

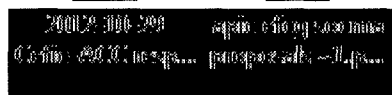
KADINOVA Desislava (TRADE)

From: TRADE F3 SECRETARIAT
Sent: 25 January 2013 17:17
To: TRADE DOCUMENT MANAGEMENT
Cc: TRADE F3 SECRETARIAT
Subject: 12/ Cefic ACC Input on regulatory cooperation incl APIC EFCD SOCMA submission

Please, register email and attachments as per agreed attributions,
 Thanks,

-----Original Message-----

From: PERENIUS Lena [<mailto:LPE@cefic.be>]
Sent: Wednesday, October 31, 2012 2:33 PM
To: TRADE F3 SECRETARIAT; ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Cc: VAN SLOTEN René
Subject: Cefic ACC Input on regulatory cooperation incl APIC EFCD SOCMA submission



Please find attached the joint Cefic-ACC proposals for possible EU-US regulatory cooperation complemented by proposals made by APIC, EFCD and SOCMA for their sector

Best regards,

Lena Perenius
 Executive Director, International Chemicals Management
 Cefic - European Chemical Industry Council

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.

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

Proposals for the EU-US High Level Working Group (HLWG) for Jobs and Growth and the High Level Regulatory Cooperation Forum (HLRCF): October 2012

Introduction

This paper provides 4 **regulatory harmonization and standardization** proposals affecting the EU and US **pharmaceutical industries** for consideration by the EU-US HLWG for Jobs and Growth and by the HLRCF, viz., a Mutual Recognition Agreement, Regulatory Assessment of Changes, Harmonisation of Pharmacopoeia, and Good Manufacturing Practices (GMP) Certification.

I. A MUTUAL RECOGNITION AGREEMENT (finished drug products and active pharmaceutical ingredients (APIs))

In the late 1980s considerable exchange took place between the US FDA and the EU to establish a Mutual Recognition Agreement (MRA)¹ in the field of GMP Inspections for pharmaceutical products. This was in line with similar such initiatives in other industrial sectors and with other regions such as Australia, Canada and Israel. However, the US and EU were unable to successfully conclude such an agreement.

In 2007, under the auspices of the Transatlantic Economic Council (TEC), a Transatlantic Administrative Simplification Workshop was held. An outcome of this was an action plan devised to support collaboration between the US FDA, The European Medicines Agency and National Medicines Agencies of the EU Member States. An important component of this was a joint inspection programme piloted by the US FDA and The European Commission and EMA in 2009. This pilot was deemed such a success at the end of 2010 that a continuing FDA-EU cooperation was confirmed² in January 2012. However, the joint inspection program is limited (to only a few sites), uses a duplication of resources, and does not meet the need of today's challenging regulatory environment.

It is paramount to have a mutual agreement between the US FDA and the EU as soon as possible, thus the need to restart discussions around an MRA in the context of the Regulatory Cooperation Component to the EU-US Economic Agreement given the extended and cooperative contacts that have been on-going for the last 20 years culminating in the Simplification Action Plan. The benefits to EU-US trade are as follows:

1. There would be an immediate savings in inspection resources to agencies on both sides of the Atlantic.
2. Given the continued growth and current high level of dependency in the supply of pharmaceuticals and active pharmaceutical ingredients from so-called third countries, EU and US Agencies would be able to refocus their inspection efforts to 3rd countries - where no mandatory inspection of API and final dosage form suppliers is currently in

place. This would be very much aligned with the objectives of the EU through its Falsified Medicines Directive and the US GDUFA (Generic Drug User Fee Act ⁱⁱⁱ) initiative. It would also be supportive of the Medicrime Convention and works towards improving product quality; in the GDUFA negotiations, industry presented a strong case for mutual agreements and FDA committed to reviewing this request.

3. It would benefit the health of EU-US citizens. It would promote EU-US trade and lead to further harmonisation of GMP standards aligned with International Conference on Harmonisation (ICH) process.

It is recommended that discussions between the US FDA and the EMA should be commenced as soon as possible with a view to finalising an MRA for pharmaceutical products including APIs. The Transatlantic Simplification Action Plan can be used as a basis for commencing this dialogue.

II. REGULATORY ASSESSMENT of CHANGES

From the pharmaceutical regulatory perspective there is also a concern that a certain type of change in the manufacture or control of APIs is assessed differently in US versus EU. For instance, what one region would consider a major change could in the other region be an annual reportable change? A change that can be implemented and only *after* implementation be reported to the health authorities versus a change that needs to be reviewed and thoroughly assessed *prior* to formal notification from the health authorities that implementation of the change is allowed.

That difference in assessment costs time and money for global companies since for API manufacturers it is difficult to implement changes *per region*. The revision of the EU Directive (COMMISSION REGULATION (EC) No 1234/2008) was an attempt or first step, but definitely not the end.

It is recommended that the US FDA and EU work an agreement for annual reportable changes as a first step.

III. HARMONISATION OF PHARMACOPOEIA

Given the globalization of the pharmaceutical industry, it would be beneficial to also have a global standard for pharmacopoeia, starting with those for the EU (Ph Eur) and US (USP). In reality, the different requirements rarely show any differences in the quality of the raw materials or products, yet the cost to industry of unnecessary multiple testing is significant without any improvements in efficacy, quality or safety to benefit the patient.

Since the Ph Eur and USP each have to cope with a huge work programme, harmonized monographs or mutually recognized monographs elaborated by one party and acknowledged by the other would bring considerable relief to both the Ph Eur and the USP.

Whilst recognising that there has been some progress on harmonisation over the past 20+ years (e.g., via the Pharmacopoeial Discussion Group in the 90's and ICH Q4B in 2003), this has been a slow process and more effort is needed. An EU-US common standardization initiative could revitalise this activity, irrespective of the different regional status of the issuing bodies (the Ph Eur is

issued by the European Directorate for the Quality of Medicines (EDQM), a European authority, whereas the USP is a private organization).

IV. GOOD MANUFACTURING PRACTICES (GMP) CERTIFICATION

The EU has reformed the rules for importing into the EU APIs for medicinal products for human use. As of 1st January 2013, all imported APIs must have been manufactured in compliance with standards of GMP at least equivalent to the GMP standards of the EU. As of 1st July 2013, this compliance must be confirmed in writing by the competent authority of the exporting country and the certification accompany the API being imported. The European Commission has provided a template for the compliance letter that would communicate all of the required information. The EC has stated that the certification is independent of the existence of MRAs, and the only means of exception from the written certification will be for exportation from a country which, following its request, has been assessed and considered as having equivalent rules for GMP to those in the EU.

Both the EU and USFDA subscribe to the use of the standards of the International Conference on Harmonization (ICH) Q7 for the manufacture of APIs, and so equivalency of standards should not be an issue for US manufacturers of APIs that wish to export to EU countries. The US FDA has historically refused to issue GMP certifications to US manufacturing sites other than by issuance of a Certificate of Pharmaceutical Product; however, this certificate does not provide all of the information specified by the EC in its template.

It is recommended that discussions should commence as soon as possible between the US FDA and the EC with a view to determining a way forward so as to prevent the construction of a trade barrier to the exportation of APIs from the US to EU countries. Possible ways for resolution include application by the US for assessment of GMP equivalency, or acceptance by the EC of the current or a modified Certificate of Pharmaceutical Product as satisfying the need for written confirmation. Failure to resolve this issue will result in the reduction of trade between the EU and US, and the possible creation of drug shortages in the EU resulting from the unavailability of APIs manufactured in the US.

Footnotes:

ⁱ Mutual Recognition Agreements or MRAs allow trading countries to mutually recognise technical standards and/or quality systems, hence removing a technical barrier to trade. In order to enhance trade with its main partners the EU has been active in pursuing such MRAs with a number of them. MRAs cover a wide range of industrial sectors. Of primary interest to the pharmaceutical sectors are annexes to MRAs that deal specifically with Current Good Manufacturing Practices (cGMPs). CEFIC's APIC and EFCG have supported the establishment of MRAs for a number of years as they see these developments as being supportive of both the continued growth of the API sector in the EU and the expansion of trade. They also see MRAs playing a supportive role in the harmonisation of standards

across the globe and, therefore, would view MRAs as being complimentary to the International Conference on Harmonisation (ICH) process...

ii News Release "Joint FDA-EMA Inspection program to Launch in January 2012" and the document "Enhancing GMP inspection cooperation between the EMA and FDA"

iii For details please see

<http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm>

or

<http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf>

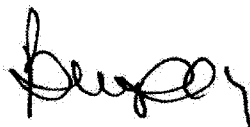
Society of Chemical Manufacturers and Affiliates (SOCMA), USA



October 15th 2012

Lawrence D. Sloan, President & CEO

European Fine Chemicals Group (EFCG), a Subsidiary of CEFIC, Belgium



October 15th 2012

Dr Brian M Murphy, President &
Chairman of the Board

Active Pharmaceutical Ingredients Committee (APIC), a Subsidiary of CEFIC, Belgium



October 15th 2012

Dr Anthony W Storey, President

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Register,pls

thanks

From: Bernard Lombard [mailto:b.lombard@cepi.org]
Sent: Monday, September 24, 2012 6:01 PM
To: TRADE F3 SECRETARIAT
Cc: Bernard Lombard
Subject: Input on regulatory issues for possible future trade agreement between EU and US

Dear Sir/Madam,

On both sides of the Atlantic, Governments have tried to promote bioenergy in order to reduce emissions and mitigate climate change.

EU Commission and US government should identify a common way of doing it through cost-efficient measures that do not distort the competition between the 2 countries/areas and secure a level playing field for companies on both sides.

The US have adopted several schemes aiming at encouraging bioenergy production and consumption, like the Alternative Fuel Mixture Tax Credit, through which the US government has given USD 9 billion to the US pulp and paper companies for what they have been doing for decades (producing and using black liquor) without any additional positive impact on the environment!!! Attached is an issue sheet, describing the problem.

Another scheme has followed: the Cellulosic Biofuel Producer Credit (CBPC) to encourage biofuel production in the same distorting way and without, here as well, any positive impact on environment. It seems that the CBPC scheme, which pulp and paper companies have been benefiting from in an unjustified way for their production of black liquor in 2010, 2011 and 2012, will be extended until the end of 2013 if the Senate approves it. This scheme was supposed to come to an end in December 2012. CEPI and DG Trade services have tried to stop these unfair subsidies as well as the Alternative Fuel Mixture Tax Credit before, in vain so far.

The European paper and board industry is very concerned about the prolongation of these unfair subsidies, which have contributed substantially to US pulp and paper companies' profitability and a massive distortion of competition.

We need a common way at looking at and promoting bioenergy production and consumption, and more generally to address the issue of climate change.

You will find attached a letter that was just sent to Commissioner De Gucht on this issue and a couple of others.

Don't hesitate to contact us should you require more information.

Kind regards,

Bernard Lombard
Trade & Competitiveness Director

CEPI

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US bioenergy subsidy scheme Cellulosic Biofuel Producer Credit

THE ISSUE

The US Internal Revenue Service¹ has given the pulp and paper industry the green light to benefit from the so-called "Cellulosic Biofuel producer Credit". A recent press release clearly indicated that mills that qualified for using black liquor as an alternative fuel and have been eligible to benefit from the US Fuel Tax Credit² this year could become eligible for the cellulosic biofuel producer credit in 2010-2012. This scheme allows a \$1.01-per-gallon credit to black liquor producers. Black liquor - an energy-rich by-product of the kraft pulping process and the main power source for pulp mills - qualifies for the cellulosic biofuel producer credits because the fuel is produced and used in the U.S. and is "*derived from lignocellulosic or hemicellulosic matter that is available on a renewable or recurring basis.*"

The IRS said that black liquor cannot be considered for both the Fuel Tax Credit and the Cellulosic Biofuel Producer Credit. If the US Environmental Protection Agency approves it, this would constitute an even larger loophole than the US Fuel Tax Credit, which is expected to expire by 31 Dec. 2009.

