the aggregated views of our large membership as a whole. Our views are therefore contained in this letter.

We are strong supporters of the HLWG process and encourage you to deliver a final report that will agree, announce, open, and fast track detailed and substantive discussions commencing as early as possible in 2013. We believe that a comprehensive transatlantic trade and investment pact would be of huge benefit to our member companies on both sides

of the Atlantic and add billions to the already-massive trade and investment relationship shared between Europe and the United States. Furthermore, a successfully concluded negotiation would create jobs, and support our member companies, entrepreneurs and creators as they seek new business opportunities in global markets while also providing new impetus for the creation of a body of world trade rules fit for the 21st century.

We are convinced that the creation of a transatlantic single market will bring benefits to consumers and businesses alike. At a macro level, the case for further transatlantic economic integration has already been well established in studies carried out by the OECD and ECORYS, amongst others. The latter in particular already delivers some sector specificity and an evidential base for a sufficient assessment of impact.

At this stage, however, our experience is that we have not seen the required investment of time and money by companies, entrepreneurs and sector trade associations in detailed descriptions of specific barriers and/or opportunities on an issue by issue, standard by standard, and regulation by regulation basis. There remains a need to build awareness, add momentum and in some cases reverse a deep rooted legacy of doubt about the commitment and ability of the EU and US to find new answers to old questions, and to find compromises on sensitive issues, such as phytosanitary access, government procurement and rules of origin.

We believe that stronger investment in specification and quantification will follow the announcement of the opening of negotiations and we stand ready to further strengthen momentum and consultation with our membership at that time.

As an interim description of policies and measures to increase EU-US trade and investment to support job creation, economic growth and international competitiveness of EU and US industry, we recommend the following focus, based on initial discussions with our member companies:

- Restate ambition for liquid, ethical and integrated transatlantic financial markets and assert the ambition as an aim and principle of all rule equivalence determinations; agree a transatlantic approach to global audit leadership; agree ambitious convergence roadmaps for specific activities such as insurance
- Agree practical acts of phytosanitary surveillance cooperation in third country supply chains to build confidence in the outcome quality of respective systems, and agree access concessions for sensitive sectors
- Dismantle remaining bilateral barriers to investment and cooperate to open third country markets
- Agree data and privacy standards as a building block for a transatlantic digital economy and single market
- Ensure national treatment for all levels of public procurement, and increase access at sub-federal and regional levels

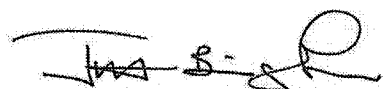
- Eliminate goods tariffs
- Take the substance of trade facilitation and services best DDA offers into U.S.- EU text, and use this as a basis for global/plurilateral template leadership
- Prioritize liberalization of transatlantic people movement to deliver enhanced visa issuance and fast track movement of business executives
- Enhance opportunities for the enhancing the compatibility of regulations and standards by providing new mandates, processes to empower and incentivize regulators and standard setters to agree such standards with their respective, de facto transatlantic opposite numbers
- Agree US/EU IPR rule convergence (e.g. patent filing grace period, resistance to erosion of the IPR system globally), and resist indigenous innovation protectionism
- Strengthen and consolidate Transatlantic Economic Council, and ensure that the TEC has guaranteed cross-Administration/Commission visibility

At a time of European and American economic fragility, the prospect of reaching an ambitious agreement on measures that would boost growth and job creation is one worth pursuing with all vigor. For sure there will be an inevitable lag between changing the rules and attaining the full economic effects of those changes. But in addition to its many other benefits, the signal sent by agreement and elaboration of a detailed agenda has the potential, in the short term, to increase confidence and so encourage the deployment of the large amounts of capital that are currently held back by uncertainty and so re-energize the European and US economies. We accordingly urge you to take the opportunity of a fall EU-US Summit to launch this new transatlantic economic partnership, and commit our full support to your efforts in this regard.

Yours sincerely,



Richard Fursland CBE
CEO
BritishAmerican Business and
The British American Business Council



Jeffries Briginshaw
Managing Director/London
BritishAmerican Business