IMPACTS ON THE INDUSTRY

This credit would provide the US pulp and paper industry with a minimum \$25 billion of additional tax benefits - in theory the amount would be close to \$50 billion but this credit is not refundable - over the coming three years that the US Congress never intended. In 2009, close to \$7-8 billion have been already received by the US pulp and paper industry through the US Fuel Tax Credit. The magnitude and the duration of this tax credit scheme to be granted to US pulp and paper mills could prevent needed mill closures and cause overproduction. It would have a big impact on global trade and would largely distort competition³ and long-term competitiveness, and without any additional benefit for the environment.

CEPI'S POSITION

The US Cellulosic Biofuel Producers Credit - if approved - would put European pulp and paper companies under huge pressure at a time where the European companies are facing a severe downturn – pulp and paper production decreased respectively by 15% and 20% over the first 8 months of the year compared to the same period of last year – and are closing plants and making jobs redundant. The implementation of this unfair subsidy should not be supported by the US Environmental Protection Agency.

Bioenergy promotion cannot be done in such a distorting way. In a context of climate change mitigation, the promotion of bioenergy has to be made by states in a cost-efficient way, in the least distorting way as possible and according to sustainable criteria.

ADDITIONAL INFORMATION

CEPI has gathered quite a lot of information on this new US scheme as well as the 'US Fuel Tax Credit scheme. Additional information can be obtained on request.

CONTACT

Bernard Lombard – Trade & Competitiveness Director: b.lombard@cepi.org / +32 2 627 49 22

Update: November 2009

¹ Legal memorandum ILM200941011, dated 3 June 2009

² A tax credit for alternative fuel mixtures produced by pulp and paper companies and aiming at encouraging substitution of traditional fossil fuels by alternative fuels (biofuels), particularly in the transport sector. The law grants \$0.5 per gallon of alternative fuel used in producing an alternative fuel mixture (0.1 Eur / litre of biofuel used).

³ US are the main trade partner of the EU: the first EU export destination for paper and the first EU supplier of paper.

TERESA PRESAS
Director General

Karel De Gucht
Commissioner - Trade
European Commission
1049 Brussels
Belgium

Brussels, Monday 24 September 2012

Dear Commissioner De Gucht,

Re.: Proliferation of protectionist measures in emerging countries, on-going subsidisation in developed countries and heavy distortion of the global level playing field

Trade is a key contributor to European economy. It must work for Europe's economic recovery by ensuring growth and jobs.

Our sector is a net exporter and this in spite of the difficult economic context and increased competition in the global market. The high level of sustainability of paper production and product standards in Europe do not always result in a competitive advantage in low-cost producing countries. The pulp and paper industry is seeking a level playing field for both its products and its raw materials through multilateral and bilateral negotiations and high level talks with EU trading partners.

As you know, EU markets have been fully open since January 2004, unlike some competitors in their home countries. In fact, we have been recently facing a number of challenges ranging from the announcement of import tariff increases in Brazil and in Russia to on-going and disproportionate renewable energy subsidy to the US pulp and paper companies. We see that an increasing number of countries are stepping up protectionism.

In Brazil, CAMEX, the Ministry for development, industry and trade, announced its intention to increase import tariffs on a list of 100 tariff lines including paper and board. As we understand, the proposed increase of the import tariffs will rise to 25% and could be followed by another list in October. To increase competitiveness and boost production, the pulp and paper sector has also benefited from payroll tax cuts, electricity tariff reductions and an increase in imported paper taxes over the past weeks. As announced in a previous letter, the Brazilian government is also considering the launching of anti-dumping investigations against fine paper imports from Europe.

In Russia, the government has decided to increase import tariffs on some graphic paper grades and on cartonboard from 5% to 15%. Although the measures do not infringe WTO commitment, they come as a surprise after the EU-Russia bilateral negotiations ahead of Russia's WTO accession last August.



In the US, it seems that the Cellulosic Biofuel Producer Credit scheme, which pulp and paper companies have been benefiting from in an unjustified way for their production of black liquor in 2010, 2011 and 2012, will be extended until the end of 2013 if the Senate¹ approves it. This scheme was supposed to come to an end in December 2012. CEPI with your services have tried to stop these unfair subsidies as well as the Alternative Fuel Mixture Tax Credit before, in vain so far.

The European paper and board industry is very concerned about the prolongation of these unfair subsidies, which have contributed substantially to US pulp and paper companies' profitability and a massive distortion of competition.

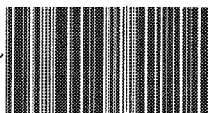
Under your leadership, DG Trade has designed the trade policy as a core component of the EU's 2020 strategy. To become a smart, sustainable and inclusive economy, Europe needs to benefit from globalisation and further develop its exports. It requires all EU trade partners to apply fair competition principles.

We would very much appreciate the opportunity for our Chairman and a delegation of CEOs from the CEPI Board to meet with you to discuss these issues of high relevance to our industry.

Sincerely yours,

Teresa Presas

¹ The "S. 3521: Family and Business Tax Cut Certainty Act of 2012" is an original bill to amend the Internal Revenue Code of 1986 to extend certain expiring provisions.



Bruxelles, le 31 octobre 2012.

Madame, Monsieur,

■ **Concertation publique sur des « apports concernant les questions réglementaires liées à un futur accord commercial avec les Etats-Unis »**

Dans le cadre de la consultation publique sur des « apports concernant les questions réglementaires liées à un futur accord commercial avec les Etats-Unis », vous demandez à recevoir des « propositions créatives » visant à guider les négociateurs chargés d'éliminer « les différences législatives qui nuisent de façon inutile au commerce ».

Même si nous ne faisons pas de commerce¹, nous pensons utile de vous rappeler que les enjeux commerciaux ont toujours un impact sur la citoyenneté, la démocratie, les droits sociaux ainsi que sur l'environnement. Autant d'enjeux qui, eux, nous concernent directement.

Commençons par rappeler qu'une politique commerciale soucieuse de l'intérêt général doit garantir le fait que les produits autorisés sur un marché soient de nature à ne pas mettre en danger la sécurité et la santé des populations. Dans l'état actuel des législations américaines et européennes, nous remarquons malheureusement que **les procédures politiques d'accès aux marchés n'offrent pas suffisamment de garanties pour les citoyens**. Trop souvent, les pouvoirs publics se reposent sur les études toxicologiques faites par des entreprises privées (à la fois juges et parties) pour accorder à une substance ou un produit le droit d'accès au marché. Pire : au nom du secret commercial, certaines entreprises sont parfois autorisées à ne pas soumettre les données brutes de l'étude (notamment le contenant exact des substances) aux autorités publiques. Or, comme l'ont prouvé, à dessein, les cas historiques de l'essence avec plomb², du tabac, de l'amiante ou plus récemment des PCB³, on ne peut faire confiance aux industriels pour analyser en toute indépendance la toxicité de produits dont les chiffres d'affaires se montent ensuite en milliers, millions ou milliards d'euros. **Si des négociations transatlantiques doivent être poursuivies, nous réclamons un renforcement des procédures d'examen scientifique sur la toxicité des produits, des procédures basées sur des études indépendantes n'autorisant plus des**

¹ La plateforme contre le transatlantisme est un groupement d'associations sans but lucratif et d'organisations syndicales mobilisées depuis quelques mois autour de la thématique transatlantique. Celle-ci nous concerne directement, car les accords législatifs et projets de constitution d'un marché transatlantique ont une influence concrète par rapport aux valeurs que nous promouvons quotidiennement : droits sociaux des travailleurs, système de solidarité collective par le biais de la sécurité sociale, droits de l'homme et droits fondamentaux démocratiques (y compris le respect de la vie privée), préservation de l'environnement, lutte contre la pauvreté, respect des peuples indigènes... Plus d'informations sur notre site internet : www.no-transat.be

² Voir à ce propos Jamie Lincoln Kitman, « *L'histoire secrète du plomb* », éditions Allia, Paris, 2005.

³ Voir à ce propos Marie-Monique Robin, « *Le monde selon Monsanto* », éditions La découverte/Arte, Paris, 2008, p.19-40.

scientifiques en conflit d'intérêt (c'est-à-dire liés de près au monde industriel) à participer aux travaux des institutions sanitaires publiques.

Bien entendu, de telles mesures imposent un refinancement des institutions et des pouvoirs publics concernés.

Il convient assurément de faire participer davantage les grands groupes privés multinationaux à ce refinancement. En effet, grâce à la compétition fiscale et à la libre-circulation planétaire (rendue possible par l'ordre juridique mis en place, reflet d'une volonté politique dont l'Union européenne est l'un des fers de lance aujourd'hui), ces multinationales paient de moins en moins d'impôt.

À ce titre, nous pensons que :

1. l'Europe devrait **mettre fin aux pratiques de dumping fiscal en son sein**, rendues possibles par la diversité juridique des législations fiscales nationales dans un monde où la libre-circulation marchande a été harmonisée par volonté politique ;
2. l'Europe devrait davantage **s'inspirer des législations américaines développées récemment pour lutter contre la fraude fiscale**. Nous songeons notamment au *Foreign Account Tax Compliance Act* qui impose aux sociétés financières étrangères installées aux Etats-Unis de révéler au fisc l'identité de tous leurs clients américains (y compris des entreprises dont 10% du capital au moins est détenu par des Américains). A défaut de s'exécuter, les entreprises concernées sont frappées d'une taxe forfaitaire de 30% sur tous leurs revenus engrangés aux Etats-Unis. De même, parmi les nombreuses dispositions du *Dodd-Frank Wall Street Reform and Consumer Act*, figure la possibilité de rémunérer des personnes dénonçant des pratiques internes à leur entreprise et nuisibles à l'intérêt général (et ce, après que l'entreprise alertée en interne ait refusé d'y mettre un terme). Il nous semble que ce type de mesures devrait être encouragé sur le sol européen, de manière à soustraire des « lanceurs d'alertes » potentiels à l'autorité de leur hiérarchie, ce qui revient, dans les faits, à les soumettre au silence alors que les enjeux concernent directement le bien-être public ;
3. dans le cadre de la **lutte internationale contre les paradis fiscaux, les Etats-Unis et l'Union européenne devraient pousser à ce que l'échange de données financières internationales se fasse de façon automatique** (et non plus sur demande) lorsqu'une autorité locale accueille sur son territoire les comptes financiers de citoyens et d'entreprises originaires d'un autre pays. Sans une telle disposition, la lutte contre les paradis fiscaux (et l'évasion fiscale) restera davantage un mythe politique qu'une réalité concrète (ainsi qu'en attestent les difficultés de nombreuses autorités publiques à obtenir des informations financières liées à leurs ressortissants dont les avoirs se retrouvent sur des territoires connus pour leur laxisme législatif et leur culte du secret bancaire) ;
4. enfin, quatre ans après la crise des *subprimes*, nous constatons qu'aucune des nouvelles mesures (américaines comme européennes) visant à mieux surveiller la finance n'a réellement envisagé de lutter contre le cœur du problème, à savoir la spéculation financière. A ce titre, nous pensons qu'un **accord politique européen et américain sur l'établissement de taxes sur les transactions financières** (particulièrement pour les produits dérivés et hautement spéculatifs) devrait être un préalable à toute négociation commerciale transatlantique liée aux matières financières. Enfin, nous considérons que les mesures

législatives encadrant le Trading Haute Fréquence⁴ sont totalement insuffisantes, et constituent à ce titre une menace grave de nouvelle déstabilisation financière pour l'avenir.

Rappelons ici que, selon les calculs de la Commission européenne, le **coût de la crise financière pour les finances publiques européennes a été de 4.600 milliards d'euros, contribuant à faire passer la dette publique des Etats membres « de moins de 60% du PIB en 2007 à 80% pour les années à venir »**⁵. A ce titre, il nous paraît édifiant de maintenir en Europe une indépendance de la Banque Centrale Européenne (BCE), laquelle doit être contrôlée de façon démocratique. À plus forte raison, il nous semble aberrant de prévoir un statut du VIP pour les sociétés financières qui ont accès directement aux prêts de la Banque Centrale Européenne, contrairement aux Etats. Prendre exemple sur les Etats-Unis en la matière nous semble une bonne idée (la FED finançant directement les pouvoirs publics) pour **abroger l'article 123 du Traité de Lisbonne interdisant tout financement direct des pouvoirs publics par la BCE.**

Il faut également se souvenir que la crise des *subprimes* a une triple origine : la spéculation, l'appauvrissement chronique de la population américaine (poussée de plus en plus à vivre à crédit) et la croyance en une autorégulation vertueuse du marché (la compétitivité du secteur marchand étant censée pousser les entreprises à adopter les choix judicieux). Toute négociation commerciale transatlantique devrait tenir compte de cette leçon historique.

Pourtant, force est de remarquer que la pression des marchés financiers (que les pouvoirs politiques se promettaient de réguler au moment de les sauver de la faillite !) a poussé les pouvoirs publics européens à des mesures iniques à l'encontre des populations. Sous la supervision directe de la troïka (où sont notamment impliquées la Commission européenne et la BCE) et au nom d'arguments purement techniques, l'Union européenne s'est lancée récemment dans une attaque en règle contre les mécanismes publics de redistribution des richesses, les législations sociales et le droit à la libre-négociation syndicale. Une telle attaque contre la démocratie économique et sociale atteste du fait que l'Europe est en train de rejoindre le modèle juridique américain, fortement inégalitaire et considérant que « ce qui est bon pour l'entreprise est toujours bon pour la population ». Si cette voie est choisie, l'Europe fait assurément fausse route, laissant derrière elle un modèle de concertation sociale et de redistribution publique des richesses qui a pourtant fait la grandeur - politique et démocratique - des nations qui sont à l'origine du projet européen. Nous pensons que **toute négociation commerciale transatlantique devrait systématiquement, et préalablement, évaluer l'impact potentiel des conséquences sur les mécanismes publics de redistribution des richesses, le maintien d'une sécurité sociale forte, le droit à la protection sociale des travailleurs et l'autonomie des négociations entre organisations patronales et syndicales.** A ce titre, un renforcement des libertés syndicales devrait certainement être exigé de la part des Etats-Unis (où les syndicats sont sous un contrôle politique plus strict que les organisations patronales), ainsi qu'un renforcement des clauses sociales liées au commerce. De même, le financement et l'indépendance de la sécurité sociale devraient également être inscrits noir sur blanc dans de tels accords, faute de quoi l'on verra des entreprises américaines coloniser peu à peu les mécanismes publics de redistribution des

⁴ Rappelons que le *Trading Haute Fréquence* consiste à confier la négociation d'opérations boursières à des logiciels d'ordinateurs où la seule intervention humaine se fait en amont, lors de la programmation des logiciels informatiques.

⁵ Source : IP/11/1085.

richesses et d'accès à des services de base (comme la santé) dans un esprit de lucre qui creusera les inégalités, plongeant alors une part croissante de la population dans le paupérisme, l'exclusion et la survie dans la rue. En ces matières, **l'Europe se doit de défendre le modèle social et démocratique développé dans certains pays (Belgique, France, Pays-Bas, ...) au milieu du XX^{ème} siècle, et non épouser les thèses américaines (dont sont friandes les grandes entreprises privées).**

Nous l'avons dit : la croyance en une autorégulation vertueuse du marché est également l'une des causes originaires de la crise des *subprimes*. A ce titre, il est vital que :

1. **toute négociation commerciale soit également évaluée et suivie quant à ses effets sur le pouvoir des entreprises** (lequel se renforce avec une montée du chiffres d'affaires, des fusions-acquisitions, le contrôle de nouveaux secteurs d'activité, etc.) ;
2. **des contre-pouvoirs démocratiques soient mis en place de manière à garantir un certain contrôle des activités économiques dans leurs impacts environnementaux, sanitaires, sécuritaires et sociaux. La sphère publique doit bien entendu y contribuer** (par exemple lors d'une analyse indépendante des produits autorisés à la mise sur le marché), **mais également les sphères syndicale et associative.** Sans cette participation de groupes d'intérêts spécialisés sur des questions directement liées au bien-être des gens (qu'ils soient travailleurs, consommateurs ou simples habitants d'une région concernée par les retombées environnementales d'activités marchandes), le régime qui se met en place accorde trop de libertés aux pouvoirs industriels et marchands, répétant ainsi les erreurs politiques qui ont mené tout droit à la crise financière des *subprimes*.

Dans un monde où les normes marchandes sont de plus en plus envahissantes (et jugées prioritaires par le monde politique), il nous semble élémentaire, tant du côté américain qu'européen, de **mettre en place de nouveaux processus permettant un contrôle démocratique et pluriel (public, syndical, associatif...) des activités du monde économique**, lequel ne peut à lui seul définir les priorités technologiques de la société, les normes sociales et fiscales auxquelles il entend être soumis, ses contraintes en matière de rejets industriels ou de productions polluantes. L'attention politique doit également inclure toutes les nouvelles technologies de fichage et d'espionnage automatique, lesquelles menacent de plus en plus ouvertement et fréquemment le droit fondamental des populations à la vie privée. Ce fait gravissime est pour l'heure encouragé par les pouvoirs publics qui, outre la mise en place de législations liberticides, encouragent les partenariats sécuritaires public-privé et recourent massivement à des technologies intrusives sans aucune consultation, information ou débat avec la population.

Pour conclure, rappelons que les données disponibles liées à l'état de santé de la planète sont de plus en plus catastrophiques. À titre d'exemple, la concentration de CO₂ dans l'atmosphère augmente en moyenne de 2 parts par millions chaque année, alors qu'elle est censée diminuer pour diminuer l'impact du réchauffement climatique provoqué par l'homme. Les accords commerciaux ne peuvent ignorer de tels faits et doivent **inclure une réflexion globale, éthique, régulant de façon contraignante les accords commerciaux.** Par exemple, les produits autorisés à entrer sur un marché (européen, américain ou transatlantique) devraient être soumis à des **standards minimaux en termes social, environnemental et de respect des droits de l'homme** dans toutes les régions impliquées dans le processus de fabrication (y compris la fourniture de matières premières). De

même, et dans le but explicite de maintenir l'emploi, la cohésion sociale et la lutte contre le réchauffement climatique, la production locale et le commerce de proximité doivent être favorisés au détriment d'organisations marchandes globales, qui usent de logiques de production mondiales basées sur le dumping social et fiscal, l'alliance avec des pouvoirs politiques peu soucieux des droits de l'homme et un mépris souverain des impacts environnementaux de leurs activités.

Nous pensons qu'un tel modèle de société n'est pas enviable, parce qu'il ne renforcera que le développement de richesses économiques favorables à un nombre restreint de groupes sociaux, la plus grande part de l'humanité étant laissée de côté, voire étant amenée à subir directement les impacts et conséquences négatives de tels choix politiques (qu'il s'agisse de détricoter les droits sociaux des populations au nom de la « rigueur nécessaire », de survie précaire dans un environnement fortement dégradé ou de maintien de pouvoirs forts aussi favorables au commerce que peu enclins à développer la démocratie). À ce titre, nous nous inquiétons que le partenariat économique avec les Etats-Unis ne soit pas soumis à des clauses minimum de protection de la démocratie, laquelle est sérieusement malmenée par la teneur des législations anti-terroristes, sur le sol européen mais encore plus fortement aux Etats-Unis avec l'existence d'un *Patriot Act* ayant enterré, depuis une décennie, de nombreux droits fondamentaux et libertés civiles.

Pour toutes ces raisons, nous nous inquiétons du fait que des négociations commerciales transatlantiques soient considérées comme une priorité absolue par les autorités européennes, sans la moindre consultation publique des populations concernées (qui ne sont nullement informées du sujet) ni la moindre place dans le processus décisionnel pour les multiples composantes de la vie démocratique de base, que sont notamment les syndicats et les ONG se préoccupant d'environnement, de droits de l'homme ou de droits socioculturels. Un des signes de ce déni est la décision, prise par le Parlement européen le 23 octobre 2012, de lancer des négociations commerciales transatlantiques sans même attendre les résultats de la consultation publique de septembre 2012 concernant d'éventuelles négociations commerciales transatlantiques (certaines questions portant notamment sur les impacts sociaux et environnementaux du commerce n'ayant tout bonnement pas pu être analysées). Pourtant, les questions commerciales ont également des impacts sur la vie démocratique, politique, syndicale et le bien-être environnemental qu'il nous semble essentiel de rappeler.

Vous remerciant d'avance de l'attention que vous porterez à ce courrier, nous espérons que nos remarques et points d'attention seront pris en compte dans vos réflexions et dans les futurs accords.

La Plateforme d'opposition au marché transatlantique.



C L E P A
European Association of
Automotive Suppliers

Motor & Equipment Manufacturers Association (MEMA)

and

European Association of Automotive Suppliers (CLEPA)

Comments to

The European Commission

U.S. and EU Joint Solicitation for Public Input

12 November 2012

The Motor & Equipment Manufacturers Association (MEMA)¹ and the European Association of Automotive Suppliers (CLEPA),² welcome the opportunity to respond to the United States Trade Representative (USTR) request for public comments³ and to the United States-European Union High-Level Regulatory Cooperation Forum (HLRCF) joint solicitation for public input.⁴ MEMA and CLEPA strongly support the efforts of the United States of America and the European Union governments to seek greater transatlantic regulatory cooperation. Such an achievement is necessary for future consideration of a US-EU Free Trade Agreement.

The growing globalization of the motor vehicle industry makes it imperative for MEMA and CLEPA members to be competitive domestically and abroad requiring greater regulatory cooperation between trading partners. The reduction of transatlantic regulatory inefficiencies will significantly increase the critical role that the motor vehicle parts industry plays in transatlantic trade. We are encouraged to know that significant progress has been made in both the HLRCF and the Transatlantic Economic Council (TEC) and hope for continued progress that will guide the work of the High-Level Working Group on Jobs and Growth (HLWG).

Technical regulations in our industry sectors are among the leading trade barriers prohibiting more robust transatlantic trade and investment. Increasing transparency in the formation of technical regulations and standards is critical to increasing regulatory cooperation. The right of both governments' to protect public health, safety, welfare, and the environment need not be diminished when seeking to achieve greater regulatory cooperation. Just as our members continually innovate to make better products, the US and EU governments should seek out innovative ideas and solutions to further deepen concerted trade relations.

A bilateral trade agreement will present an opportunity, particularly for our industry sectors, to address obstacles to free trade. Our global industry sectors would greatly benefit from improved

¹ In the United States, MEMA represents more than 900 companies that manufacture motor vehicle parts and systems for use in the light- and heavy-duty vehicle original equipment and aftermarket industries.

² In Europe, CLEPA represents 94 suppliers for automotive parts, systems and modules and 23 national trade associations and European sector associations, in total 3000 companies in the European Union

³ *Federal Register*, Vol. 77 at 59702, 28 September 2012.

⁴ US-EU High-Level Regulatory Cooperation Forum, Joint Solicitation to EU & US stakeholders, September 2012, http://www.whitehouse.gov/omb/oira_irc_europe and http://trade.ec.europa.eu/consultations/?consul_id=170

efficiencies and ultimately contribute to the US and EU economies. Both US and EU have long had robust regulatory regimes. To improve trade relations, convergence can offer shared recognition of performance requirements and certification procedures as well as reduction or elimination of compounded engineering and testing resources.

The growth of country-specific technical requirements inhibits access to markets. For example, the need for greater global regulatory cooperation is reflected in the current Trans-Pacific Partnership (TPP) trade negotiations, as well as in the FTA discussions between the EU and various countries, where regulatory coherence is a major objective and will continue to be an important part of future bilateral and multilateral trade negotiations. As our market is global, MEMA and CLEPA support and encourage global technical regulation development and harmonization efforts under the United Nations' World Forum for the Harmonization of Vehicle Regulations (a.k.a. WP.29). Its focus is on promoting the use of common test procedures and performance requirements across nations. WP29 should remain the only Forum for technical harmonization.

While the GTR process has had its share of challenges, we believe that the general sentiment of the signatories of the WP.29 1998 Agreement is the need of the nations and industry to look forward and anticipate future global regulatory needs and develop them accordingly. The supplier industry believes there are situations where global cooperation to establish common procedures would be beneficial, e.g. where:

- new unregulated technologies are emerging that significantly enhance vehicle performance;
- government vehicle-related policies, which are undergoing a significant shift; and/or,
- new testing technologies promise significant enhancements in regulatory or product effectiveness.

When technical standards are to be used in developing new GTRs, it is recommended that the World Trade Organization Article 2.4, Agreement on Technical Barriers to Trade, should be followed. For existing regulations, we propose to look how they can be considered as equivalent in terms of safety and environment protection. Please see the Attachment (Annexes 1, 2 and 3) for preliminary details on specific vehicle parts and systems requiring regulatory convergence.

Building upon the lessons of past collaborative successes can help promote regulatory cooperation – be it mutual recognition, performance standard equivalency or other measures. Recognizing important and differing aspects of the U.S. and European regulatory systems is critical, yet, at the same time, finding new mechanisms to break down unnecessary regulatory barriers should be a priority for both governments in trade agreement negotiations.

In today's globalized economy, vehicle parts suppliers source inputs from and send their products around the world. Achieving technical and regulatory cooperation is a goal strongly supported by MEMA and CLEPA. Companies in the US and EU will greatly benefit from the elimination of regulatory redundancies and overlapping or duplicative certification procedures as it will lower the costs of doing business, expand new market opportunities, and enhance global competitiveness. While recognizing the challenges that lay ahead, MEMA and CLEPA encourage you to seek the most ambitious goals to strengthen our transatlantic commercial ties.

#

Attachments

MEMA and CLEPA proposal on EU-US Regulatory Convergence in the Automotive Sector

ANNEX 1

Existing Regulations on subjects not covered by Global Technical Regulations (GTRs) where regulatory convergence should be considered.

US Federal Motor Vehicle Safety Standard	Topic	Corresponding EU/UN Regulation
FMVSS 101	Controls and displays	UN-R 121
FMVSS 103	Windshield defrosting and defogging systems	78/317/EEC + (EU) 672/2010
FMVSS 104	Windshield wiping and washing systems	78/318/EEC + (EU) 1008/2010
FMVSS 105	Hydraulic brake systems	UN-R13
FMVSS 108	Lamps, reflective devices	UN-R 48 + separate regulations for different lighting, light signaling, and reflective units
FMVSS 111	Rear view mirrors	UN-R 46
FMVSS 114	Theft prevention	UN-R 116
FMVSS 118	Power operated window / roof panel systems	UN-R 21
FMVSS 121	Air brake system	UN-R 13
FMVSS 126	Electronic stability control	UN-R 13H
FMVSS 135	Passenger car brake systems	UN-R 13H
FMVSS 138	Tire pressure monitoring system	UN-R 64
FMVSS 201	Occupant protection in interior impact	UN-R 21
FMVSS 203	Impact protection for the driver (steering wheel)	UN-R 12
FMVSS 204	Steering control rearward displacement	UN-R 12
FMVSS 206	Door locks and door retention components	UN-R 11
FMVSS 207	Seating systems	UN-R 17
FMVSS 208	Occupant crash protection	UN-R 94
FMVSS 209	Seat belt assemblies	UN-R 16
FMVSS 210	Seat belt assembly anchorages	UN-R 14
FMVSS 213	Child restraint systems	UN-R 44
FMVSS 214	Side impact protection	UN-R 95
FMVSS 225	Child Restraint Anchorage Systems	UN-R 14
FMVSS 303	Fuel system integrity of CNG vehicles	UN- R 110
FMVSS 304	Compressed natural gas fuel container integrity	UN-R 110
40CFR Part 25	Noise	UN-R 51 + New draft EU Regulation
40CFR Part 86	Light Duty Emissions	UN-R 83 + (EC) 715/2007
40CFR Part 86	Heavy Duty Emissions	UN-R 49 + (EC) 595/2009

**MEMA and CLEPA proposal on
EU-US Regulatory Convergence in the Automotive Sector**

ANNEX 2

For subjects covered by established GTRs, common transpositions of the technical requirements should be agreed.

GTR 1	Door Locks and Door Retention Components
GTR 4	Test procedure for Heavy-Duty Vehicles with regard to the Emissions of Pollution
GTR 5	On Board Diagnostic systems for Heavy-Duty Vehicles
GTR 6	Safety Glazing
GTR 8	Electronic Stability Control Systems
GTR 9	Pedestrian Safety
GTR 10	Off-Cycle Emissions from Heavy-Duty Vehicles

ANNEX 3

For future GTRs – whether establishing new subject GTRs or reviewing established, existing GTRs – foster the UN Process under the 1998 Agreement by bilateral cooperation, then transpose the technical requirements of the established GTRs the same way.

The GTR development process is designed to engage contracting parties in a full, transparent discourse and to promote comprehensive transposition among the CPs. Concurrently, there also must be recognition that the US and EU have different legal processes to adopt into their own regulatory frameworks.

Future GTR Subjects
Pedestrian Safety - Phase 2
Head Restraint - Phase 2
Worldwide Harmonized Light Vehicles Test Procedure (WLTP)
Hydrogen/Fuel Cell Vehicles
Pole Side Impact
Electric Vehicles (Safety and Environment)
Quiet Road Transport Vehicles

VALASTRO Silvia (TRADE)

From: Louis-Sylvain Ayral <LS.Ayral@clepa.be>
Sent: 12 November 2012 22:09
To: TRADE F3 SECRETARIAT; ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Cc: DEMARTY Jean-Luc (TRADE); GARCIA BERCERO Ignacio (TRADE); PERREAU DE PINNINCK Fernando (TRADE); CALLEJA CRESPO Daniel (ENTR); PETTINELLI Carlo (ENTR); JEAN Philippe (ENTR); Pierre Laurent; Eleri Wessman; SORENSEN Carsten (TRADE); PADURARIU Amelia (TRADE); SCHMITZ Jan (TRADE); Jean-Marc Gales
Subject: EU-US Regulatory Cooperation. EU-US joint solicitation to Industry
Attachments: MEMA CLEPA reg cooperatoin comments vF1.pdf

Dear Madam, dear Sir,

You will find attached the common comments from our US colleagues MEMA and from us on the EU-US joint solicitation dated 7 September 2012.

MEMA sent similar document to the US authorities

We remain at your disposal for any further information.

Best regards

Louis-Sylvain AYRAL

Technical Director

CLEPA aisbl- The European Association of Automotive Suppliers

Boulevard Brand Whitlock, 87

B- 1200 BRUSSELS

Phone: +32 2 743 91 31

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E-mail: techsec@clepa.be <<mailto:techsec@clepa.be>> or Ls.ayral@clepa.be <<mailto:Ls.ayral@clepa.be>>

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Sent by e-mail to:

- TRADE-F3-SECRETARIAT@ec.europa.eu
- entr-international-aspects@ec.europa.eu

Input on regulatory issues for possible future trade agreement between EU and US

The Confederation of Danish Industry strongly supports a further deepening of the Trans-Atlantic trade and investment relationship. Seeking progress in the Doha Development Round in the WTO should obviously be the main priority for the EU. However, the lack progress on this multilateral track makes it all the more important to pursue bilateral agreements with our trading partners.

In this respect, the Trans-Atlantic track is of major importance. Our political, social, cultural and economic ties have created a relationship, which today accounts for about half the global GDP and nearly a third of world trade flows. By further improving the framework that binds our relationship together, we will be able to bring about increased economic benefits in both the EU and the US.

Tariffs and quotas are generally not a major obstacle to EU-US trade, although we would of course advocate for a full elimination of these. The major problem in Trans-Atlantic trade lies in non-tariff barriers such as technical and regulatory issues. Making the regulatory regimes more compatible across the Atlantic, is therefore an essential part in improving Trans-Atlantic trade ties.

To ensure this, the following regulatory issues should be addressed:

- The handling of goods at **customs and port** should be made more efficient, for instance by establishing mutual recognition of trusted shipper programs, as well as harmonizing safety and customs standards across the Atlantic.
- **Certification and standardization** regimes should be harmonized across the Atlantic, so that businesses can benefit from mutual recognition of certificates and compliance with standards.
- The US system of accredited **National Recognized Test Laboratories** (NRTLs) needs to be revised and made more business friendly, e.g. by introducing obligatory recognition among the NRTLs of component certificates.
- The **US Consumer Product Safety Commission** (CPSC) notification procedure in case of a potential safety issue needs to be simplified. The current procedure is very time consuming and without legal support from spe-

cialized counsel. Therefore, it is not possible to manage without risking huge fines and massive recalls in the US market.

- **Sanitary and phytosanitary measures** (SPS) need to be interpreted and implemented in a more consistent manner across the Atlantic, for instance by development of equivalence in standards and inspection requirements.
- **Rules of origin** should be as simple, predictable and legally certain as possible.
- The regulation on **pharmaceuticals and medical devices** needs to be harmonized, e.g. by allowing for mutual recognition of approved products.
- The regulation on **export controls** of dual-use items and defense related items should be harmonized, and transshipment of regulated items within the Trans-Atlantic marketplace should be eased.
- **Consumer protection logos** (e.g. IEC, CE, WEEE) need to be made mutually recognized across the Atlantic. There is a trend in the US that some logos are not accepted in the US without additional written explanation. This inevitably leads to special US-only packaging requirements, which creates additional and unnecessary costs for manufacturers.
- There is an untapped potential related to increased trade in consumer products across the Atlantic by way of **e-commerce**. However, a number of obstacles impede this, e.g. geographical segmentation of the retail market for digital commodities (movies, music, software etc.), burdensome customs procedures on retail goods purchased online, lack of common standards etc.
- **Trade in services** needs to be given specific focus, as there is a huge potential for both sides of the Atlantic, if services can be provided more freely. Hence, all aspects of services liberalization need to be discussed as part of the continued dialogue.
- The dialogue should also focus **on telecommunication and roaming**, specifically on how to reduce the high roaming charges when travelling between the two regions.

We stand available should you have any questions related to the above. We will be following the negotiations closely and look forward to giving further input along the way.

Kind regards,

Peter Bay Kirkegaard
Senior advisor, International Market Policy

(+45) 3377 4685
(+45) 2311 9479
pbki@di.dk

VALASTRO Silvia (TRADE)

From: Peter Bay Kirkegaard <PBKI@DI.DK>
Sent: 31 October 2012 17:32
To: TRADE F3 SECRETARIAT; ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Cc: Peter Thagesen; Pi Wegefelt; Lars Zøfting-Larsen; Christian Hannibal
Subject: Consultation on regulatory issues for possible future trade agreement between EU and US - Input from Confederation of Danish Industry
Attachments: 20121031 - Confederation of Danish Industry - Input re Regulatory Cooperation.pdf

Please find our input regarding this consultation on regulatory issues for possible future trade agreement between EU and US.

Kind regards,

Peter Bay Kirkegaard
Chief advisor, International Market Policy

(+45) 3377 4685
(+45) 2311 9479 (Mobile)
pbki@di.dk
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Confederation of Danish Industry

Desislava KADINOVA
Assistant to the Head of Unit

European Commission
DG TRADE
Unit F3
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B-1049 Brussels/Belgium
+32 2 295 61 97/ 296 74 19
TRADE-F3-SECRETARIAT@ec.europa.eu
dessislava.KADINOVA@ec.europa.eu

From: Deneve Olivier (ODE) [mailto:deneve@cocir.org]
Sent: Wednesday, October 31, 2012 4:19 PM
To: TRADE F3 SECRETARIAT; ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Cc: Denjoy Nicole (NDY)
Subject: Joint US - Europe trade associations response to the EU - US consultation on regulatory issues for possible future trade agreement

Dear Madam, Sir,

On behalf of Nicole Denjoy –COCIR Secretary General– you will find attached the joint US-Europe trade associations' response to the EU US public consultation on regulatory issues for possible future trade agreement.

MITA (representing the US industry) and COCIR (representing the European industry) have decided to jointly respond as the leading industry in medical imaging and healthcare IT.

If you have any questions, please do not hesitate to contact us.

Thank you for your consideration.

Best regards,

Olivier

Olivier Denève

Technical and Regulatory Manager

COCIR

Diamant Building - 80 Bd A. Reyers - 1030 BRUSSELS (B)

Tel.: +32 (0) 2 706 89 62 - Fax: +32 (0) 2 706 89 69 - Mobile: +32 (0)470 042 992

Mail: deneve@cocir.org - Web: <http://www.cocir.org>



COCIR/MITA Joint Contribution

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

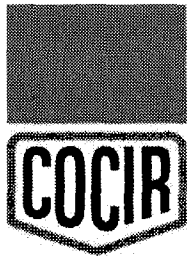
COCIR and MITA welcome the opportunity to share ideas with the United States government and the European Commission on how greater transatlantic regulatory compatibility between the European Union and United States can be achieved in the healthcare sector.

COCIR is the voice of the European radiological, electromedical and healthcare IT industry. A non-profit trade association founded in 1959, COCIR represents the medical technology industry in Europe and its members play a driving role in developing the future of healthcare in Europe and worldwide. The Medical Imaging & Technology Alliance (MITA) is the collective voice for medical imaging, radiation therapy equipment and radiopharmaceutical manufacturers, innovators and product developers in the United States. Combined, COCIR and MITA represent companies whose sales comprise more than 90 percent of the global market for medical imaging technology.

MITA provides leadership for the medical imaging and radiation therapy industries on legislative and regulatory issues at the state and federal level in the US and internationally by working with COCIR and others as part of the Global Diagnostic Imaging, Healthcare IT, and Radiation Therapy Trade Association (DITTA). COCIR and MITA both serve their constituencies as an advocate for fair legislative and regulatory proposals that encourage innovation, investment in research and development, as well as the continued global competitiveness of the medical imaging and radiation therapy industries.

In 1998, the US and EU agreed to a Mutual Recognition Agreement (MRA) for medical device approvals that was never fully implemented. MITA and COCIR recognize that a comprehensive agreement such as an MRA is not likely achievable. However, we believe that there are several specific, discrete regulatory areas where the regulators can work together towards a harmonized approach aiming at increasing transatlantic economic cooperation.

MITA and COCIR propose that the following three key priorities within the healthcare economic sector be considered in the EU-US regulatory cooperation efforts:



MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF **NEMA**

Both the US and EU medical device regulators are members of IMDRF. Not only will the mutual recognition of the ISO 13485 Quality Systems standard and audits enhance transatlantic regulatory compatibility, it will serve to lead other global regulators in their efforts to develop worldwide and mutually recognized regulatory frameworks and processes such as the single audit of medical device quality systems.

B. Single Harmonized Marketing Application Documentation

Both the EU DG SANCO and US FDA require medical device manufacturers to gain marketing clearance/approval from regulators on most classes of medical devices before placing them on the market. To gain approval, manufacturers submit extensive documentation as part of the medical device marketing application. The types of information submitted includes but is not limited to: device description and photographs/schematics, the device use(s) and targeted patient demographics, operator manuals, device design testing data, and often clinical testing data.

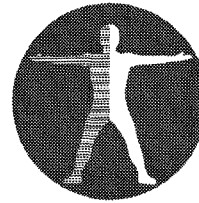
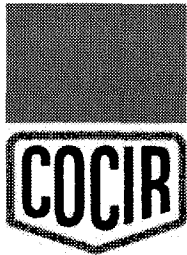
Currently, manufacturers must complete two separate marketing applications utilizing two separate templates for the same medical device, one for the EU and one for the US. For the most part, both templates request medical device information that is either the same or similar.

Additionally, some portions of the marketing application may be submitted electronically, whereas for other portions this capability does not yet exist.

COCIR and MITA urge greater EU-US regulatory compatibility through the harmonization of a single model for a medical device marketing application with electronic submission capabilities.

The US FDA recently released its draft guidance for a new "eCopy Program for Medical Devices". This program will allow for the electronic submission of US marketing applications. While the eCopy program is intended to improve efficiencies in the US FDA review process, it is not intended to change the data required in the submission or to be a globally harmonized standard for electronic market applications.

A harmonized standard for electronic submission of medical device marketing applications will expedite time to market, thereby improving patient access to the latest technologies, and reduce costs for manufacturers by eliminating the need for redundant submissions.



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IMDRF represents an existing forum for the EU-US to address and resolve the outstanding GUDID issues. Mutual development and acceptance of a singular standard for a Global Unique Device Identification Database by the EU and US, represents an opportunity to lead other global regulators in their efforts to develop mutually recognized regulatory frameworks and standards worldwide.

COCIR and MITA appreciate the opportunity to share these recommendations, and look forward to concrete achievements in regulatory convergence. This would be an important advance in our mutual goal of fair competition and removal of unnecessary trade barriers. Please contact us if there is anything further we can contribute.

VALASTRO Silvia (TRADE)

From: Deneve Olivier (ODE) <deneve@cocir.org>
Sent: 31 October 2012 16:19
To: TRADE F3 SECRETARIAT; ENTR /A/2 INTL AFFAIRS MISSIONS GROWTH
Cc: Denjoy Nicole (NDY)
Subject: Joint US - Europe trade associations response to the EU - US consultation on regulatory issues for possible future trade agreement
Attachments: COCIR MITA joint contribution to EU US Public Consultation on Regulatory Convergence_31 October 2012.pdf

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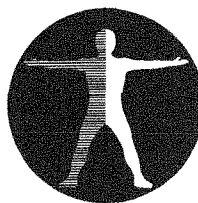
Olivier Denève

Technical and Regulatory Manager
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COCIR/MITA Joint Contribution

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

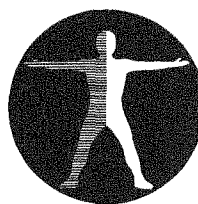
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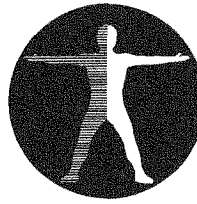
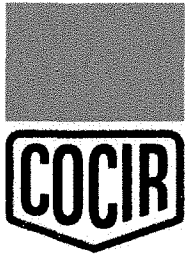
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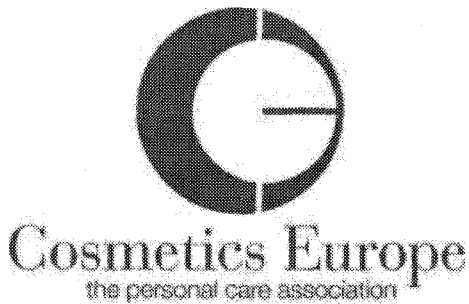


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October 31, 2012

Ambassador Miriam Sapiro
Deputy U.S. Trade Representative
Office of the United States Trade Representative
600 17th Street NW
Washington, DC 20508
USA

Director General Jean-Luc Demarty
DG Trade
Policy Coordination Unit - Trade 01
European Commission
B-1049 Brussels, Belgium

RE: U.S.-EU High Level Working Group on Jobs and Growth

Dear Director General Demarty and Ambassador Sapiro:

Thank you for the opportunity to provide our input on how to promote greater transatlantic regulatory compatibility for the cosmetic sector. As the leading trade associations for the \$250 billion global cosmetics and personal care industry, the U.S. Personal Care Products Council and Cosmetics Europe represent the full supply chain of companies who produce and market personal care products. Our companies range from major international cosmetics manufacturers to small family-run businesses operating in niche markets.

International trade is a critical component to the success of our industry, and significantly contributes to our ability to expand manufacturing and employment, as well as to support local ancillary industries such as advertising, packaging, and transportation.

Our member companies continually strive to uphold and surpass the most stringent regulatory and product integrity standards worldwide, and are actively engaged in providing consumers with safe, innovative and high quality cosmetic and personal care products, the ingredients for which are globally sourced.

The economies of the United States and Europe are among the most integrated in the world. The personal care products industry benefits from the efficient movement of goods across our borders. We believe both countries would benefit from increased cooperation on cosmetic regulations.

In fact trade between the European Union and the United States is a strong part of our industry's success. In 2010, the U.S. exported more than \$2.1 billion worth of personal care products to the EU 27 and imported more than \$4.7 billion. It is a relationship that continues to grow and benefit both countries/regions.

The U.S. Personal Care Products Industry and Cosmetics Europe are strong supporters of the High Level Regulatory Working Group on Jobs and Growth. We seek to use this opportunity to expand the work we have been doing in the International Cooperation on Cosmetics Regulation (ICCR). We consider our industry's work, together with our regulators, in the ICCR, is essential to creating a multilateral framework that will pave the way for the removal of regulatory obstacles to international trade, while maintaining global consumer protection. We urge both the United States and the European Union to continue their valued work in the ICCR process and to make every effort to align their regulatory standards according to decisions taken in the ICCR process.

However, we also understand that there are limits to what we can achieve in the ICCR process. Therefore, our associations are very supportive of efforts now underway to eliminate unnecessary technical and regulatory requirements that disrupt exports and limit trade opportunities between the United States and Europe. Our top priorities for the cosmetics and personal care products industry include:

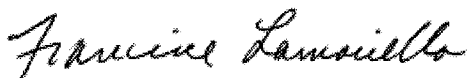
- Mutual recognition of Cosmetics and Cosmetic Ingredients.
 - The U.S. should recognize EU positive list materials (e.g. UV filters)
 - The Commission should enforce the rules for cosmetics, rather than allowing the individual member states to determine what is considered a cosmetic or a drug. Currently, different member states impose different requirements for the same borderline products.
- Test Methods
 - Acceptance of Alternatives to Animal Testing on Cosmetic Products. Animal testing is currently being phased out in various regulatory jurisdictions, such as the European Union. It is critical that this process becomes harmonized so that alternative validated test methods to animal testing be accepted in all jurisdictions. We urge the Commission and the US government to work together to assure that the EU animal test ban is implemented in a way that avoids trade barriers and allows for the continued marketing and trade of new and innovative cosmetics products in the European Union.
 - U.S. and European SPF test methods should be harmonized on the basis of the International Standards Organization (ISO) standards
 - Fully apply the principle of marketer's responsibility for safety: end the requirement for specific colorant batch testing in the United States
 - Promote the harmonization of purity specifications for cosmetics colorants between the US and the EU
- Good Manufacturing Practice.
 - ISO22716. Both countries should implement the ICCR decision to promote the use of Cosmetic Good Manufacturing Practice (GMP) guidelines i.e., ISO 22716.

- Labeling.
 - The U.S. and EU should mutually recognize the labeling of ingredients in cosmetics and sunscreens.
 - The U.S. should fully adopt INCI Nomenclature and end its requirement to use the term 'water' rather than 'aqua.' This requirement is a costly and very unnecessary exercise given the total lack of a health risk from using this ingredient.
 - The EU and U.S. should harmonize the criteria for net content labeling.
- Nanotechnology. As part of the ICCR mandate, members agreed to a common definition of nanotechnology as it pertains to cosmetic products. The U.S. and EU should adopt the definition that was agreed to during this forum.
- Other issues:
 - The EU should not require the imposition of warning statements that are unnecessary or redundant. For example, the EU imposes hair-dyes allergy warnings as well as warnings on ingredients that are already listed in the ingredients list. This is unnecessary and redundant.
 - Negative list. The EU's Annex II should be restructured and/or reorganized to reflect ingredients that are relevant to cosmetic ingredients and products. Most of the substances included in Annex II are not used in finished cosmetic products, and historically were not likely to have been used in finished products. The inclusion of these ingredients in Annex II is thus clearly confusing, if not misleading, to cosmetics manufacturers, other regulatory authorities and the public.

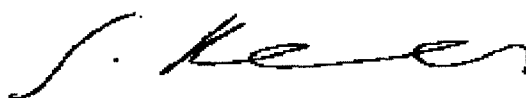
The cosmetics and personal care products industry is a truly global one, dependent on open markets and transparent, consistent regulatory environments around the world. Our companies actively engage in international efforts to align global regulatory standards for consumer products, to eliminate trade barriers, and to ensure a level playing field for member companies while at the same time reinforcing consumer confidence in product safety. The Personal Care Products Council and Cosmetics Europe believe regulatory harmonization promotes trade, enables innovation and protects consumers.

We appreciate the opportunity to provide these comments and would be pleased to provide any additional information or answer any questions raised by this submission.

Respectfully submitted,



Francine Lamoriello
Executive Vice President Global Strategies
Personal Care Products Council



Dr. Gerald Renner
Director, Technical Regulatory Affairs
Cosmetics Europe

Brussels, 31 October 2012

DIGITALEUROPE POSITION ON THE EU-US REGULATORY COOPERATION

DIGITALEUROPE welcomes this opportunity to express industry views on how to make regulatory regimes more compatible across the Atlantic. This paper presents key issues for the European ICT industry which could be considered in the framework of the preparations for the EU-US agreement. We believe that those initiatives would substantially improve the environment for conducting business on both sides of the Atlantic.

DIGITALEUROPE is promoting free trade; we stand for openness and we call for a level playing field across the globe. As a consequence of the global nature of the ICT industry, globalisation of supply chains, and expansion of the digital economy, we support trade liberalisation and cooperation on multinational trade arena, as well as conclusion of comprehensive free trade agreements. Those actions will further release trade potential, create new economic opportunities and hopefully reinvigorate much needed growth.

We recognise the momentum in the transatlantic relations; we observed prominent European and American leaders expressing their strong interest in market opening arrangements. The European Union and the United States are important markets for the ICT sector. We believe that their economic partnership would benefit from further enablers, such as a comprehensive trade agreement. We are particularly glad that the European Commission and the US Government share the goal of reducing excessive regulatory costs, unjustified regulatory differences and unnecessary red tape. A more harmonised or compatible transatlantic market would have a positive effect on market growth by increasing the competitiveness of our industries and reducing their costs.

With regard to regulations, a strong set of common principles has been jointly affirmed in the High-Level Regulatory Cooperation Forum's statement on "Common Understanding on Regulatory Principles and Best Practices." However, differences in the EU and US regulatory systems and approaches to risk management make it difficult to apply these principles to achieve harmonisation. Moreover, in practice product requirements imposed by EU and US technical regulations at times diverge, even when underlying regulatory objectives are equivalent. Those regional differences in product requirements may force the industry to develop different versions or functionalities of the same product; this leads to delays in time to market and significant additional costs. Removing unnecessary divergences in regulatory requirements that products and services need to comply with in order to achieve general market access or be eligible for (or enjoy a preferential status in) public procurement would

DIGITALEUROPE

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Transparency register member for the Commission: 64270747023-20

lead to significant efficiencies and cost reduction. Solving existing discrepancies and avoiding future regulatory divergences should be a priority.

The European ICT industry asks for an improved and more coherent regulatory environment. In this paper we recommend an approximation or mutual recognition of regulations in the areas of standardisation, e-accessibility, e-health, conformity assessment, e-labelling, intellectual property (IP) and environment. We also think this is a great opportunity for both the EU and the US to remain leaders in developing digital services and hence to stress the need for a framework guaranteeing global data flows. Those topics are discussed in detail in this contribution.

In addition, DIGITALEUROPE wishes to call on the European Commission and the Government of the United States to avoid divergent policy approaches. For instance, coordination between the EU and the US with regards to the nascent Internet of Things would be commendable. Secondly, the work of the EU-US cyber security working group should continue with a view to guarantee compatible solutions. Security of infrastructure and devices is crucial in enabling further trust in the Global Digital Infrastructure. DIGITALEUROPE welcomes the creation of the EU – US cyber security working group and calls for the EU and the US to continue coordination on various cyber security policies that third countries are creating to ensure that these do not disrupt the Global Digital Infrastructure (GDI). The transatlantic cooperation should also increasingly focus on ensuring that third country approaches to security are not restricting market access.

Further, we ask for coherent policy in regard to European and American R&D programmes. Given the global nature of the ICT industry and its product markets, large enterprises transfer IP across borders throughout their organisations as a normal course of action. Such enterprises have design and product development teams located in multiple countries that share “know-how” and ideas among their employees, and the products that these teams develop are in most cases sold in global markets regardless of where IP is created, legally owned or registered. Therefore, there should not be any restrictions on the transfer of foreground IP to other affiliated entities in the framework of publicly financed R&D. Furthermore, affiliated entities worldwide should have the same access rights as participants.

Looking beyond the regulation of the European and American markets, DIGITALEUROPE wishes to encourage the EU and the US to jointly promote trade liberalisation and to address problems created elsewhere, such as requests to provide far too much unnecessary confidential business information to show compliance with technical regulations and thus gain market access. The EU and the US need to address the increasing tendency of some emerging markets to develop regulations that mandate the use of specific technologies rather than being performance based. We hope that the two partners will work together towards elimination of forced localisation requirements. Governments are increasingly requiring businesses to locate R&D, IP, manufacturing, etc. as a condition of market access. An EU-US agreement should prohibit such trade distorting requirements and commit both governments to push back on those measures wherever they occur.

In this regard, the agreement should be creative – for example, where binding language cannot be employed to address specific third party issues, the document could still include helpful preamble language that provides policy direction and/or incorporate best practices or policy principles on evolving topics like cyber security and forced localisation requirements.

Finally, we encourage the two partners to reaffirm their joint commitment to maintain the status quo on Internet governance (ICANN/IGF, etc.) and ensure that the Internet ecosystem remains open to innovation and commerce globally. The EU and the US should continue to promote this arrangement globally.

We are pleased that industry was invited to participate in the task to map initiatives to be undertaken by the two partners. We are prepared to work with you to achieve the ultimate goal of regulatory coherence.

1- COMMENTS AND SUGGESTIONS ON EU-US COOPERATION ON STANDARDS IN THEIR POTENTIAL TO FORM NON-TARIFF TRADE BARRIERS

Generally, EU as well as US policies with regard to standards in their potential to limit or burden trade between nations are strongly founded in a firm commitment to the WTO TBT Agreement, including an emphasis on the use of voluntary global standards.

This forms a strong common basis that the EU and the US should seek to further exploit in trade relations – in the bilateral EU-US trade relation, as well as in cooperating towards reducing barriers faced by both in third countries.

In the bilateral EU-US relation, and in spite of sound basis of common policy principles, the actual standards systems in the EU and the US display notable differences and are built on different regulatory traditions. Generally, the ICT industry has not encountered dramatic trade issues as a consequence of these differences, but there is potential for further reducing unnecessary cost factors introduced by divergences in the actual standards requirements that products and services need to comply with in order to satisfy conformance requirements, in order to be eligible for (or enjoy a preferential status in) public purchasing, or to satisfy public policy goals.

The ICT industry in general operates on a global scale. Differences in standards requirements between the US and the EU will typically require the implementation of more than one standard for the same functionality, and hence lead to duplicated implementation efforts and costs. In some cases, such duplications are unavoidable consequences of, and economically reasonable responses to different market-driven requirements expressed by different voluntary standards. However, non-market driven divergences in standards requirements lead to unnecessary and economically unreasonable duplication of cost and effort. More harmonised or compatible requirements on products for the same market

segment would have a positive effect on market growth and create more opportunities for industries in the US as well as the EU.

A full harmonisation of standards systems between the EU and the US is neither likely, nor necessary to avoid negative trade impacts. However, cooperation and tools to address and prevent such impacts can be improved. Some valuable principles towards this aim have been jointly laid down at the EU-US Transatlantic Economic Council in November 2011 (“Building Bridges between the U.S. and EU Standards Systems”). Implementation of those principles and intentions should be one matter of priority for the EU and the US. At a more detailed level, the new EU framework on standards provides for enhanced convergence opportunities. The recognition of the role of global fora & consortium standards in the ICT industry in that new legal framework enhances the scope of specific standards and technical specifications that can potentially be commonly be referenced in EU and US public purchasing and policy. This opportunity should be exploited; the EU should explicitly consider and address transatlantic trade aspects in processes towards the identification of ICT technical specifications eligible for direct referencing in public purchasing and sectoral policies (and the US and the EU already cooperate in a number of sectoral policy areas, such as eHealth, smart grid and eVehicles). The EU should ensure that processes around identification of ICT standards in the multi-stakeholder platform foster transatlantic compatibility. In particular, it is important to avoid handicapping cooperation towards compatible sets of standards by using this process to unduly discriminate or exclude relevant specifications that represent US Voluntary Consensus Standards that comply with the European framework’s criterion that such standards meet the WTO TBT criteria for international standards.

In relation to third countries, the EU and the US should exploit their substantial commonalities in policy principles around standards in trade. EU and US industry is often facing the same standards-related trade issues in countries with different policy principles – issues that have to do with lack of compliance with, or a different interpretation of WTO TBT principles. The US and the EU should strengthen their cooperation on a trade political level to jointly promote common policy principles and interpretations, to jointly address concrete issues as they arise, and to jointly lead global evolution towards unimpeded trade with demonstrated best known implementation methods.

2- AN EU-US COOPERATION IN THE AREA OF E-ACCESSIBILITY

In keeping with the intent on the new EU Regulation on **standardisation**, the area of accessibility requires recognition by any relevant regulations and policy makers of the importance of international standards and global fora & consortia technical specifications as they relate to accessibility. In particular the W3C WCAG 2.0 guidelines and the emerging W3C WAI-ARIA specifications are critical and their importance is recognised within both Section 508 in the US and the Mandate 376 work underway in the European Standardisation Organisations (ESOs). Additional standardisation efforts or references in trade arenas

should contribute to the international work in this area, be consistent and compatible to international and global standardisation approaches, and subject to mutual recognition procedures. Any limitation to ESO or national standards should be minimised and subject to the criteria of consistency and compatibility.

Examples that highlight the need for consistency with international approaches and mutual recognition would include use of ANSI/IEEE C63.19 2011 which covers the compatibility between hearing aids and mobile phones.

Supplier Declaration of Conformity (SDoC) has been successfully used for accessibility compliance in the U.S and is a stable and proven approach. If accessibility compliance in the EU is subject to regulation (as has been proposed), the SDoC approach should be replicated and form the basis of a mutual recognition agreement. Any requirements should be based on standards which specify functional requirements, are cross-platform, objectively testable, technology neutral and support further innovation and competition.

A consistent approach to accessibility and any requirement to conform to accessibility standards is critical to maximise the availability and effectiveness of accessible solutions. Market fragmentation via differing technical standards can only harm levels of accessibility. DIGITALEUROPE therefore proposes **mutual recognition** as the appropriate method to drive cooperation and coordination to achieve the highest level of consistency without creating a barrier to innovation.

Accessibility approaches should recognise the constant innovation in accessibility approaches and technology capability as well as a pragmatic approach to promoting accessibility in new product areas.

3- ACCEPTANCE OF E-LABELLING

It is currently an obligation that all apparatus complying with the essential R&TTE requirements in both the EU and US affix the regulatory marking (e.g. CE mark in the EU, FCC mark in the US) on the product or its data plate. The role of regulatory marking like CE is to indicate to the consumer that the product is in compliance with all the regulatory requirements and safe to use, as well as assisting Market Surveillance authorities in ensuring this.

However, the fast pace of technology development has led to a reduction in the size of devices like hand held mobile devices whilst at the same time increasing their complexity. This has meant more labelling requirements and ever decreasing areas in which to place them. In addition, the future use of software defined radio (SDR) would allow devices to be configured post sale, which could potentially render any label affixed at point of sale redundant.

To answer those challenges, DIGITALEUROPE proposes the acceptance of an optional Electronic Marking on Radio and Telecommunication Terminal Equipment with integral display in the framework of the EU-US Free Trade Agreement.

The mobile industry has already been proactive in this area in both Europa and the US and has specified the use of MMI Command **#07#* within 3GPP TS 22.030 for the purposes of displaying this regulatory information. Electronic marking would ensure that where the device is reconfigured, any changes to the regulatory markings e.g. Alert symbol could be updated and remain relevant. In addition the use of electronic marking would give the consumer better access and understanding of the regulatory information as well as paving the way for improved accessibility to the disabled user.

Electronic marking or labelling (e-labelling) is an option (for products with screens) to display via a product's integral screen, some of the required and voluntary regulatory marking information instead of physically affixing a permanent label to the product. For the purpose of this proposal, *regulatory marking requirements* shall be the marking required to be placed on the product (In the EU by R&TTE Directive).

1. CE Mark.
2. Notified Body identification number – when applicable
3. Equipment Class Identifier – when applicable
4. Type, batch and/or serial numbers and the name of the manufacturer or the person responsible for placing the apparatus on the market.)

With the proposed electronic marking, the regulatory marking requirements for the packaging and accompanying documentation would remain unchanged.

Furthermore, and following needs from Authorities when performing Market Surveillance activities, the requirement to place the *Identification of the product* (point 4 above) on the device would also remain as a method of linking the product to its Declaration of Conformity.

Finally, a temporary label (e.g. film label) would be added to the product allowing the consumer and any Market Surveillance Authority to see all product regulatory markings (points 1 to 4 above) at the time of purchase without having to switch the device on. After purchase, the remaining regulatory marking (points 1 to 4 above) would be accessed e.g. via the device keypad using an industry recognised method.

In short, the benefits of e-labelling are:

- Better access and information on regulatory and compliance information for the consumer;
- Better design flexibility for the manufacturers;
- Faster time to market; and
- Reduction of costs.

4- ENHANCE MARKET ACCESS: SUPPLIER'S DECLARATION OF CONFORMITY

The ICT industry, as truly global, considers the ongoing proliferation of national/regional product safety regulations a major restraint on achieving free trade. The European Union has established a concept of 'New Approach' which allows free trade between Member States, based on Directives which contain high level 'essential requirements' combined with conformity assessment modules to show compliance of the involved products, such as electrical and medical products, machinery, toys, etc. The success of this system was supported by the possibility to allow the manufacturer to issue a **Supplier's Declaration of Conformity** (SDoC) based on harmonised European standards. These standards are typically derived from international (IEC) safety standards, as also used in the IECEE (CB scheme) and their status of harmonisation is determined by the Commission.

Another element of this concept is **Market Surveillance** performed by the national authorities. Market Surveillance ensures that products are safe after they have accessed the market, and that Economic operators have a diligent approach. Instances where IT products that have been the object of inspection in the EU have obtained 3rd Party safety approval for other countries yet requiring correction, are not infrequent.

In this context, DIGITALEUROPE believes that the acceptance of a Supplier's Declaration of Conformity (SDoC) on both markets as sole prerequisite to put products on the US Market would enhance trades without prejudice to safety.

SDoC is mostly used for products and sectors which involve a low or medium risk to health, safety and the environment. However, an analysis of risks is not the only factor that Members take into account in their decisions to allow for the use of SDoC for a specific product or in a specific sector. The following elements may be considered in combination with the nature of the risks involved:

- the particular characteristics and the infrastructure of a given sector;
- the number of existing voluntary marking schemes for a product;
- the types of production methods used for the manufacture of the product;
- the level of commercial confidence; and
- other economic and social factors.

SDoC has been used for the following categories of products: disposable lighters; electrical products; electromagnetic compatibility (EMC) and radio and telecommunication terminal attachment equipment (RTTE); electronic safety equipment; electronics; equipment for use in potentially explosive atmospheres; machinery; medical devices; motor vehicles and motor vehicle equipment; personal computers (PC's) and PC peripherals; personal protective equipment; recreational crafts; steel profiles for power transmission towers; telecommunications; toys; vehicle catalysts; and, vehicular natural gas.

The following summary describes the scheme recommended by DIGITALEUROPE:

- **Market Access Conformity Assessment**

SDoC should be the preferred option, used already today by nearly all participants from the ICT/CE industry. The preferred choice of the manufacturer should be a SDoC based on qualified manufacturers Laboratories (accredited to ISO/IEC 17025 or integrated into the manufacturer's ISO quality system) or 3rd Party Conformity Assessment Bodies accredited (by IECEE CB Scheme, or ILAC/IAF schemes to 17025) with appropriate Product Certification Labs (accredited for ILAC Schemes). In any case SDoC is based on profound technical documentation residing at the manufacturer and available for the authorities. Duplication of identical efforts, including time consuming administrative processes, already performed at the Supplier's qualified testing laboratories, by additional 3rd Party Testing (independent from Manufacturer Labs) does not provide additional 'assurance of safety'.

- **Product Liability**

The product liability is described and resides with the company that brings the product into the respective national markets. This is either the 'Manufacturer' or an 'Importer' as the 'authorised representative' of the 'Manufacturer' or as a 'Distributor'. In any cases the responsibility for product liability resides with this company, regardless of the usage of SDoC or 3rd party testing

- **After Market Surveillance**

In the EU, it is the responsibility of national authorities established by Member States to ensure market surveillance and worker safety and levy penalties for false or misleading declarations. Member States' organisation of market surveillance varies: some have a centralised system while others deal with it through local governments. Despite the differences in approaches and procedures, the EU is continuously improving its effective market surveillance along with its Member States through initiatives such as "joint visit programs", EMARS. These initiatives could, in the future, lead to the application of common criteria for market surveillance for all Member States. In the use of SDoC, the EU has identified, through market surveillance, two categories of products for which there is a high degree of non-conformance, namely electronic goods and toys. In the case of obvious safety hazards, the "safeguard clause" of the EU Directives is used to prevent unsafe products entering the EU market. This means that if a safety problem is detected in one Member State, all Member States are immediately informed, steps are taken to withdraw the product from all markets and a system to investigate is set up.

Market surveillance is necessary for all types of Conformity Assurance systems. Systems that require mandatory 3rd Party Product Certification & Manufacturing Inspections do NOT have lesser recall rates nor do they need less emphasis on market surveillance than systems based on the 'Supplier's Declaration of Conformity'. Statistical data from Europe and the US clearly show, that also detected and recalled unsafe products have been certified.

The EU experience clearly proves that this balanced approach of Market Access, Product liability and After Market Surveillance is the fastest, most flexible and the most cost efficient way for suppliers and at the same time ensures a steady improvement in consumer and workers safety.

Nowadays manufacturing sites are distributed globally and products are used globally – it does not matter by whom the product and its subcomponents are manufactured; what matters, however, is that the product placed on any specific national market should be safe as defined by that Nation's regulation. The essential product requirements and respective test standards should be internationally harmonised based on commonly defined regulatory requirements. Those are a key factor to the success of global market players.

We strongly advocate the use of harmonised international standards to define the technical requirements that have to be met. The EU experience successfully shows that it is possible to harmonise the requirements of many national legal requirements. We also support the suggestion that all ICT Equipment should be allowed to be brought into the US market based on meeting the requirements of the current international product safety standards, particularly including the international Safety Standard IEC 60950.

5- AN EU – US TRADE AGREEMENT SHOULD ADDRESS DIGITAL ECONOMY ISSUES AND ENSURE CROSS-BORDER DATA FLOWS

Global cross-border trade in services has grown strongly in recent years. From 2003 to 2008, world exports of services more than doubled, jumping from \$1.8 trillion to \$3.8 trillion, before falling back to \$3.3 trillion in 2009. Trade in these services, which include transportation and travel, insurance and other financial services, telecommunications and IT services, business professional and technical services, royalties, license fees and many other services, has yielded clear global economic benefits. The European Union and the United States, as large services exporters, have much to gain by promoting services liberalisation in the EU-US trade agreement.

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

The group of services enabled by ICT extends far beyond computer and related services and telecommunication services. As the European Centre for International Political Economy (ECIPE) has pointed out, a sampling of ICT-dependent services would include financial analysis, engineering, research and development, insurance claims processing, design, education, publishing, medical services and journalistic work.

Enabled by robust ICT networks, it is knowledge and expertise that is crossing borders in these cases. As such, cross-border trade in these services is, fundamentally, the exchange of data across borders. Innovative firms in many service industries are increasingly able to use data to more effectively serve customers around the world, reduce transaction costs and improve efficiency. This has in turn driven economic growth, productivity and innovation.

However, the tremendous increase in cross-border data flows that has accompanied burgeoning services trade has raised concerns on the part of many governments. Some are enacting, or considering, restrictions on such flows on the basis of privacy, consumer protection, security or other reasons. Given that cross-border services trade is, at its essence, the exchange of data, unnecessary restrictions on data flows have the effect of creating barriers to trade in services. These restrictions, like localisation of resources, could actually harm European service providers and their workers. There are a number of possible mechanisms to ensure that data flows, and the services trade that depends on them, can continue.

Restrictions on cross-border data flows could become a major barrier to trade in services. International trade in many services depends on cross-border data flows between service providers and their clients. Electronic delivery of services across borders is simply not possible without the ability to send and receive information over networks. While a government might make cross-border services market access commitments in trade agreements, if it blocks or severely restricts data flows unnecessarily, those commitments would be undermined and would provide no benefit to multinational service providers.

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

There are a number of possible mechanisms to ensure that data flows, and the services trade that depends on them, can continue such as ensuring greater legal harmony between EU Member States on data protection and IPR arrangements. In addition, ensuring more interoperability between the EU and third countries in for example data protection will also provide more legal certainty to users and organisations.

The discussion in the EU on a new data protection regime is an opportunity to discuss the issue in a cooperative spirit and with the goal of avoiding obstacles to transatlantic and global flows.

The prospect of a bilateral EU-US agreement presents an important opportunity for the world's two leading services economies to establish a model agreement and rules to enable the global digital economy, ensuring the ability of their service providers and multinational businesses to move data around the world so that they can manage their businesses and server their customers most efficiently. The EU and the US should follow through on their pledge to implement the EU-US Trade Principles for ICT Services and should also seek to incorporate the OECD Internet Policy Principles in any agreements that they negotiate with each other or with other parties.

Together, the EU and the US can set a positive example for how to enable strong growth and job creation in the digital economy. The EU and US should hold regular bilateral dialogues on assessing impact of various government actions that are restricting such flows and creating barriers to trade, which should be addressed both bilaterally but also in the EU and US governments' dealings with third countries. The current Information Society Dialogues (ISD) could serve as such a platform if it includes participants from all relevant agencies/departments on both sides.

6- IMPROVED IP FRAMEWORK – PATENTS, TRADE SECRETS, CONTENT PROTECTION AND TRADEMARK¹

DIGITALEUROPE is delighted that the EU and the US share the goal of reducing excessive regulatory costs, unjustified regulatory differences, and unnecessary red tape. We fully agree that promoting this goal will help businesses to grow, create jobs, and compete globally.

In the field of intellectual property, this common objective is fully in line with earlier agreements made in the WTO Agreement on trade-related aspects of intellectual property rights (IPRs), in which Articles 41 and 62 state that procedures concerning enforcement and acquisition of IPRs shall not be unnecessarily complicated or costly.

In this framework we applaud the US' intention to join the international industrial design registration system that is administered by the World Intellectual Property Organisation ("WIPO"), as this will greatly simplify the acquisition of industrial design rights ("design patents") for innovators at both sides of the Atlantic. The EU is already a party to this system.

As regards **patents**, in 2000 the WIPO Patent Law Treaty ("PLT") was concluded, aiming to reduce red tape in the acquisition of patents for inventions. While the European patent system has been largely adjusted to the PLT standards by means of a revision of the

¹ Please note that this position paper has been adopted under a broad majority (DIGITALEUROPE By-laws require a two-thirds majority). Opposing DIGITALEUROPE member does not agree with some parts of section 6 of the paper. Opposing member considers the requirement for an inventor's signature on a patent declaration in the United States to be indispensable because it is a manifestation of an inventor's rights granted by the US Constitution, protects the rights of the inventor and the company/entity that the inventor chooses to assign the patent, and prevents others from taking what is not theirs or claiming more than what is specified in the patent.

European Patent Convention ("EPC2000"), the European Patent Organisation has not yet ratified the PLT. This omission should be repaired. We applaud the US' intention to ratify the PLT, and we hope that in this connection the US will also bring its patent system more fully in line with the PLT standards.

We applaud the US' recent introduction of the possibility for corporate applicants to file patent applications, which was already possible elsewhere in the world. However, the US requirement that the inventors need to sign declarations is at odds with the requirement of Article 6(6) PLT that evidence may only be asked for if the office may reasonably doubt the applicant's statements. In Europe, the applicant only needs to state the names of the inventors and how he got the right to be granted a patent (for which purpose it suffices to state: employment agreement). We believe that the US should similarly do away with the need to chase the inventors for signatures.

Just as Europe has done when the EPC2000 entered into force, the US should withdraw all its notices of incompatibility that prevent applicants from benefiting from modernisations in WIPO's Patent Cooperation Treaty ("PCT"), which facilitates patent acquisition for 146 states.

We believe it to be important that the EU and the US join efforts in convincing other states to fully meet the WTO-TRIPs agreement to ensure that IPR procedures are not unnecessarily complicated or costly. However, to be able to do so, the EU and the US should lead by example, and the ratification and full and unreserved implementation of the PLT by both sides is essential in this respect.

Protection of **trade secrets** is also increasingly important as their theft and forced regulatory disclosure is on the rise. The patchwork of different approaches across Europe has likely led to costly or inefficient protection of trade secrets within the EU's internal market. The lack of adequate protection of trade secrets impairs their dissemination from employer to employee and customer/supplier, which is a further hindrance to domestic innovation. Moreover, inconsistencies within European legal systems undermine EU demands that its trading partners treat European trade secrets as a form of intellectual property and increase their protection.

Effective trade secret protection as a form of intellectual property is crucial for industry investment decisions. U.S. authorities generally treat trade secrets the same as other forms of IPRs such as patents or copyrights. In recent years, trade secret law in the US has become largely statutory through the model Uniform Trade Secrets Act, which has now been adopted in the great majority of states. Once it has been established that a trade secret has been misappropriated, a number of remedies are available including injunctions and damages for the actual loss caused by the misappropriation, largely consistent with infringement of other forms of IPRs. In contrast, there are significant discrepancies among the trade secrets laws of the EU's member states, and not all member states or the EU even clearly recognise trade secrets as a form of intellectual property right. This leaves the EU in a weak position in seeking better protection of European trade secrets by foreign nations like China and India, particularly compared to countries with more robust trade secret regimes like Japan/US. The EU is at a disadvantage in safeguarding its trade secrets and

should not miss an opportunity to fix its IPR system – especially since this form of IP has become more important over time as critical “know-how” in services and manufacturing is increasingly difficult and expensive to protect as patents. Therefore, the parties to the incoming agreement should abide by their duty to implement Section 7, Art. 39 of the TRIPS agreement on protecting undisclosed information as a form of intellectual property, and the European Union should start considering how to more fully implement its TRIPS obligation concerning trade secrets. In order to provide adequate border measures, Union-wide trade secrets, as other intellectual property rights, should also come within the ambit of the Customs Regulation.

In terms of **content protection**, an appropriate action of the European Union might be to encourage continued industry discussions regarding private agreements that would provide for the pan-European licensing of content and market-driven private agreements related to development and implementation of technological solutions, such as those that exist today to protect premium content from unauthorised use, copying and distribution. DIGITALEUROPE believes that a “markets, not mandates” approach to copyright should govern all content protection issues. In our view “content protection” is achievable, but “consumer policing” is not effective.

DIGITALEUROPE also wants to present remarks regarding **trademark**. Since there are no uniform trademark protection laws across the world, some countries almost appear to encourage the theft or misuse of this type of intellectual property; those involved in trademark infringements and selling fake non-or-barely-working hardware, true counterfeit products, or remarked products pass themselves off as legitimate sellers of the manufacturer’s products and the end user or buyer becomes a serious victim. The traffickers in copied trademarks and products who are transporting (importing and exporting) or selling the products find ways to avoid paying appropriate taxes which hurts the government and the honest tax payers; the trademark violations can also be contractual issues against a company’s vertical distribution agreements and contractual agreements for production limits, sales in certain countries or sales outlets, etc. The EU and the US should work together. Two actions would improve the fight against trademark infractions and counterfeits: better product classification systems by government and purchasers so that critical components are only purchased through appropriate authorised distribution and increased coordination and information exchange between brand owners and law enforcement and customs organisations to better utilise the manufacturer in identifying authentic versus suspect counterfeit products at the borders to each country. Neither side can do this on its own – it must be a working partnership. To this end, we propose better training for those trying to stop electronic and semiconductor counterfeits at the borders. Improvements must be made to the system of allowing stakeholders to identify counterfeit products at the borders or with local and regional law enforcement to ensure efficient enforcement of intellectual property laws domestically. We recommend that actions are taken to ensure that Customs provide brand owners with sufficient information about seized goods to enable the brand owners to distinguish between their genuine products and counterfeit goods, and to better assist Customs with their duties, improved cross-border information sharing so that both the exporters and importers can be investigated and prosecuted, better (and preferably cross-Atlantic) cross-functional teams

between brand owners, law enforcement and customs organisations. Interoperability between EU and US data exchange systems should be provided to avoid that IP owners have to fill databases in different ways with the same info.

7- ENVIRONMENTAL REGULATION

As there has been certain instances where environmental regulation constitutes barriers to free trade this regulation need to be addressed also in this context.

Substance restrictions: There is increased interest by individual US states (e.g., CA, MN, WI) in prohibiting the usage or reducing the exposure of certain priority chemicals that may be deemed to pose risks to the environment or human health if not managed properly. Some of these efforts overlap or are similar to the objectives of EU REACH Regulation and RoHS Directive, but are not entirely the same for legal and jurisdictional reasons. The challenges are compounded when efforts to identify priority chemicals by US states is not entirely the same, nor are the methodologies to measure exposure or risk. One result could be varying regulations across the US states, banning different chemicals with different implementation dates. The result could be that for the US market there are either different product lines for sale within US (and the US and Canada), or there are no products sold at all because compliance costs are too high. The EU RoHS has become a de facto international standard that most large companies follow globally. We propose that the US and the EU should strengthen their cooperation on a political level to jointly promote common policy principles regarding substance restrictions in order to ensure that products fulfil the highest standards on both markets and to eliminate any unnecessary delays in bringing new products to market because of different bureaucracy or differing product requirements.

Energy efficiency: There are various efforts underway to improve the efficiency of external power supplies or battery charging systems in many markets, we recommend that efforts to enable global commerce and the widest gains on efficiency can be made by using common definitions, standards, common methods for measurement and developing realistic timelines for implementation.

ABOUT DIGITALEUROPE

DIGITALEUROPE represents the digital technology industry in Europe. Our members include some of the world's largest IT, telecoms and consumer electronics companies and national associations from every part of Europe. DIGITALEUROPE wants European businesses and citizens to benefit from digital technologies and for Europe to grow, attract and sustain the world's best digital technology companies.

DIGITALEUROPE ensures industry participation in the development and implementation of EU policies. DIGITALEUROPE's members include 60 global corporations and 33 national trade associations from across Europe. In total, 10,000 companies employing two million citizens and generating €1 trillion in revenues. Our website provides further information on our recent news and activities: <http://www.digitaleurope.org>

THE MEMBERSHIP OF DIGITALEUROPE

COMPANY MEMBERS:

Acer, Alcatel-Lucent, AMD, APC by Schneider Electric, Apple, Bang & Olufsen, BenQ Europa BV, Bose, Brother, Canon, Cassidian, Cisco, Dell, Epson, Ericsson, Fujitsu, Hitachi, HP, Huawei, IBM, Ingram Micro, Intel, JVC Kenwood Group, Kodak, Konica Minolta, Kyocera Document Solutions, Lexmark, LG, Loewe, Microsoft, Mitsubishi Electric, Motorola Mobility, Motorola Solutions, NEC, Nokia, Nokia Siemens Networks, Océ, Oki, Optoma, Oracle, Panasonic, Philips, Pioneer, Qualcomm, Research In Motion, Ricoh International, Samsung, SAP, Sharp, Siemens, SMART Technologies, Sony, Sony Ericsson, Swatch Group, Technicolor, Texas Instruments, Toshiba, TP Vision, Xerox, ZTE Corporation.

NATIONAL TRADE ASSOCIATIONS:

Belgium: AGORIA; **Bulgaria:** BAIT; **Cyprus:** CITEA; **Denmark:** DI ITEK, IT-BRANCHEN; **Estonia:** ITL; **Finland:** FFTI; **France:** SIMAVELEC; **Germany:** BITKOM, ZVEI; **Greece:** SEPE; **Hungary:** IVSZ; **Ireland:** ICT IRELAND; **Italy:** ANITEC; **Lithuania:** INFOBALT; **Netherlands:** ICT OFFICE, FIAR; **Poland:** KIGEIT, PIIT; **Portugal:** AGEFE, APDC; **Romania:** APDETIC; **Slovakia:** ITAS; **Slovenia:** GZS; **Spain:** AMETIC, **Sweden:** IT&Telekomföretagen; **United Kingdom:** INTELLECT
Belarus: INFOPARK; **Norway:** IKT NORGE; **Switzerland:** SWICO; **Turkey:** ECID, TESID, TÜBISAD; **Ukraine:** IT UKRAINE.